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Abstract

Non-communicable diseases (NCDs) are leading causes of premature mortality worldwide. Artificial intelligence (AI)-enhanced mobile health applications may support NCD prevention and self-management, but their effectiveness depends on user-centered and inclusive design. The EU-funded WARIFA project developed an AI-powered application to prevent NCDs in the general population through risk assessment and personalized lifestyle recommendations, and to support type 1 diabetes (T1D) self-management and complication prevention. This study describes the app's co-creation process using a mixed-methods, user-centered approach in Norway, Spain, and Romania. Eighteen focus groups, involving 142 participants and 22 individual interviews, were conducted with members of the general population, people with T1D, and seldom-heard participants. Data from semi-structured focus groups and interviews were analyzed using deductive content analysis and iteratively incorporated into development. Key themes concerned usability, privacy, functionality, app feedback, and device integration. Participants prioritized simple navigation, personalized evidence-based feedback, and real-time data visualization, particularly glucose data for T1D. The final app incorporated risk calculators, lifestyle questionnaires, environmental data, and customizable features, with feedback informed by World Health Organization and European Commission guidance. Co-creation enhanced the app's relevance and usability.

Keywords: Co-creation, non-communicable diseases, mHealth applications, type 1 diabetes, artificial intelligence, user-centered design.

1 Introduction

In today's digital landscape, mobile health (mHealth) applications (apps) have emerged as powerful tools for empowering individuals and promoting healthy lifestyles[1], with potential benefits for improving health outcomes and enhancing self-management of physical and emotional well-being[2]. However, their effectiveness largely depends on the extent to which they address users' actual needs and preferences, ensuring personalized and meaningful engagement[3].

This is particularly critical in the context of non-communicable diseases (NCDs), the leading causes of premature death and disability worldwide, which place a significant social and economic burden on individuals and health systems. Cardiovascular diseases (CVDs), chronic respiratory diseases, cancer, and diabetes are the four major NCDs, posing ongoing challenges for individuals, healthcare professionals and health services[4].

To address these challenges, the World Health Organization (WHO) introduced the "Global Action Plan for the Prevention and Control of NCDs 2013-2030"[4], developed originally for 2013–2020[5] and extended to 2030 in 2019, to align with the 2030 Sustainable Development Agenda. This plan outlines a comprehensive strategy based on six key objectives, focusing on the prevention of modifiable risk factors, the creation of healthier environments, person centered care within the framework of universal health coverage, and the strengthening of research and monitoring systems for NCDs.

In response to the growing need for effective strategies to prevent NCDs, mHealth technologies represent a promising and innovative solution. mHealth apps stand out for their broad accessibility, user-friendly interfaces, and wide acceptance across diverse demographic groups. In addition to improving access to health information and services, these apps promote behavior change and support the prevention of both acute and chronic diseases[6].

Artificial intelligence (AI) further enhances the potential of mHealth, particularly in the field of primary prevention[7]. However, to realize these benefits, it is crucial to actively involve end-users in the development of both algorithms and interfaces[8]. A co-creation approach ensures that mHealth solutions are designed in close collaboration with potential users[9], making them more friendly, relevant, and attuned to the needs of diverse populations[10]. In this sense, it is especially important to include the voices of those who are "seldom heard" - individuals often underrepresented in research and development due to systemic barriers or social disadvantage[11]. Consequently, methodological strategies such as co-creation are essential to improve outcomes, as they bridge the gap between research and practice by integrating the knowledge of diverse stakeholders to develop evidence-based interventions[12].

Within this framework, the EU-funded WARIFA project ("Watching the risk factors (WARIFA): Artificial intelligence and the personalized prevention and management of chronic conditions.")[13] aimed to develop a mobile app powered by AI to assess users' current health status and risk of NCDs—including cardiovascular diseases, chronic respiratory diseases, melanoma (a form of skin cancer) and diabetes. For members of the general population, the app focused primarily on disease prevention through

evidence-based, personalized recommendations that encourage meaningful changes in health-related behaviors. In parallel, although type 1 diabetes (T1D) cannot currently be prevented, the app was designed to support the self-management of T1D and to contribute to both prevention and ongoing care for related chronic conditions.

This article describes the co-creation processes undertaken in three partner countries –Norway, Spain and Romania- during the development of the WARIFA mHealth app.

Methods

In this section, we first present the study design, followed by a description of the participants involved in the co-creation process and the recruitment methods used. We then outline the main data collection methods, namely the focus groups and interviews, including how they were conducted. Finally, we describe the data analysis process, the way in which findings from the focus groups and interviews were implemented, and the structure of the app.

1.1 Study Design

The WARIFA project followed a mixed-methods approach, combining qualitative, user-centered design with quantitative descriptive data. It employed co-creation methodology, defined as an iterative and collaborative process that generates shared knowledge[14].

For the development of the WARIFA app, it has been essential to consider the needs and expectations of potential end-users, incorporating their input from the first stages of software development.

The co-creation consisted of an iterative process with the following structure: 1) the organization of focus groups and individual interviews; 2) the transfer of the participants' recommendations and opinions to other partners of the WARIFA project; and 3) the implementation of these recommendations in the WARIFA app, which was then presented to new focus groups.

1.2 Participants and Recruitment

The sampling frame included both members of the general population and people with type 1 diabetes because the WARIFA app addressed two related but distinct use cases. For the general population, it focused primarily on the prevention of non-communicable diseases through risk assessment and personalized lifestyle recommendations. For T1D, the app aimed to support its day-to-day management and help reduce the risk of acute and long-term complications. People with T1D were therefore included to ensure that the specific functionalities developed for this group reflected their particular needs and experiences.

Particular efforts were also made to include seldom-heard participants. These participants were included to broaden the diversity of experiences represented in the co-creation process and to identify potential barriers to the accessibility and usability of the app

Participants were eligible if they were aged 18 years or older and had access to a smartphone and an internet connection. Exclusion criteria were insufficient proficiency

in the language in which the study activities were conducted to provide informed consent and participate meaningfully, cognitive impairment that could interfere with the ability to use the app or understand the study procedures, and health conditions that might hinder participation.

Recruitment materials (Supplementary Fig. S1), such as flyers, leaflets, and posters, were specifically designed. They provided general information about the project and specific information about the focus groups, including their purpose and relevance for the development of the app. They also included a contact phone number and email address, allowing interested individuals to reach out for further information or participation. The content was tailored to the target populations and was offered in a combination of printed material and through social media. Additional targeted recruitment strategies were used to reach seldom-heard participants, as described below.

Participants with T1D were recruited through the local diabetes association and from the endocrinology out-patient clinic at the Insular University Hospital of Gran Canaria. They were informed and, if interested in participating, they contacted the research team by phone, messaging or e-mail. Several endocrinologists also supported recruitment by providing their patients with a brief explanation and leaflet on the WARIFA project during their scheduled visits to the clinic. The leaflet included information on how to contact the research team (via phone, messaging, or e-mail). Patients were also asked to share their glucose sensor and insulin pump data after signing a specific informed consent form.

Participants of the general population were recruited to the focus groups from different locations (community associations, The Red Cross, Las Palmas Food Bank). Researchers contacted each location and provided them with information about the project for distribution to their members or patrons. In Spain, flyers were also distributed during face-to-face recruitment in large supermarket.

Seldom-heard individuals were recruited in Norway, via flyers placed in local centers (a library, a center that donates second-hand items to refugees, a bar/movie theatre, etc.), and in Spain, from the social services of a municipality, for individual face-to-face interviews. Snowballing recruitment was also used, by asking participants to inform those in their social networks about the study and to contact the research team in case of interest.

Given initial difficulties in recruiting participants, it was decided to give each participant a gift card of 40 EURO (Spain) or 200 NOK (Norway), to compensate for transport costs and time dedicated to the project.

1.3 Data collection

1.3.1 Focus groups

Focus groups were the primary method used for data collection. They were conducted between September 2022 and January 2025 in Norway (2 focus groups), Spain (15 focus groups), and Romania (1 focus group). Seven aimed at T1D and 11 aimed at the general

population. All the TID groups were conducted in Spain, specifically in Gran Canaria (see figure 1 in the Results section).

All focus groups were conducted in the participants' native language (Spanish, Norwegian, or Romanian), with moderators who were fluent in the respective language.

Participants shared their opinions and comments related to the app and discussed them collectively.

An internal pilot was first conducted at the Instituto Universitario de Investigaciones Biomédicas y Sanitarias with researchers not involved in the WARIFA project. This initial session aimed to gather early insights and facilitate brainstorming, as well as focus group planning. Following the pilot, minor refinements were made to the focus group protocol, including reducing the duration of the scheduled break.

1.3.1.1 Participant Characteristics

Focus groups, both general population and T1D, were heterogeneous in terms of age, gender, and level of education. For participants with T1D, heterogeneity was also sought in the type of treatment (subcutaneous insulin injections vs. insulin pumps) and complications of diabetes.

Some participants took part in more than one focus group round to evaluate successive versions of the prototype.

1.3.1.2 Structure and script development

All focus groups were divided into two parts, separated by a 10–15-min break during which refreshments were provided to promote a comfortable and positive atmosphere. The total duration of the sessions ranged from 120 to 180 min.

Each focus group was facilitated by one or two moderators and supported by designated note-takers. At least one moderator and one observer were present in every session, in accordance with established methodological validity criteria for focus group research[15].

The moderators followed semi-structured scripts designed to guide the discussion and elicit insights relevant to the development of the WARIFA app. The content and structure of the scripts were adapted according to four main factors: i) the number of participants, which influenced the estimated duration of the activities, ii) the type of study population (different activities were designed depending on whether the participants belonged to the general population or were individuals with T1D), iii) the number of moderators and observers available, and iv) the stage of development of the WARIFA prototype.

During the early stages of the co-creation process, interface sketches and other participatory activities were used to elicit feedback on the design and functionalities of the future app. In addition, some functionalities were evaluated before their integration into the app. Specifically, selected questionnaires and the corresponding feedback provided to users were tested using REDCap (Research Electronic Data Capture), hosted at the Universidad de Las Palmas de Gran Canaria–Instituto Universitario de Microelectrónica Aplicada. REDCap[16,17] is a secure, web-based software platform designed to support data collection for research studies. It provides an intuitive

interface for validated data capture, audit trails for tracking data manipulation and export procedures, automated export procedures for seamless data downloads to common statistical packages and procedures for data integration and interoperability with external sources.

1.3.1.3 Topics covered

Each focus group addressed one or more topics according to the objectives of the session and the stage of development of the WARIFA app. The main areas explored were: (i) participants' attitudes towards health and technology; (ii) their views on the app's content, information, privacy, recommendations, and feedback; (iii) the evaluation of specific functionalities; and (iv) the testing of the WARIFA questionnaires and the feedback generated from participants' responses.

The topics and activities evolved throughout the co-creation process. During the early focus groups, participants were asked what information and functionalities they would like to see in the WARIFA app. Their feedback covered usability aspects as well as medical, health, and lifestyle-related content. In some sessions, participants created hand-drawn interface sketches, which were subsequently digitalized and used to inform the design of the app.

Once an interactive interface or prototype became available, participants tested it during the focus groups and provided feedback on its usability, content, and presentation. New and modified functionalities were also discussed and evaluated throughout the development process. These included registration and login procedures; the automatic collection and display of physical activity data; the presentation of local air quality and ultraviolet index information; and tools for the management of T1D, such as time-in-range data and a graph displaying predicted glucose levels for the following hour.

1.3.1.4 Technological Tools and Devices Used

Participants used standardized Android-based devices provided for testing: two *Samsung Galaxy tablets* (Tab A7 lite), two *Samsung smartphones* (Galaxy S6 and A14) and three *Realme smartphones* (C30).

1.4 Individual interviews

Nine interviews were conducted in Norway (June-August 2023) and thirteen were conducted in Spain (November 2023). A script adapted to the population and the state of the app in that moment was also developed. This script included questions related to the following topics: i) perception of the healthcare system, ii) perception of their own health and iii) reflections on technology and health. Their previous experience with technology and health technology and their expectations of health technology were explored. Finally, they tested the questionnaires and feedback messages (only in the interviews in Spain) with the same devices described above. Interviews lasted between 30-45 min. Additional information regarding the interviews is available in Broadway et al.[18].

2 Data analysis and implementation

2.1 Data analysis

The focus groups and interviews were analyzed by a descriptive deductive content analysis[15]: i) *in-depth analysis of the video-registration*, ii) *identification of relevant issues discussed*, iii) *code generation for each relevant topic*, iv) *clustering of information obtained on each topic*, v) *critical analysis and interpretation of information collected on each explored topic*, vi) *incorporation of the moderator and note-taker`s observations*, and vii) *synthesis of results and report*.

2.2 Implementation

Insights derived from the qualitative phase were evaluated and integrated into the app's features and design through an iterative development process (agile methodology)[18]. This included ongoing meetings with project researchers to incorporate feedback and ensure continuous improvement. Daily stand-up meetings were held among developers, technical and clinical experts, allowing for alignment and problem-solving. Each app version was tested by internal superusers – i.e., project members that used the app together with the associated sensors and services, as well as by participants of the focus groups.

3 WARIFA app sections

3.1 Questionnaires

3.1.1 Basic Questionnaire

This questionnaire collects information on the following variables: *year of birth*, *gender*, *weight*, *height*, and *the presence of pre-existing conditions* such as hypertension, hypercholesterolemia, and myocardial infarction.

3.1.2 NCD Questionnaire development and testing

The NCD questionnaire was originally developed in Norway and tested between 2016 and 2019 for a study piloting a smartphone-based tool collecting data on four key modifiable risk factors for NCDs (unhealthy diet, physical inactivity, tobacco use and harmful use of alcohol). The questionnaire included 26 questions: eight on socioeconomic factors, 17 on the four risk factors mentioned above, and one about NCD diagnoses[19].

For the WARIFA app, a subset of these questions was adapted and used. Specifically, eight on socioeconomic factors, 17 on the four risk factors, and a similar question about current or previous NCDs. Two new items were added to the NCD questions, and two existing ones were combined into a single question. A question about *snuff* consumption was omitted in Spain and Romania due to its very limited use in these countries. A question about annual income was also modified, as its initial formulation caused discomfort among participants.

3.1.3 Sun habit questionnaire development

A brief questionnaire on *sun-related habits* was developed based on the internationally recognized measures of sun protection with eight questions: i) *limiting time in the midday sun*, ii) *use of shade*, iii) *wearing protective clothing*, iv) *wearing a hat*, v) *wearing*

sunglasses, vi) *sunscreen use*, vii) *sun protection factor of the sunscreen,* and viii) *ultraviolet (UV) index data*. Related to this point, as the UV index forms the basis for current sun safety recommendations[20], the app recorded UV index data from public databases such as Yr[21] and OpenWeatherMap[22], as long as location services were enabled.

3.2 Feedback, recommendations and messages to improve users' health literacy

Feedback messages and evidence-based recommendations were developed to support users in adopting healthier behaviors. Feedback was implemented as a behavior change technique, following the approach described by Krukowski et al.[23], and consistent with frameworks proposed in previous research[24–26], with the goal of promoting sustainable lifestyle improvements.

The messages delivered to potential users included: i) informative and evaluative feedback on behavioral performance, based on responses to structured questionnaires; ii) positive reinforcement to encourage sustained engagement and motivation; and iii) practical guidance to help users align their behavior with recommended health goals.

These recommendations were grounded in current guidelines from the WHO[27–29] and the European Commission[30], and were subsequently modified using the context engine—a tool designed to tailor content to specific implementation settings and user profiles.

Additionally, a "Do you want to know more?" section was created to improve users' health literacy. Informative messages for the prevention of NCDs were designed, also based on scientific evidence for health promotion, and appropriate links to the sources were provided.

3.2.1 Risk calculators and risk assessment

To assess the risk of developing various NCDs, different tools were implemented and evaluated during the focus groups (Table 1).

Table 1. Risk calculators and assessment tools implemented in the WARIFA app.

Tool	Risk assessed and target population	Application in WARIFA app
SCORE2 (Systematic Coronary Risk Evaluation 2)	Ten-year risk of cardiovascular events in adults aged 40–69 years without previous cardiovascular disease[31].	The low-risk model was used in Spain and the high-risk model in Romania[32].
NORRISK 2	Ten-year risk of acute myocardial infarction or stroke, based on Norwegian data.	Implemented exclusively in the Norwegian version of the app.
T1D CVD risk calculator	Cardiovascular risk in people with T1D. Based on a Bayesian belief network that incorporates causal relationships and handles missing data[33].	Provided personalized risk estimates, with an AUC of approximately 0.75.
FINDRISC (Finnish Diabetes Risk Score)	Ten-year risk of developing type 2 diabetes among adults without a previous diabetes diagnosis[34].	Implemented for type 2 diabetes risk screening.
COPD-PS (Chronic Obstructive Pulmonary Disease Population Screener)	Identification of individuals at risk of COPD[35].	Implemented for COPD risk screening.
NOWAC (Norwegian Women and Cancer Study)	Melanoma risk based on pigmentary characteristics and age-specific and lifetime ultraviolet radiation exposure, including sun exposure and indoor tanning[36–40] .	Implemented using evidence derived from the Norwegian population.
MIA (Melanoma Institute Australia)	Lifetime risk of developing a first primary invasive melanoma. Developed in Australia and validated in four independent population-based studies, including studies in Sweden and England [41,42].	Implemented for melanoma risk assessment.

4 Ethics

All participants signed an informed consent form after receiving detailed oral and written information on the project.

This study complies with the Declaration of Helsinki and European and national legislation (General Data Protection Regulation). The Norwegian coordinating institution, acting on behalf of the WARIFA consortium, requested an assessment of the co-creation sub-study (Sub-study 3) from the Regional Committees for Medical and Health Research Ethics (REK). In its determination, REK concluded that the sub-study fell outside the scope of the Norwegian Health Research Act and therefore did not require submission for ethics approval by REK. In Spain, because patients with type 1 diabetes also participated, an additional consultation was sought from the Comité de Ética de la Investigación con Medicamentos de Las Palmas (CEIm provincial de Las Palmas Hospital Dr Negrín). The committee also confirmed that WARIFA Sub-study 3,

which comprises the co-creation activities reported here, was exempt from review by that committee.

5 Results

A total of 18 focus groups were held (Figure 1), including 142 participants: 99 participants from the general population and 43 participants with T1D. Overall, 55.6% (n=79) were women and 44.4% (n=63) men. Eleven focus groups involved the general population and seven involved participants with T1D. Additionally, 22 individual interviews were held with seldom-heard participants, 77.3% (n = 17/22) women and 22.7% (n = 5) men.

The following main themes were identified: *usability*, *privacy*, *functionality preferences*, *feedback of the app for the users* and *device integration* (Table 2).

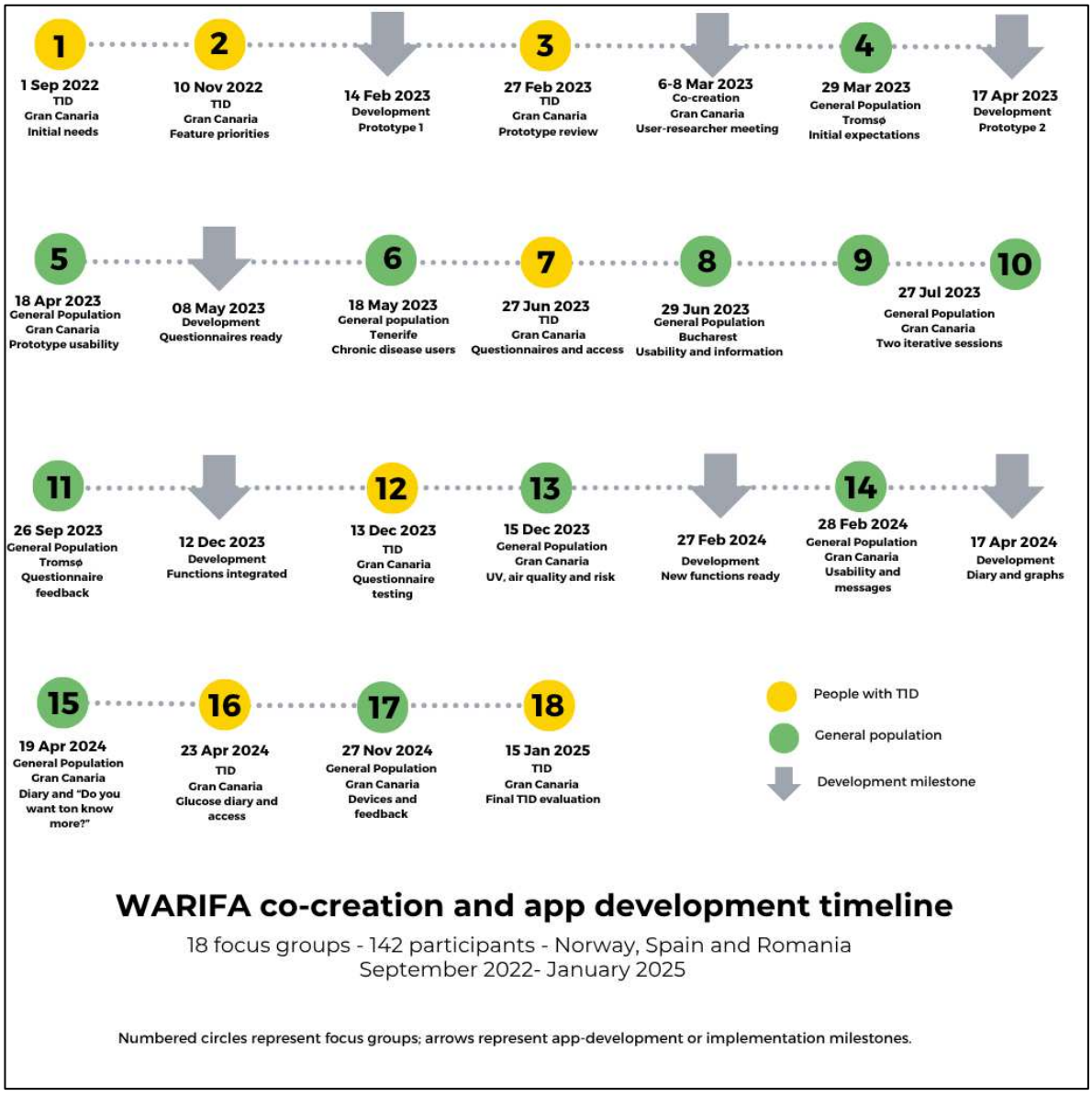


Figure 1. Focus groups conducted during the co-creation phase.

5.1 Focus groups with general population

The highest number of participants in Spain was obtained by contact with the association Food bank of Las Palmas (n=24), while face-to-face recruitment in a large supermarket did not yield any participants at all. Six rounds of focus groups were conducted (Table 3).

Table 2. Themes and subthemes identified in the thematic analysis.

Themes	Subthemes
Usability	• Simple Navigation. • Customization.
Data Privacy & Security	• Selective data sharing. • Reputable Support.
Functionality Preferences	• Health Data Visualization. • Feedback focuses on actionable guidance. • Real-time Data: Timely feedback, particularly for glucose and lifestyle monitoring.
Feedback on the app	• Evidence-based recommendations. • Concise Messaging. • Adjustable Notifications.
Device Integration	• Compatibility with other health tracking devices. • Human Contact Option.

- The first round took place between March and June 2023 in Tromsø (Norway), Gran Canaria and Tenerife (Spain) and Bucharest (Romania). The main topics of this round were: i) brainstorming about participants' needs and preferences, ii) app usability, iii) security, iv) time willing to be dedicated to the apps, and v) their opinions and perceptions of AI, both in general terms and specifically as applied to healthcare. In this round, participants across countries raised concerns about data privacy and emphasized the importance of transparency, choice, and simplicity in both content and design. Preferences included visual and personalized risk feedback, use of local language, simple navigation, and credible sources. Opinions on time willing to spend using the app ranged widely (from 5-10 min to 1 h), and gamification was suggested by some. Participants were also concerned about how certain users, particularly those who are more alarmist or hypochondriacal, might react to the health information provided. They suggested that the app should allow each user to choose how much information and feedback they wish to receive.
- The second round, conducted between July and September 2023 in Tromsø and Gran Canaria, focused on testing questionnaires, feedback messages, and the initial app prototype. Due to the high number of participants in this phase, in Spain, they were divided into two parallel groups to facilitate discussion and

ensure active participation. Participants found most of the questionnaires clear and reasonably timed, though some content (e.g., income questions or the melanoma risk questionnaire) required adjustment. Feedback messages were generally well received, with suggestions to include additional detail and maintain a non-alarming tone.

- The third round was held in December 2023 in Gran Canaria, to test the sign-up process of the WARIFA prototype and to check the different functionalities in Spanish. The process was seen as simple, but improvements were suggested to increase understandability of certain features, such as cardiovascular risk graphs.
- Round number four was held in February 2024 in Gran Canaria and aimed to gather feedback on the overall impression of the app and recommendation messages. In this round, participants' feedback was similar to previous sessions. The limited functionality of the app at the time restricted the depth of feedback. Some components were presented outside the app, and several participants experienced difficulties with the usability questionnaires.
- The fifth round, in April 2024, also took place in Gran Canaria only and its aim was to show and receive feedback about the app in general, and specifically about two functionalities: the diary and the "*Do you want to know more?*" section, aimed at increasing end-users' health literacy. Participants reported usability issues, mainly related to the app's organization and terminology. They suggested renaming the questionnaires and expressed a need for greater flexibility when using the diary feature. Participants also mentioned that they would recommend the app if improvements were implemented.
- The sixth and last round was also conducted in Gran Canaria. Its main aim was to test the new functionalities before the validation of the app. In this round, participants requested broader access to the cardiovascular risk calculator (starting from age 18). They preferred displaying risk ranges instead of single values, and emphasized the need for clearer explanatory messages and practical suggestions to help users reduce their risk.

414 **Table 3.** Summary of focus groups with general population.

Focus Group Round	Location	Participants (n)	Key Feedback Summary
Round 1	Tromsø	7	- Valued data entry but concerned about privacy. - Preferred positive feedback. - Younger participants preferred shorter usage time.
	Gran Canaria	8	- Preferred a simple app with useful content. - Wanted easy and personalized risk visualization. - Supported gamification. - Local language.
	Tenerife	13	- Viewed the WARIFA app as a useful complement to healthcare gaps and suggested future features (e.g., air pollution data, mole tracking). - Concerning the credibility and personalization of recommendations.
	Bucharest	6	- Wanted data taken from other apps, not only from questionnaires. - Emphasized local language and clarity. - Concerned about excessive info and credibility of recommendations.
Round 2	Gran Canaria	24	- Divided into 2 groups. - Tested Non-Communicable Diseases questionnaires (6–12 min). - Found them understandable and time acceptable. - Income question was rephrased. - Melanoma questionnaire was found difficult and long: modified accordingly. - Tested feedback messages via REDCap. - Wanted more depth. - 'Do you want to know more?' section added.
	Tromsø	5	- Tested shortened melanoma questionnaire. - Found it appropriate. - Suggested positive, non-alarming feedback.
Round 3	Gran Canaria	9	- Tested sign-up, ultraviolet, cardiovascular risk and diary functionalities. - Risk graph hard to interpret. - Diary well received.
Round 4	Gran Canaria	10	- Participants downloaded the app 3 days prior. - Some content was shown externally (e.g., messages). - Usability questionnaires presented difficulties. - General feedback was consistent with previous groups.
Round 5	Gran Canaria	9	- App seen as non-intuitive. - Recommended reorganization and clearer questionnaire names. - Wanted to choose diary frequency (daily, weekly, monthly).
Round 6	Gran Canaria	8	- Final test before pilot. - Preferred cardiovascular risk calculator accessible from age 18. - Wanted risk shown as a range. - Lacked explanatory messages and practical advice to reduce their risk.

5.2 Focus groups with T1D participants

Seven focus groups with people with T1D were conducted in Spain between September 2022 and January 2025 (Table 4).

In the first focus group, in addition to discussing desired app features, participants shared their views on the use of AI in health care. Their perspectives were diverse: while some saw AI as a useful and innovative tool, others expressed doubts about its reliability and its ability to understand individual health conditions. As in the groups representing the general population, concerns were raised about privacy, transparency, and the risk of receiving generic or non-personalized recommendations.

In the second group, the sketches provided by participants reflected their preference for a clean and simple design, showing only key information on the home screen. They highlighted the importance of prominently displaying glucose levels and having easy access to essential tools such as insulin dose calculators. Participants also emphasized the need for customization, especially regarding notification frequency (they would like it weekly or monthly) and the ability to adjust settings to their daily routines.

In the third session, despite the limited number of T1D-specific features in the prototype, participants missed a more interactive experience. All three participants included in their sketches the possibility of chatting with a healthcare professional directly through the app. In terms of colors and font sizes used on the home screen, they found them acceptable, although they would like to be able to customize them.

In the fourth group, although the questionnaires were considered quick and easy to complete, participants suggested allowing users to skip certain sections or answer them later. In terms of diabetes management, they requested more advanced features, such as alarms for critical values and the option to generate reports that could be shared with their healthcare team.

In the fifth group, participants expressed low interest in the diary functionality, as they already use specific apps for their diabetes management and did not want to increase their burden with an additional app. Despite this, they appreciated the ability to visualize their own glucose levels over the last 24 h and see a short-term prediction. However, they stressed that this information must be presented clearly and in real time, rather than retrospectively, as it was shown, to be truly useful.

In the sixth group, participants tested the "*Do you want to know more?*" functionality. They appreciated the idea and requested that messages be short, clear and non-intrusive, with the option to access more detailed content only if desired. They also asked to be able to control the frequency and quantity of these messages, to avoid information overload.

In the final focus group, participants tested the app on their personal devices, including newly implemented features such as 30-min glucose prediction, nocturnal hypoglycemia prediction, and glucose data visualization. While these features were positively received for their clarity and potential usefulness, users also reported technical malfunctions, lack of explanation behind the predictions, and a need for further customization, especially regarding graph display and integration with daily

routines. The manual hypoglycemia register diary was generally considered impractical for everyday use.

In the different focus groups, both with general population and potential T1D users, participants expressed their preference for having someone to contact through the app (human contact), receiving evidence-based information, and getting personalized feedback messages.

Table 4. Summary of Focus Groups with Participants with T1D.

Focus Group	Participants (n)	Main Objectives	Key Findings
1	5	- Understand experiences with health apps and AI. - Identify desired features.	- Preferred apps that are easy to use, provide useful info in 2–3 steps, and minimize data entry. - Most valued features: ease of use, personalized recommendations, data security, and evidence-based content.
2	4	- Explore T1D-specific needs and interface preferences.	- Desired real-time glucose display, customizable alarms, concise content. - For insulin: dose calculator, dose history, active insulin estimation. - Participants drew interface sketches.
3	3	- Test early prototype on Android. - Gather feedback on design/functionality.	- Lacked diabetes-specific features and interaction. Visuals acceptable. - Preferred customizable home screen. - All participants included a chat with a healthcare professional in their sketches.
4	10	- Test more mature prototype. - Collect glucose and insulin data. - Test questionnaires.	- Positive feedback on questionnaires (quick/easy). - Suggested optional questions and delayed answers. - Requested connection to healthcare team, alerts for poor data. - Called for better diabetes functionality.
5	8	- Test diabetes features and evaluate blood glucose visualizations.	- Most app functions well received. - Cardiovascular risk input is confusing. - Preferred real-time data upload. - Low interest in diary due to app overload. - Researchers uploaded their data for glucose visualization and prediction.
6	6	- Test “Do you want to know more?” feature.	- Preferred short, clear messages with optional links. - Wanted to choose frequency and amount of information.
7	7	- Test the app on personal devices. - Evaluate new diabetes features. - Assess the manual hypoglycemia diary.	- Positive feedback on 60-min glucose prediction and nocturnal hypoglycemia prediction. - Users valued clear, intuitive design and requested actionable recommendations. - Participants highlighted technical issues, requested greater customization (e.g., adjustable graph intervals), and clearer explanation of prediction inputs. - Manual diary was considered tedious and impractical.

5.3 Individual interviews

A total of 22 individuals were interviewed in Norway (n=9) and Spain (n=13). Most participants were born outside their country of residence. Spanish participants (mainly female, aged 30–62) were either unemployed or employed in unskilled jobs (cleaner, waiters and construction workers). Norwegian participants (aged 18–60, mostly female) shared a broad interpretation of health, encompassing both physical and mental well-being, like the Spanish group. Norwegians emphasized balance and flexibility in healthy living, while Spanish participants highlighted basic needs such as peace of mind, stable employment, and/or social support. More detailed results of these interviews are available in Bradley et al[18].

Participants in both countries had a general understanding of digital health technologies and recognized their potential benefits, particularly for convenience and access. However, concerns were raised about the loss of human interaction and autonomy in decision-making. Most relied on doctors or the internet for health-related questions and valued human guidance over automated systems.

Commonly used technologies included step counters, menstrual tracking apps, YouTube or Instagram for exercise, and apps like Strava, Flow, and Yuka. Spanish participants also reported using Google and YouTube for health information, with some using pregnancy tracking and food quality apps.

In Spain, participants tested the WARIFA questionnaires and feedback. They found the questionnaires clear and easy to complete, with minor suggestions for improved wording, such as using 'skin cancer' instead of just 'melanoma'. The feedback provided by the app was considered useful, understandable, and appropriate for this population.

5.4 Implementation

The proposed functions and modifications that could be implemented, given the project's aims and constraints (such as security, privacy, time and cost), were included both in the app and in the back-end servers of the system.

As was mentioned above, the app and connected server functionalities were tested on different smartphones daily in lab-settings. This approach ensured that the platform was consistently and continuously updated with new and improved features and functions, readily available to participants of the focus group to reassess, discuss, and then approve or disapprove the current feature or design choice.

Also, regarding the functionality development, health-related sensor integration, reducing battery consumption, and finding an intuitive way of organizing and navigating among all functionalities were the most challenging issues to solve.

5.5 Final WARIFA app sections

The WARIFA app was created through an iterative process with careful consideration of the feedback and recommendations from all participants, incorporating continuous refinements based on their input (Supplementary Fig. S2). It was developed with a simple and intuitive interface and incorporates information from public databases, such as the UV and air quality indices, as well as personal data provided by users. These data

could be entered manually or automatically collected through connected sensors, including glucose sensors used by participants with T1D (FreeStyle Libre 2 and 3, Abbott, Chicago, IL, USA). Personalized and evidence-based recommendations and feedback were provided through the app.

The final version of the app included the following sections:

5.5.1 Assess your lifestyle

This section included all questionnaires that were tested and discussed during the focus groups and interviews. Based on participants' feedback, the wording of recommendations and feedback messages was revised to improve clarity and usefulness. The titles of the questionnaires were also modified to make them more intuitive. Finally, the NCD questionnaire (described above) was divided into three sections: i) eating habits, ii) sun exposure habits and other lifestyle habits that included tobacco use, alcohol consumption, and iii) physical activity.

5.5.2 My health predictions

Based on participant feedback, the risk assessment tools were presented in the app under accessible, condition-based labels. The label "Cardiovascular disease" included SCORE2, NORRISK 2, or the T1D-specific cardiovascular risk calculator, as applicable to the user's country and health profile. "Type 2 diabetes" included FINDRISC, "Melanoma skin cancer" included the MIA calculator, and "Chronic obstructive pulmonary disease" included COPD-PS. For melanoma risk assessment, participants found the MIA questionnaire easier to understand and complete than the NOWAC questionnaire; therefore, MIA was selected for implementation in the final version of the app.

5.5.3 My community

This section allowed users to receive personalized recommendations based on environmental data. Using geolocation (when permission was granted), tailored advice was generated according to the UV index and air quality levels in the user's geographical area. Additionally, a link to a webpage with further information about the local environment was displayed[43].

5.5.4 My day

A diary was available for users to easily and intuitively track their chosen daily lifestyle factors. The diary could be customized to include variables such as fruit and vegetable intake, body weight, number of cigarettes smoked, alcohol consumption, and sun safety practices, including sunscreen use. Users were able to view the evolution of their data over the past week, alongside a marker representing their personal goals. In addition, individualized messages—generated using a combination of human expert knowledge and AI— offered tailored feedback and recommendations to support positive behavior change (e.g., "*One goal at a time!*", "*Well done! You´ve reached your goal today.*", "*Don't forget why you started, keep pursuing your goal.*"). For people living with T1D, the diary also included an option to log hypoglycemic events.

5.5.5 Step functionality, heart rate function and sleep function

These sections were available to participants who had a physical activity monitor compatible with the app. In this case, they were able to monitor their daily steps, review their progress compared with the previous six days, visualize a graph with their current heart rate, and assess their daily sleep duration with the option of comparing with the preceding six days.

5.5.6 My top recommendations

Important recommendations were displayed each day based on the information provided by the participants manually (questionnaires and diary) or automatically (physical activity device). These recommendations were developed, based on current guidelines from the WHO and the European Commission and were subsequently adapted using the context engine.

5.5.7 Diabetes functionality

People with T1D could look at their glucose data by connecting to the glucose sensor. They could also view historical glucose data through graphs showing information such as time in target range, and historical glucose values. Using AI, they received an estimate of the interstitial glucose prediction over the coming 30 min, as well as a personalized risk of nocturnal hypoglycemia.

5.5.8 Settings and other functions

In this section, participants could customize which functionalities of the WARIFA app they wanted to view, as well as adjust settings such as notifications, sounds, font styles, and language.

6 Discussion

This study describes the development of the WARIFA app, which was based on a co-creation approach. To ensure the app addressed real needs and expectations, the project adopted a participatory design approach involving individuals with T1D, seldom-heard populations, and general population.

Input was gathered through 18 focus groups involving 142 participants and 22 individual interviews across three countries. Participants' contributions guided the integration of key features, including user control over data privacy, a simple and intuitive interface, culturally sensitive and personalized content, and evidence-based recommendations. Concerns regarding data security and privacy remain a central challenge to the integration of AI-based mHealth solutions into healthcare and their wider acceptance among users[44]. Both members of the general population and people with T1D emphasized the importance of receiving clear and comprehensible feedback and expressed a desire for direct communication with healthcare professionals. However, participants with T1D also identified more immediate and condition-specific needs, including real-time glucose monitoring and decision-support visualizations, while considering a diary for recording hypoglycemic episodes unnecessary. These findings show that participants had both shared and population-specific needs. Clear

information, trust, and communication were important to both groups. However, participants with T1D had additional needs related to the day-to-day management of their condition and the use of real-time health data. They generally showed little interest in diary features, particularly a hypoglycemia diary, because entering additional information would increase the burden of managing their diabetes. Overall, these findings support combining common app features with functionalities tailored to the needs of each target population[45].

Although many priorities were shared across countries, including simple navigation, data privacy, personalized feedback, and access to credible information, the findings also highlighted the importance of adapting the app to each setting. Participants emphasized the use of local languages, and some content and functionalities required contextual adaptation, such as country-specific cardiovascular risk calculators and the modification or omission of questionnaire items that were not equally relevant or acceptable across countries. These observations suggest that cultural and healthcare-system contexts may have influenced some preferences and reinforce the need for local adaptation when implementing the app in different settings. This is consistent with previous research showing that digital health interventions should be adapted not only linguistically, but also to the broader cultural, socioeconomic, and healthcare context of their intended users[46].

The input provided by our participants is consistent with the existing literature. For example, Jakob et al.[46] identified personalization and user-friendly support as critical factors influencing adherence to mHealth apps. Similarly, a global survey of 1,130 individuals reported that 45% of users desired communication features with healthcare professionals, while 61% sought support to better understand their health condition and treatment options[47].

Regarding feedback, and following prior recommendations[48], this study enabled participants to visualize and interact with their health data to potentially enhance engagement. Personalized feedback may contribute to increased engagement and could help foster self-efficacy, potentially empowering users to make more informed healthcare decisions[49]. In line with this, the WARIFA project developed personalized feedback messages aimed at supporting users in adopting healthier habits, guided by recommendations supported by official health organizations. Feedback emerged as a consistent theme across all focus groups and interviews, particularly conducted with seldom heard populations. This agrees with our findings and those of other researchers, which highlight the central role of personalized feedback in developing engaging and impactful digital health tools[50–52].

The co-creation approach used in WARIFA is aligned with participatory design methodologies, which have demonstrated improved health outcomes compared to standard care or interventions developed without user input. Evidence suggests that participatory, user-centered approaches can enhance health-related outcomes and contribute more broadly to public health, underlining the importance of tailoring digital tools to reduce health disparities[53]. However, few studies have explored their longer-

term effects, which remains an important area for further research – particularly in relation to sustained user engagement and behavior change[54].

The participatory design process adopted in WARIFA may also contribute to the long-term sustainability of the intervention by fostering a stronger alignment between the app's functionalities and users' evolving needs and preferences. Features such as personalized feedback, user control over privacy settings, and culturally sensitive content may support continued engagement over time, although this remains to be confirmed through longitudinal evaluation. Furthermore, the modular and user-centered design adopted in WARIFA may facilitate future adaptation and implementation in other healthcare settings, populations, and countries, supporting the potential scalability of the intervention while allowing context-specific customization.

A major strength of the WARIFA project lies in its commitment, involving users from the earliest stages of development. This iterative, user-centered process not only enriched the app's design but also ensured its alignment with current trends in mHealth, such as personalization and automation of data input. Furthermore, the app includes features specifically tailored for T1D management and delivers evidence-based recommendations, contributing to the growth of knowledge and improvement of the users' health literacy.

Despite the strengths of this study, several limitations exist. Although the number of participants was limited, no substantially new themes emerged during the later focus groups, suggesting that data saturation was achieved. Nevertheless, the findings should be interpreted within the context of the participating countries and user groups. In addition, while efforts were made to include seldom heard populations, certain vulnerable groups, for example individuals with low literacy, or those who are blind or visually impaired, were not represented. Additionally, the long-term impact of the co-creation process on user engagement, behavior change, and chronic disease prevention remains to be established through longitudinal evaluation.

In conclusion, the co-creation process underlying the development of the WARIFA app demonstrates the value of involving end-users to enhance the relevance, usability, and effectiveness of digital health solutions. This experience highlights the importance of user control over data privacy, simplicity of design, and personalized features. Beyond serving as a development strategy, co-creation also emerges as a robust methodological approach for designing digital health interventions that aim to strengthen users' health literacy, engagement, and capacity for self-management.

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A.M.W.: contributed to the study design and supervision and to the interpretation of the results; and critically reviewed the manuscript.
G.Z.Z.: contributed to participant recruitment and focus group observation and prepared the figures.
C.B.A.: contributed to the focus groups and co-creation activities.
L.P.-P.: contributed to the design and supervision of the focus groups conducted in Tenerife and was responsible for the “My Community” section of the app.
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The datasets generated and/or analysed during this study are not publicly available due to privacy and ethical restrictions, as they contain potentially identifiable qualitative data. De-identified data may be available from the corresponding author upon reasonable request and subject to applicable ethical and data protection requirements.

Competing interests

The authors declare no competing interests.

Abbreviations

AI: Artificial Intelligence
AUC: Area Under the Curve
BBN: Bayesian Belief Network
CEIM: Comité de Ética de la Investigación con Medicamentos
COPD: Chronic Obstructive Pulmonary Disease
COPD-PS: Chronic Obstructive Pulmonary Disease Population Screener
CVD: Cardiovascular Disease
eHealth: Electronic Health
FINDRISC: Finnish Diabetes Risk Score
MIA: Melanoma Institute Australia
mHealth: Mobile Health
NCD: Non-Communicable Diseases
NORRISK 2: Norwegian Risk model for cardiovascular events
NOWAC: Norwegian Women and Cancer cohort study
REDCap: Research Electronic Data Capture
REK: Regional Komiteer for Medisinsk og Helsefaglig Forskningsetikk
SCORE-2: Systematic Coronary Risk Evaluation 2
T1D: Type 1 Diabetes
UV: Ultraviolet
WARIFA: Watching the Risk Factors: Artificial Intelligence and the Prevention of Chronic Conditions
WHO: World Health Organization

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