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ORIGINAL RESEARCH

Descriptive study of a clinical and educational telemedicine intervention in patients with diabetes receiving glargine 300 U/ml (Toujeo) in Spain: results of the T-Coach programme

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Abstract

Background: Diabetes is one of the most prevalent chronic diseases worldwide, and innovative patient support programmes can help and inform patients about their disease and improve their quality of life. The purpose of this study was to evaluate the effect of the T-Coach programme in terms of improvement of disease knowledge, self-management and adherence to treatment in a real-world setting in Spain between July 2016 and October 2018.

Methods: We analyzed data from the T-Coach programme, a telephone platform that gives support to patients with type 2 diabetes mellitus treated with insulin glargine 300 U/ml (Gla-300). Support was provided by diabetes care nurses. Patients followed their treatment and aimed to achieve fasting blood glucose targets through diabetes education.

Results: A total of 479 patients were included in the programme. The mean (SD) dose of Gla-300 was 28.5 (16.3) U at baseline and 31.8 (16.1) U, 31.4 (16.4) U and 32.2 (16.3) U, respectively, at 3, 6 and 12 months. A satisfaction survey was completed by 240 (50.1%) patients, who, on average, were very highly satisfied with the programme, general assistance provided, recommendations received, and calls from nurses.

Conclusions: T-Coach could be an effective tool to help patients achieve their optimal dose of Gla-300 insulin and manage their blood glucose levels. It could also act as an effective support for diabetes education.

Keywords: basal insulin, diabetes, education, glargine 300 U/mL, T-Coach, telemedicine, titration, Toujeo.

Citation

Bellido V, Morales C, Muñoz Garach A, García Almeida JM, Fernández Morera JL, González Aguilera B, López de la Torre M, Bellido D. Descriptive study of a clinical and educational telemedicine intervention in patients with diabetes receiving glargine 300 U/ml (Toujeo) in Spain: results of the T-Coach programme. *Drugs Context*. 2023;12:2023-1-1. https://doi.org/10.7573/dic.2023-1-1

Introduction

Diabetes mellitus (DM) encompasses a group of disorders characterized by altered glucose metabolism. It is associated with various complications, leading to high morbidity and mortality rates, and is one of the most prevalent chronic diseases worldwide. About 415 million people aged between 20 and 79 years (global prevalence, 8.8%) had DM in 2015, and it is estimated that this number will increase progressively to 642 million by 2040.[1] Global expenditure on diabetes was estimated to increase by 12% in 2014 compared with 2013, with North America and the Caribbean and Europe accounting for 69% of the total global diabetes-related expenditure.[2] In the United States, more than half of DM-associated costs are attributable to the disease and 13% to antidiabetic therapies.[3] In Europe, a French study estimated that 49% of diabetes-specific expenditure (€1.1 billion)

ISSN: 1740-4398

corresponded to antidiabetic drugs, with insulin therapy accounting for €400 million of that total.[4]

Insulin is an essential treatment for patients with diabetes. In type 2 DM (T2DM), insulin is prescribed if the blood glucose target is not reached despite lifestyle changes and optimized therapy with oral antidiabetic drugs and non-insulin injectable therapies. Insulin should be also introduced earlier if there is evidence of ongoing catabolism, symptoms of hyperglycaemia or when HbA1c levels are above 10%.[5] However, therapy usually requires complex dosing schedules with frequent adjustments, and this burdensome regimen has been identified as an important patient-related and physician-related barrier, leading to clinical inertia and poor therapeutic adherence.[6] Together with the existing gaps in patient awareness and disease knowledge, these problems negatively impact blood glucose levels and DM outcomes.[7]

As in other chronic diseases, strategies in DM should focus on patient empowerment for outcomes to improve. Thus, self-management as part of a patient-centred care model has become a key element for successful diabetes care, involving not only disease-related aspects, such as medication and glucose monitoring, but also identification of problems and strategies to solve them, reduction of the risk of diabetes complications and behavioural changes resulting from lifestyle choices.[8] Patient support programmes (PSPs) have been developed to provide patients with high-quality diabetes self-management education and have been shown to improve self-management, patient satisfaction, and glucose outcomes.[9] Telemonitoring and active insulin titration also result in improved outcomes.[10] However, a recent analysis of diabetes self-management education programmes in the EU showed that only a small percentage of stakeholders (7.0–12.3%) make use of information technology for teaching and learning.[11]

The use of telecommunications to deliver health services, expertise and information (i.e. telemedicine) emerged as a promising tool to help people with diabetes with self-management and is already yielding results.[12,13] The recently published results of the eStar programme, a 6-month telephone-based programme for patients with T2DM treated with Gla-100, showed the tool to be useful in helping patients reach an adequate insulin titration that allows achievement of target fasting blood glucose levels.[14]

Given the proven benefit of PSPs and telecommunications in persons with diabetes, the T-Coach programme was created to empower patients with T2DM receiving Gla-300 in terms of disease education and management. The T-Coach differs from other approaches in that it provides much more than telephone support for patients (despite the positive results reported for this aspect to date[14,15]). T-Coach includes a comprehensive platform with individualized learning modules for patients adapted to baseline and periodic assessment of patient needs and knowledge. In addition, it also acts as an integrated tool for health-care practitioners, enabling practitioners to follow up on their patient's progress.

The aim of this study was to analyze the data collected from this PSP and to evaluate the effect of the programme in terms of treatment satisfaction, adherence and effect on disease knowledge. Here, we present our 6-month results.

Methods

Analysis design and participants

This analysis addresses the satisfaction with the programme and improvement in diabetes education amongst patients who participated in the T-Coach programme in order to evaluate the effect of a telemedicine tool for patients with T2DM receiving treatment with Gla-300.

The patients included in the T-Coach programme comprised adults diagnosed with T2DM starting or having started treatment with Gla-300 (Toujeo) during the previous year. All patients signed the informed consent document. Likewise, patients receiving concomitant treatment with oral antidiabetics or GLP-1 analogues could be selected for inclusion, according to the study criteria. In contrast, those diagnosed with type 1 DM and those treated with an insulin other than Toujeo as well as those receiving concomitant treatment with pre-prandial insulin were excluded.

Programme data were extracted from the T-Coach patient database between July 2016 and July 2018. Since the information collected from this database was anonymized, no additional informed consent was requested from patients to use their data in the study.

The analysis protocol was approved by the Autonomic Ethics Committee of Galicia (Spain).

The T-COACH programme

The T-Coach programme was a 2-year telemedicine educational tool to empower patients with T2DM treated with Gla-300 in terms of disease knowledge, self-management and long-term adherence to treatment. The programme consisted of e-learning modules and telephone sessions carried out by a team of nurses specialized in diabetes education. Regarding the educational modules that make up the programme, modules 1 and 2 are basic and were

completed by all participants, whilst modules 3–7 are support modules and were taken according to individual needs for knowledge and motivation (Table 1).

Needs were assessed using questionnaires after inclusion in the programme. Knowledge needs were established using a non-validated questionnaire to assess diabetes education (administration of insulin and management of hypoglycaemia); knowledge was scored from 0 points (very poor) to 8 points (very good) (Table 2). These questions were not asked directly but introduced during a conversation. Motivation needs were assessed using the 4-item Morinsky-Green medication adherence questionnaire validated for people with diabetes. The questionnaire distinguishes between those with high adherence (0–1 points) and those with low adherence (2–3 points). Education planning was tailored to the individual patient according to the score achieved in both questionnaires.

Although e-learning modules were available, most patients preferred to be contacted via telephone and use e-learning as additional content. After 3 months, patients were reassessed to determine whether they could graduate from the programme. During the following 21 months, patients were supported by telephone sessions to adjust Gla-300 dosing according to their personal glycaemic goal and the titration algorithm defined by their physician. The follow-up accounted for a total of 11 scheduled touchpoints throughout the programme. A 24-hour telephone contact was available for patients who needed further assistance with insulin titration. Patient progression could be followed-up by the physician through the T-Coach website. A satisfaction survey was offered to graduates of the programme (0 [lowest satisfaction] to 10 [highest satisfaction]). According to the protocol, patients were considered to have graduated when they completed their individualized educational plan and had adhered to the insulin titration algorithm. Patients were considered titrated when the optimal insulin dose for their personal glycaemic goals was reached.

Study outcomes

The study outcomes were the length of stay in the programme, the difference in knowledge and motivation questionnaires throughout the programme, insulin dose modifications, satisfaction with the programme, completion of the educational modules, number of outbound

Table 1. Educational modules and learning objectives.

Module n°	Title	Learning objectives
1	Skills, abilities and self-confidence to adjust dosing	• Why your doctor asks you to adjust your dose of insulin • The insulin titration function to achieve the treatment goals • Strengthen your confidence and ability to adjust the insulin dose as your doctor advises
2	How to improve management of hypoglycaemia	• What is hypoglycaemia, what causes it and how to recognize it • Why it is important to recognize hypoglycaemic episodes • How to best manage hypoglycaemia
3	Understanding diabetes	• Develop understanding of diabetes • Recognize the importance of controlling glucose levels • Understand the importance of blood sugar target values • Understand the need for insulin to control diabetes
4	FAQs about insulin injection	• How to inject insulin • Address some of your concerns and build your confidence with regards to insulin injections
5	How to adapt insulin treatment to your lifestyle	• Making insulin a part of your life • Offer solutions and address any specific insulin-related challenge
6	How to manage common changes in insulin regimens for treatment of diabetes	• Identify any challenges you may have when adapting to changes in your diabetes treatment • Manage these changes with practical tips
7	FAQs before/after starting insulin treatment	• Identify any questions or concerns you may have regarding insulin • Offer you support to overcome them

Table 2. Questionnaires and educational modules.
a) Knowledge and motivation assessment

Knowledge questionnaire[a]		**Motivation questionnaire**	
Question	Scoring (yes = 1; no = 0)	Question	Scoring (yes = 1; no = 0)
The patient does not fear self-administering insulin		Do you sometimes forget to take your medication?	
The patient understands that insulin is necessary to treat their diabetes		Are you careless at times about taking your medication?	
The patient is not concerned about the effect insulin may have on them		When you feel better, do you sometimes stop taking your medication?	
The patient has the skills, ability, and self-confidence to adjust insulin dosing according to their doctor's indications		If you feel worse when you take your medication, do you sometimes stop taking it?	
The patient is able to decide their insulin dose based on self-monitoring of glucose			
The patient has the skills, ability and self-confidence to avoid hypoglycaemic episodes			
The patient does not find difficulties in managing their insulin regimen			
The patient does not find difficulties in accepting frequent changes in their insulin regimen			
Total	≥4 = moderate needs <4 = high needs	Total	0–1 = high adherence 2–4 = low adherence

[a]Questions were not asked directly but included as part of a conversation.

Table 2. Questionnaires and educational modules.
b) Educational module assignment algorithm

Incorrect answer to question	**Module assignment**
1	1–3
2	4
3	6
4	5
5	3–7
6	2
7	3–5
8	5–7

calls, and the correlation between the number of calls and achieving an appropriate insulin titration.

Statistical methods

The analyses were performed using descriptive statistical methods, with measures of central tendency and dispersion for quantitative variables and absolute and relative frequencies, with their 95% confidence interval for qualitative variables. Changes (baseline *versus* final) in quantitative variables were assessed using the *t*-test; changes in qualitative variables were assessed using the McNemar test. Non-parametric tests were applied when necessary. Statistical significance was set at $p<0.05$ (two-tailed).

All statistical analyses were performed using SAS (Version 9.4).

Results

Participants

The T-Coach database included 778 patients, of whom 479 were evaluable and included for analysis after completing 6 months in the programme. Patients were distributed across 6 Spanish provinces (Sevilla, 159 patients, 33.2%; Málaga, 133, 27.8%; La Coruña, 76, 15.9%; Asturias, 73, 15.2%; Vizcaya, 24, 5.0%; and Granada 14, 2.9%).

The mean (SD) age of the study sample was 65.6 (11.0) years. Women accounted for slightly more than half of participants (246; 51.4%). Less than half of the patients (219; 45.7%) were younger than 65 years. The mean (SD) initial A1C was 9.2% (1.8), and baseline glycaemia was 204.9 (71.1) mg/dL. The mean (SD) body mass index of the total sample was 30.6 (6.0) kg/m^2; 235 (49.1%) patients had obesity (BMI ≥30), and 164 (34.2%) had overweight (BMI 25–29.9). Most patients (383; 80.0%) had had T2DM for more than 1 year.

The mean (SD) dose of Gla-300 was 28.5 (16.3) U at baseline and 31.8 (16.1) U, 31.4 (16.4) U and 32.2 (16.3) U at 3, 6 and 12 months, respectively, as a result of an adequate basal insulin titration. Two-thirds of participants (325; 67.8%) were previously receiving basal insulin treatment with or without oral antidiabetic agents, and the remaining one-third (154; 32.2%) were receiving oral antidiabetic agents.

Outcomes

Mean (SD) stay in the T-Coach programme was 404.0 (279.5) days, with 331 (69.1%) patients staying 6 months or longer. Thus, the results shown below reflect those obtained 6 months after the patients were included in the programme. At baseline, the mean (SD) score in the knowledge and adherence questionnaires was 4.9 (1.6) and 0.3 (0.7) points, respectively.

Once the initial 3-month period of individualized educational intervention was complete, 323 (67.4%) patients managed to graduate after a mean (SD) of 79.8 (45.6) days. Titration was achieved by 336 (70.1%) patients after a mean (SD) of 84.1 (81.0) days. The mean (SD) Gla-300 titration dose was 32.1 (17.0) U. Patients' knowledge improved after the learning period to a mean (SD) of 7.6 (0.9) points, whereas adherence remained similar (0.2 (0.6) points). This improvement was consistent across the subgroups by age and by prior medications (Table 3).

Participants received a mean (SD) number of 9.2 (5.2) calls throughout the programme, whilst 4.7 (1.2) outbound calls per patient on average had been initially planned for the graduation period. Patients who achieved titration received significantly more calls from nurses than those not reaching this goal (11.5 *versus* 3.8; $p<0.0001$).

The satisfaction survey was completed by 240 (50.1%) patients, who were highly satisfied overall with the support provided by T-Coach (Table 4). The questions addressing ease of enrolment and support scored 9.5 (0.7) and 9.4 (1.0) points on average.

Discussion

Our results show the T-Coach programme to be useful for empowering patients with T2DM to self-manage their disease because it places the patient as the driver of the entire process. Its comprehensive approach enables patients not only to reach their optimal insulin Gla-300 dose but also to enhance their knowledge of the disease and its management, which resulted in a very high level of patient satisfaction. Results for patients achieving titration and mean baseline and titration insulin doses were consistent with those recently reported in another study assessing a telephone-based intervention in patients with T2DM.[14]

Titration of insulin according to personal glycaemia goals and treatment adherence and persistence are of capital importance for patients with T2DM. Consequently, patients must learn to self-manage insulin dosing. However, they are often not sufficiently self-confident to titrate their medication appropriately or to manage insulin thereafter.[16] Consequently, it is usual in clinical practice to see patients whose insulin doses remain unchanged between visits.[17] Besides, clinical inertia is still common amongst clinicians, contributing to the titration gap.[18,19] Titration algorithms have tried to overcome this barrier, and their usefulness has been demonstrated in clinical trials with patients with T2DM receiving Gla-300, who reported significant differences favouring self-managed algorithms.[20,21] Automating insulin dosing using a device with built-in algorithms has also been shown to significantly facilitate titration for patients with DM.[22] However, reported data suggest that there is still room for improvement. A considerable percentage of patients do not achieve adequate titration,[16] and it has been estimated that more than 30% of patients with T2DM receiving insulin are non-adherent in the long term.[23,24]

The reasons for these findings are heterogeneous and include both motivational aspects (limited motivation and involvement) and educational/behavioural aspects (difficulty understanding how to increase the dose, beliefs that treatment is a burden and dose increase means the disease is getting worse, fear of adverse effects, resistance to complex regimens, and frustration that the time to reach the treatment goal is too long).[16,19] Most of these barriers may be addressed through educational and

Table 3. Changes in questionnaire global scores and distribution of profiles amongst patients who graduated.

	Overall		By age					By antidiabetic therapy prior to Toujeo				
	<65 years			65–75 years		>75 years		Basal insulin		Other antidiabetic drugs		
	Baseline (*n*=323)	Final (*n*=323)	Baseline (*n*=134)	Final (*n*=134)	Baseline (*n*=120)	Final (*n*=120)	Baseline (*n*=69)	Final (*n*=69)	Baseline (*n*=223)	Final (*n*=223)	Baseline (*n*=100)	Final (*n*=100)
Knowledge questionnaire												
Mean (SD)	4.9 (1.6)	7.6 (0.9)	4.9 (1.5)	7.7 (0.8)	4.8 (1.5)	7.6 (0.9)	4.9 (1.7)	7.4 (1.1)	4.9 (1.5)	7.7 (0.9)	4.7 (1.7)	4.7 (1.7)
95% CI	(4.7–5.1)	(7.5–7.7)	(4.7–5.2)	(7.6–7.8)	(4.5–5.1)	(7.5–7.8)	(4.5–5.4)	(7.2–7.7)	(4.8–5.1)	(7.5–7.8)	(4.4–5.1)	(4.4–5.1)
Adherence questionnaire												
Mean (SD)	0.3 (0.7)	0.2 (0.6)	0.4 (0.7)	0.2 (0.6)	0.3 (0.6)	0.2 (0.5)	0.4 (0.6)	0.2 (0.5)	0.3 (0.6)	0.2 (0.5)	0.4 (0.8)	0.3 (0.7)
95% CI	(0.3–0.4)	(0.2–0.3)	(0.2–0.5)	(0.1–0.3)	(0.2–0.4)	(0.1–0.3)	(0.2–0.5)	(0.1–0.3)	(0.2–0.4)	(0.1–0.3)	(0.2–0.5)	(0.1–0.4)

CI, confidence interval; SD, standard deviation.

Table 4. Satisfaction survey.

	Overall	By age			By antidiabetic drug prior to Toujeo	
		<65 years	65–75 years	>75 years	Basal insulin	Other antidiabetic drugs
How well did the T-Coach programme meet your expectations?	*n*=240	*n*=96	*n*=92	*n*=52	*n*=162	*n*=78
Mean (SD)	9.0 (1.5)	9.0 (1.4)	9.0 (1.5)	8.8 (1.8)	9.0 (1.5)	8.9 (1.7)
95% CI	(8.8–9.2)	(8.7–9.3)	(8.7–9.3)	(8.3–9.4)	(8.7–9.2)	(8.5–9.3)
How supportive was the T-Coach programme overall?	*n*=240	*n*=96	*n*=92	*n*=52	*n*=162	*n*=78
Mean (SD)	9.4 (1.0)	9.3 (1.0)	9.5 (0.9)	9.5 (1.0)	9.4 (1.0)	9.5 (0.9)
95% CI	(9.3–9.6)	(9.1–9.5)	(9.3–9.7)	(9.2–9.8)	(9.3–9.6)	(9.3–9.7)
Ease of enrolment	*n*=70	*n*=27	*n*=27	*n*=16	*n*=45	*n*=25
Mean (SD)	9.5 (0.7)	9.3 (0.9)	9.7 (0.6)	9.6 (0.6)	9.6 (0.7)	9.4 (0.8)
95% CI	(9.4–9.7)	(9.0–9.7)	(9.4–9.9)	(9.3–10.0)	(9.4–9.8)	(9.1–9.8)
Time it took to enrol	*n*=68	*n*=25	*n*=27	*n*=16	*n*=43	*n*=25
Mean (SD)	9.4 (0.9)	9.2 (1.0)	9.5 (0.9)	9.8 (0.6)	9.4 (1.0)	9.5 (0.8)
95% CI	(9.2–9.7)	(8.8–9.6)	(9.1–9.9)	(9.4–10.1)	(9.1–9.7)	(9.1–9.8)
How likely to recommend	*n*=240	*n*=96	*n*=92	*n*=52	*n*=162	*n*=78
Mean (SD)	9.6 (1.3)	9.7 (1.1)	9.5 (1.4)	9.6 (1.2)	9.6 (1.3)	9.7 (1.3)
95% CI	(9.4–9.8)	(9.4–9.9)	(9.2–9.8)	(9.2–9.9)	(9.4–9.8)	(9.4–10.0)
e-Learning modules	*n*=16	*n*=4	*n*=7	*n*=5	*n*=7	*n*=9
Mean (SD)	5.1 (4.7)	6.5 (4.4)	5.1 (4.9)	4.0 (5.5)	5.1 (4.8)	5.1 (4.9)
95% CI	(2.6–7.6)	(−0.4 to 13.4)	(0.6–9.7)	(−2.8 to 10.8)	(0.7–9.6)	(1.3–8.9)
Website	*n*=13	*n*=5	*n*=4	*n*=4	*n*=4	*n*=9
Mean (SD)	4.8 (4.2)	6.2 (3.8)	4.0 (4.6)	3.8 (4.8)	4.5 (5.2)	4.9 (4.0)
95% CI	(2.3–7.3)	(1.4–11.0)	(−3.3 to 11.3)	(−3.9 to 11.4)	(−3.8 to 12.8)	(1.8–8.0)
Nurse calls	*n*=240	*n*=96	*n*=92	*n*=52	*n*=162	*n*=78
Mean (SD)	9.6 (0.8)	9.5 (0.8)	9.7 (0.6)	9.7 (0.9)	9.6 (0.7)	9.5 (0.8)
95% CI	(9.5–9.7)	(9.3–9.7)	(9.5–9.8)	(9.4–9.9)	(9.5–9.7)	(9.4–9.7)
Inbound phone call	*n*=58	*n*=21	*n*=22	*n*=15	*n*=34	*n*=24
Mean (SD)	9.1 (2.3)	9.0 (2.2)	9.2 (2.2)	9.1 (2.6)	9.2 (2.4)	9.0 (2.1)
95% CI	(8.5–9.7)	(8.0–10.0)	(8.3–10.2)	(7.7–10.6)	(8.4–10.0)	(8.1–9.9)

CI, confidence interval; SD, standard deviation.

motivational support, thus enhancing patient empowerment. The results from the abovementioned clinical trials showed that self-management was associated with a tendency towards reduced patient emotional burden[21] and higher levels of patient satisfaction, which could translate into behavioural changes.[22] It is worth mentioning that the T-Coach intervention goes beyond titration support to emphasize diabetes education, which is a key element according to the patient-centred management model promoted by both the American Diabetes Association and the European Association for the Study of Diabetes in their latest positioning reports.[25] The benefits of diabetes education for clinical and behavioural goals have been well established and demonstrate that

patient empowerment yields positive outcomes (which may even become long-lasting if patients achieve self-sufficiency[26,27]) and generates cost savings.[28]

T-Coach is delivered via information technology (telephone sessions, online sessions, website access), which is emphasized in the chronic care model for DM management.[25,29] Information technology-based interventions overcome location-related limitations, thus enhancing communication amongst and between health-care providers and patients, and have been shown to improve DM management.[13,30] Additionally, the COVID-19 outbreak represented a big stimulus for the development of large telemedicine programmes in routine clinical practice because they represented an useful solution to improving patient care.[31] Our results support the helpful role of telemedicine in diabetes. We found that patients were more satisfied with nurse-led telephone sessions than with e-learning modules and that this also led to a higher achievement of an adequate basal insulin titration; this moderate satisfaction with technology-based assisting tools contrasts with the high levels of satisfaction reported by other authors.[32] These results could be explained, albeit partially, by the limited number of patients using e-learning modules, along with the age of the patients surveyed (60% above 65 years of age).

Our study is subject to a series of limitations. First, the lack of a control group precludes comparisons with standard patient support or even with other PSPs. Second, though this is a 2-year telemedicine educational programme, we only presented results concerning the effects on patients' knowledge and motivation at 6 months. Third, the real-world design of the study implied a lack of data on certain variables. Finally, patient needs were assessed based on two questionnaires, one of which has not been validated, and both used closed questions, with the result that the response may not fully reflect the reality of the situation.

Nevertheless, our findings reflect patient perceptions in a real-world context. Furthermore, the long duration of the T-Coach programme and the large number of patients enrolled will generate further results and, therefore, provide interesting information on the long-term effect of PSPs.

Conclusion

Our study shows that the T-Coach programme was successfully implemented in Spain. This telemedicine programme features a comprehensive approach based on continuous, nurse-led titration support, telemonitoring and disease education in consonance with a patient-centred diabetes care model. Implementation was associated with the achievement of Gla-300 titration, improved disease-related knowledge, and a high degree of patient satisfaction.

Contributions: All authors contributed to the article conceptualization, study design, data collection and analysis, writing of the original draft and critical review, approval of the final manuscript version. All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

Disclosure and potential conflicts of interest: VB has received consulting fees, honoraria for lectures, and support for attending meetings and/or travel from Abbott, AstraZeneca, Boehringer Ingelheim, Eli Lilly, Esteve, Janssen, Merck, Mundipharma, Novartis, Novo Nordisk, Roche and Sanofi. CM has received honoraria for lectures and participated on the advisory board for Novo Nordisk, Eli Lilly, Boehringer Ingelheim, Abbott, Sanofi, AstraZeneca, MSD and Amgen. BGA has received honoraria for lectures and support for attending meetings and/or travel from Novo Nordisk, Eli Lilly, Abbott, Fresenius and Nutricia. MLdlT has received grants and contracts from Eli Lilly as well as honoraria for lectures and support for attending meetings and/or travel from Novo Nordisk, Eli Lilly, Novartis, Sanofi, MSD, Boehringer Ingelheim, AstraZeneca, Esteve, Abbott, Amgen and Mundipharma. DB has received honoraria for lectures and support for attending meetings and/or travel and participated on the advisory board for Sanofi, Novo Nordisk, Abbott, Eli Lilly, Boehringer Ingelheim, Persan Pharma and Menarini. DB has also participated in a leadership role on boards or committees for SEEDO (Sociedade Española de Obesidad) and SEEN (Sociedad Española de Endocrinología y Nutrición). AMG, JMG and JLFM declare that they have no conflicts of interest. The International Committee of Medical Journal Editors (ICMJE) Potential Conflicts of Interests form for the authors is available for download at: https://www.drugsincontext.com/wp-content/uploads/2023/04/dic.2023-1-1-COI.pdf

Acknowledgements: All statistical analyses were performed by SAIL (Servicio de Asesoría Investigación y Logística), S.L. Medical writing support during the preparation of this paper was provided by Dynamic Science, S.L.U., and funded by Sanofi. Editing service has been provided by Content Ed Net, Madrid and funded by Sanofi.

Funding declaration: The T-Coach PSP was funded by Sanofi.

Article URL: https://www.drugsincontext.com/descriptive-study-of-a-clinical-and-educational-telemedicineintervention-in-patients-with-diabetes-receiving-glargine-300u-ml-toujeo-in-spain-results-of-the-t-coach-programme

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Provenance: Submitted; externally peer reviewed.

Submitted: 2 January 2023; **Accepted:** 29 March 2023; **Published:** 24 May 2023.

Drugs in Context is published by BioExcel Publishing Ltd. Registered office: 6 Green Lane Business Park, 238 Green Lane, New Eltham, London, SE9 3TL, UK.

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