Evaluation of a mobile AI-powered decision support system for insulin dosing and glucose prediction in type 1 diabetes: The glUCModel clinical trial protocol

ABSYS Group
Universidad Complutense de Madrid
absys@ucm.es

September 1st, 2025

Contents

Abstract

Introduction: Artificial Intelligence (AI) opens new possibilities for supporting decision-making in diabetes care. glUCModel is a mobile application that provides insulin dose recommendations, predictions of glucose levels, and predictive glucose alerts, utilizing proprietary AI technology. Unlike conventional tools, glUCModel provides early warnings of hypoglycemia and hyperglycemia up to two hours in advance. glUCModel also offers general and customizable glucose prediction models to support the user in decision making.

Methods: We will conduct a randomized, open-label, controlled clinical trial with two parallel arms involving people with type 1 diabetes and suboptimal metabolic control, treated with multiple daily insulin injections (MDI). The study will take place at two Spanish university hospitals. The total duration is 14 weeks, comprising a 2-week run-in phase and a 12-week active treatment phase. Patients in the intervention arm will use glUCModel alongside standard therapy.

Primary Outcomes: Time in range (TIR) defined as 70–180 mg/dL during the last 2 weeks of the intervention. Usability of the app.

Secondary Outcomes: Reduction in hypoglycemia and hyperglycemia episodes, glycemic variability, treatment satisfaction (DTSQ and ITSQ), and adherence to insulin correction recommendations.

Discussion: This study aims to evaluate the safety and efficacy of integrating predictive models into insulin therapy management via a user-centered mobile app. Insights may inform future digital health strategies in type 1 diabetes care.

Ethics and dissemination: Ethical approval to conduct this study has been granted by the University Hospital "Principe de Asturias" of Alcalá de Henares Ethical committee (EC-11/2018). Participants in the study will provide written consent.

Trial registration: NCXXXXXXXX

1 Introduction

Diabetes mellitus is a chronic, metabolic disorder characterized by impaired regulation of blood glucose, affecting more than 400 million people worldwide [1]. Insulin, a hormone produced by the pancreas, facilitates the uptake of glucose into cells for energy production. In diabetes, either insufficient insulin is produced or the body cannot use it effectively, leading to persistent hyperglycemia. Over time, uncontrolled glucose levels can result in serious complications, including cardiovascular disease, neuropathy, retinopathy, and nephropathy. Effective management is therefore essential to prevent both acute and long-term adverse outcomes.

Two main forms of diabetes can be distinguished. Type 1 diabetes mellitus (T1DM) is an autoimmune condition in which pancreatic β-cells are destroyed, resulting in absolute insulin deficiency. It accounts for approximately 10% of all cases. Individuals with T1DM require lifelong insulin replacement therapy, typically delivered as multiple daily injections (MDI) or via an insulin pump. In contrast, type 2 diabetes mellitus (T2DM), the more prevalent form, is characterized primarily by insulin resistance. While insulin production is preserved in early stages, progressive dysfunction may ultimately necessitate pharmacological therapy, including insulin. Lifestyle interventions such as healthy diet and physical activity can delay or prevent T2DM onset and progression.

For individuals with diabetes, day-to-day self-management requires frequent glucose monitoring and insulin dose adjustments that must take into account meals, physical activity, stress, illness, and other factors. Capillary glucose meters and, more recently, continuous glucose monitoring systems (CGMs) have greatly improved access to real-time glucose data. However, interpreting these data and deciding on corrective actions remains challenging, and errors in insulin dosing can lead to hypoglycemia or persistent hyperglycemia. Both acute complications and the constant decision-making load contribute to reduced quality of life and treatment fatigue.

To support patients in these complex tasks, predictive models of glucose dynamics have been extensively investigated. Accurate prediction could enable early warnings of hypo- or hyperglycemia and assist in optimizing insulin therapy. The ultimate vision is the development of a fully automated "artificial pancreas" combining glucose sensing, insulin delivery, and robust prediction algorithms. Various machine learning (ML) approaches have been explored for glucose forecasting, including Genetic Programming [9], Random Forests [7], K-Nearest Neighbours [2], Grammatical Evolution[5], and, most prominently, Neural Networks[13]. Among neural architectures, Long Short-Term Memory (LSTM) and other recurrent models have demonstrated strong performance for time-series data such as CGM traces, although convolutional and multilayer perceptron (MLP) networks have also been applied. Despite encouraging results, challenges remain in ensuring accuracy, robustness, and real-world usability across diverse patient populations.

Managing T1DM, particularly in patients using MDI, continues to pose a major challenge. While CGM and insulin pumps have improved outcomes, decisions about insulin dosing still depend heavily on patient intuition and experience, leaving room for error and variability. There is therefore a clear need for decision-support tools that combine predictive analytics with personalized recommendations to enhance safety, autonomy, and treatment adherence.

The *glUCModel* mobile application was developed to address this need. Since its early versions [8], it integrates proprietary, patented artificial intelligence models to provide real-time insulin rec-

ommendations, short-term glucose forecasts, and predictive alerts for hypo- and hyperglycemia. With a forecast horizon of up to two hours, the system aims to reduce glycemic variability and support timely corrective actions.

This protocol describes a randomized, open-label clinical study to evaluate the efficacy and safety of the *glUCModel* application in patients with T1DM using MDI therapy. The primary objective is to assess improvement in short-term glycemic control, measured by the percentage of time spent in target range (70–180 mg/dL). Secondary objectives include reductions in glycemic excursions, improved treatment satisfaction, and evaluation of usability and adherence in a real-world setting.

2 Study Design

This study will be a 14-week, open-label, randomized clinical trial with a control group and two parallel arms. The trial includes a 2-week run-in phase and a 12-week active intervention phase. Patients will be recruited at the Endocrinology and Nutrition Departments of the Hospital Universitario de Toledo This protocol includes all the elements necessary to register at clinicaltrials.gov protocol registration and results system (PRRS). The protocol was developed following the SPIRIT guidelines for individual randomized controlled trials (IRCT) through the COBWEB system [1].

The Endocrinology and Nutrition department of Hospital Universitario de Toledo, in collaboration with the Adaptive and Bioinspired Systems (ABSYS) research group at Universidad Complutense de Madrid, and the Bioinspired Intelligence company, is conducting this trial in Toledo (Spain). The trial is registered in the clinical trials registry with the number NCTXXXXXXXX.

2.1 Participants

2.1.1 Inclusion criteria

Eligible participants are adults with T1DM with the following characteristic:

- Aged between 18 and 65 years old.
- HbA1c $< 9\%$
- Currently following an MDI Bolus-Basal therapy.
- Wearing CGMs connected to a mobile phone.
- Spanish language proficiency.
- Willingness to participate in the trial.
- At least one year since the time of diabetes diagnosis.
- Ability to use a mobile application like glUCModel.
- Own a mobile phone running Android or iOS operating system.
- Ability to follow a Portion-controlled diet for diabetes.
- Educated to do an active management of insulin dosing.

[1] https://cobweb.clinicalepidemio.fr/

2.1.2 Exclusion criteria

Exclusion criteria are:

- HbA1c $< 9\%$.
- Not wearing CGMs.
- Non-Spanish language proficiency.
- Less than one year since the time of diabetes diagnosis
- Unable to use a mobile application like *glUCModel*
- Unable to follow a Portion-controlled diet for diabetes
- Unable to do an active management of insulin dosing.
- Diagnosed with a significant psychiatric disorder.
- Subjects in treatment with corticoids
- Patients who have required hospitalization or surgery in the last six months.
- Pregnancy or planning a pregnancy

2.1.3 Size

At least 34 participants of both sexes, aged between 18 and 65 years old will be recruited from the Endocrinology and Nutrition department of Hospital Universitario de Toledo (Spain) and the Endocrinology and Nutrition department of Hospital Universitario Príncipe de Asturias (Alcalá de Henares, Spain). The sample size was estimated using the G*Power3 software establishing an effect size $d = 0.875$, a significance level $\alpha = 0.05$, a power $(1 - \beta) = 0.8$, an allocation ratio $\frac{N2}{N1} = 1$ with One tail, considering that the time in range (primary outcome) would only increase with the use of the *glUCModel*.

Table 1 shows the output parameters of G*Power3 for those assumptions. We consider the TIR to be the primary outcome, and suppose an average value of 75 % with a Standard deviation of 8 before the intervention, and a value of TIR of 82% (standard deviation = 8). Final effect size and power will be evaluated at the end of the trial. Figure 1 shows a representation of the sample size versus the power for the selected effect size (0.875).

2.1.4 Randomization

Eligible participants who provide written informed consent will be randomly assigned in a 1:1 ratio to either the intervention (*glUCModel* application) or the control group. Randomization will be performed using a computer-generated sequence (https://www.randomizer.org/) with variable block sizes (e.g., 4 and 6) to ensure balanced allocation while reducing predictability. The randomization list will be generated by an independent statistician not involved in participant recruitment, clinical management, or outcome assessment. Allocation will be concealed through [sealed, opaque, sequentially numbered envelopes / a centralized password-protected database—choose method] until the moment of assignment. Each participant will be assigned a unique study identification code, which will be used throughout the study for data entry, analysis, and reporting to maintain confidentiality.

Output parameter	Value
Noncentrality parameter δ	2.5510415
Critical t	1.693887
Df	32
Sample size group 1	17
Sample size group 2	17
Actual Power	0.8240859
hline	

Table 1: output parameters of G*Power for $d = 1$, $\alpha = 0.05$, $(1 - \beta) = 0.8$, and $\frac{N2}{N1} = 1$, with One tail

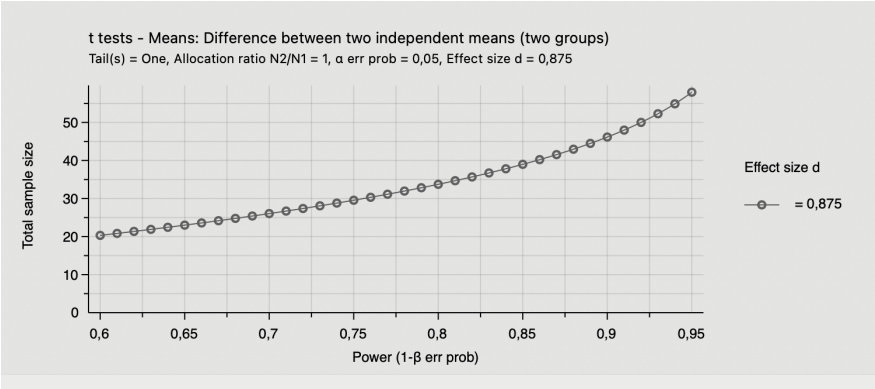

Figure 1: Sample size vs power

2.1.5 Blinding

Due to the nature of the intervention, blinding of participants and treating clinicians is not feasible. Participants allocated to the *glUCModel* group will necessarily be aware of their assignment. However, outcome assessors, investigators, and data analysts will remain blinded to group allocation. Group codes will not be disclosed until the study database is locked and all primary analyses have been completed. This approach minimizes bias in outcome assessment and statistical analysis

2.2 Outcomes

The main objective of this study is to assess the utility of *glUCModel* to improve the quality of the management of diabetes in people with T1DM following the Bolus-Basal regime of insulin administration. It is also important to evaluate the usability of the application. To evaluate the final results, additional information regarding sleep quality and physical condition will be recorded.

2.2.1 Primary Outcome

- Time in Range (TIR), defined as the percentage of time that interstitial glucose is between 70–180 mg/dL during the final 2 weeks of the intervention phase

2.2.2 Secondary Outcomes

- Frequency and duration of Level 1 hyperglycemia ($180 \leq$ interstitial glucose ≤ 240).

Outcome	Measure	Tool
Time in Range	%	CGM
Hyperglycemia	%	CGM
Hypoglycemia	%	CGM
Glycemic variability	Average glucose, SD, CV	CGM
Accepted Insulin Recommendations	#	*glUCModel*
Quality of predictions	Parkes EG	*glUCModel*
Treatment satisfaction	Index	DTSQ
Usability	Index	uMARS

Table 2: Outcomes measured in the trial

- Frequency and duration of Level 2 hyperglycemia ($241 \leq$ interstitial glucose ≤ 400).
- Frequency and duration of Level 1 hypoglycemia ($40 \leq$ interstitial glucose < 55).
- Frequency and duration of Level 2 hypoglycemia ($55 \leq$ interstitial glucose ≤ 70).
- Glycemic variability through coefficient of variation and standard deviation. Standard Deviation (SD) is measured as the dispersion of glucose values from the average. Coefficient of Variation (CV) is calculated by dividing the SD by the mean glucose.
- Percentage of insulin recommendations accepted and applied.
- Quality of predictions measured using the Parkes Errod Grid analysis [12].
- Treatment satisfaction using the Diabetes Treatment Satisfaction Questionnaire (DTSQ) [4].
- Patient-reported outcomes on usability and adherence through uMARS [10]

2.2.3 Sleep Quality

We will evaluate Sleep Quality before and after the intervention. The Pittsburg Sleep Quality Index (PSQI) will be used. This questionaire has been used in previous research [3]. Patients will self-complete the (PSQI) questionnaire to assess habitual self-perceived sleep quality [6]. PSQI is composed of 19 questions that examines seven components: sleep quality, latency, habitual sleep efficiency, sleep duration, sleep disturbances, use of sleep medication, and daytime dysfunction. Participants rate the components on a scale of 0 to 3, ranging from 0 to 21, with higher scores indicating worse sleep quality (> 5 reveal poor sleepers). We prepared an online questionaire to record the answers.

2.2.4 Physical Condition

Physical condition will be self assessed by the participants using The International Fitness Scale (IFIS) [2] [11]. It is a scale that has been translated into nine different languages and aims to assess overall physical condition as well as each of its main components specifically, namely aerobic capacity, muscle strength, speed-agility, and flexibility.

[2]https://profith.ugr.es/recursos/ifis/ accesed 24th september 2025

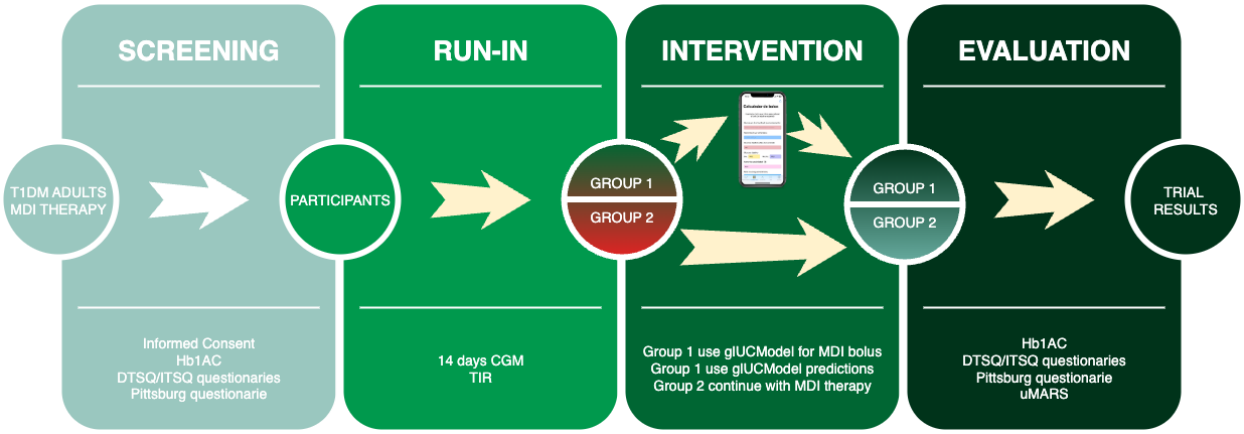

Figure 2: Phases of the trial

2.3 Phases of the Trial

The study will comprise four phases (see Figure 2):

- **Screening phase:** Informed consent, collection of sociodemographic and clinical data, and baseline Pittsburg, IFIS and DTSQ questionnaires.
- **Run-in phase:** 2 weeks of standard care with CGM. Data will be used to generate personalized predictive models in the intervention group.
- **Active treatment phase:** Participants continue MDI therapy. The intervention group will additionally use the *glUCModel* app. CGM data from the final 2 weeks will be analyzed.
- **Evaluation and analysis phase:** Participants will complete the uMARS, Pittsburg, and DTSQ questionnaires. Statistical analysis and correlations amomg outcomes will be processed.

3 The intervention - The *glUCModel* App

glUCModel is an application that puts artificial intelligence at the service of people with diabetes.

3.1 Description of the application

glUCModel is an application designed to help people with diabetes manage their condition. It features a suite of artificial intelligence tools and statistical techniques for capturing and managing key information that people with diabetes need to track, as well as for predicting glucose values to aid users in informed decision-making.

The available features are:

- Automatic recording of biometric data
- Intelligent insulin bolus calculator
- Glucose prediction using three different types of technology:

  - Neural networks
  - Grammatical evolution
  - Fuzzy logic + evolutionary algorithms.
- Generation of prediction models
- Intelligent estimation of optimal hypoglycaemia thresholds
- Intelligent calculation of insulin sensitivity
- Recording of bolus recommendations and glucose predictions
- Testing of external models
- Generation of hypoglycaemia and hyperglycaemia prediction models
- Generation of alerts for hypoglycaemia and hyperglycaemia at different time horizons

3.2 Tools used

The models are trained in an external interface that allows the use of graphics cards to accelerate model training. The interface was developed in Python, and the models use the necessary libraries to perform all training in Python. Once trained, these models can be downloaded to a mobile phone so that they are available at all times. To do this, simplified models are generated using the corresponding Apple tools. An SQL database is used, and the server has the usual tools installed, such as PHP, Apache, and MySQL.

3.3 Main functionality

It has three main functionalities, although the most important is the recommendation of insulin boluses and the corresponding prediction of the glucose values that the user will have as a result of the application of the recommended insulin bolus. It also includes a system for generating models and alerts for hypoglycaemia and hyperglycaemia at different time horizons.

3.3.1 Recording of variables obtained by sensors:

The application allows automatic connection to glucose sensors that provide real-time values and allow the user to maintain control of their levels within the range recommended by medical staff at all times. In addition to glucose sensors, information on insulin delivery and food intake is stored, either through the glucose sensors and applications themselves, or manually through the application's interface. It also allows connection to smart devices such as the Apple Watch or other Android smartwatches. The smartwatches automatically collects biometric information on calories, steps, heart rate, etc. With all the variables collected, predictive models are generated that allow the user to know, as accurately as possible, their glucose value up to two hours in advance.

Figure 3 shows two screenshots of the main view of *glUCModel*. On the left we can observe the glucose values of the day as a continuous graph. This view can show also other variables such as heart rate, steps, calories burned , insulin dosing and carbohydrates intakes. This view also gives information about the last value of glucose, the average glucose, the hypoglycemia risk and the percentage of time in range after clicking on the drop of blood draw (right).

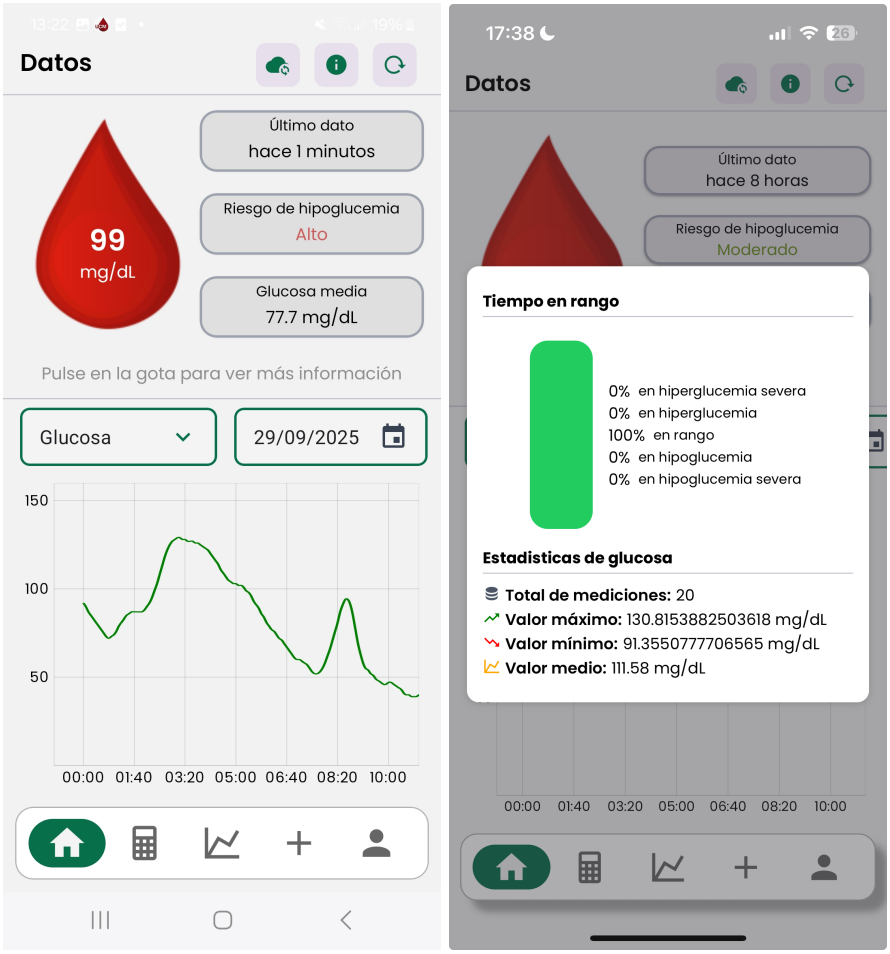

Figure 3: Recording of variables obtained by sensors

Figure **??** shows two screenshots of the main view of *glUCModel*. On the left we can observe the glucose values of the day as a continuous graph. This view can also show other variables such as heart rate, steps, calories burned, insulin dosing, and carbohydrate intakes. This view also gives information about the last value of glucose, the average glucose, the hypoglycemia risk and the percentage of time in range after clicking on the drop of blood draw (right).

3.3.2 Insulin bolus recommendation

This is the core of the application, as it allows people with diabetes to obtain a recommendation for the amount of insulin they should inject based on the glucose values available from the sensors, the insulin previously administered, and factors such as sensitivity. This recommendation can also be validated and evaluated using artificial intelligence algorithms, which are explained in the following section. If the user is not satisfied with the insulin recommendation, they can modify it and request a new prediction to assess whether it is more appropriate.

Figure 4 shows two screenshots of the insulin bolus calculator. The bolus calculator provides insulin bolus recommendations based on glucose levels, carbohydrate portions, remaining insulin, insulin/ carbohydrates ratio, and the individual's sensitivity factor. The calculation is performed using an algorithm developed under the supervision of the medical team.

3.3.3 Glucose value prediction using artificial intelligence

This section, located third in the app's main tab bar, consists of a form with several fields to fill in to request a glucose prediction using predictive models. To restrict the values in each field of the form to a discrete range of possible values, the user will not type anything but will select values for each field through a selector view provided by iOS that allows developers to customise the necessary options to choose from. The fields available on the form are as follows:

- Model type: This field allows the user to decide whether to use a general model or a custom model for glucose prediction.
- Model technique: This field currently offers three possible options for the technique used to train the model: neural networks, grammatical evolution, or fuzzy logic.
- Sample source: The user can choose where their samples will be read from in order to send them to the chosen model and generate a prediction. They can choose between providing samples that they have previously uploaded to the *glUCModel* database or providing a series of 25 samples manually. If the user decides to provide samples directly from the database, the next field for which they must choose a value is 'Types of samples used in the prediction,' which offers different options: Heart rate, Glucose, Glucose and insulin, etc.
- Time horizon: Allows the user to choose at what point in time they want to predict their glucose level from that moment onwards. In other words, choose the time distance, in minutes, that your prediction will cover. Users can choose to predict for now (a time horizon of zero minutes) or when 15, 30, 60, 90 or 120 minutes have elapsed.
- Save settings for future predictions: The user can use a button below to ask the application to remember their selected options in the form fields if it suits them and they want to save time and go faster the next time they request a new prediction. Since this functionality is available in the Apple Watch version of the application, but with a much simpler interface, the user

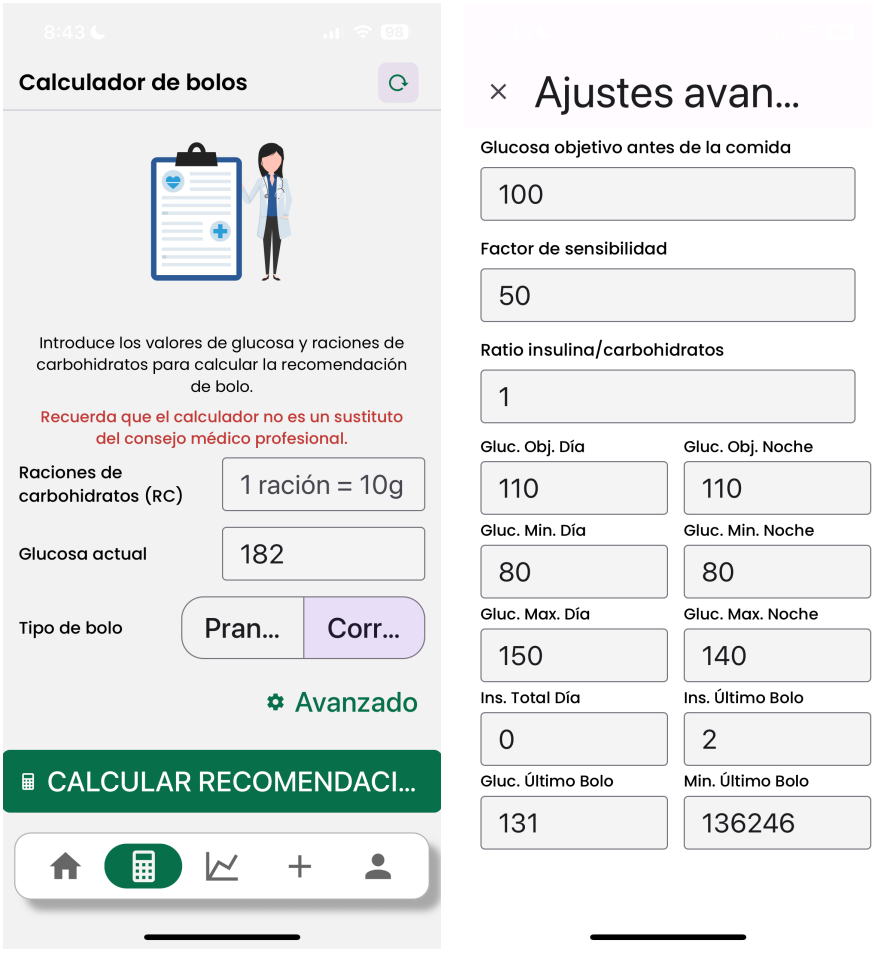

Figure 4: Insulin bolus recommendation

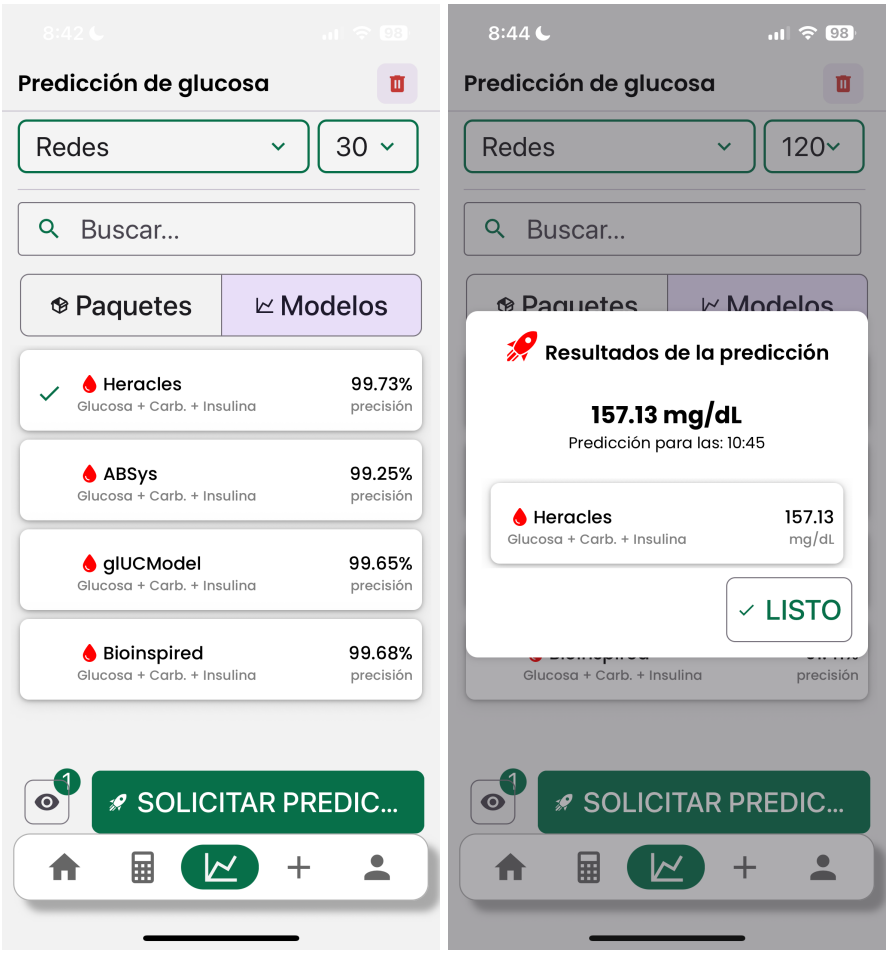

Figure 5: Glucose value prediction using artificial intelligence

can also choose to save some of their selected values for when they request a prediction from the Watch application.

- Requesting a prediction: At the bottom of the view, the user has a button to request a prediction. Each time it is pressed, a message will first appear warning the user not to make any medical decisions based on glucose predictions, as the models are generated by artificial intelligence and may contain errors or inaccuracies. After pressing again to dismiss the warning, the prediction will begin. Once the application has received the model's result, the waiting indicator will fade away and the view will scroll up to display the result at the top of the screen in several parts. First, the user will be reminded of the chosen time horizon and, next to it, the target time for which the prediction was requested, in order to make it easier for the user to know when to expect that glucose level. Next, the user will see the predicted result in mg/dL units in a larger, bold font. If the user chooses to obtain their samples from the database, they will finally be shown the date range to which the samples used belong. The user can then request unlimited new predictions by making as many changes as they wish to the fields in the form

Figure 5 shows screenshots of the prediction view. Although *glUCModel* allows training with three different techniques, in this trial, only four models generated with neural networks and one ensemble model will be made available to patients in order to simplify the task and focus on the objectives.

3.3.4 Other funcionalities

Figure 6 is the main profile and additional functionalities screen of the *glUCModel* application. This screen displays the user profile section, including patient identification and diabetes type. The settings icon (*Configuración* – Settings) allows the user to adjust application preferences. Below, the *Funcionalidades* (Functionalities) menu provides access to the core modules of the system: *Modelos de predicción* (Prediction models), which contain personalized glucose forecasting tools; *Modelos de alarma* (Alarm models), which configure early warning alerts for hypo- or hyperglycemia; *Recomendaciones de bolos* (Bolus recommendations), where insulin dose suggestions are provided; and *Predicciones de glucosa* (Glucose predictions), which offer real-time estimates of future glycemic trends. Navigation buttons are displayed at the bottom of the screen for quick access to the home dashboard, calculator, graphical reports, data entry, and the user profile.

Figure 7 shows the health data entry screen of the *glUCModel* application. This view, labeled *Datos de salud* (Health data), allows the user to manage physiological records such as glucose levels. The button *Datos* (Data) provides access to the stored entries, while the option *+ Añadir* (+ Add) enables manual incorporation of new measurements. The drop-down menu *Glucosa* (Glucose) specifies the type of data being visualized, and the adjacent date selector allows filtering by day. Below, time-stamped glucose measurements are displayed in chronological order, including source annotations and corresponding units (mg/dL). At the bottom of the interface, the navigation bar provides shortcuts to the home dashboard, calculator, graphical reports, data entry, and user profile.

Figure 8 shows an screenshot of the prediction models screen of the *glUCModel* application. This view, labeled *Modelos de predicción* (Prediction models), provides an overview of the available machine learning models for glucose forecasting. The search bar (*Buscar...* – Search) allows filtering of stored models, while the button *+* enables the addition of new models. Each listed model displays its identifier, creation timestamp, and the input variables used for training, such as glucose,

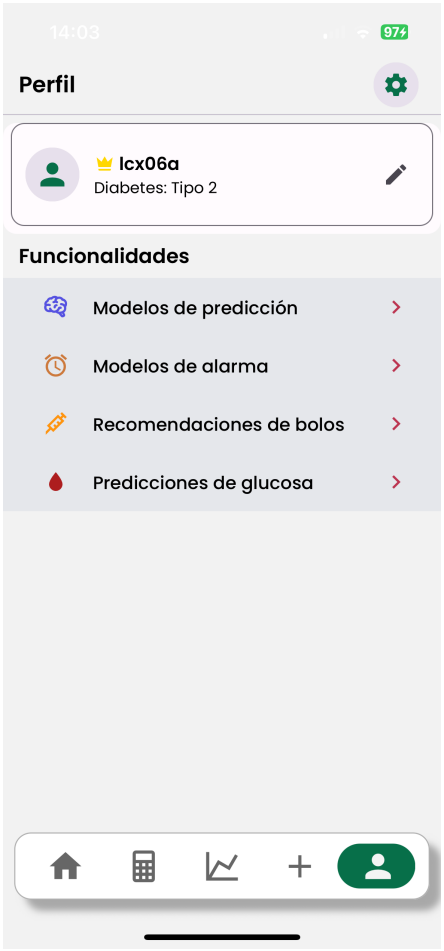

Figure 6: Main profile and functionalities screen of the *glUCModel* application

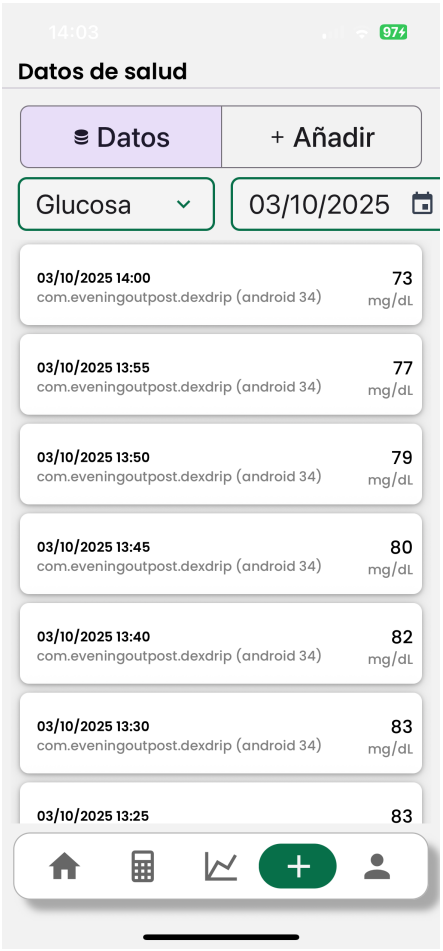

Figure 7: health data entry screen of the *glUCModel* application

carbohydrate intake, and insulin administration. Additionally, the interface presents the precision value (*precisión* – Accuracy) as a quality indicator of each model. A refresh icon is included to update the model list. At the bottom of the interface, the navigation bar provides shortcuts to the home dashboard, calculator, graphical reports, data entry, and user profile.

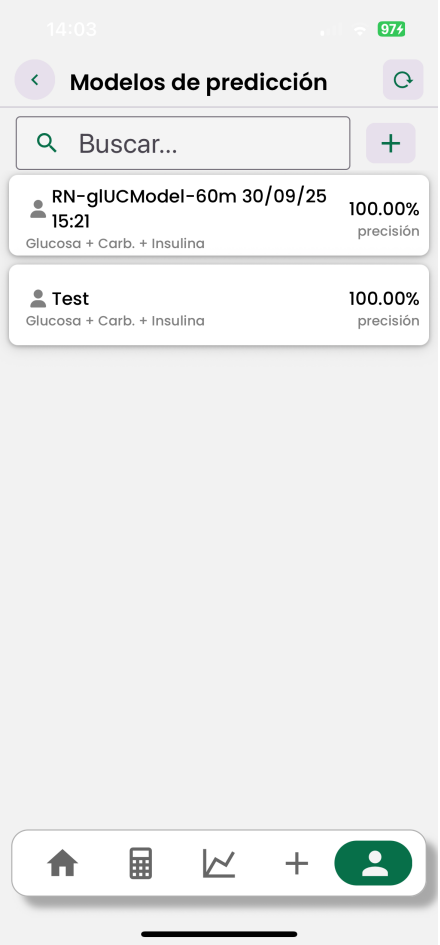

Figure 8: prediction models screen of the *glUCModel* application

Figure 9 represents the glucose prediction results screen of the *glUCModel* application. This view, labeled *Predicciones de glucosa* (Glucose predictions), presents a list of prediction events with their corresponding real values. Each entry contains the prediction timestamp, the evaluation timestamp, and two numerical values: the predicted glucose level (*Predicha* – Predicted) and the actual recorded glucose level (*Real* – Real), both expressed in mg/dL. This comparison enables quantitative validation of model performance in real-world conditions. The interface also allows for the expansion of individual records via the arrow icon for additional details. The bottom navigation bar provides quick access to the home dashboard, calculator, graphical reports, data entry, and the user profile.

3.4 Statistical Analysis

Data will be analyzed using both intention-to-treat (ITT) and per-protocol (PP) approaches. Descriptive statistics will be used to summarize baseline characteristics of the study groups. Normality

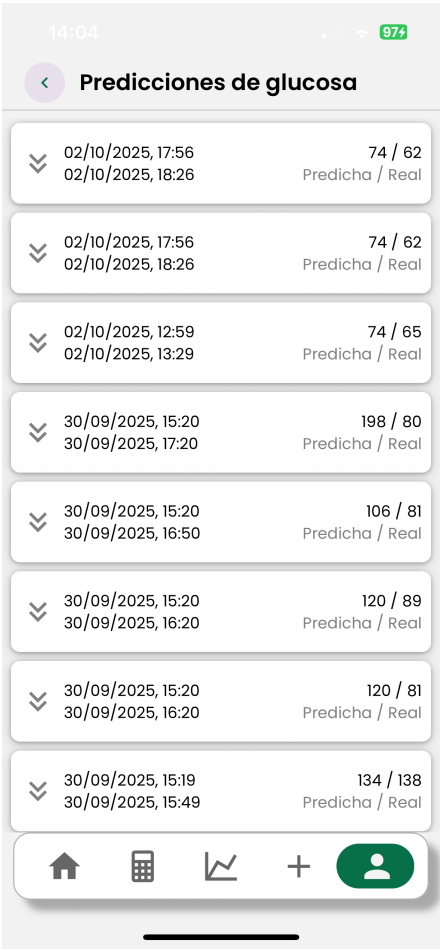

Figure 9: Glucose prediction results screen of the *glUCModel* application

of data will be assessed using the Shapiro-Wilk test. Between-group comparisons will use independent samples t-tests for normally distributed data or Mann–Whitney U tests otherwise. Chi-square tests will be used for categorical variables.

Primary outcome (TIR) and secondary outcomes will be evaluated using mixed-effects repeated measures models to account for within-subject correlation over time. Effect sizes and 95% confidence intervals will be reported. A p-value ¡ 0.05 will be considered statistically significant. Missing data will be handled using multiple imputation methods where appropriate.

4 Discussion

This study will evaluate for the first time the real-world effectiveness of integrating predictive glucose models into insulin dosing through the glUCModel app. If successful, the intervention may provide a scalable, user-centered approach to improving glycemic control in patients using multiple daily insulin injections.

While prior studies have investigated digital health tools in diabetes management, few have focused specifically on predictive algorithms for insulin adjustment combined with real-time decision support.

The trial's design, with CGM-based outcomes, validated questionnaires, and real clinical endpoints, is expected to yield meaningful insights into the potential of AI-powered mHealth interventions in type 1 diabetes care.

Glucmodel uses artificial intelligence models to help people with diabetes calculate the most appropriate insulin doses. Glucmodel can predict a patient's glucose levels up to two hours in advance. It also generates warnings of dangerous levels up to 24 hours in advance.

Glucmodel works in a web, app and watch environment that allows both patients and medical professionals to monitor the disease.

The most important features are:

- Automatic recording of biometric data
- Intelligent insulin bolus calculator
- Glucose prediction based on neural networks
- Generation of prediction models
- Intelligent estimation of optimal hypoglycaemia thresholds
- Intelligent calculation of insulin sensitivity

The group's proprietary predictive algorithms are patented or in the process of being patented: patents P202230016 and P201331726. Numerous international publications have been produced and the group has received the 2021 Roche Award for Research in Personalised Precision Medicine.

Ethics and Dissemination

This study has been approved by the relevant ethics committee of Hospital Universitario Príncipe de Asturias at Alcalá de Henares, Madrid, Spain. Written informed consent will be obtained from all participants prior to enrollment.

All procedures will comply with the Declaration of Helsinki and GDPR regulations. Results will be disseminated through peer-reviewed publications and scientific conferences.

Data Collection methods and managments ...

Author Contributions

Funding

Conflict of Interest

The authors declare no conflicts of interest related to this study. The glUCModel app is used strictly for research purposes and is not yet commercially available.

References

[1] *IDF Diabetes Atlas, 10th edition*. International Diabetes Federation, Brussels, Belgium, 2023.

[2] Eleonora Maria Aiello, Chiara Toffanin, Mirko Messori, Claudio Cobelli, and Lalo Magni. Postprandial glucose regulation via knn meal classification in type 1 diabetes. *IEEE Control Systems Letters*, 3(2):230–235, 2019.

[3] Marta Botella-Serrano, Jose Manuel Velasco, Almudena Sánchez-Sánchez, Oscar Garnica, and J Ignacio Hidalgo. Evaluating the influence of sleep quality and quantity on glycemic control in adults with type 1 diabetes. *Frontiers in endocrinology*, 14:998881, 2023.

[4] Clare Bradley. Diabetes treatment satisfaction questionnaire (dtsq). In *Handbook of psychology and diabetes*, pages 111–132. Routledge, 2013.

[5] Sergio Contador, J Manuel Colmenar, Oscar Garnica, J Manuel Velasco, and J Ignacio Hidalgo. Blood glucose prediction using multi-objective grammatical evolution: analysis of the "agnostic" and "what-if" scenarios. *Genetic Programming and Evolvable Machines*, 23(2):161–192, 2022.

[6] Hristina Denic-Roberts, Tina Costacou, and Trevor J. Orchard. Subjective sleep disturbances and glycemic control in adults with long-standing type 1 diabetes: The pittsburgh's epidemiology of diabetes complications study. *Diabetes Research and Clinical Practice*, 119:1–12, 2016.

[7] J Ignacio Hidalgo, J Manuel Colmenar, J Manuel Velasco, Gabriel Kronberger, Stephan M Winkler, Oscar Garnica, and Juan Lanchares. Identification of models for glucose blood values in diabetics by grammatical evolution. *Handbook of Grammatical Evolution*, pages 367–393, 2018.

[8] J Ignacio Hidalgo, Esther Maqueda, José L Risco-Martín, Alfredo Cuesta-Infante, J Manuel Colmenar, and Javier Nobel. glucmodel: A monitoring and modeling system for chronic diseases applied to diabetes. *Journal of biomedical informatics*, 48:183–192, 2014.

[9] J Ignacio Hidalgo, Jose Manuel Velasco, Daniel Parra, and Oscar Garnica. Genetic programming techniques for glucose prediction in people with diabetes. In *Genetic Programming Theory and Practice XX*, pages 105–124. Springer, 2024.

[10] Ruben Martin-Payo, Sergio Carrasco-Santos, Marcelino Cuesta, Stoyan Stoyan, Xana Gonzalez-Mendez, and María del Mar Fernandez-Alvarez. Spanish adaptation and validation of the user version of the mobile application rating scale (umars). *Journal of the American Medical Informatics Association*, 28(12):2681–2686, 2021.

[11] Eugenio Merellano-Navarro, Daniel Collado-Mateo, Javier García-Rubio, Narcís Gusi, and Pedro R. Olivares. Validity of the international fitness scale "ifis" in older adults. *Experimental Gerontology*, 95:77–81, 2017.

[12] JL Parkes, SL Slatin, S Pardo, and BH Ginsberg. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. *Diabetes Care*, 23(8):1143–1148., 2000.

[13] Félix Tena, Oscar Garnica, Juan Lanchares, and Jose Ignacio Hidalgo. Ensemble models of cutting-edge deep neural networks for blood glucose prediction in patients with diabetes. *Sensors*, 21(21):7090, 2021.