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Effect of the WARIFA app on user-defined objectives, healthy lifestyles and management of type 1 diabetes (T1D): a pilot randomised controlled trial protocol

Carmelo Betancort Acosta, Garlene Zamora Zamorano, María Luisa Álvarez Malé, Lilisbeth Perestelo-Perez, Alezandra Torres Castaño, Marit B. Veierød, Kristina Reyes Suárez, Alejandro Déniz García, Eirik Årsand, Inger Torhild Gram, Maja-Lisa Løchen, Cristina Soguero-Ruiz, André Henriksen, Antonio J. Rodríguez Almeida, Miroslav Muzny, Reetta Välimäki, Thomas Schopf, Himar Fabelo Gomez, Conceição Granja, Ana M. Wägner

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Abstract

Background: Non-communicable diseases (NCDs) are the leading cause of death and have a high global prevalence. The four main diseases are cardiovascular and respiratory diseases, cancer and diabetes, which share common risk factors and can be prevented through physical activity, a healthy diet, avoiding smoking and alcohol consumption, and other lifestyle changes. Watching the Risk Factors (WARIFA) is a mHealth application (app) created for general health awareness and to support users in adopting healthier behaviours. It also has a functionality to support type 1 diabetes (T1D) management.

Objective: To evaluate the effectiveness of the WARIFA app with personalised artificial intelligence (AI) driven messages, compared to a non-personalised version, in promoting health-related behaviour change among general population and individuals with T1D.

Methods: A total of 108 European participants, including individuals with T1D, are randomised (computer-generated sequence, double-blind, 1:1 ratio) to an intervention or control group. In the intervention group, participants use the WARIFA app with personalised messages and the use of AI. This applies to some functionalities, such as personalised recommendations and risk prediction for the four main NCDs. In the control group, participants use a WARIFA app without personalised messages or AI. Both groups are provided with an activity monitor and will use the WARIFA app for 12 weeks. The primary outcome is a self-

defined goal, chosen from a set of proposed objectives at baseline and assessed at the end of the study using a Likert scale (0 to 10 points, 0 being no achievement at all and 10 being full achievement of the proposed objective). Secondary outcomes include: engagement with the app, changes in lifestyle behaviour, body composition, lipid profile, glycated haemoglobin (T1D only), hypoglycaemic events (T1D only) and health related quality of life, as well as acquired knowledge, self-efficacy and usability.

Results: .

Conclusions: There is evidence that improving lifestyle behaviour can prevent NCDs. In this study, we aim to evaluate the effectiveness of the WARIFA app to improve lifestyle behaviours and T1D management. Clinical Trial: NCT06918444.

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Effect of the WARIFA app on user-defined objectives, healthy lifestyles and management of type 1 diabetes (T1D): a pilot randomised controlled trial protocol.

Protocol

Authors

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Abstract

Background: Non-communicable diseases (NCDs) are the leading cause of death and have a high global prevalence. The four main diseases are cardiovascular and respiratory diseases, cancer and diabetes, which share common risk factors and can be prevented through physical activity, a healthy diet, avoiding smoking and alcohol consumption, and other lifestyle changes. Watching the Risk Factors (WARIFA) is a mHealth application (app) created for general health awareness and to support users in adopting healthier behaviours. It also has a functionality to support type 1 diabetes (T1D) management.
Aim: To evaluate the effectiveness of the WARIFA app with personalised artificial intelligence (AI) driven messages, compared to a non-personalised version, in promoting health-related behaviour change among general population and individuals with T1D.
Methods: A total of 108 European participants, including individuals with T1D, are randomised (computer-generated sequence, double-blind, 1:1 ratio) to an intervention or control group. In the intervention group, participants use the WARIFA app with personalised messages and the use of AI. This applies to some functionalities, such as personalised recommendations and risk prediction for the four main NCDs. In the control group, participants use a WARIFA app without personalised messages or AI. Both groups are provided with an activity monitor and will use the WARIFA app for 12 weeks.
The primary outcome is a self-defined goal, chosen from a set of proposed objectives at baseline and assessed at the end of the study using a Likert scale (0 to 10 points, 0 being no achievement at all and 10 being full achievement of the proposed objective). Secondary outcomes include: engagement with the app, changes in lifestyle behaviour, body composition, lipid profile, glycated haemoglobin (T1D only), hypoglycaemic events (T1D only) and health related quality of life, as well as acquired knowledge, self-efficacy and usability.
Discussion: There is evidence that improving lifestyle behaviour can prevent NCDs. In this study, we aim to evaluate the effectiveness of the WARIFA app to improve lifestyle behaviours and T1D management.

Trial Registration: NCT06918444.

Keywords: non-communicable diseases, Type 1 Diabetes, mHealth app, artificial intelligence, behaviour changes, lifestyle, user-centered.

Introduction

Chronic non-communicable diseases (NCDs) are a major global health problem. They are the leading cause of mortality and morbidity, accounting for 74% of all deaths worldwide [1]. Their management and treatment are a major economic concern, accounting for 25% of the total healthcare budget in Europe [2]. The major NCDs are cardiovascular (CVD), respiratory diseases, cancer and diabetes.

CVD is the leading cause of death worldwide and in Europe, accounting for 32.7% of all deaths in 2022 [3]. Ischaemic heart disease and cerebrovascular disease are the most common causes, accounting for 32.4% and 20.8% of CVD deaths, respectively [3]. There is variability between high-income and middle-income countries in the proportion of premature CVD deaths, with the proportion being higher in middle-income countries in both sexes (36% in women and men in middle-income countries, vs. 16% and 24% in women and men in high-income countries, respectively) [4]. These diseases were responsible for an estimated 70 million disability-adjusted life years in European Society of Cardiology member countries in 2019 [4]. There is

also an unequal distribution of CVD deaths in Europe, with more than half of all deaths occurring in eastern countries, compared with 23% in northern and western countries. [4,5,6]. Metabolic risk factors include hypertension, hyperglycaemia, hyperlipidaemia and obesity. Lifestyle risk factors include tobacco and alcohol use, physical inactivity and unhealthy diet.

Respiratory diseases are the third leading cause of death in Europe, accounting for 7% of all causes of death in 2022 [3]. Chronic obstructive pulmonary disease (COPD) and asthma are the most common of respiratory diseases. COPD reduces quality of life and increases morbidity, hospital admissions and premature death. Most COPD is preventable and the main risk factors are smoking and air pollution [3,7].

Despite a decrease of 11.9% in the standardized death rates between 2012 and 2022, cancer is still the second most frequent cause of death in the EU, accounting for 22.3% of all deaths in 2022. Lung, colorectal and breast cancer account for 19.8%, 11.5% and 7.4% of all deaths from cancer in the EU [3]. Globally, the most commonly diagnosed group of cancers is skin cancers, and cutaneous melanoma, the most deadly, account for 1 in 5 of skin cancers [8]. As with CVD, many cancers can be prevented by adopting a healthy lifestyle. Smoking, alcohol, physical inactivity and unhealthy diet, the latter two leading to overweight and obesity, are responsible for the majority of cancer incidence [4]. In addition, ultraviolet (UV) radiation exposure is the leading environmental cause of melanoma, a type of cancer that continues to increase in fair-skinned populations worldwide [8].

Type 2 diabetes (T2D) has a prevalence of 5-20% in the adult population. It is associated with other NCDs and includes risk factors such as smoking, physical inactivity, unhealthy diet and obesity. Prevention can reduce the risk of diabetes by up to 78% and reduce cardiovascular mortality, cancer mortality and the incidence of CVD in people with T2D [9,10]. For type 1 diabetes (T1D), there are no established recommendations for prevention. However, controlling risk factors such as smoking, alcohol consumption, sedentary lifestyle and unhealthy diet improves disease control and delays the onset of complications such as CVD [11,12,13,14]. The incorporation of technology such as continuous glucose monitoring (CGM) devices and automated insulin delivery systems facilitates diabetes management by providing relevant information and improved glycaemic control [15,16].

The risk of developing some of these NCDs can be assessed based on known risk factors. This is important as we can act on those risk factors that are modifiable, provide personalised recommendations for each individual and prevent or postpone the onset of NCDs, reducing morbidity and mortality and economic expenditure. Furthermore, the four major NCDs share common risk factors: physical inactivity, an unhealthy diet and alcohol and tobacco consumption. Addressing these four risk factors could reduce the risk of NCDs.

An increasing number of people use mobile apps to improve their health. These apps offer direct access to information on specific health topics, as well as useful features, such as medication reminders and physical activity and vital sign recording [17]. Artificial intelligence (AI) is also becoming an increasingly popular tool. Some studies have examined the potential application of AI in mobile health apps, particularly in relation to mental and oral health [18,19].

WARIFA (Watching the Risk Factors) [20] is a project funded by the European Commission and coordinated by the Norwegian Centre for E-Health Research (NSE). It involves 12 partners from

six European countries. Its aim is to provide early risk assessment to enable individualised risk prevention. An mHealth application (the WARIFA app) has been developed, which utilizes user-generated data analysis and AI to provide personalised NCD risk assessment, as well as personalised messages, based on scientific evidence, to promote healthy behaviours.

A co-creation process was used to develop the WARIFA app. Eighteen focus groups, comprised by 3-10 users, were held to identify end-users' needs and to show and test subsequent versions of the app. After the co-creation process, the randomised controlled trial described in this paper is performed to evaluate the WARIFA app.

Objective and Hypothesis

The aim of this pilot randomised controlled trial is to evaluate the effectiveness of the WARIFA app in promoting healthy lifestyles and in the self-management of T1D.

The hypothesis is that use of the WARIFA app will improve healthy eating habits, increase physical activity, reduce alcohol consumption, promote smoking cessation, and improve sun protection behaviours. In addition, it is expected to reduce hypoglycaemic events and lower glycosylated haemoglobin (HbA1c) in people with T1D.

Methods

This study protocol was developed in accordance with the recommendations for interventional trials 2013 statement SPIRIT (Standard Protocol Items: Recommendations for Intervention Trials) [21] and SPIRIT-AI guidance published for trials of artificial intelligence interventions [22].

It was submitted to and approved by the Las Palmas Ethics Committee in September 2024 (reference 2024-330-1). It was submitted to clinicaltrials.gov in June 2024 and approved with ID NCT06918444. An insurance policy has been signed for the entire duration of the study. The study is being conducted during the first half of 2025.

Study Design and Setting

A randomised, controlled, double blind, parallel, multicentre pilot trial is conducted in two populations (general population and individuals with T1D) in three European countries. For this purpose, participants are provided, either with the WARIFA app with personalised recommendations or the same WARIFA app without personalised recommendations. The participating centres are: the Research Institute for Biomedical and Health Sciences (iUIBS), Gran Canaria, Spain; the NSE, Tromsø, Norway; and in Brasov, Romania.

Participants and recruitment

A total of 108 participants are planned to be enrolled and followed for 12 weeks. Two participant populations are studied: general population and people with T1D. Thirteen participants with T1D are to be recruited from the endocrinology clinics at the Hospital Universitario Insular-Materno Infantil (Las Palmas De Gran Canaria, Spain). The 95 participants

from the general population will be recruited through flyers and social media advertisements in the three study centres.

Those who meet the inclusion criteria are given an explanation about the nature of the study and are invited to participate. Those who agree to participate sign a written, informed consent form.

Inclusion criteria

-Common to both populations: adults over 18 years of age with an Android smartphone and internet access.

-General population group: healthy or diagnosed with no more than one NCD (CVD, cancer, T2D or COPD).

-T1D group: diagnosed with T1D treated with multiple insulin injections and using a CGM of the brand Freestyle Libre (FSL; Abbott; Chicago, IL, United States).

Exclusion criteria

-Common to both groups: individuals under the age of 18, pregnancy, mobile phone incompatible with the WARIFA app (e.g., Apple devices), not understanding any of the languages used in the app (English, Spanish, Norwegian and Romanian) or any other reason which precludes follow-up.

-General population: people with two or more NCDs (CVD, cancer, T2D or COPD).

Randomisation and blinding

During registration in the WARIFA app, participants are randomly assigned in a 1:1 ratio using a computer-generated randomisation list. The app is downloaded from Google Play, with the same download link for all participants. Once downloaded, and after registration, eligibility criteria are confirmed, informed consent is given and participants are randomised: one feature set in the app will be available for the control group and another for the intervention group.

In the Norwegian and Romanian centres, the app is downloaded online. In the Spanish centre, visits are face-to-face, as blood tests and physical examination is carried out. The researchers are unaware of participants' group allocation. To avoid bias, participants are also unaware of their study group. Likewise, the researchers who analyse the data are blinded to the intervention allocation.

Intervention

The intervention consists of using during 12 weeks a version of the WARIFA app with personalised risk estimations for different NCDs and individualised recommendations, based on each participant's personal preferences.

To do this, the app uses a simple and intuitive interface, using data available from public databases (for UV index, air quality index) and data from the participants themselves (entered

manually [subjective data] or automatically [objective data] via sensors). The app uses AI to create recommendations and feedback based on scientific evidence and behaviour change models.

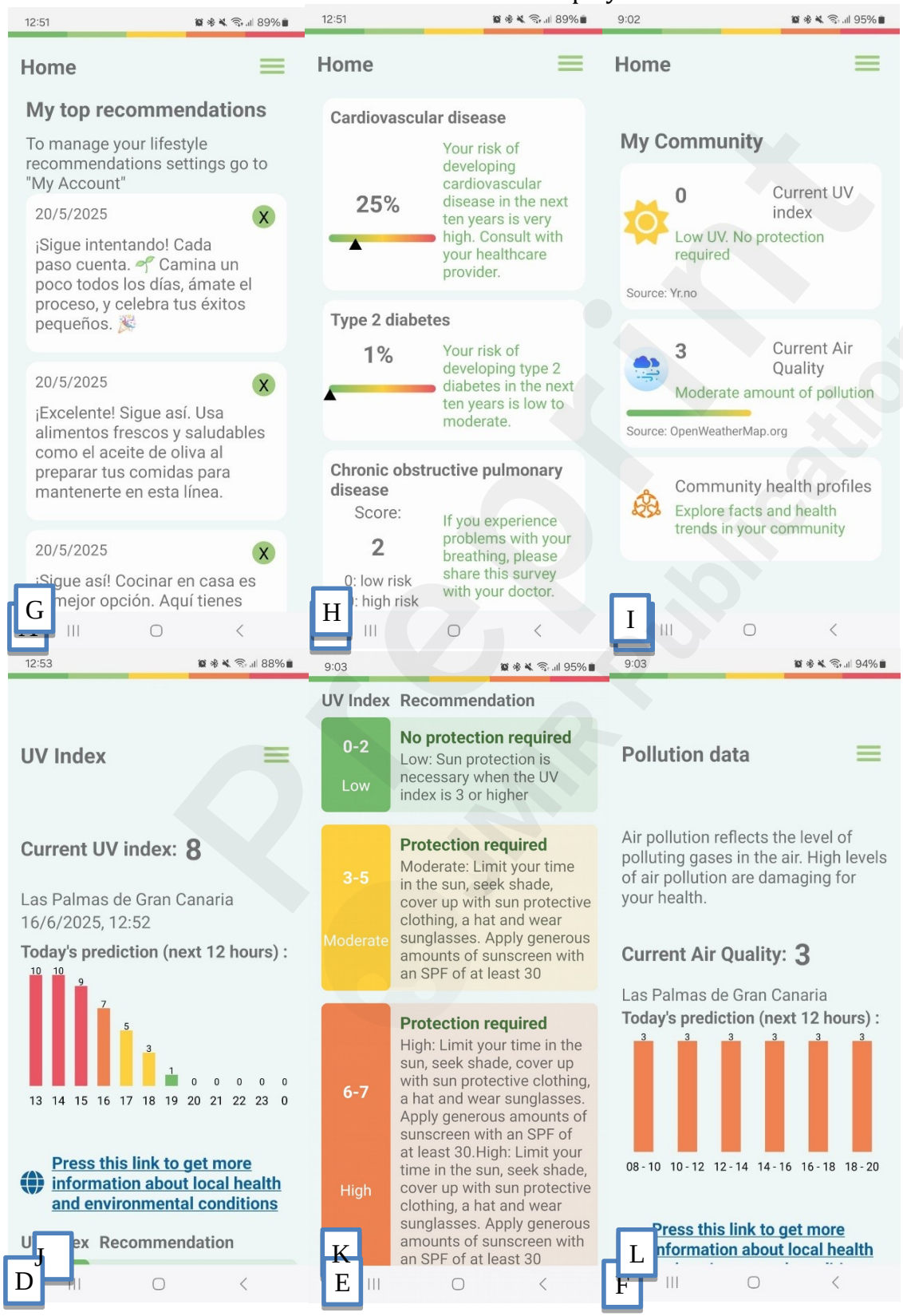
The WARIFA app is downloaded to participants' own smartphones, who is also provided with a physical activity monitor (Samsung Galaxy Fit 3; Suwon, South Korea) to track physical activity, heart rate and sleep. This will be connected to the WARIFA app. Participants with T1D use their glucose sensors (FSL 2 and 3, Abbott; Chicago, IL, United States), which are also linked to the WARIFA app.

Participants use the app for 12 weeks, with two face-to-face visits (in Spain only): one at the start of the study and one at the end of the study. At the first visit, the app is downloaded and linked to the activity monitor (all) and glucose monitors (T1D participants only). Both visits will include blood tests and a physical examination. The Norwegian and Romanian centres will not perform in person studies, and all participant information will be provided through the app in these countries. Questionnaires will be completed within the app itself for all centres.

The WARIFA app includes several functionalities:

-*My day:* A diary is available to record various items [figure 1, H]. Participants are able to easily and intuitively record their fruit and vegetable intake, alcohol and tobacco consumption and sunscreen use every day. They are able to customise the diary to choose the items they want to record. They see a graphical presentation of the records of the last 7 days, with a marker for their personal goal [figure 1,I], as well as individual and personalised messages generated with the use of AI for the improvement of their goals. People with T1D can also record their hypoglycaemic events.
-*Assess your lifestyle:* Participants complete questionnaires that provide data for WARIFA to personalise their risk calculation and recommendations. These questionnaires are basic variables (age, gender, weight, height), lifestyle habits (alcohol consumption, smoking and physical activity), eating habits and sun exposure, as well as risk factors for melanoma. Once the questionnaires have been completed, the app delivers the first messages with personalised recommendations. If the user enters this section at another stage in the trial, and changes data in the questionnaires new recommendations are generated and delivered to the user.
-*My top recommendations:* personalised recommendations appear for each participant each day, based on the data obtained through the initial questionnaires and how far they are from the recommended target for each item [figure 1,A]. These recommendations are based on scientific evidence and updated WHO guidelines.
-*My health predictions:* Will give access to risk calculators [figure 1,B] for different NCDs (T2D, CVD and melanoma) with personalised risk estimation over the next 10 years. During the WARIFA project, some risk calculators were developed, including the cardiovascular risk calculator for T1D [23]. The melanoma risk calculator was developed based on the first primary risk prediction tool created by the Melanoma Institute Australia (MIA) [24]. The FINDRISK calculator, which has been validated in several European countries, is used to calculate the risk of T2D [25]. To calculate cardiovascular risk in the general population, the SCORE2/SCORE2OP calculator was used; this has been validated in the European countries participating in the study [26,27]. Finally, the self-scored COPD population screener questionnaire (COPD-PS) [28] was used to screen for COPD in smokers, since there is no COPD risk calculator validated in the European population. In all cases, the personalised risk of the different NCDs is accompanied by an explanatory message. If the COPD-Q score is high, it is

recommended that participants visit their health service physician for further assessment.
-*My Community*: Through the use of geolocation (if permission is granted), it will provide personalised recommendations based on the UV index and air quality in the participant's geographical area [figure 1, C,D,E,F,G]. A link to a web page [29] with additional health-relevant information (air pollution and UV rays, statistics on NCDs of the population, lifestyle habits...) about the area where the user is located is also displayed.



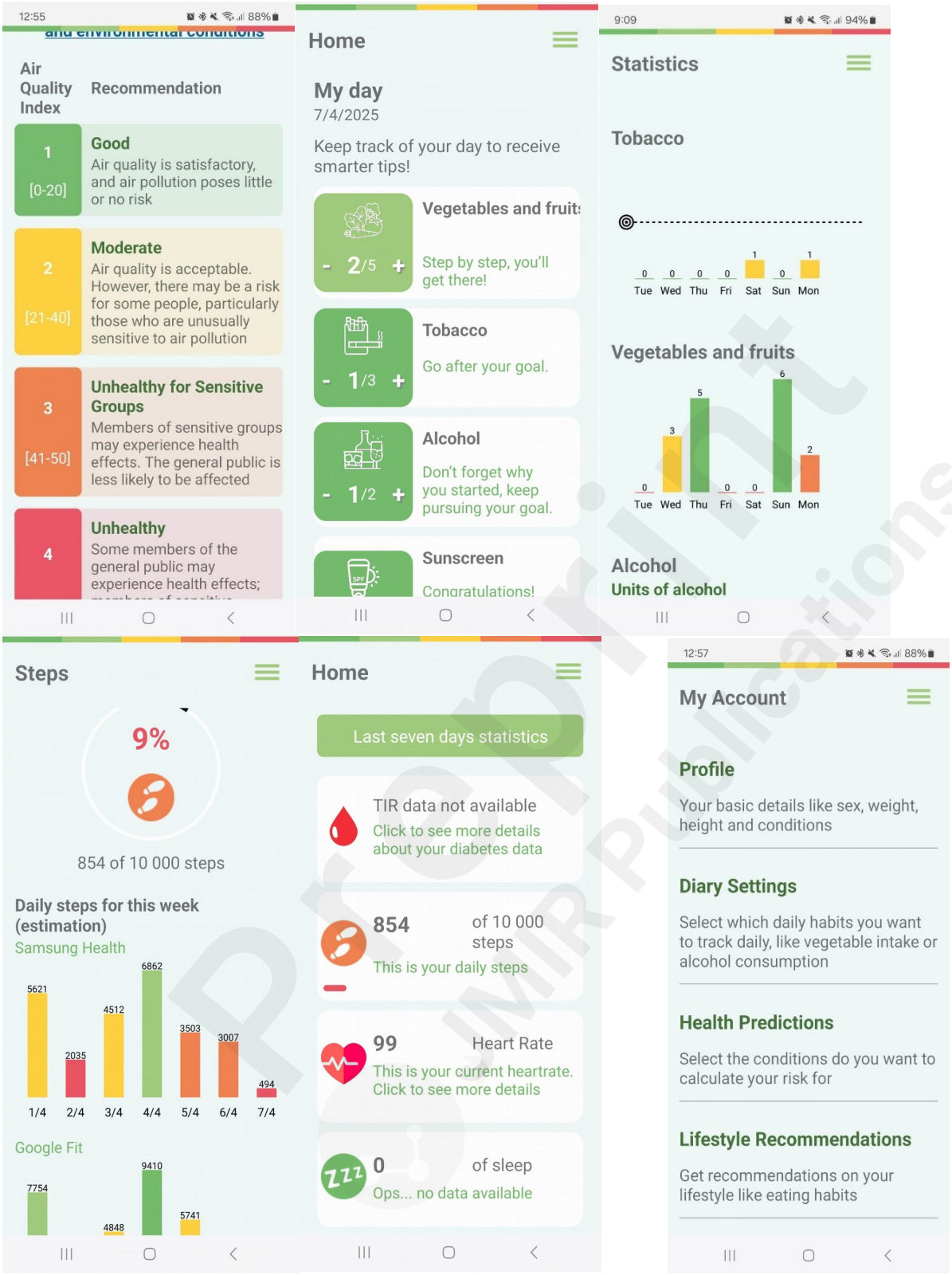
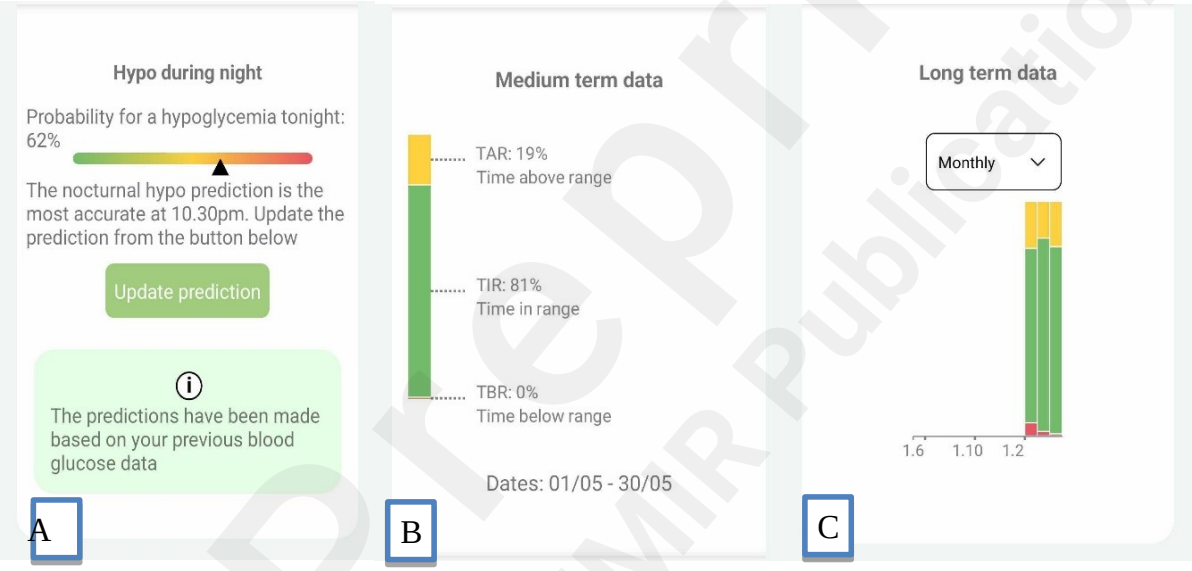


Figure 1. Functions of the WARIFA app: (A) Personalised recommendations displayed based on each participant's data; (B) Risk calculators for different NCDs and COPD screening; (C) My community functionality, including the UV index (D) for each geographical area and recommendations based on the UV index level (E); and (F) air quality with recommendations based on the air quality level (G). (H) Diary functionality for recording personalised items and viewing statistics for the last 7 days (I). (J) Steps functionality with diary log and comparison with the previous seven days. (K) The main page provides quick access to the different functionalities. (L) Options menu.

-*Step functionality:* Shows the number of steps taken by participants at any point in each day, as well as a graphical presentation of the number of steps for the last seven days [figure 1,J]. Recording is automatic via the physical activity monitor.
-*Heart rate function:* Shows the current heart rate and a graph with its evolution in relation to the measurements in the last 24 hours. The source of the data is the physical activity monitor.
-*Sleep function:* Shows today's hours of sleep and a bar graph of the hours of sleep the last seven days recorded by the physical activity monitor.
-*Diabetes functionality:* People with T1D can view their glucose data in near real time (with a delay of 30 minutes) by connecting to the glucose sensor. They can also view historical glucose data through various graphs such as time in different range [figure 2, B and C], glucose management index and hypoglycaemic events. Using AI, they receive an estimate of the interstitial glucose prediction over the coming 30 minutes and two hours [figure 2, D], as well as a personalised risk of nocturnal hypoglycaemia [figure 2, A].
-*Settings and other functions:* In this section, participants can customise which parts of the WARIFA app they want to see, as well as the notifications, sounds, fonts and language used.



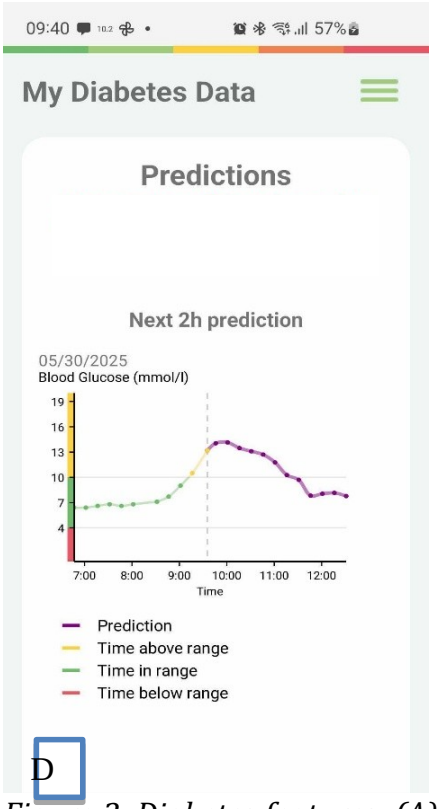


Figure 2. Diabetes features: (A) Overnight hypoglycaemia prediction functionality; (B) display of % range times in the last month; (C) comparison of monthly range times; and (D) glucose prediction functionality.

Control group

The control group will have access to a WARIFA app version where almost all the functionalities mentioned above are available, except for the diary, risk calculators and personalised recommendations. AI features such as near real-time glucose prediction, night time hypoglycaemia risk and the motivational feedback in top recommendations section are not available in this version, either. Data is collected in a similar manner, and an activity monitor is provided for the duration of the study, too.

Patient and public involvement

The results of the ongoing (summer 2025) RCT will be presented in a research article. The results will also be made available on the project website and on the European Commission's CORDIS platform [30].

Outcomes

The primary outcome is a participant-defined goal, whose fulfilment is assessed at the end of the study using a Likert scale ranging from 1 ('far below expectations') to 10 ('far above expectations') [31].

Participants can choose their own goal from a range of options: increase fruit and vegetable consumption, increase physical activity, reduce alcohol consumption, stop smoking, improve sun protection behaviour and reduce the number of weekly hypoglycaemic episodes (the latter only for T1D participants).

The secondary outcomes are: Frequency of app use, time spent using the app, consistency in data recording, changes in eating habits, increase in physical activity, reduction in smoking and alcohol consumption, changes in sun protection behaviour, total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, non-HDL cholesterol, triglycerides, weight, body-mass index (BMI), body fat, lean mass, abdominal, waist and biceps circumference, abdominal skinfold thickness, tricipital skinfold thickness, dynamometry, sit to stand 5 reps test, perceived quality of life, acquired knowledge, self-efficacy and usability.

For participants with T1D, hypoglycaemic events (number of episodes of at least 15 min duration with glucose concentration <70mg/dl according to the CGM and manually registered episodes), HbA1c, average glucose (average glucose in mg/dl over the last 14 days), glucose management indicator (GMI, a measure of glycaemic control calculated from average glucose, which is an estimation of HbA1c) and time in range (% of time in the last 14 days that glucose is within (70-180mg/dl), below (<70mg/dl), above (181-240mg/dl), or significantly above (>240mg/dl) the recommended target will be measured.

Direct Adherence

Adherence is measured by frequency of app use (number of times participants log in per day), duration of use (number of hours per day) and consistency of data recording (interactions with the app like using diary, changes in the questionnaire answers and entering hypoglycaemia data).

Behaviour Change

Changes in dietary habits, tobacco and alcohol consumption and sunscreen use will be measured by diary entries. Changes in physical activity (steps) is automatically measured by the physical activity monitor.

Biomedical Outcomes:

Blood test and physical examination are only be carried out in Spain. A blood test is performed at the beginning and end of the study to measure blood count, creatinine, urea, glucose, GPT, GOT, GGT, total cholesterol, HDL cholesterol, and triglycerides in all participants. Automated, routine colourimetric methods are used. Non-HDL cholesterol is calculated by substracting HDL from total cholesterol and LDL cholesterol is estimated using Friedewald's formula [32]. HbA1c is measured by HPLC (using DCCT standards, following National Glycohaemoglobin Standardisation Programme) in people with T1D only.

As part of the physical examination, the patient's weight and height are measured to calculate BMI. Measurements of the abdomen, arm, and calve circumferences are taken with a non-extensible measuring tape. Grip strength is assessed using a Jamar dynamometer, and a Holtain plicometer (Holtain Ltd, Crymych, United Kingdom) is used to measure the triceps skinfold. Body fat and muscle mass are estimated using a Tanita DC-360 (Tanita, Tokio, Japan) bioimpedance meter. Arm muscle circumference is calculated from the triceps skinfold and arm circumference measurement. Muscle quality is calculated based on the muscle mass from the bioimpedance analysis and the grip strength measurement [33]. Finally, the functional test sit-to-stand with five repetitions is performed. [34].

For participants with T1D, time in relevant ranges (see above), average glucose, GMI and hypoglycaemic events are recorded by the app from a CGM FSL 2 or 3 (Abbott, Chicago, IL, USA). Hypoglycaemic events are also recorded or confirmed manually.

Perceived quality of life:

The EQ-5D questionnaire [35] is used to assess health-related quality of life in all participants. It consists of two parts: The first part contains five health dimensions (mobility, self-care, activities of daily living, pain/discomfort and anxiety/depression). For each dimension of the EQ-5D, severity levels are coded: 1 if the answer choice is 'no (I have) problems', 2 if the answer choice is 'some or moderate problems', and 3 if the answer choice is 'many problems'. The higher the score, the worse the health dimension. The second part of the EQ-5D is a scale from 0 to 100. On this scale, the individual should mark the point that best reflects their assessment of their overall health status, with 0 being the lowest assessment of their health status and 100 being the best.

The ViDa1 [36], a questionnaire for health-related quality of life in patients with T1D, is also used for the group of individuals with T1D. The ViDa1 has 34 items that are grouped into four different dimensions: interference with life, self-care, well-being and worry about the disease. It is a questionnaire that can be self-administered with a Likert-type response format in which a total score per subscale is obtained. Interference with life: (items 1-12), self-care (13-23), well-being (24-29) and worry about illness (30-34). Each item is scored from 1 'strongly disagree' to 5 'strongly agree'. For correction, the scores obtained in each subscale are added together. To ensure an accurate interpretation, the scoring for items 12, 23 and 27 must be reversed (a score of 1 indicates strongly agree, while a score of 5 indicates strongly disagree).

Knowledge and attitudes:

To measure diabetes self-management behaviours, the Summary of Diabetes Self-Care Activities (SDSCA) is used [37]. It consists of 11 items that address different areas of self-care present in people with diabetes mellitus, such as diet, physical activity, medication, self-testing of capillary glycaemia and smoking. It presents a response scale from 0 to 7, depending on the number of days that the person has carried out a certain behaviour in the previous week. The smoking item has a dichotomous response. The questionnaire has no cut-off point, so each item must be assessed individually.

To assess the knowledge acquired about healthy habits, the European Health Literacy Survey is used [38]. The questionnaire consists of 16 questions that classify the degree of difficulty perceived by the participant in each task or situation as: 1 'very easy', 2 'easy', 3 "difficult", 4 'very difficult' or 5 'don't know/no answer'.

Satisfaction and feedback:

The System Usability scale (SUS) [39] and mHealth App Usability Questionnaire (MAUQ) [40] are used. The SUS scale is a 10-item questionnaire scored on a 5-point Likert-type scale from 1 (strongly disagree) to 5 (strongly agree). The overall score ranges from 0 to 100. A system with a score above 85 is considered to have excellent usability. The MAUQ assesses the ease of use, interface, satisfaction with and usefulness of mHealth apps for end users. It consists of 18 items, with seven response options for each item, ranging from 1 "strongly disagree" to 7

"strongly agree".

Statistical Analysis

Descriptive results will be presented as means and standard deviations (SDs), or medians and interquartile ranges (IQRs) for continuous variables, and frequencies and percentages for categorical variables. The primary end point is the difference in Likert score between the two groups in the self-reported achievement of the individual, self-defined aim at the end of the study. The intervention and control groups will be compared using a Student's t test or a Mann-Whitney U test. For comparison of changes in variables measured at baseline and end of study, we will use linear regression or logistic regression adjusting for the baseline measurement [41]. Logarithmic transformation may be used. A p-value below 0.05 will be considered significant.

An intention to treat analysis will be performed (including all randomised participants, regardless of their adherence to the intervention).

Power

The sample size was calculated for the primary outcome (Likert scale from 1 to 10 with a target defined by the participant). A population of people with T1D was used as the reference population, based on a previous study [31,42]. The common standard deviation in the intervention and control groups is assumed to be 2.07 [31]. With a significance level of 0.05 and a power of 0.8 in a two-sided two-sample t-test, 47 subjects are necessary in both groups to detect a statistically significant difference greater than or equal to 1.3 units. Allowing for a potential loss to follow-up of 10%, we estimated a total required sample size of 52 participants in each group. Participants with T1D are only recruited in Spain. All three centres aim to recruit an equal number of participants, i.e 36 participants each (aiming at a total of 108).

Discussion

The randomised controlled pilot trial we propose aims to assess the effectiveness of the WARIFA app in promoting healthy behaviours of participants to reduce the risk of NCDs and improve self-management of T1D.

Other mHealth apps have been used for behaviour change and disease management in patients with hypertension and obesity [43,44], although they do not provide estimates of the risk of NCDs.

The main strengths of this trial are that it is conducted in three European countries and will include more than 100 participants in total, which should support the applicability of the results. Furthermore, the use of a low-intervention app and a physical activity monitor as control, as well as the double-blind nature of the trial, reduce the risk of bias. The WARIFA app can provide personalised risk estimations for the major NCDs over the next 10 years, as well as identifying the habits to change and the most effective way to do so for each individual. This is in contrast to the generic messages typically used in community-based prevention. The app will be able to deliver these personalised messages to participants' devices to encourage adherence.

We also acknowledge some limitations in the design of the trial. Although we believe that 108

participants is an appropriate number for a pilot study and an initial evaluation on the WARIFA application, it may not be sufficient to assess some of the secondary outcomes addressed, or the smaller group. Another limitation is that the biomedical outcomes (anthropometry and blood tests) are performed at one of the centres only and these data will not be available for all participants. Restrictions also include the fact that the WARIFA app is only compatible with Android mobile phones, as well as certain activity devices and glucose sensors. mHealth apps have boomed in recent years as a tool that is free, voluntary and easy to obtain. However, many users uninstall the app shortly after installation [45].

Many mHealth applications have demonstrated their effectiveness in promoting healthy habits and managing chronic diseases such as diabetes and cardiovascular conditions, most of them rely on short-term interventions and have limitations in terms of long-term applicability and accessibility for the entire population [46,47,48,49]. In contrast, the WARIFA app has been designed using an integrative, personalised approach that targets adults of all ages, including those with low digital literacy skills and hard-to-reach population, areas that are often missed by similar apps.

Furthermore, the WARIFA app was developed by actively incorporating feedback from potential users and healthcare professionals through focus groups. This participatory process allowed the design, functionality and content to be tailored to users' real needs. This participatory process improves usability, acceptability and scalability. WARIFA aims to promote healthy behaviours, through a more inclusive and user-centred tool than many existing applications.

The pilot controlled clinical trial is set to conclude in June 2025, pending a thorough data analysis.

Conclusions

This randomized, double blind, controlled, parallel-group, pilot trial will assess the effectiveness of the WARIFA health app in promoting healthy behaviours. It will also allow to identify its weaknesses and limitations, with the aim of further improving and developing this, or similar apps. A longer-term study would be needed to assess its effect on the risk for major NCDs, as well as its integration into healthcare systems.

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Conflicts of Interest

European project funded by the European Commission. No conflicts of interest.

Abbreviations

AI: Artificial Intelligence
AQI: Air Quality Index
BMI: Body-mass index
COPD: Chronic obstructive pulmonary disease
CVD: Cardiovascular diseases

ESC: European Society of Cardiology
FSL: Free Style Libre
GGT: Gamma-glutamyl transferase
GPT: Glutamic Pyruvic Transaminase
GOT: Glutamic oxaloacetic transaminase
HbA1c: Glycosylated haemoglobin
HBSCQ: Health Behavior and Stages of Change Questionnaire
HDL: High-density lipoprotein
IUIBS: Research Institute for Biomedical and Health Sciences
LDL: Low-density lipoprotein
MAUQ: mHealth App Usability Questionnaire
NCD: Non-communicable diseases
NSE: The Norwegian Centre for E-health Research
SDSCA: Summary of Diabetes Self-Care Activities
SUS: System Usability Scale
TAR: Time above range
T1D: Type 1 Diabetes
T2D: Type 2 Diabetes
TBR: Time below range
TIR: Time in range
ULPGC: University of Las Palmas de Gran Canaria
UV: Ultraviolet
ViDa1: Life with Type 1 Diabetes (Vida con Diabetes tipo 1)

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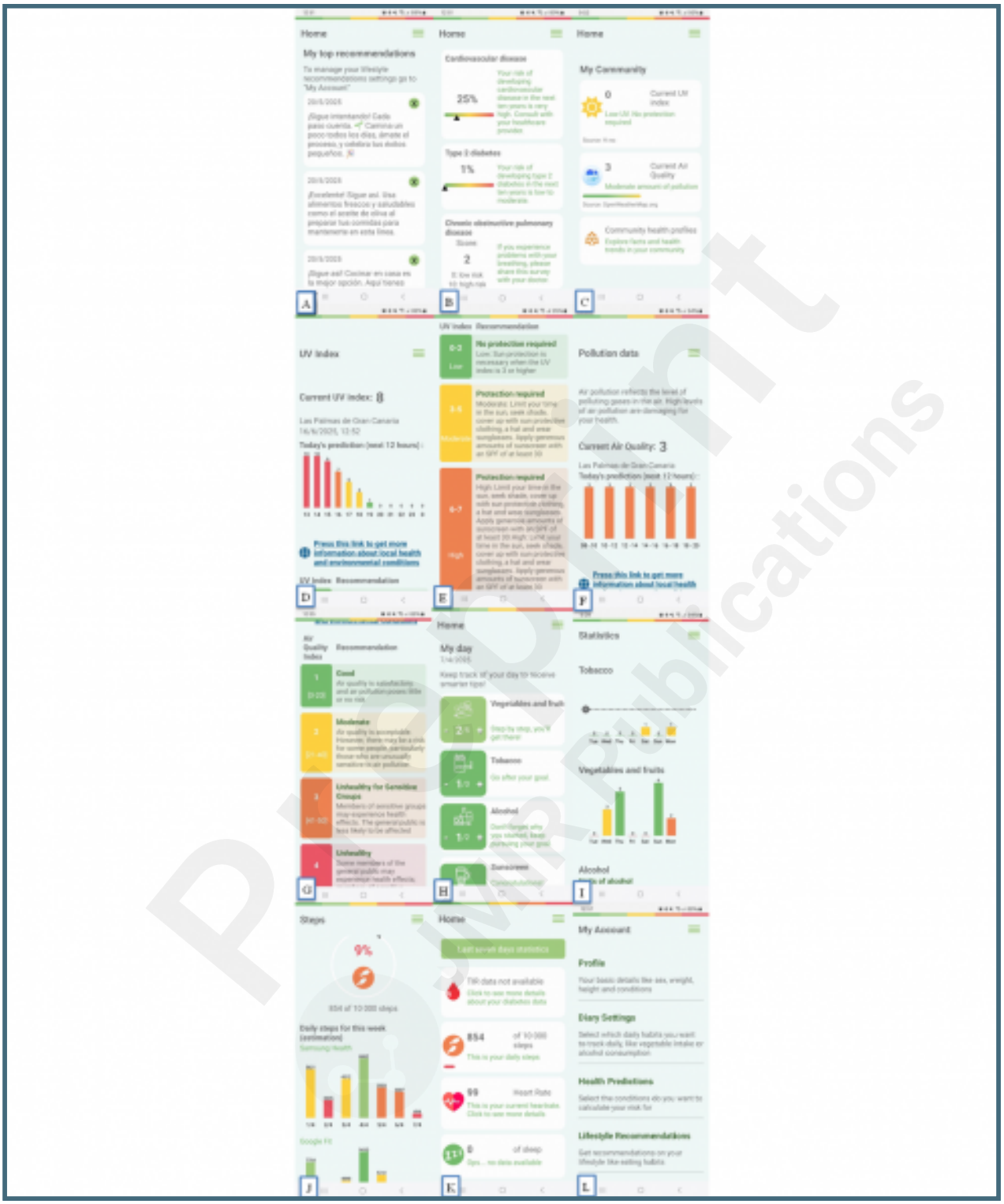
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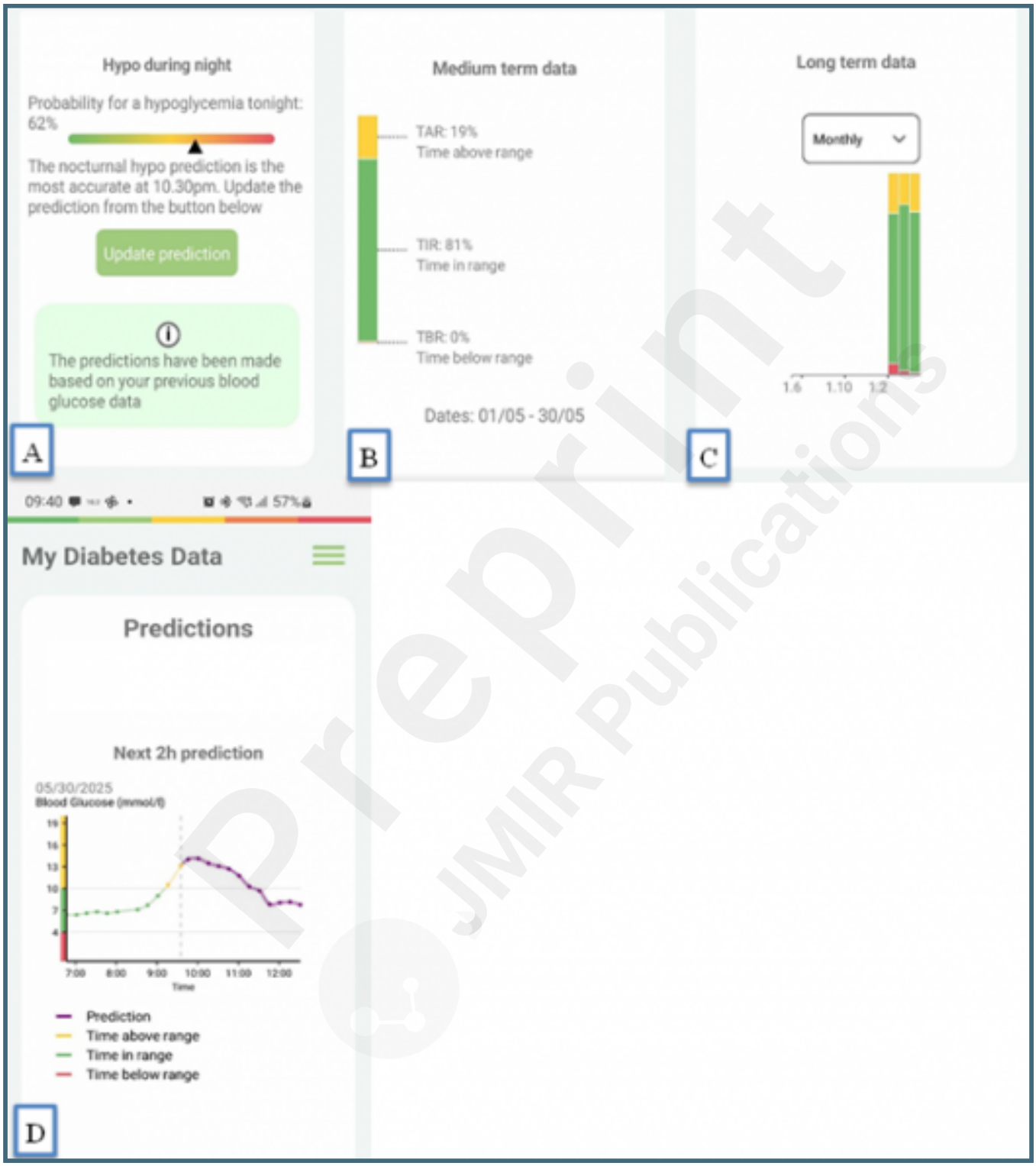


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Figures

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Diabetes features: (A) Overnight hypoglycaemia prediction functionality; (B) display of % range times in the last month; (C) comparison of monthly range times; and (D) glucose prediction functionality.



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