BMC Digital Health

RESEARCH

Open Access

Digital solution for supporting suicide prevention: human-centered, participatory development, usage trend analysis and adverse risk assessment

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Abstract

Background Suicidal behavior is often the result of psychosocial crises and mental illness. Effective assessment and management of suicidal behavior are critical components of intervention. Digital tools, including self-management apps, offer a novel approach to help individuals actively manage their suicidal behavior. This study aims to develop and evaluate a digital application, the SERO app, tailored for suicide prevention with a focus on self-management and self-assessment for individuals at risk. It includes involvement of the relatives.

Results The SERO app, result from a human-centered, participatory design development approach, provides an evidence-based platform for rapid self-assessment of suicide risk using the PRISM™-S method. It facilitates the creation and sharing of personalized safety plans, suggests activities based on these plans, and enhances community support by connecting users with supportive individuals such as relatives and crisis support organizations. Data is stored as HL7 FHIR® resources in a secure health database. Post-launch analysis has shown that the safety plan and self-assessment features are the most commonly used features.

Conclusions While evidence-based practices are built into the SERO app, it is important to acknowledge that its use may lead to unintended consequences. In the future, we intend to implement countermeasures to mitigate potential misuse and minimize harm. Our findings suggest that early assessment of possible risks related to the interaction with a digital health intervention plays a critical role in ensuring patient safety, particularly in sensitive areas such as mental health.

Keywords Suicide, Suicide prevention, Digital health, Digital health intervention, Patient-centered care, Human-centered design, Participatory design

Background

Suicide is a major global health and social problem. In 2019, it accounted for over 700,000 deaths worldwide, with an age-standardized rate of 9.0 per 100,000 population ([1], p. 4). This alarming statistic highlights the urgent need for effective suicide prevention strategies.

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Although suicidal behavior can occur in anyone, it is most commonly associated with psychosocial crises and mental illness [2]. This risk is significantly higher in people with mental illness [3]. Suicidality encompasses a range of thoughts, behaviors and experiences that lead individuals to actively or passively contemplate or accept their own death as a possible consequence of their actions [2].

The management of suicidal behavior focuses on four key areas: (A) diagnosis and treatment of any underlying mental health conditions; (B) assessment and evaluation of current suicide risk; (C) implementation of suicide prevention measures; and (D) provision of targeted treatments to reduce suicide risk [4]. Each aspect plays a critical role in a comprehensive approach to suicide prevention.

Accurately predicting suicide risk is challenging and accuracy decreases over time from the initial assessment [5]. Clinical assessment typically involves standardized instruments such as the Patient Health Questionnaire-9 Depression (PHQ-9) [6], the Ask Suicide-Screening Questions [7] or the Patient Safety Screener (PSS-3, [8]). However, these instruments often lack sensitivity and specificity, leading to inaccurate risk assessments [9]. Concerns have been raised that these instruments follow the wrong approach of considering suicidal ideation as "gateway to suicidal behavior" [10]. Recent studies, such as those by Hawton et al., emphasize the importance of building a therapeutic alliance to understand each individual's unique needs and risk factors. This approach promotes a more personalized and effective treatment plan [11]. Asking a person to fill a questionnaire does not support the therapeutic alliance. This limitation is addressed by the PRISM™ method which has been developed as a brief nonverbal measure of illness impact and therapeutic aid in psychosomatic medicine [12]. In its adaptation PRISM™-S (Pictorial Representation of Illness and Self Measure—Suicidality), it is a validated method for assessing current suicidality [13–15] by allowing for a collaborative assessment approach. The standardized instrument consists of a white A4 metal plate with an orange disc seven centimeters in diameter in the bottom right corner and a black plastic disc. The plate represents the "life" of the individual at risk and the orange disc represents the individual him or herself. The black disc with a diameter of five centimeters represents the "urge to take one's own life". PRISM™-S can be used to assess how far an individual at risk is literally "away" from a suicidal act. From the individual's perspective and experience, professionals gain insights into a) the intensity of the perceived suffering and b) the remaining capacity to resist it. The open communication about the suicidal crisis is intended to help strengthen the therapeutic relationship by allowing professionals and patients to explore the patient's suicidal impulses together. PRISM™-S encourages a collaborative approach by inviting professionals to "see through the patient's eyes" [16] visually capturing the subjective experience of suicidality [14]. The method is easy to understand and quick to carry out which makes it suited for self-management in contrast to other self-reporting methods. In a validity assessment study with 156 eligible inpatients high correlations were found between PRISM™-S and the Beck Scale of Suicide Ideation (BSS) ($r=-0.73$) as well as the Depressive Symptom Inventory—Subscale (DSI-SS) scores ($r=-0.76$) [13]. Moving this assessment from a physical to a digital format could improve its usability and accessibility, making it an ideal tool for digital suicide prevention strategies.

Psychosocial interventions are crucial in managing suicidal impulses [4], with a primary focus on establishing a therapeutic alliance [11]. This relationship promotes connection, empowerment and improved interpersonal skills [17]. Providing patients with digital tools, such as safety plans [18, 19] and self-management apps [20], empowers them to actively manage their suicidal thoughts. Research has shown the effectiveness of these digital interventions, particularly in regions with limited access to healthcare [20, 21]. However, user non-adherence remains a challenge, often leading to high dropout rates [22].

Therefore, the aim of this paper is to describe the development of a user-friendly digital application for suicide prevention. This application will facilitate self-management for people at risk and provide a tool for self-assessment of suicidal behavior. Specifically, the PRISM™-S method will be integrated. The development process will prioritize user involvement and human-centered, participatory design to ensure that the app meets the real needs of its users.

Methods

This paper describes the design and development process of a mobile application to support people with suicidal tendencies and their families. The development is part of the SERO project (Suizidprävention einheitlich regional organisiert (Suicide prevention uniformly regional organized) [23, 24]). The SERO project aims to reduce the number of suicides and suicide attempts in Switzerland. It is designed to support both individuals affected by suicidal behavior and their families, focusing on improving self-management skills. The project also supports professionals in making reliable clinical assessments of suicide risk, enabling them to provide appropriate help in emergency situations.

In this section, we describe the human-centered development process. The SERO app has been available for download since December 2022. We will analyze basic

usage statistics. As the app is designed to be used on an individual basis without accompanying therapeutic support, we have considered possible unintended consequences of its use. The methodology is described below.

Human-centered development

The SERO app was designed and developed following a human-centered, participatory design approach comprising 6 steps (see Fig. 1). Participatory design is "a process that includes the stakeholders in the early stages of design" [25]. This approach was chosen to ensure that the solution is perceived useful by its users, to ensure usability and to increase the user's sense of ownership. A project team was set up at the beginning of the project. It was involved in all steps of the development and consisted of a relative, 2 health professionals (nursing background, mental health care), 1 nursing scientist (specialized in mental health care) and 1 patient representative. They could provide feedback at any time of the project. Regular workshops (user testings) were conducted with an extended project team consisting of the project team and 4 additional persons (2 members of a nationally operating patient agency in the field of mental health and 2 additional patient representatives). A graphic designer was involved for creating icons to be used within the app.

Requirements gathering

For gathering user requirements, we conducted structured focus group discussions with three different groups of participants: health professionals, people with personal experience of suicidality and their family members (project team, see description above). At the same time, a pilot study was initiated to adapt the PRISM™-S assessment for autonomous use by patients in an inpatient context, as opposed to its traditional use, which typically requires supervision by a mental health professional. The main aim of this adaptation was to develop a comprehensive and unambiguous set of instructions to enable patients to use the PRISM™-S tool independently.

Furthermore, we derived requirements from the six essential app-based strategies for suicide prevention identified by Martinengo et al. [26]: 1) tracking of mood and suicidal thoughts, 2) development of a safety plan, 3) recommendation of activities to deter suicidal thoughts, 4) information and education, 5) access to support networks and 6) access to emergency counselling. Specifically, it was ensured that for each of these six strategies at least one corresponding requirement is included. The collected requirements were weighted together with the project team.

Mockup generation

To validate the collected requirements, a non-functional, clickable mockup was evaluated by eleven persons with suicidality in a workshop. Of these, nine participated in group-based evaluations, while the remaining two participated in individual sessions. They provided feedback on the onboarding process, functionalities and features, visualizations and were invited to describe additional desired features. The insights gained from this evaluation phase were crucial in refining the final design and ensuring its alignment with the defined requirements and user expectations.

Prototype generation (App version 1)

A first version of the SERO app was implemented in parallel for iOS and Android devices with React Native and released to the stores in December 2022. At three different stages of development feedback from the extended project team was collected. In each test, different features were tested and modifications conducted in the previous iteration were tested. Their feedback was collected using questionnaires and by taking notes during the discussions. Reported errors in functionalities or navigation, unclear instructions, wording or information as shown in

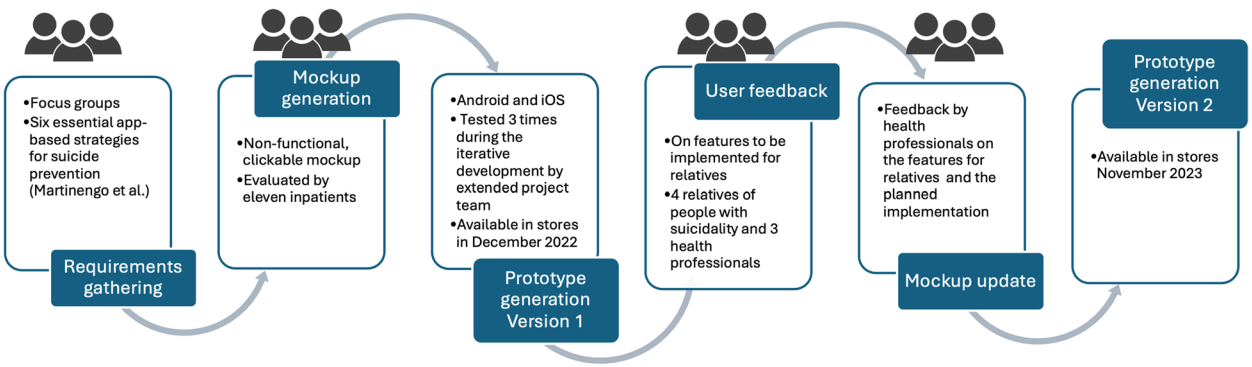

Fig. 1 Human-centered, participatory design and development process of the SERO app

Table 1 Measure of User- and human-centered design (UCD-11[a], [27], Creative Common Attribution License https://creativecommons.org/licenses/by/4.0/)

UCD-11 item	Scoring (0 = no, 1 = yes)
Were potential end users (e.g., patients, caregivers, family and friends, surrogates) involved in any steps to help understand users (e.g., who they are, in what context might they use the tool) and their needs?	1
Were potential end users involved in any steps of designing, developing, and/or refining a prototype?	1
Were potential end users involved in any steps intended to evaluate prototypes or a final version of the tool?	1
Were potential end users asked on their opinions of the tool in any way?	1
Were potential end users observed using the tool in any way?	1
Did the development process have 3 or more iterative cycles?	1
Were changes between iterative cycles explicitly reported in any way?	0
Were health professionals asked their opinion of the tool at any point?	1
Were health professionals consulted at any point before a first prototype was developed?	1
Were health professionals consulted between initial and final prototype?	1
Was an expert panel involved?	1
	Sum: 10 / 11

the app were considered to improve the app in the next development cycle.

Feedback collection

An online workshop was conducted with four relatives of people with suicidality and three health professionals to collect feedback on the app and to collect requirements for features supporting relatives. Two out of three health professionals self-identified additionally as relatives of people with suicidality.

Mockup update

The collected feedback was used to adapt the mockup for the SERO app. Features for relatives were included. This mockup was again reviewed by health professionals before the development started to ensure its evidence base.

Prototype generation (App version 2)

The SERO app was extended by the newly defined features and released to the stores in November 2023.

In Table 1, we document the user- and human-centeredness of the design and development process using the UCD-11 measure of user- and human-centered design [27].

The advertisement concept of the SERO app bases upon the idea, that individuals at risk and their relatives get informed about the app through health professionals who serve as multiplicators. Therefore, the app was advertised at LinkedIn. Information was spread by mail to the professional networks of the project team as well as in online meetings, two focusing on the region of central Switzerland and two focusing on Switzerland.

Reflection of unintended consequences

The possible unintended consequences of the SERO app usage were assessed using the DTx (Digital Therapeutics) Risk Assessment[1] Canvas proposed by Denecke et al. [28], published under Creative Commons Attribution (CC BY) license (https://creativecommons.org/licenses/by/4.0/). The DTx Risk Assessment Canvas was designed to enable researchers, developers, and practitioners to reflect on the negative consequences of a digital health solution in a participatory process [28]. It is organized into 15 thematic blocks, which are divided into three groups related to the DTx itself, the users of the DTx and the impact of the DTx. For each thematic block a set of guiding questions is provided that can form the basis to collect information on the single block.

To reflect the unintended consequences of the SERO app, a group of 6 persons, 2 with a psychological background, 2 with a background in nursing and nursing science and 2 with a background in engineering and health informatics, conducted the workshop in an online setting moderated by a seventh person. All participants have tested the SERO app in advance and were involved in the design and development process.

The workshop took place on January 10, 2024. First, the DTx Risk Assessment Canvas and the procedure was briefly introduced to the participants. Then, the 6 participants were randomly split in two groups of three persons who met in two separate online meeting groups. They had 60 min split into three rounds to summarize their reflections on the three groups of risks suggested in the canvas which are the digital solution, its users

[1] https://www.mdpi.com/2075-4426/13/10/1523

and possible unintended consequences. They were using the guiding questions listed in the canvas to collect the information requested. The moderator assisted in case questions arose in the groups. The groups shared their thoughts in a follow-up discussion and aggregated the group results.

Usage analysis

Usage statistics were analyzed over a time span of twelve months in 2023 which ended 1 month after the release of version 2. Data was acquired using the open-source web analytics platform Matomo (http://www.matomo.org), on an instance securely run by the Bern University of Applied Sciences. Users are represented by an anonymized ID generated by MIDATA [29] (see Sect. "SERO app, its architecture and functionalities"), that allows to correlate statistics over multiple devices of the same user. Usage statistics were then collected with logging different events in the app, e.g. when the user clicked on a given button. Specifically, we assessed times of usage and access to the single features of the app. Since the second version of the SERO app (with support for relatives) was only released in November 2023, the results basically refer to the first version, i.e. the version that supports only the persons with suicidality. The data originates from usage of the SERO app of 1597 registered users (March 9, 2024).

Results

SERO app, its architecture and functionalities

In this section, we describe the SERO app including the functionalities, its system architecture and technical details.

User groups and functionalities

The SERO app is designed for supporting two user groups: 1) individuals with suicidality and 2) their relatives. Accordingly, users can log in with one of these two roles. Individuals with suicidal behavior can use the app for self-assessment, seeking help, and safety plan generation. They can access and share their personal safety plan with relatives. The relatives are able to access the safety plan of a person at risk who decided to share this information with him or her, and get support in self-reflection by the app as well as information for supporting the help seeking individual. The app is available free of charge in four languages: German, French, Italian and English. In more detail, the aspects of the six-point approach followed [26] comprising 1) tracking of mood and suicidal thoughts, 2) development of a safety plan, 3) recommendation of activities to deter suicidal thoughts, 4) information and education, 5) access to support networks and 6) access to emergency counselling were implemented in the app as shown in Table 2. The core elements are described in more details in the following.

When both, the individual with suicidality and the relative, are using the app, the safety plan can be shared with the relative who in turn can agree or disagree to get access to it. The app is supposed to be used outside any therapeutic setting, but it can also be integrated in the

Table 2 Functionalities of the SERO app

Functionality	Beneficiary	Underlying Strategy
PRISM™-S assessment method for rapid self-assessment of suicidality and educational content on its use	Individuals with suicidality	Mood and suicidal behavior tracking [26]
Generation of and access to the safety plan for crisis moments	Individuals with suicidality	Safety plan development [26] to empower individuals with suicidality
Automatic suggestion of engaging activities derived from the user's safety plan (as push notification or within the app)	Individuals with suicidality	Recommendation of engaging activities [26], diverting focus from distressing thoughts and fostering resilience and coping mechanisms
Offering information about organizations for crisis help	Individuals with suicidality and relatives	Information and education [26]
Generation and access of the resource plan for crisis moments	Relatives	Empower relatives
Facilitating connections to supportive people, allowing sharing of the safety plan to reduce isolation and strengthen community support	Individuals with suicidality and relatives	Access to support network [26]
Accessing shared safety plan	Relatives	Safety plan development [26] to empower relatives
Offering immediate access to professional counselling services in emergency situations	Individuals with suicidality and relatives	Access to emergency counselling [26]

therapeutic setting since the app allows to access all the suicide risk assessments the user made in the past using the app. This could become a starting point for reflection with the therapist. In case a person at risk is not using the SERO app, a relative can anyway benefit from the support the app is providing.

In the SERO app, suicide risk is assessed using the PRISM™-S tool [13, 14], a visual clinical assessment method adapted for self-use. Unlike most digital interventions that use the PHQ-9 depression questionnaire, PRISM™-S offers a more intuitive, visual approach to app-based self-assessment [12, 15]. Users place a black disc, symbolizing suicidal behavior, in relation to an orange disc, representing themselves, on a white rectangle (representing their life), with the assessment saved as an image (Fig. 2). This is complemented by a five-question survey covering personal interpretation, thoughts, physical perceptions, emotions and resilience (Fig. 3). After completing an assessment, the app advises users to review their safety plan or contact a relative. In a previous study, which was preceding the app development process, this method has been pilot tested for inpatient use without professional guidance with 9 patients. 8 out of them were aware of the PRISM™-S methodology already from their medical history interview.

The safety plan in the app is designed to help users identify and use their strengths and coping mechanisms. It consists of six customizable sections: 1. Motivation to live, 2. Coping strategies, 3. Distraction strategies, 4. Early warning signs, 5. Personal contacts, and 6. Professional support and emergency numbers. Users can personalize each section with their own text. The modular format of the plan allows sections to be rearranged according to individual preferences. Personal contacts, is a separate module integrated into the main screen, with

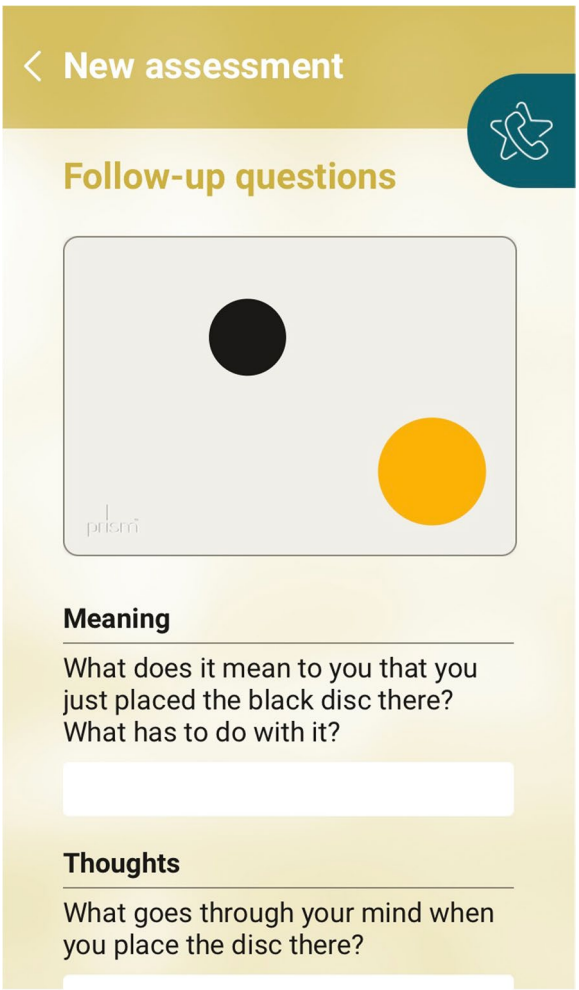

Fig. 3 Screenshot from SERO App: Questions following a PRISM™-S self-assessment

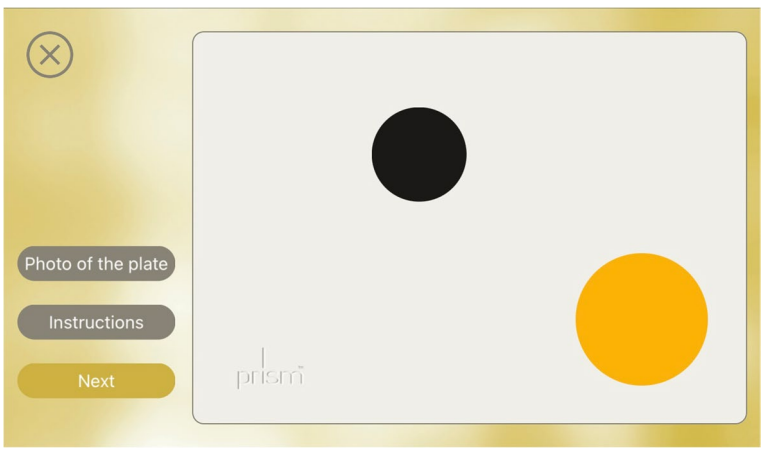

Fig. 2 Screenshot from SERO App: PRISM™-S self-assessment

all emergency numbers accessible from any screen and callable directly from the app. Users can add personal emergency contacts, including profile pictures, while official emergency numbers such as ambulance or police are pre-set in the app and available 24/7. The safety plan was developed by reviewing existing plans from which a group of experts in mental health identified relevant questions. These were adapted to the language peculiarities of Switzerland and visualized with icons. This process was conducted in several iterations resulting in a final wording for the safety plan. This version was again reviewed by another group of experts with background in mental health with feedback integrated in a final version. Translations of the safety plan were done by professional translators.

In addition to the emergency numbers, the home screen always displays a subsection of the safety plan for users to memorize their personal strategies. An example might be, "One of your distraction strategies is 'do relaxation exercises'. You should give this a try soon." Furthermore, push notifications are sent to users who enable this feature, providing reminders of different sections of the safety plan. This feature must be manually activated. Users can choose between daily, weekly and monthly notifications. For users acting in the role of a relative, information from the resource plan is made accessible in the same manner.

Technical implementation

Implementation of the app was done cross-platform and in parallel for iOS and Android devices with React Native [30]. To enable the SERO app to be distributed throughout Switzerland and to support later data analysis for research, secure data storage and access must be provided. Therefore, the SERO app uses MIDATA [29], a General Data Protection Regulation (GDPR)-compliant and citizen-owned health data platform, where each user has individual control over their personal data stored in their account. The data is stored as Fast Healthcare Interoperability Resources (FHIR[2®]) resources [31] in the personal health record of the user on the secured MIDATA server environment. Data transmission between the SERO app and MIDATA is encrypted, as well as data storage on MIDATA and on the patient's device. Further security aspects will be implemented, such as the app can only be used if the mobile phone is protected with a pin, fingerprint, or Face ID. As mentioned before the app development was conducted in two versions to rapidly provide a minimum marketable product. The MIDATA platform supports sharing of selected data with others by means of an advanced consent management mechanism, where users can give access to defined personal data to third parties.

We use FHIR® R4 and following resources: User master data is stored and communicated using the Patient resource, whilst contacts are managed as RelatedPerson resource. Requests for and sharing data is controlled with the Consent resource. The safety plan is modeled as a CarePlan resource, where the individual modules are stored as embedded CarePlan. Storing the PRISM™-S self-assessment uses multiple resources: The result of the PRISM™-S plate is stored as an Observation resource containing the coordinates of the plate, as well as a rendering of the final plate as Media resource. The additional questions are dynamically rendered from a Questionnaire resource that is stored statically in the SERO app, the patients' responses are processed as QuestionnaireResponse resource. All these resources related to a PRISM™-S session are transferred to MIDATA at once in a FHIR® Bundle.

All data is stored in the secure MIDATA platform. The app requests and stores data through MIDATA's FHIR® API over https. The resources are cached locally in an encrypted storage, allowing offline usage. They are synchronized when an Internet connection is available. The handling of the FHIR® resources and the rendering of the questionnaire are based on generic libraries developed by us. The system architecture is shown in Fig. 4.

Possible unintended consequences of the SERO app

The risk assessment workshop resulted in multiple risks for relatives, for the individual with suicidality and for the society or healthcare system. They are listed in Table 3. Ideas for possible countermeasures are summarized in the discussion section.

Usage analysis

The usage analysis shows that the app is used all over the day (Fig. 5). We see peak times between 9 and 11 am as well as between 1 and 4 pm. The app is also used at night of around 150 times in the period between 6 and 11 pm. 49.1% of the visits to the SERO app did not take longer than 1 min. 26.1% of the visits took between 1–4 min; 4–7 min of usage was recorded for 8.8% of the users; 7–10 min for 4.1%; 10–15 min 4.2%; 15–30 min for 5%, and more than 30 min for 2.6.% of the users.

Figure 6 shows the distribution of features used. As the resource plan and safety plan sharing features were only implemented in the second version of the SERO app, the statistics for resource plan access (0.5%) and safety plan sharing (1.2%) are not representative. The most frequently used functionalities were accessing and editing

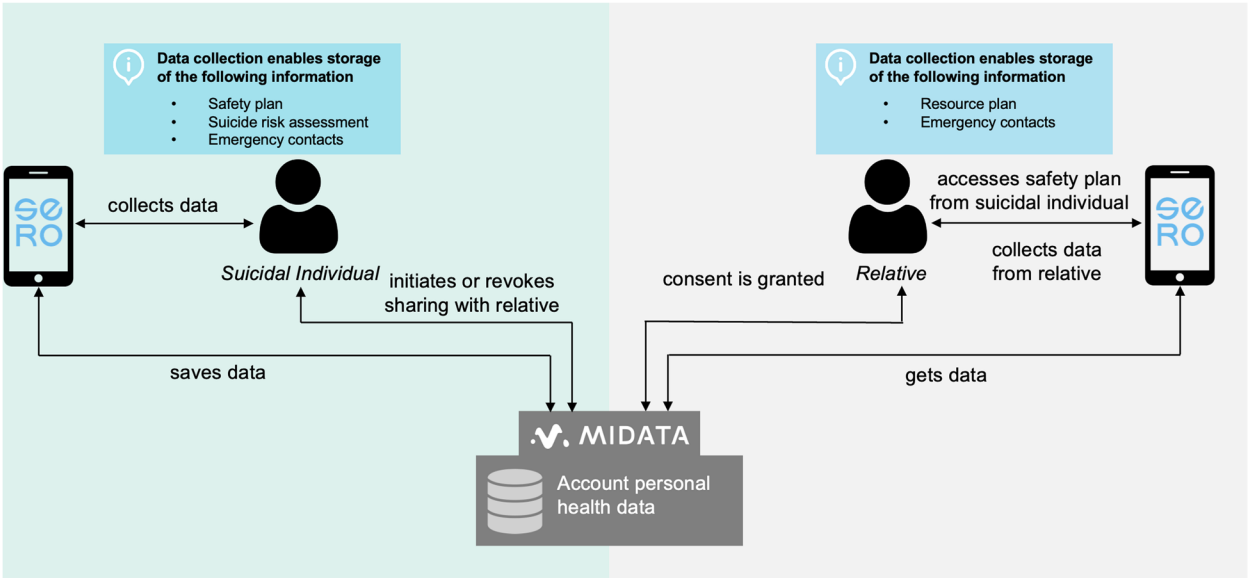

Fig. 4 SERO system architecture: Two user groups access the app – the individual with suicidality and the relative. The relative can access the safety plan of a suicidal individual in case both have consented. All data is stored securely at MIDATA, a health data platform

Table 3 Possible unintended consequences of SERO app usage. They were collecting using the DTx risk assessment canvas

Unintended consequences	Brief description
Negative impact on relatives	
Overburdening and stress of family members	Using the app can cause significant stress for relatives, particularly due to the difficulty in separating from the loved one's risk situations. This can strain relationships and exacerbate emotional distress for both parties. Particularly, information in safety plans can inadvertently cause fear and anxiety among relatives when individuals at risk enter destructive items
Negative consequences for individuals with suicidality	
False expectations and potential misuse	The app may create unrealistic expectations due to lack of action recommendations or feedback on self-assessment, leading to confusion and potential misuse. Safety plans might contain items that inadvertently contribute to negative outcomes if not properly managed or contextualized
Inappropriate emotional responses	Using the app might trigger false senses of well-being, delaying or complicating the seeking of professional help
Emergence of negative emotions	Frequent self-assessment and a focus on mental well-being could lead to an increased awareness of suicidal thoughts
Realization of lack of personal support	Users may become demoralized upon realizing their lack of personal support contacts or resources, counteracting the app's supportive intent. The app's effectiveness is compromised in crisis situations if users have not previously entered resources or integrated contacts
Misuse and misunderstandings by users	Misunderstandings of instructions or onboarding information can lead to misuse and frustration, originating from misplaced expectations about the app's functionality. Users may struggle with navigating the app or lack clear guidance, leading to frustration and decreased utility of the app
Involuntary disclosure of suicide risk	Using a suicide prevention app could unintentionally reveal a user's suicide risk, potentially leading to bullying, discrimination, social isolation, and stigmatization
Language barriers	The app currently supports four languages. But many explanations require good reading skills. The app's effectiveness is limited for those with limited language proficiency
Unintended consequences for society or healthcare system	
Conflict between app and professional advice	Tensions might arise between the app's self-management features and professional medical advice, leading to confusion and undermined trust in the app
Increased use of support services and costs	The app might escalate users to paid emergency call services, which may not be appropriate or feasible in all situations, leading to an increase of healthcare costs

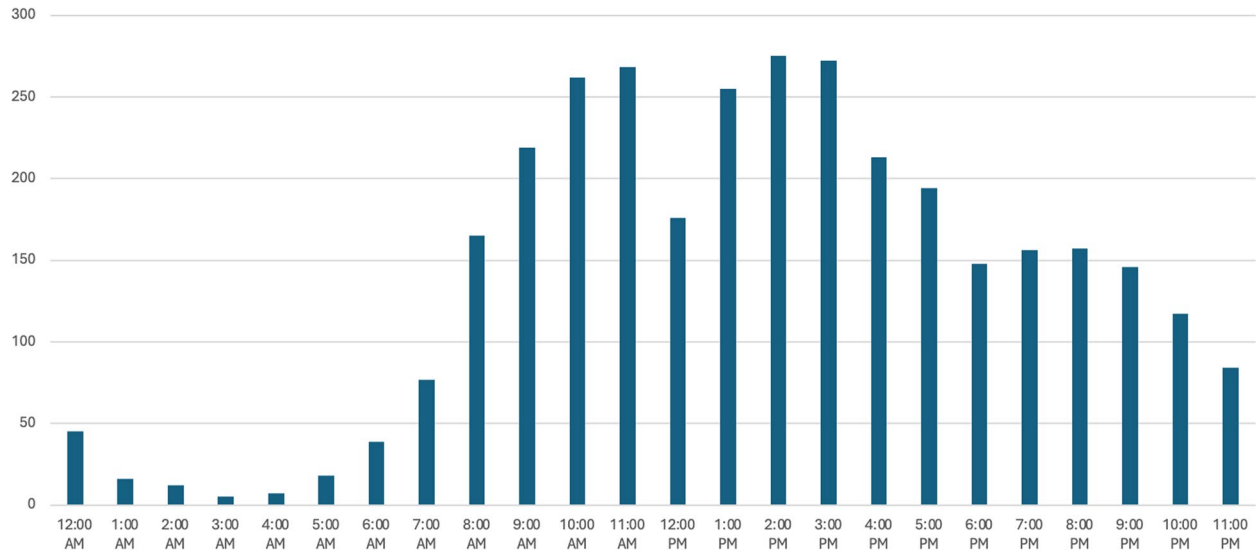

Fig. 5 App usage over the day (average between 01/01/2023 and 31/12/2023)

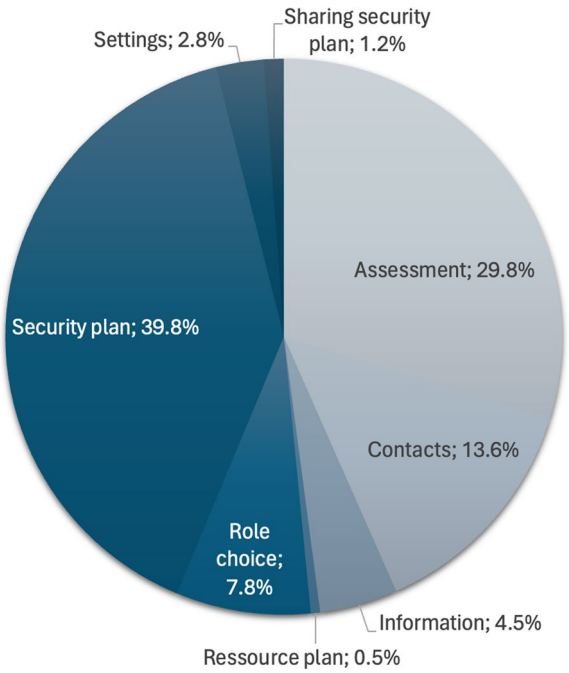

Fig. 6 Distribution of using the different functionalities ($n = 15'677$)

the safety plan (39.8%) and the self-assessment (29.8%). The contact list was consulted in 13.6% of cases. The information section in the app, which explains the app with all its functionalities, provides answers to frequently asked questions about the app and lists relevant links, was evaluated in 4.5% of the events.

Within one year, we recognized 1'960 events related to a contact of one of the official helplines in Switzerland specialized on mental health ("Dargebotene Hand", "Pro Juventute", Pro Mente Sana"). 25% of the events refer to a call of "Die Dargebotene Hand", which is the first point of contact for people in difficult situations in Switzerland, but also for those with everyday worries. 34.4% were emergency calls and 0.8% were directed to the police. The Lucerne Psychiatry, project partner initiating the development of the app and placing it into market, was called 0.8%. 17.6% of the call events are related to a personal contact. 20.9% were directed towards "Pro Juventute". With its counselling service, Pro Juventute supports children and adolescents in situations of crisis as well as parents and carers with both minor and major concerns. 0.2% of the events were directed to "Pro Mente Sana". Pro Mente Sana offers free counselling on psychosocial and legal issues for people with a mental impairment, their relatives and loved ones as well as other caregivers.

Figure 7 shows the distribution of re-visits. 47.3% of the visits are new visits to the app. However, 18.6% users revisit the app on the same day. 5% of the visits take place each after 1 day, 8–14 days or 15–30 days.

Discussion

We developed the suicide prevention app SERO that offers tracking of mood and suicidal thoughts, keeping and sharing a safety plan, recommendation of preventive activities, information and education, access to a support network and to emergency counselling. It was developed in a trialogue with health professionals, individuals at risk and their families. Individuals at risk can share their safety plan with their relatives who in turn are supported by the app with information and

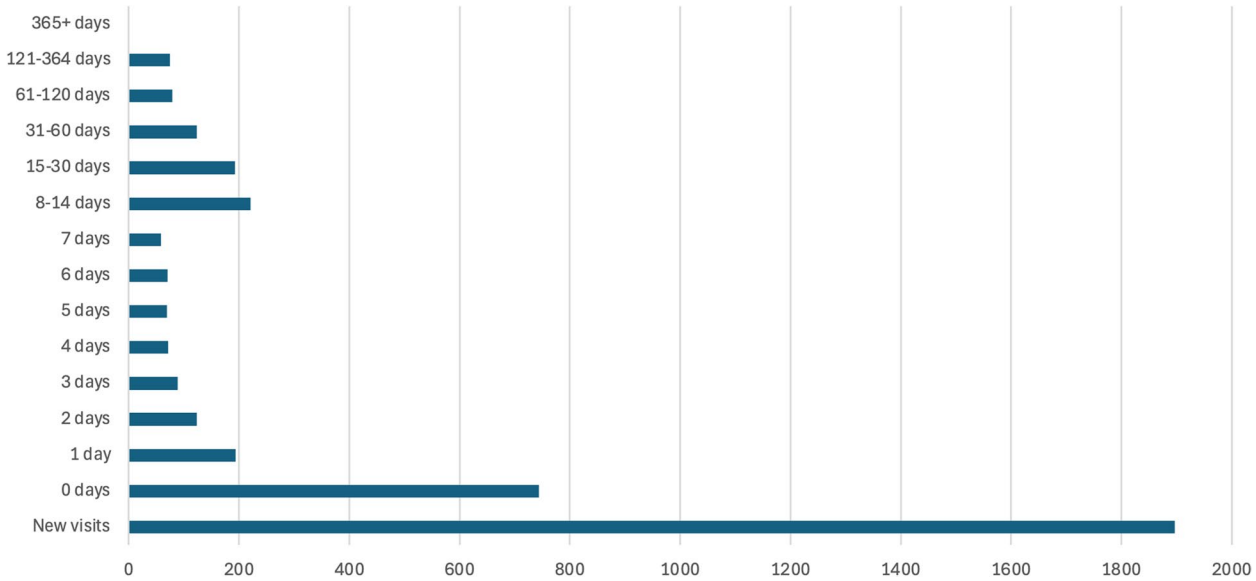

Fig. 7 Re-visits of the SERO app ($n = 4'009$ visits)

support in self-reflection. The app can be recommended by therapists to their clients and can be integrated in the therapeutic process. For example, the safety plan can be shared with a therapist and form the basis for discussion. Or the individual at risk can show the self-assessments in the therapeutic session where it supports the interaction between individual and therapist. All data collected by the app, including the visual assessment of the suicide risk as an image file, are stored in a GDPR-compliant health data space in HL7 FHIR® format, ensuring interoperability in case the app is embedded into a care process.

Relation to existing research

There are several apps for suicide prevention available. Their basic functionalities are provision of interactive screening strategies that use normally custom screening tools for detecting suicidality (including items on suicidal thoughts, social withdrawal and other warning signs) [32]. These are similar to the 6 suicide prevention strategies normally integrated in apps [26]. Depression-focused suicide prevention apps implemented the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) scale or the PHQ-9 scale [32] as assessment tool. Additionally most existing apps focus on obtaining support from friends and families and safety planning [32]. The SERO app also provides these functionalities. In contrast, our solution additionally provides mental health support for relatives of individuals with suicidality. We integrated an evidence-based visual assessment tool, the PRISM™-S assessment, which has never been done before.

The intuitive use of the PRISM™-S method in its digital manner still has to be studied. Mühleisen et al. conducted a study with the PRISM™ method in its physical appearance (i.e. a metal board with disc to be placed) [15]. They asked patients to use the tool and place the disc to answer the question: "Where would you put the illness in your life at this moment?". Based on this experiment and the observations made, the authors concluded "The completion of the PRISM tasks was speedy and intuitive to the patient." [15]. A usability test of the SERO app and all its functionalities including the PRISM™-S method measuring mis-click rate and user satisfaction could help in collecting data on the intuitive use.

We also did not yet assessed the efficacy of the app as it was done for other existing digital solutions [33]. Specifically, an assessment of the efficacy and helpfulness of PRISM™-S assessment in an outpatient, individual setting still has to be done. Effectiveness of this assessment method as part of a therapeutic setting was already demonstrated [13]. Instead of assessing the efficacy, we studied the actual use of the app by analyzing the usage statistics showing an impressive use within one year although the app was not advertised by a comprehensive marketing campaign. We can see that in particular the self-assessment and the safety plan are important and well-used features of the solution. After one year of availability in stores, we have more than 1'000 users.

In contrast to reported clinical trials on suicide prevention apps [33], we studied the actual use of our solution within one year after initial release to stores. This reflects the actual use instead of usage behavior studied

in controlled settings such as randomized controlled clinical trials.

The duration of usage of the app by its users is not too long: almost the half of the visits took less than 1 min. One explanation might be that the users stopped after scrolling through the onboarding screens or they just used the emergency or contact numbers which is reflected by the large number of calls to supporting helplines. Another explanation might be that health professionals took a quick look at the features offered by the app. Second largest group of users used the app for 1–4 min. This usage time would allow to access the safety plan or make an assessment. To the best of our knowledge this is the first paper that studies the long-term usage of a suicide prevention app outside a clinical trial. Usefulness of the app and feedback on the single features have not yet been studied. We are currently collecting feedback on the usefulness of the single features and usability in a survey distributed among all registered SERO app users.

Further, the technical implementation of the SERO app is unique through the usage of HL7 FHIR® to store the information captured in the app. This allows in principle to transfer the collected data to other information systems. We can envision such integration when the app is used as part of a therapeutic setting. The assessments could then be recorded on a therapist's information system for continuous monitoring. The data governance is entirely handled by the MIDATA platform: Patients are in full control of the use of their data – any third-party access has to be approved by them. At the same time, this implementation of the data storage allows researchers to analyze the data—when users agree—to learn more about coping strategies or other aspects.

Many re-visits to the app took place on the same day. We assume that in situations of crisis the app is used more frequently on the same day. Users also return to the app after some time (8–14 days or 15–30 days), demonstrating that they regularly engage with the app. A big challenge in digital health interventions is to ensure continuous use or – in case of the SERO app—at least awareness and use in situations of suicidality. To support this, the SERO app provides an optional feature of enabling notification messages to the screen of the mobile phone as a reminder. Notifications were only enabled 19 times in one year. It seems that this feature is either not well perceived or users are not aware of it. To ensure regular usage, an integration into care settings would be useful. However, it remains an open issue which strategies could help in pointing the user to the app in cases of crises outside a therapeutical setting without overwhelming the user in times where support is not necessary.

We explicitly decided not to integrate an automatic interpretation and classification of the potential suicide risk based on the self-assessment. Such interpretation may have multiple, legal and ethical consequences, e.g. the question of who is responsible when the risk was not recognized correctly, and a user commits suicide. One extension to personalize the support of the app would be to monitor the frequency of use and triggering a message to seek help when the app is used very frequently. However, it remains open to future research how users would perceive such message and monitoring. Furthermore, we explicitly decided not to let individuals with suicidality share their PRISM™-S assessment with relatives. This was an outcome of the workshop conducted before developing the second version of the SERO app. The relatives had concerns that they would feel under pressure.

Countermeasures for identified risks

Unintended consequences of digital health solutions are so far often ignored [28, 34] and have not been yet sufficiently assessed for existing apps. Our work thus provides first ideas of unintended consequences that should be considered in the development of suicide prevention apps.

A key risk mitigation strategy for some of the identified risks is to integrate the use of the app into a care process. This integration could allow users to discuss their experiences and concerns with a human professional, enhancing the app's support capabilities. In addition, regular reminders could be sent to users to encourage them to seek help in critical situations. These reminders can also inform users of the app's capabilities and limitations, and encourage them to reflect on their use. Another concern is the potential misuse of the app's sharing functionality. To address this, limiting the number of people with whom users can share their information could be an effective strategy. This step could help maintain privacy and prevent the spread of sensitive information.

In addition, the emotional burden on family and loved ones is a significant concern. To mitigate this, the app could promote help-seeking behavior for relatives and regularly post messages encouraging users to reflect on their mental health. This approach can create a more supportive environment for both users and their loved ones. Addressing language and interaction barriers is also crucial. Inclusive design, which has not been prioritized enough, can play an important role in making the app more accessible. This could include the inclusion of visual aids and audio guides to accommodate a wider range of users.

Finally, improving the educational content within the app is another key area of focus. By providing more comprehensive information about the importance of professional intervention, the app can help limit the risk of users developing a false sense of well-being.

This educational aspect is crucial in ensuring that users understand the role of the app as a supportive tool rather than a complete solution. At the end, the SERO app is designed as self-management app and is not supposed to replace interaction with health professionals in therapeutic settings.

Limitations of the study

The human-centered, participatory approach applied in this paper has the benefit of including the ideas of experts and future users which is supposed to increase usefulness, efficacy, and acceptance. Restrictions in project budget is in conflict with such procedure, since we could not consider all comments retrieved in this process. Design decisions were therefore made in a way that balances the input received in the workshops with the available budget.

The workshop for assessing the risks was conducted with 6 persons that were involved in the development. This has the benefit that all implementation details of the SERO app were known to everybody participating in this workshop. However, a critical view from outside could even reveal additional risks. Beyond, in that assessment neither individuals at risk nor their relatives were involved. Their involvement in risk assessment could provide another perspective. We believe that risk assessment is a process to be continued when further developing the app. We plan to involve other groups of persons in next phases.

The usage analysis based on access statistics does not allow to study individual user access stories. Information on interaction paths would be of interest to improve the solution. Since the view for relatives was only published in November 2023, the data in the usage analysis on the features related to this view is still limited and cannot be considered representative. It only provides first insights. Since the usage data still contains periods of testing, we resisted at this stage to analyze subgroups of users (e.g. those who used the app longer than 5 min). This will be done in future. We also have no information on the demographics of the individuals who used the app and from whom we collected the statistics. This is to protect the privacy of the app users. More in depths insights could be received by contacting users directly which would allow for collecting some demographic data.

Conclusion

This study outlines the human-centered design and development process of the SERO app, a suicide prevention tool that integrates evidence-based practices for assessing suicidality and supporting self-management. The app provides several features to help in promoting awareness of coping strategies and improving access to key resources such as support hotlines and facilities. The app also supports collaborative interactions between users, their families and mental health professionals, fostering a network of shared knowledge and mutual support.

It is important to recognize the potential for unintended consequences, such as the risk of over-reliance on the app or misinterpretation of its guidance. This highlights the importance of early assessment of possible risks to ensure patient safety, particularly in the sensitive area of mental health. The study's findings highlight the need for iterative development processes to identify and implement countermeasures to minimize harm and mitigate potential misuse of the digital solution. In future work, the SERO app will be further refined to address these risks and increase its effectiveness. The lessons learned from this study may have broader implications for the design and implementation of digital solutions in mental health care, highlighting the importance of balancing technological innovation with user safety and ethical considerations.

Abbreviations

SERO	Suizidprävention einheitlich regional organisiert (Suicide prevention uniformly regional organized)
DSM- 5	Diagnostic and Statistical Manual of Mental Disorders
DTx	Digital therapeutics
GDPR	General data protection regulation
HL7 FHIR®	Health Level 7 Fast Healthcare Interoperability Resource
MIDATA	Data platform for personal health data
PHQ-9	Patient Health Questionnaire – 9 Depression
PRISM™-S	Pictoral Representation of Illness and Self Measure - Suicidality
UCD	User-centered Design

Authors' contributions

MD, CG contributed the psychological background. GH, FK were involved in the technical implementation of the solution and described the technical details. All authors were involved in the app design and development. KD prepared the paper draft and aggregated the content from the co-authors. KD analyzed the usage statistics. All authors approved the final version of the manuscript and agreed with publication. The draft of this paper was refined using the AI tools ChatGPT and DeepL Write to increase clarity and comprehensibility.

Funding

This research was partially funded by Gesundheitsförderung Schweiz and Bern University of Applied Sciences.

Data availability

The SERO app is available in the Swiss app stores. Google Play store: Google Play store: https://play.google.com/store/apps/details?id=ch.bfh.i4mi.sero. Apple store: https://apps.apple.com/ch/app/sero/id1591211599.

Declarations

Ethics approval and consent to participate

The participatory design process described in this paper is part of the SERO project. User involvement in the project was approved by the ethics committee of Northwestern and Central Switzerland under number 2022–00870. All participants provided informed consent in participating the participatory

design workshops. All registered users agreed in the use of their anonymized data for research purposes when registering to the app.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Received: 9 March 2024 Accepted: 15 January 2025
Published online: 08 April 2025

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