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Original Research

Comparing quality of life in traditional face-to-face visits with a hybrid approach of telemedicine with in-person follow-ups in recent users of advanced closed-loop systems: a randomized controlled clinical trial in patients with type 1 diabetes

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Lía Nattero-Chávez, Esther de La Calle, Edurne Lecumberri-Pascual, Ane Bayona Cebada, Teresa Ruiz Gracia, Alejandra Quintero Tobar, Mar Lorenzo Moñino, Cristina Sánchez Rodríguez, Ana Izquierdo, Héctor F. Escobar-Morreale and Manuel Luque-Ramírez

Correspondence to:
Lía Nattero-Chávez
Department of Endocrinology and Nutrition, Hospital Universitario Ramón y Cajal, Carretera de Colmenar, Km 9.1, E-28034 Madrid, Spain

Grupo de Investigación en Diabetes, Obesidad y Reproducción Humana, Instituto Ramón y Cajal de Investigación Sanitaria (IRYCIS) & Centro de Investigación Biomédica en Red de Diabetes y Enfermedades Metabólicas Asociadas (CIBERDEM) & Universidad de Alcalá, Madrid, Spain
marialia.nattero@salud.madrid.org

Esther de La Calle
Edurne Lecumberri-Pascual
Teresa Ruiz Gracia
Mar Lorenzo Moñino
Cristina Sánchez Rodríguez
Ana Izquierdo
Department of Endocrinology and Nutrition, Hospital Universitario Ramón y Cajal, Madrid, Spain

Ane Bayona Cebada
Department of Endocrinology and Nutrition, Hospital Universitario Ramón y Cajal, Madrid, Spain

Grupo de Investigación en Diabetes, Obesidad y Reproducción Humana, Instituto Ramón y Cajal de Investigación Sanitaria (IRYCIS) & Centro de Investigación Biomédica en Red de Diabetes y Enfermedades Metabólicas Asociadas (CIBERDEM) & Universidad de Alcalá, Madrid, Spain

Abstract

Background: Our objective was to assess the effect of a hybrid telemedicine approach, in conjunction with face-to-face follow-up, on the quality of life in recent users of an advanced hybrid closed-loop (AHCL) system.

Methods: A 1-year open randomized (1:1) clinical trial (ClinicalTrials.gov ID NCT04900636). Participants with type 1 diabetes (T1D) recent users of an AHCL system (Minimed® 780G) for at least 2–6 months, and ⩾18 years old were eligible. The primary outcome was the change in quality of life measured by the Type 1 Diabetes Life (ViDa1) Questionnaire from baseline to 12 months of hybrid telemedicine plus face-to-face follow-up compared to standard clinical practice. Additionally, impacts on A_{1c} levels, glucose metrics, advert events, and safety outcomes were assessed.

Results: Between January and December 2021, 46 participants were randomly assigned in a 1:1 ratio to either the hybrid telemedicine group ($n = 23$) or the control group ($n = 23$); 45 participants completed the study, with only 1 from the control group withdrawing before visit 3. At baseline, mean age was 37 ± 15 years and A_{1c} was $6.9 \pm 0.5\%$. After 12 months, no statistically significant differences in ViDa1 scores between groups were observed. Despite reducing in-person visits in the hybrid follow-up arm, there were no increases in adverse events. Overall, A_{1c} levels significantly decreased from $6.9 \pm 0.5\%$ at baseline to $6.7 \pm 0.5\%$ after 12 months ($P = 0.006$) without differences between treatment arms, accompanied by reductions in glycemic variability and time below the target range.

Conclusion: Our study suggests that there were no significant differences in ViDa1 scores between the two groups at the end of the follow-up. However, among adult patients with T1D who recently adopted an AHCL system, satisfactory glycemic control can be attained through a hybrid follow-up approach, reducing face-to-face visits, without increasing technical complications.

Keywords: closed-loop system, Minimed® 780G, quality of life, telemedicine, type 1 diabetes, ViDa1

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Alejandra Quintero Tobar
Grupo de Investigación en Diabetes, Obesidad y Reproducción Humana, Instituto Ramón y Cajal de Investigación Sanitaria (IRYCIS) & Centro de Investigación Biomédica en Red de Diabetes y Enfermedades Metabólicas Asociadas (CIBERDEM) & Universidad de Alcalá, Madrid, Spain

Héctor F. Escobar-Morreale
Manuel Luque-Ramírez
Department of Endocrinology and Nutrition, Hospital Universitario Ramón y Cajal, Madrid, Spain

Grupo de Investigación en Diabetes, Obesidad y Reproducción Humana, Instituto Ramón y Cajal de Investigación Sanitaria (IRYCIS) & Centro de Investigación Biomédica en Red de Diabetes y Enfermedades Metabólicas Asociadas (CIBERDEM) & Universidad de Alcalá, Madrid, Spain

Department of Medicine, Universidad de Alcalá, Alcalá de Henares, Madrid, Spain

Introduction

Diabetes distress is increasingly recognized as one of the most significant psychosocial challenges in the management of people with type 1 diabetes (T1D).[1,2] Challenges in maintaining optimal glucose levels contribute substantially to the stress associated with T1D. Consequently, numerous studies have explored the correlation between T1D, psychological distress, and lower scores in the assessment of health-related quality of life (HRQoL).[1–4] In a study population of patients with T1D between 8 and 17 years of age, a significant association was estimated between poor glycemic control with both depression and HRQoL.[5] Poor glycemic control[6] and hyperglycemic symptoms[7] were also associated with reduced HRQoL in adult patients, even after adjustment for diabetes-related complications. Furthermore, these psychological issues have been found to be closely intertwined with metabolic control, since higher levels of depression, anxiety, and stress are associated with elevated A_{1c} levels, indicating poorer glycemic control in affected patients.[8,9]

In recent years, there have been remarkable advances in diabetes technology. With the commercial availability of closed-loop systems, studies on various automated insulin delivery systems have unequivocally demonstrated improved glycemic outcomes. As a result, there has been a noticeable enhancement in the quality of life for patients with T1D, regardless of age, sex, duration of diabetes, previous insulin delivery method, and baseline A_{1c}.[10–14]

The advances in smartphone-based technology offer patients convenient and potentially cost-effective self-management tools. The availability of telemedicine systems that enable frequent and stable remote communication with the healthcare team contributes positively to patient monitoring and provides highly valuable insights for the management of T1D.[7] The rapid advancement of technology in the treatment and monitoring of T1D has revolutionized the communication of diabetes-related data between patients and healthcare professionals.

The implementation of telehealth services for the treatment and management of individuals with T1D has increased in the last few years. However, the potential of these technologies to enable widespread adoption of remote consultations, also known as telemedicine, remains uncertain. Several concerns regarding data security, heightened physician workload, and technical equipment issues are raised in this context.[15–18] Moreover, the evidence on the implementation of telemedicine in advanced hybrid closed-loop (AHCL) system users derives from limited retrospective or observational studies.[19,20]

Could the use of telemedicine in patients using an AHCL system reduce the need for face-to-face visits and provide constant remote support, without worsening the quality of life? The objective of this study was to determine the impact on quality of life of a smartphone telemedicine application designed for T1D patients treated with an AHCL system, as compared to usual standard care, by conducting a randomized controlled trial. We hypothesized that implementing a hybrid follow-up approach (combining telemedicine with face-to-face visits) for patients with T1D using an AHCL system, as compared with standard clinical practice, would lead to improved metabolic control despite reducing the need for in-person physician visits, while not worsening the quality of life.

Methods

Study population

We recruited consecutive adult patients diagnosed with type 1 diabetes mellitus and using the Medtronic MiniMed® 780G (Northridge, CA, USA) for at least 2–6 months. This selection procedure aimed to provide a cohort with consistent durations of system usage, promoting homogeneity, and comparability among participants. Inclusion criteria comprised a diagnosis of T1D treated with insulin for at least 1 year, current use of the MiniMed 780G system, age $\geq$18 years, and $A_{1c} < 9\%$. Diagnosis of T1D required a previous episode of ketoacidosis and/or diabetic autoimmunity, along with mandatory insulin use for survival, in accordance with the criteria outlined by the American Diabetes Association.[21] At baseline, all participants received comprehensive face-to-face diabetes education, including carbohydrate counting if necessary, from a diabetes nurse educator. Moreover, prior to enrollment, all participants were trained in the use of a diabetes self-management telemedicine application.

Exclusion criteria were: (i) diagnosis of types of diabetes mellitus other than T1D; (ii) inability to undertake training and/or acquire the knowledge

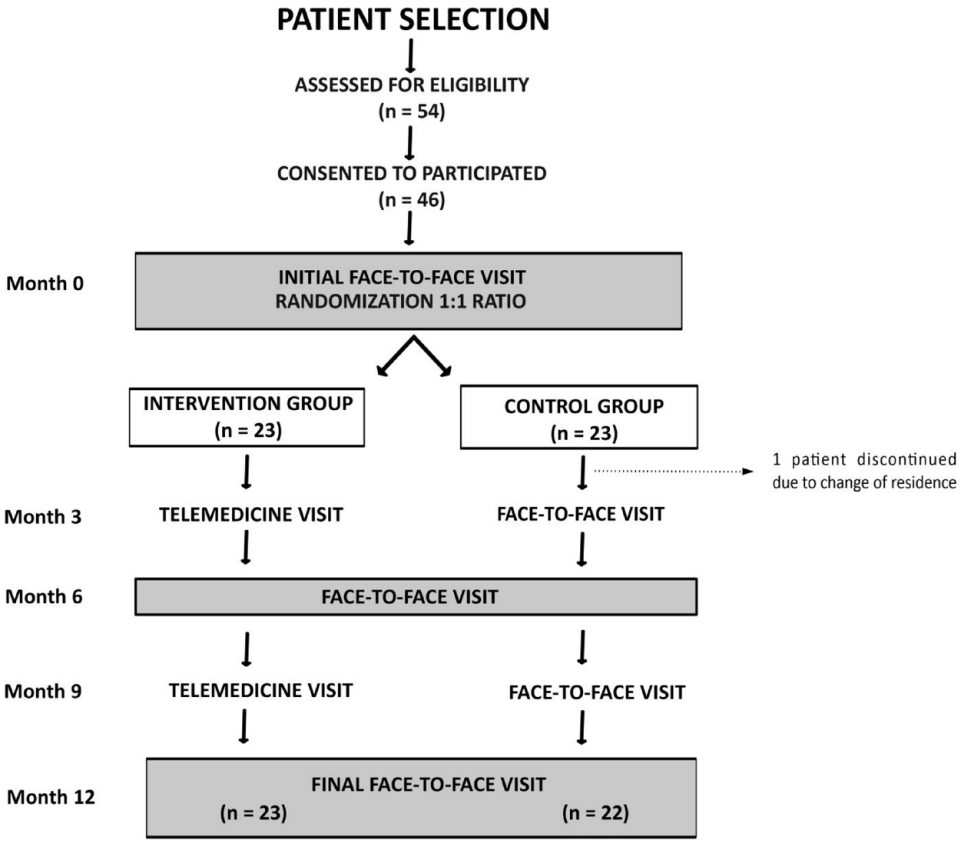

Figure 1. Protocol visit schedule.

needed to use the application; (iii) use of an AHCL other than the MiniMed 780G system; (iv) ongoing pregnancy; (v) refusal to sign the informed consent form.

Study design

This 12-month randomized, non-blinded, parallel-group clinical trial was conducted at the outpatient clinic of an Academic Hospital in Madrid, Spain. Randomization was performed in a 1:1 ratio using a web-based application and was stratified by sex, duration of diabetes, and A_{1c} level. All participants used the MiniMed 780G system and were enrolled either in a hybrid follow-up program that incorporated a telemedicine application alongside face-to-face visits or in conventional face-to-face follow-up care following a standard clinical practice.

Outcomes

The primary objective of our study was to compare the changes in quality of life, as assessed by Type 1 Diabetes Life (ViDa1) Questionnaire, in both arms of intervention. Secondary objectives assessed changes in metabolic control, glucometric variables derived from continuous glucose monitoring (CGM), and safety variables.

Study protocol and intervention

Patients assigned to the intervention arm had face-to-face visits at months 0, 6, and 12. Additionally, they had remote telemedicine consultations through the smartphone app (Integrated Care Platform Mymobile; Tunstall, Madrid, Spain; https://www.tunstall.es/recursos/fichas-de-producto/icp-mymobile/) at months 3 and 9. Hence, the study comprised five visits (three face-to-face and two remote visits) during the 12-month duration as compared with five face-to-face visits at months 0, 3, 6, 9, and 12 in the control arm. The visit schedule and flowchart of the study are depicted in Figure 1.

After obtaining signed informed consent forms, patients were instructed to download a mobile

app after being assigned to their respective treatment groups. Participants assigned to the intervention group received an email containing a unique username and password, enabling access to the telemedicine app on their personal cell phones. On the scheduled telemedicine visit days, patients received reminders to download online data platform (Carelink™ Personal) with data from their Minimed 780G device. The app enabled participants to complete questionnaires related to their quality-of-life assessments and evaluations for the risk of inadvertent hypoglycemia. The questionnaires were automatically synchronized on a web platform for healthcare professionals. This allowed healthcare providers to review these results in conjunction with clinical information, facilitating informed decision-making for optimized patient care.

All patients, regardless of the randomized treatment arm, started Mimined 780G device according to our hospital protocol. The first month was started with a target of glucose in 110 mg/dL and an insulin duration of 3 h. At 1 month, the program was optimized to a target of 100 mg/dL and an active insulin duration of 2 h, if the patient had not experienced hypoglycemia. At the end of the study, all patients were programmed according to the manufacturer's recommendation. During the follow-up evaluation, if necessary, the insulin-to-carb ratio was changed.

Furthermore, physicians monitored the information provided by patients through the app, enabling remote follow-up and the delivery of therapeutic recommendations. Whenever needed, physicians could arrange additional face-to-face appointments aside from those already scheduled in the protocol.

Data collection and measures

Baseline demographic and clinical data. At the baseline visit, participants underwent confirmation of eligibility criteria and provided consent for study participation. We collected demographic and clinical data relevant to diabetes. This encompassed an assessment of clinical parameters associated with T1D, including duration of diabetes, metabolic control, and history of severe hypoglycemia. Additionally, we documented information regarding sex, current medications, cardiovascular risk factors (such as hypertension, dyslipidemia, and smoking status), microvascular complications (such as diabetic retinopathy), neuropathy (defined as any diabetes-related neurological complication), nephropathy (defined as any diabetes-related kidney disease), and macrovascular complications.

Physical examination and biochemical parameters. Patients underwent a comprehensive physical examination during all their face-to-face visits, which included measurements of blood pressure, heart rate, height, and weight (the latter measured while wearing light clothing without shoes).

Renal function, serum lipid profiles, and A_{1c} levels were assessed during face-to-face medical visits at baseline and after 6 and 12 months of follow-up. Fasting blood and urine samples were collected for the measurement of creatinine (using immunoturbidimetry on the Abbott Architect system; Abbott Laboratories, Chicago, IL, USA) and A_{1c} levels (using high-performance ion-exchange chromatography on the HA-8160 analyzer; A. Menarini Diagnostics, Florence, Italy).

Quality of life by the ViDa1 questionnaire. The ViDa1 questionnaire is an easily administered and validated tool that measures quality of life in individuals with T1D and is useful for both clinical practice and research.[22] The ViDa1 addresses the most relevant aspects of living with T1D by a series of questions, including physical, emotional, and social health, as well as satisfaction with treatment and the ability to carry out daily activities.[22] The ViDa1 questionnaire presents four sections that include: (i) interference of diabetes with daily life (12 items), (ii) self-care (11 items), (iii) well-being (6 items), and (iv) concern about the disease (5 items). We used participants' responses to calculate a partial score for each of the four areas, with the total score reflecting their overall perception of diabetes-related quality of life. Lower scores indicated a better quality of life. The ViDa1 questionnaire was completed while attending face-to-face visits at months 0, 6, and 12 in both arms of treatment. We chose the ViDa1 questionnaire to assess quality of life due to our familiarity with it and our involvement in its design and validation. This questionnaire, specifically tailored for patients with T1D, includes an assessment of the impact of insulin pumps on treatment satisfaction and overall quality of life.[22]

Awareness hypoglycemia assessed by Clarke's score. All participants were required to complete

a survey aimed at documenting severe hypoglycemic events and assessing hypoglycemia awareness status using Clarke's questionnaire.[23] A severe hypoglycemic event was defined as an episode requiring external assistance.[24] Clarke's questionnaire was completed during face-to-face visits at months 0, 6, and 12 in both groups. Clarke's questionnaire has been previously validated using both retrospective recall and prospective records of severe hypoglycemia in the T1D patient population, as well as hypoglycemic clamping.[25] It comprises an 8-item survey aimed at estimating awareness of hypoglycemia symptoms.[23] Participants provided responses regarding the frequency of hypoglycemic episodes experienced in the past 2 months and their symptomatic responses to hypoglycemia. Responses were categorized as "R" for reduced awareness or "A" for awareness, with each "R" response assigned a score of 1 and each "A" response assigned a score of 0. Three or more "R" responses (score ≥ 3) indicated impaired hypoglycemia awareness.[16]

CGM data. Time in range (TIR), time in hypoglycemia below 70 mg/dL and below 54 mg/dL, and time in hyperglycemia above 180 mg/dL and above 250 mg/dL were analyzed, according to the International Consensus on Time in Range.[26] The glucose management indicator, mean, standard deviation (SD), and coefficient of variation (CV) of sensor glucose were recorded. Data were also collected on adherence to treatment, use of the sensor and automatic mode (time, %), change of the reservoir, and infusion set (days). Fourteen-day data from CGM systems and Minimed 780G were analyzed at months 6 and 12 using CareLink system software.

Safety outcomes. Participants were asked to complete a questionnaire gathering self-reported data on their experiences since their last visit. The questionnaire covered a comprehensive range of information related to adverse events, including any issues associated with the insulin pump (such as malfunctions or alarms), problems with equipment or infusion sites, challenges with the CGM system, incidents of ketosis or diabetic ketoacidosis (DKA), and episodes of severe hypoglycemia. Participants were also queried about the resolution of any issues, including whether they were resolved independently, with assistance from another individual, or if hospitalization or admission to the emergency department was required.

Sample size analysis

The sample size calculation was performed using the free online software GRANMO Version 7.11 March 2011 (https://apisal.es/Investigacion/Recursos/granmo.html). Based on the subscale of Interference in daily living activities of the ViDa1 questionnaire,[22] we considered a minimum difference between treatment arms at the end of the study of 6 points, equivalent to 10% of the total score on this item, as clinically relevant. Assuming a SD of ± 10 points, a sample size of 23 subjects in each arm of treatment was needed for 0.05 alpha and 0.20 beta, in a two-sided contrast. We considered a predicted loss-to-follow-up rate of 5% for these calculations.

Statistical analysis

Data are shown as means $\pm$ SD for continuous variables and counts and percentage (%) for categorical variables, with 95% confidence intervals. For continuous variables, we checked normality using the Kolmogorov–Smirnov test and ensured normality as needed by applying logarithmic transformation. For unpaired samples, the independent samples t test or Mann–Whitney U test was used for baseline comparisons. We used a repeated-measures general linear model to analyze the changes in continuous outcomes, introducing the arm of treatment as between-subjects effect, and the visit (months 0, 6, and 12) as within-subjects effect. A statistically significant interaction among the between- and within-effects would mean different responses to treatments. For categorical differences in longitudinal changes on the prevalence of impaired hypoglycemia awareness, adverse events with the insulin pump, problems with the infusion site or CGM system, incidents of ketosis or DKA, and episodes of severe hypoglycemia throughout the study, we used generalized estimating equation analyses.

We used intention-to-treat analysis including all patients: for missing observations, we carried forward the last valid value observed. Statistical significance was set at $P < 0.05$. The SPSS Statistics

v. 29 software package (IBM España S.A., Madrid, Spain) was used for calculations.

Results

Study population characteristics

From May to December 2021, a total of 56 patients were assessed for eligibility in the study. Of these, 46 participants consented to participate and were randomly assigned in a 1:1 ratio to either the telemedicine group ($n = 23$) or the control group receiving standard medical care ($n = 23$). The most common reasons for declining participation in the trial were reluctance to engage in a follow-up program using a smartphone and a preference for traditional face-to-face medical visits. Forty-five participants successfully completed the study, concluding the last visit of the trial on January 27, 2023. One participant, originally allocated to the control group, withdrew from the study prior to visit 3 because of changing residence to a place outside Madrid. The study cohort comprised primarily young patients with satisfactory metabolic control. At baseline, the mean age was 37 ± 15 years (minimum age 19 years old and maximum age 66 years old), with a mean duration of diabetes of 20 ± 10 years, and a mean A_{1c} of $6.9 \pm 0.5\%$ (52.7 ± 5.5 mmol/mol). Additional demographic and baseline diabetes data are summarized in Table 1, encompassing all patients as a whole and further subdividing them into the intervention (telemedicine group) and control groups. Both groups' demonstrated balanced characteristics, with no discernible clinical or glycemic disparities being observed on CGM data collected at the baseline visit.

Use of the MiniMed 780G system and glycaemic control

Throughout the study, all participants used the Guardian 3® sensor as part of the MiniMed 780G system. Sensor usage remained consistent, with subjects wearing the sensor for an average of $87 \pm 13\%$ of the study duration and automation being active for $92 \pm 12\%$ of the sensor wearing time. Notably, there were no discernible differences in sensor usage or automation rates between the intervention and control groups.

When considering the entire cohort as a whole, significant reductions in A_{1c} levels were observed from baseline to the 12-month follow-up visit ($6.9 \pm 0.5\%$ vs $6.7 \pm 0.5\%$, respectively, $P = 0.006$), with improvements that were similar in both arms of treatment. Furthermore, a notable decrease in the CV and time spent below the target range was evident after 12 months, regardless of the arm of the trial. Importantly, we observed an increase in total insulin dose, resulting from concurrent elevations in both automatic basal insulin and automatic self-correcting bolus doses, as detailed in Table 2. Additionally, Table 2 summarizes the TIR and time spent in hyperglycemia at baseline, 6 months, and 12 months of follow-up.

Patient-reported outcomes

The scores from the questionnaires, including total scores and scores for different subscales, at 6 and 12 months compared to baseline for both groups, are presented in Table 2 and Figure 2. No statistically significant between- or within-subjects effects were observed in the ViDa1 quality of life questionnaire scores, either when analyzing the entire cohort as a whole or when comparing both arms of treatment (Table 2 and Figure 2).

No reduction in Clarke score neither was observed from baseline to the end of the follow-up period, either when considering all subjects as a whole or when considering each arm of treatment (Table 2). However, changes in the frequency of impaired hypoglycemia awareness were noted from baseline to the 6- and 12-month follow-up visits when considering the entire cohort as a whole (from baseline: 12 (27%) to 6 (11%) at 6 and 12 months, $P < 0.001$), that occurred regardless of the arm of treatment (Table 2).

Safety outcomes. None of the subjects had been hospitalized in the 12 months preceding the study, nor were hospitalized during the study period. Additionally, no episodes of DKA occurred during the follow-up period, and none of the subjects discontinued the use of the AHCL system or the telemedicine application before the completion of the evaluation period. However, two patients (4%), one from each treatment arm, reported elevated ketone levels without DKA between the 3- and 6-month visits, which were attributed to issues with the infusion set or injection site. These incidents were resolved on an outpatient basis. Analysis of adherence to the infusion set change recommendations indicated a satisfactory level of compliance, with intervals of 3 and 3.7 days,

Table 1. Demographic, clinical characteristics, and continuous glucose monitoring metrics considering all patients as a whole, and as a function of the randomization group.

Variable	All patients (*n* = 46)	Randomization		
		Hybrid program (*n* = 23)	Control (*n* = 23)	*P*-Value
Demographics				
Age (years)	34 [27]	44 [29]	28 [18]	0.071
Duration of diabetes (years)	20 ± 10	24 ± 10	17 ± 9	0.160
Sex (female)	30 (65)	14 (61)	16 (70)	0.399
Onset as ketoacidosis	12 (26)	8 (33)	4 (18)	0.242
Severe hypoglycemia	5 (11)	2 (9)	3 (13)	0.776
Time with AHCL (months)	3.7 ± 1.0	3.8 ± 1.1	3.4 ± 0.2	0.177
Comorbid conditions				
Microangiopathy, *n* (%)	5 (11)	4 (17)	1 (4)	0.349
Macroangiopathy, *n* (%)	1 (2)	0 (0)	1 (4)	0.478
Hypertension, *n* (%)	6 (13)	4 (17)	2 (9)	0.667
Smoking, *n* (%)	8 (17)	4 (17)	4 (17)	1.000
Mean BMI (kg/m^2)	25.1 ± 4.2	25.9 ± 4.2	24.1 ± 3.3	0.095
Obesity, *n* (%)	4 (9)	2 (8)	2 (9)	1.000
Biochemical variables				
Fasting plasma glucose (mg/dL)	130 ± 47	131 ± 43	129 ± 51	0.890
Total cholesterol (mg/dL)	177 ± 36	173 ± 37	181 ± 35	0.435
LDL-cholesterol (mg/dL)	97 ± 29	97 ± 32	98 ± 26	0.945
Triglycerides (mg/dL)	74 ± 36	81 ± 41	68 ± 31	0.244
eGFR (mL/min/1.73 m^2)	90 ± 14	89 ± 13	90 ± 14	0.735
UACR (mg/g)	7 [9]	7 [9]	7 [9]	0.401
A_{1c} (%)	6.9 ± 0.5	7.0 ± 0.5	6.8 ± 0.5	0.234
Concomitant medications				
Total daily insulin dose (U/kg)	0.6 ± 0.2	0.5 ± 0.2	0.6 ± 0.2	0.410
Basal daily insulin (U/kg)	0.2 ± 0.1	0.2 ± 0.1	0.3 ± 0.1	0.329
Bolus daily insulin (U/kg)	0.3 ± 0.1	0.3 ± 0.1	0.3 ± 0.1	0.627
Automatic correction bolus (U/kg)	0.06 ± 0.04	0.06 ± 0.04	0.06 ± 0.04	0.647
Antiaggregant therapy, *n* (%)	2 (4)	1 (4)	1 (4)	1.000

(Continued)

Table 1. (Continued)

Variable	All patients (*n* = 46)	Randomization		
		Hybrid program (*n* = 23)	Control (*n* = 23)	*P*-Value
Statin therapy, *n* (%)	12 (26)	8 (33)	4 (17)	0.321
Antypertensive therapy, *n* (%)	6 (13)	4 (17)	2 (9)	0.665
Continuous glucose monitoring metrics				
TBR <54 mg/dL	0 [0]	0 [0]	0 [0]	0.802
TBR <70 mg/dL	2 [2]	2 [2]	2 [2]	0.766
Total TBR <70 mg/dL	3 [3]	2 [2]	3 [2]	0.280
TIR 70 and 180 mg/dL	82 ± 9	82 ± 9	82 ± 9	0.950
TAR >180 mg/dL	13 ± 6	14 ± 6	12 ± 5	0.452
TAR >250 mg/dL	2 [2]	2 [2]	1 [4]	0.988
Total TAR >180 mg/dL	15 ± 8	16 ± 8	15 ± 7	0.280
Other outcomes				
Mean sensor usage (%)	87 ± 9	87 ± 9	87 ± 10	0.972
Time in auto mode (%)	91 ± 13	90 ± 15	92 ± 12	0.630
GMI (%)	6.6 [0.4]	6.6 [0.4]	6.6 [0.3]	0.915
Mean sensor glucose (mg/dL)	134 ± 12	135 ± 13	133 ± 12	0.623
CV of sensor glucose (%)	36 ± 7	35 ± 8	36 ± 7	0.761
SD of sensor glucose	44 ± 9	44 ± 7	44 ± 11	0.971

Continuous and discrete variables are shown as means ± SD or median [IQR] for quantitative variables; and raw numbers (percentage), respectively. AHCL, advanced hybrid closed-loop, BMI, body mass index; CV, coefficient of variation; eGFR, estimated glomerular filtration rate; GMI, glucose management indicator; HDL, high density lipoprotein; LDL, low density lipoprotein; SD, standard deviation; TAR, time above range; TBR, time below range; TIR, time in range; UACR, urinary albumin–to–creatinine ratio.

respectively, for these two patients. Notably, both individuals had been using AHCL systems for 12 months at the time of the events. One (2%) participant in the telemedicine group, aged 45 years, reported an episode of severe hypoglycemia at the 6-month follow-up visit, attributed to an error in intake calculation. This individual had been using the AHCL system for 9.5 months at the time of the hypoglycemic episode.

Reported technical problems were comparable between both groups during the 12-month follow-up period (Table 2, safety outcomes). Patients in both the control and intervention groups exhibited similar patterns in changing infusion sets. Overall, there was a decrease in blood glucose (BG) monitoring sensor calibration at the 12-month follow-up compared to baseline visits, with no discernible differences between the arms of treatment. The number of events reported was 1.2 per person/year, with no differences between the groups.

Discussion

Our study aimed to evaluate the 1-year follow-up performance of a hybrid follow-up approach (combining telemedicine with face-to-face visits)

Table 2. Continues glucose monitoring metrics, biochemical parameters, and insulin doses at baseline, 6 months, and 12 months as a function of the randomization group.

Variable	Baseline		After 6 months		After 12 months		*P*
	Hybrid program	Control	Hybrid program	Control	Hybrid program	Control	
Continuous glucose monitoring metrics							
TBR < 54 mg/dL	0 [1]	0 [0]	0 [0]	0 [0]	0 [1]	0 [0]	0.640
TBR < 70 mg/dL	3 [2]	2 [2]	2 [2]	2 [2]	2 [3]	2 [2]	0.992
Total TBR < 70 mg/dL[a,b]	3 [3]	3 [2]	3 [2]	2 [3]	2 [3]	2 [2]	0.011
TIR 70 and 180 mg/dL	82 ± 9	82 ± 9	80 ± 7	81 ± 9	83 ± 6	81 ± 6	0.769
TAR > 180 mg/dL	13 ± 6	12 ± 5	15 ± 6	14 ± 6	13 ± 4	14 ± 5	0.384
TAR > 250 mg/dL	2 [2]	2 [4]	1 [2]	2 [3]	2 [1]	2 [2]	0.748
Total TAR > 180 mg/dL	16 ± 8	15 ± 7	17 ± 7	17 ± 8	15 ± 6	17 ± 6	0.593
Other outcomes							
Mean sensor usage (%)	90 [11]	90 [14]	92 [13]	92 [7]	90 [10]	92 [6]	0.521
GMI (%)	6.6 [0.4]	6.6 [0.3]	6.5 [0.3]	6.6 [0.5]	6.6 [0.3]	6.7 [0.3]	0.121
Mean sensor glucose (mg/dL)	135 ± 13	133 ± 12	137 ± 12	134 ± 12	139 ± 20	140 ± 11	0.776
CV of sensor glucose (%)[a,c]	35 ± 8	36 ± 7	32 ± 4	31 ± 4	32 ± 4	32 ± 4	0.008
SD of sensor glucose	44 ± 7	44 ± 11	45 ± 7	43 ± 9	44 ± 9	44 ± 7	0.379
Time in closed-loop system (%)	97 [12]	97 [15]	97 [10]	97 [4]	96 [13]	99 [4]	0.554
Daily carbohydrate amount (gr/d)	125 ± 51	115 ± 31	134 ± 61	122 ± 50	124 ± 56	123 ± 38	0.455
Biochemical variables							
eGFR (mL/min/1.73 m^2)[c]	89 ± 13	90 ± 15	96 ± 11	100 ± 27	91 ± 17	93 ± 16	0.022
UACR (mg/g)	7 [10]	7 [9]	5 [5]	9 [8]	5 [7]	7 [8]	0.538
A_{1c} (%)[c]	7.0 ± 0.5	6.8 ± 0.47	6.7 ± 0.6	6.6 ± 0.5	6.7 ± 0.5	6.7 ± 0.5	0.006
Daily insulin dose							
Total daily insulin dose (U/kg)[c]	0.54 ± 0.15	0.58 ± 0.17	0.58 ± 0.15	0.62 ± 0.20	0.55 ± 0.15	0.58 ± 0.18	0.048
Auto basal daily insulin (U/kg)[c]	0.22 ± 0.07	0.25 ± 0.10	0.25 ± 0.09	0.25 ± 0.10	0.23 ± 0.07	0.23 ± 0.08	0.034
Bolus daily insulin (U/kg)	0.32 ± 0.09	0.33 ± 0.09	0.33 ± 0.09	0.37 ± 0.13	0.32 ± 0.09	0.35 ± 0.11	0.182
Auto correction bolus (U/kg)[a,c]	0.06 ± 0.04	0.06 ± 0.04	0.08 ± 0.05	0.09 ± 0.06	0.08 ± 0.04	0.09 ± 0.05	0.004
Patient-reported outcomes							
ViDa1 questionnaire							
Interference of diabetes in daily life	27 ± 9	29 ± 9	24 ± 8	30 ± 10	25 ± 6	28 ± 8	0.393

(Continued)

Table 2. (Continued)

Variable	Baseline		After 6 months		After 12 months		*P*
	Hybrid program	Control	Hybrid program	Control	Hybrid program	Control	
Self-care	44 ± 7	43 ± 6	43 ± 5	42 ± 6	44 ± 3	43 ± 6	0.505
Well-being	21 ± 3	19 ± 4	21 ± 2	20 ± 5	22 ± 5	20 ± 4	0.596
Concern about the disease	15 ± 4	16 ± 5	15 ± 3	16 ± 5	14 ± 4	15 ± 5	0.074
Total score	107 ± 11	108 ± 9	103 ± 11	107 ± 14	104 ± 9	106 ± 9	0.178
Clarke's questionnaire							
Clarke's score	1.26 ± 1.50	1.55 ± 1.61	1.26 ± 1.40	1.10 ± 1.31	1.10 ± 1.41	0.91 ± 1.22	0.105
Impaired hypoglycemia awareness[a,c]	5 (22)	7 (30)	4 (17)	1 (4)	3 (13)	2 (9)	<0.001
Safety outcomes							
Problems with insulin pump or equipment infusion	6 (26)	2 (9)	4 (14)	1 (4)	6 (26)	7 (30)	0.087
Problems with glucose sensor	5 (22)	2 (9)	5 (22)	7 (30)	5 (22)	1 (4)	0.270
Episodes of ketosis	0 (0)	0 (0)	1 (4)	1 (5)	0 (0)	0 (0)	0.680
Episodes of severe hypoglycemia	0 (0)	0 (0)	1 (4)	0 (0)	0 (0)	0 (0)	0.605
Change of infusion set (days)	3.9 ± 1.0	3.5 ± 1.1	3.9 ± 1.2	3.7 ± 1.1	4.0 ± 1.5	3.7 ± 1.3	0.660
Glucose sensor calibration (times/day)[a]	3.6 ± 1.5	3.3 ± 0.9	3.0 ± 1.3	3.2 ± 1.6	2.6 ± 0.5	2.9 ± 0.6	0.001

Patient-reported outcomes. Quality of life and Clarke questionnaire scores, general and subscales, and safety outcomes at baseline and after 6 and 12 months. Data are mean ± SD or median [IQR] for quantitative variables; or number of subjects (%). ViDa1: lower scores indicate a better quality of life.
[a]Significant differences between V0 with V12.
[b]Statistically significant differences between V6 with V12.
[c]Significant differences between V0 with V6.
BMI, body mass index; CV, coefficient of variation; eGFR, estimated glomerular filtration rate (MDRD-4 formula); GMI, glucose management indicator; SD, standard deviation; TAR, time above range; TBR, time below range; TIR, time in range; UACR, urinary albumin–to–creatinine ratio; ViDa1, Type 1 Diabetes Life.

in adult AHCL system users with T1D, focusing on the impact on quality of life, glucose control, and the safety of system use. The importance of assessing patient-reported outcomes related to the use of AHCL systems has been increasingly recognized.[27] In our study, we used the ViDa1 life questionnaire,[22] chosen for its comprehensive evaluation of quality of life following the initiation of continuous insulin infusion pump therapy. Despite the reduction in face-to-face visits facilitated by the hybrid follow-up approach, our trial did not detect statistically significant differences in any of the HRQoL areas assessed by the ViDa1 questionnaire. This suggests that the implementation of telemedicine within our cohort did not result in a deterioration of quality of life, despite being recent users of a closed handle system. Because participants were relatively novel in their use of the Minimed 780G system, there may have been an initial need for additional visits beyond the study protocol, which did not materialize during the year-long follow-up. The facilitation of rapid access to support by the healthcare team through the app likely contributed to this finding. As this was a pilot program, video calls were not utilized. It is conceivable that incorporating video calls into the hybrid follow-up program could have yielded a more favorable impact on the perceived quality of life for the patients. To our knowledge, this is the first randomized clinical

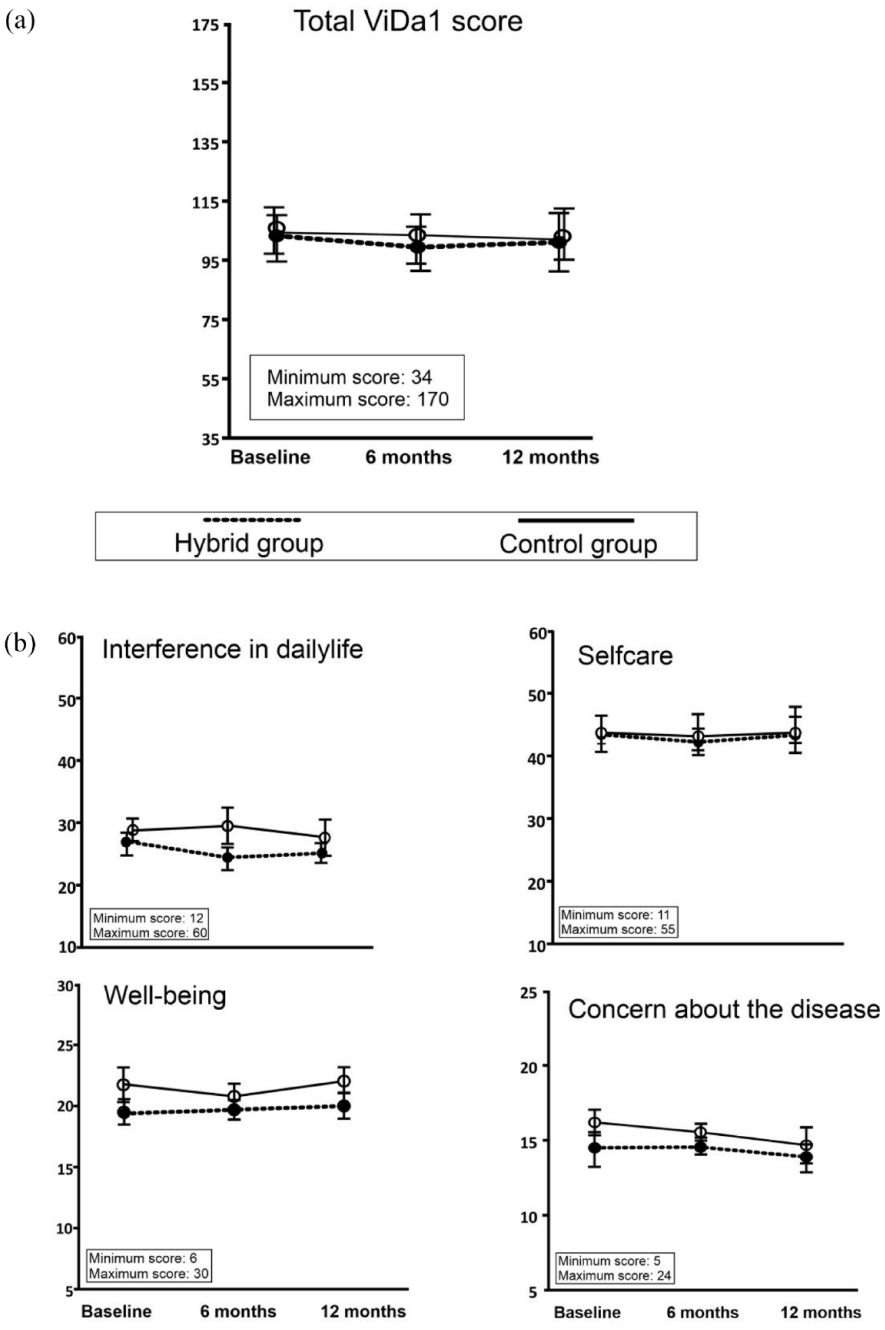

Figure 2. Changes in questionnaire scores at 0, 6, and 12 months. (a) ViDa1 total score (mean ± SD). Minimum and maximum test scores are shown in the graph. Lower scores indicate better quality of life. (b) Values for each section of the ViDa1 questionnaire: Interference with daily life, Self-care, Well-being, and Concern about the disease (mean ± SD). The minimum and maximum scores for each section are shown in the graph.
SD, standard deviation; ViDa1, Type 1 Diabetes Life.

trial to assess the impact on quality of life of a hybrid follow-up program among patients utilizing AHCL systems.

T1D may be considered an ideal candidate for the integration of telemedicine, offering significant advantages in managing chronic conditions.

The COVID-19 pandemic accelerated the adoption of telemedicine, leading to a re-evaluation of its efficacy in healthcare delivery. Scott et al.[28] conducted a survey assessing telemedicine utilization among individuals with T1D during the pandemic, noting increased remote appointments but decreased willingness to consider them in the future. This finding highlights the necessity for customized approaches to telemedicine implementation, potentially incorporating a hybrid model that combines in-person and remote care.[28]

For patients already proficient in the use of technology, particularly those utilizing closed-loop systems, the integration of telemedicine into clinical practice presents a hopeful avenue. Nonetheless, the effectiveness of telemedicine implementation among AHCL system users remains constrained. As advocated by an International Panel on Digital Technologies for Diabetes,[18] the incorporation of randomized controlled trials is recommended to strengthen the findings from real-world observational studies. Our study adds to this discourse by specifically assessing the outcomes of telemedicine in AHCL system users. Few studies have investigated the efficacy of telemedicine utilization among AHCL system users, and those that have typically focused on its impact on enhancing metabolic control and therapeutic compliance within an observational context. However, these studies often neglect to assess safety and quality-of-life parameters.[19,20] Longo et al.,[19] in a retrospective study, demonstrated notable improvements in glucose control metrics among adults with T1D utilizing closed-loop systems during the COVID-19 lockdown period, with monitoring conducted via telemedicine. In a similar vein, Gómez Medina et al.[20] documented favorable results from a 6-month prospective cohort study involving AHCL system users within a virtual clinic environment, demonstrating successful achievement of TIR objectives. This virtual diabetes clinic follow-up not only enhanced adherence to sensor utilization but also maintained consistent use of the system's automatic mode. Nevertheless, it is important to acknowledge that this study lacked a control group for comparative analysis, and did not evaluate quality-of-life outcomes.

However, we observed a significant drop in trial participation, with up to 18% of patients potentially favoring traditional in-person visits. This decline might be attributed to the consecutive recruitment process, which commenced soon after the reintroduction of face-to-face consultations following the COVID-19 pandemic. We speculate that some patients who opted out of the study may have felt a renewed need for direct, in-person interactions in the diabetes clinic post-pandemic. Current evidence suggests that the effectiveness and acceptance of telemedicine vary across different populations.[29,30] Thus, additional studies are needed to assess its suitability and preference among specific populations with T1D to validate these findings.

While there was no significant difference in TIR after 12 months, we noted a decrease of 0.3% in A_{1c} levels, with no discernible differences between treatment groups following 1 year from initial randomization. Although we do not have specific data to analyze, it is possible that changes in device settings, dietary habits, and/or physical activity during the study period influenced these outcomes. Another important consideration is that, as these participants were new users of the Minimed 780G, factors such as optimal device setup, the system's efficiency, and the self-learning capabilities of the algorithm may have contributed to the observed improvements in metabolic control. Our present findings reinforce and expand these earlier observations. These results corroborate the extensively documented enhancements in glycemic variability, time to hypoglycemia, and clinically significant reductions in A_{1c} associated with AHCL systems.[31] In addition, we find differences between doses at the basal visit with 6 and 12 months follow-up that could explain problems such as meals not being consumed on time or difficulties with accurate carbohydrate counting. This could shed light on the impact of these automated functions on meal management and accuracy of carbohydrate intake, offering insights into their role in glycemic control strategies.

Moreover, patients enrolled in the hybrid follow-up approach exhibited comparable enhancements in metabolic control while reducing the need for in-person visits and commuting to the hospital, while maintaining a safety profile consistent with conventional follow-up.

At 6 months of the study, an improvement in renal function was observed in both treatment arms. This is in agreement with previously published results showing that intensive glycemic

control in patients with T1D has a nephroprotective effect (risk ratio 0.37, 0.27–0.50; $P < 0.00001$).[32]

With regard to safety, our hybrid follow-up program exhibited no association with heightened technical or metabolic adverse events throughout the follow-up period. In fact, the incidence of adverse events reported by patients was even lower than that observed in previous studies.[33] After 12 months, there was a noticeable decrease in the number of calibrations, accompanied by a reduction in hypoglycemia incidents. This reduction may have potentially led to fewer BG checks for confirmation purposes. This observation suggests a complex relationship between calibration frequency, hypoglycemia rates, and the need for BG verification, highlighting the importance of further discussion on how these factors affect glucose management strategies. Additionally, the overall reduction in sensor calibrations at 12 months may reflect an increasing trust in the system over time. It is also noteworthy that the average number of calibrations at both the beginning and end of the study remained above the manufacturer's recommended threshold of two calibrations per day. It is worth highlighting that the average number of calibrations at both baseline and the study's conclusion remained above the manufacturer's recommended threshold of two calibrations per day.

Importantly, there was an improvement in the recognition of neurogenic hypoglycemia symptoms, accompanied by enhancements in exposure to hypoglycemia and A_{1c} levels. These findings align with our previous research outcomes[34] and those of similar cohorts.[33] The HypoCOMPaSS study[35] underscores the effectiveness of a holistic approach to managing individuals with impaired hypoglycemia awareness, which integrates structured educational programs with optimized insulin therapy, resulting in notable benefits compared to standard interventions. Notably, regular communication with diabetes education personnel played a pivotal role in achieving substantial reductions in severe hypoglycemia and improvements in Clarke's scores. The integration of telemedicine into diabetes education may provide continuous support in addressing these challenges.

Our study is subject to some limitations primarily arising from the specific inclusion criteria, encompassing individuals with predetermined baseline glycemic levels and recent utilization of AHCL systems, potentially constraining the applicability of our findings to broader or more diverse populations. Likewise, new users of the Minimed 780G may experience an improvement in quality of life in the first year of use, and that may limit differences in our primary endpoint.[36] Notably, our patient cohort initially exhibited satisfactory metabolic control and adherence to clinical follow-up. Factors such as differences in the assessment of socioeconomic strata could limit the application of these findings in other populations. The study design was completed before the COVID-19 pandemic, when telemedicine was not as well established in our routine clinical practice, so the design of our study was conservative in that respect (only two traditional visits were changed to telemedicine), and may not be sufficient to demonstrate differences in patients' quality of life. We do not have information on lifestyle, diet, physical activity, and the configuration of the closed-loop system during the monitoring year.

It is noteworthy that the observed decrease in self-reported hypoglycemia awareness may be attributed to an enhanced "technological awareness" rather than genuine physiological restoration.[37] Additionally, our study lacks supplementary evaluations such as quality-of-life assessments by scales other than the ViDa1 questionnaire, stress related to diabetes or treatment satisfaction questionnaires. We chose the ViDa1 questionnaire to assess quality of life due to our familiarity with it and our involvement in its design and validation.[22] This questionnaire, specifically tailored for patients with T1D, includes an assessment of the impact of insulin pumps on treatment satisfaction and overall quality of life.[22] Additionally, validation studies of the ViDa1 questionnaire have demonstrated strong correlations with traditional quality-of-life assessments commonly used in diabetes research.[22] However, our aim was to evaluate quality of life without imposing excessive questionnaire burdens on patients. It is worth noting that patients also completed a questionnaire regarding adverse effects and safety during the telemedicine visits. Despite these limitations, the strengths of our study, including its randomized controlled design, meticulously calculated sample size, and 1-year follow-up duration, underscore the significance of our present findings.

In conclusion, the escalating prevalence of T1D and the concurrent shortage of healthcare professionals present significant challenges to clinicians,

health systems, payers, and policymakers alike. Digital diabetes technologies have emerged as promising tools to mitigate these challenges by enhancing access to care, mitigating costs, and fostering improvements in clinical outcomes and quality of life. Despite initially being perceived as futuristic, telemedicine technologies have demonstrated their viability in delivering essential healthcare services to individuals with T1D, providing them with convenience, accessibility, and continuous support. Our study contributes substantial evidence corroborating the current real-world data, indicating that a hybrid follow-up program effectively assists AHCL system users in achieving glycemic targets and reducing the need for face-to-face visits, all without worsening the quality of life in people living with T1D.

Declarations

Ethics approval and consent to participate

The institutional review board of Hospital Universitario Ramón y Cajal approved the study (protocol ID: 317/19, date of approval February 27, 2020). The study was performed in accordance with the Helsinki Declaration of 1964, and its later amendments and agreed with national regulations. Written informed consent to use the clinical and biochemical data for research was obtained from each participant. The protocol study was registered at ClinicalTrials.gov (ID NCT04900636).

Consent for publication

All authors have reviewed and approved the final version of this manuscript and give their consent for its publication.

Author contributions

Lía Nattero-Chávez: Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Writing – original draft; Writing – review & editing.

Esther de La Calle: Investigation; Writing – review & editing.

Edurne Lecumberri-Pascual: Investigation; Methodology; Writing – review & editing.

Ane Bayona Cebada: Investigation; Writing – review & editing.

Teresa Ruiz Gracia: Investigation; Writing – review & editing.

Alejandra Quintero Tobar: Project administration; Writing – review & editing.

Mar Lorenzo Moñino: Investigation; Writing – review & editing.

Cristina Sánchez Rodríguez: Investigation; Writing – review & editing.

Ana Izquierdo: Investigation; Writing – review & editing.

Héctor F. Escobar-Morreale: Investigation; Methodology; Writing – review & editing.

Manuel Luque-Ramírez: Investigation; Methodology; Writing – review & editing.

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Competing interests

The authors declare that there is no conflict of interest.

Availability of data and materials

Derived data supporting the findings of this study are available from the corresponding author L.N.-C. on request.

ORCID iD

Lía Nattero-Chávez https://orcid.org/0000-0002-9758-9397

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