



ORIGINAL ARTICLE

Treatment adherence and wellness, nutrition, and physical activity outcomes of diabetic patients with comorbid depression during the 18-month follow-up of the TELE-DD study

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Abstract

Background: A good adherence to pharmacological treatment in chronic pathologies such as type 2 diabetes and clinical depression is essential to improve illness prognosis.

Aims: The main goal of the TELE-DD study was to analyze the effectiveness of a telephone, psychoeducational, and individualized intervention carried out by nurses in patients with type 2 diabetes mellitus and comorbid clinical depression with prior nonadherence to pharmacological treatment. In this paper, we describe and analyze secondary outcomes of the trial intervention.

Methods: A prospective cohort study was used to assess the effectiveness of a telephonic intervention (IG) in $n=191$ participants with a similar control group (CG). Adherence to pharmacological treatment was assessed using the patient's self-perceived adherence questionnaire. In addition to clinical (HbA_{1c}, HDL, LDL), physical (body mass index, blood pressure) and psychological measures (Patient Health Questionnaire-9 affective state), and psychosocial distress due to Diabetes Distress Scale Questionnaire at 3, 6, 12, and 18 months of follow-up were also analyzed.

Results: The proportion of "Total Adherents" in the IG was higher throughout the study. This was particularly true at month 18 of the intervention. Self-perceived adherence rates increased by 27.1% in the IG and by 1.1% in the CG. Results of clinical and physical measures were higher in the IG than in the CG at month 18 of the intervention.

Linking Evidence to Action: The interview based on positive reinforcement as well as individualized attention and flexibility in making telephone calls and dissemination of the intervention in the media closest to the patients were key to achieving good participation and collaboration as well as continuity in adherence to treatment and self-care.

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KEYWORDS

depression, medication adherence, nursing, patient education, type 2 diabetes mellitus

INTRODUCTION

Chronic diseases evolve towards deterioration and systemic effects, highlighting devastating complications in diabetes mellitus (DM) and clinical depression (CD) comorbidity (Nouwen et al., 2019). Occasionally, they lead to a deterioration in metabolic control, requiring the modification of pharmacological treatments according to tolerability and side effects (2). In these cases, patient compliance is essential.

Compared to healthy people, people with chronic diabetes show poorer values of quality of life (QOL), affecting also the goals of clinical condition, as only 10% of adults with diabetes associated with hyperlipidemia and arterial hypertension are considered to be in optimal clinical condition (Saydah, 2004), while having an increased risk of hospitalization and mortality (Ho et al., 2006). Moreover, diabetes has been shown to be a risk factor for worsening infectious processes, including a worse prognosis in patients with COVID-19 (Zoppini et al., 2018). Diabetes is one of the most common comorbidities in patients hospitalized for COVID-19 (Zhou et al., 2020), and increases the severity and mortality rates..

Diabetes care has become patient-centered (Ho et al., 2006), as this approach improves patients' participation in self-care activities (Inzucchi et al., 2012). Their preferences and opinions are used to define treatment goals and strategies (American Diabetes Association [ADA], 2018a). According to ADA (2018b), the attitude and quality of patients' self-care directly influence the potential risk of hypoglycemia, disease duration, life expectancy, and vascular complications. The external resources (i.e., cultural and socio-economic) available to each patient should be considered, as the healthcare professional needs to individualize clinical goals and interventions. Although increasingly better results have been observed in the achievement of better control of DM, CD, and QOL, a lot of family and professional support is required to achieve them (Hoerger et al., 2008).

Nursing intervention is essential in order to influence adherence to treatment while improving outcomes and QOL. Educational interventions are one of the most widely used and evaluated methods (Ferrera et al., 2010), with probed success while using telephone calls (Kumar et al., 2020). Educational interventions are effective in improving adherence in several chronic diseases, such as diabetic retinopathy, hypertension, and coronary events (Ferrera et al., 2010). Theory-based motivational interviewing recognizes that motivation is essential for change and aims to promote treatment adherence. It has been used in mental health problems and chronic conditions such as DM and CD and also helps to increase motivation for healthier lifestyles (Beydoun & Wang, 2010). The impact of these interventions is enhanced when an empathic relationship of acceptance and support is established between those communicating by telephone (Polonsky et al., 2017).

The COVID-19 pandemic has led the therapeutic relationship to adopt the use of new resources based on telemedicine (Fadini et al., 2020). Telemedicine is implemented to a greater or lesser extent in health centers to provide greater accessibility to patients with mobility or scheduling difficulties (Ryu, 2012). Studies such as PLATEDIAN (Telemedicine on Metabolic Control in Type 1 Diabetes Mellitus Andalusian Patients), provide positive results and conclude that a telemedicine intervention has a similar impact to the traditional office-based intervention in terms of glycemic control, acute complications, and perceived QOL (Ruiz de Adana et al., 2020).

As people with diabetes require highly specific self-care involving complex daily tasks, professional and specialized nursing support for regular or on-demand follow-up builds trust and promotes treatment adherence. The main goal of the TELE-DD study was to analyze the effectiveness of a telephone, psychoeducational, and individualized intervention carried out by nurses in patients with type 2 DM and comorbid CD with prior nonadherence to pharmacological treatment. In this paper, we describe and analyze secondary outcomes of the trial intervention.

METHODS

Study design

The intervention was delivered by primary care specialist nurses as described in Roy et al. (2021). This publication was developed in the context of a prospective cohort study (Roy et al., 2021). The TELE-DD RCT (phase 2) was preceded by a previous study in the community (phase 1), which aimed to identify the population of type 2 diabetic individuals (DM2) over 21 years of age with comorbid DC (diagnosed according to the International Classification of Primary Care with codes T90 and P76), with pharmacological treatment for both diseases of at least 1 year of evolution. This population came from Health Sector II in Zaragoza, Aragón (Spain). In this cohort ($n=3601$), patients who were not adherent to either of the two pharmacological treatments were identified as 35% ($n=1274$). Both the TELE-DD prospective cohort and nested trial detailed design included a complete flowchart demonstrating the cohort population and trial sample characteristics and evolution. Detailed information regarding instruments, protocols, and other methodological aspects, have been previously published in prior TELE-DD scientific reports (Lozano del Hoyo et al., 2022; Roy et al., 2021).

Participants

The study population was recruited from Health Sector II in Zaragoza, Aragón (Spain) from 2017 to 2018. A total of 1274

patients diagnosed with diabetes and DC with adherence problems to pharmacological treatment were finally included in phase I of the TELE-DD study.

The sample size calculation was performed using the formula for comparing populations for finite populations, resulting in a total of 360 patients. To ensure the minimum sample size, a population of 428 patients was decided upon. The sample size of the non-adherent population in the Health Sector was calculated based on the proportion of patients not adhering to any treatment in the total population (35%). After randomization, the Intervention Group (IG) was comprised of 225 patients and the Control Group (CG) was 203 patients (Figure 1). Participants who completed the entire study period were 191 in the CG and 191 in the IG, and their data were ultimately analyzed. Reasons for dropout included death, inclusion in a nursing home, and change of residence.

Intervention design

The educational intervention was based on the Joint Position Statement of the ADA, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics (Powers et al., 2015). It consisted of a monthly structured telephone call for 18 months, with an average duration of 30 min by previously trained primary care nurses. We started with a single standardized interview for all participants but adapted to the cultural and literacy level of the interlocutors (Appendix S1). In the IG, the follow-up interview had a motivational approach, to promote positive reinforcement, while praising medication intake and proper adherence to the therapeutic regimen (Rollnick & Miller, 2013). In the CG, the usual therapeutic attitude was adopted, and no additional follow-up was performed by the nursing intervention team (NIT), nor monthly telephone educational support. The patients, both in the CG and in the IG, kept routine face-to-face follow-up appointments at their primary care centers throughout the study. Following the telephone interview, clinical (HbAc1, HDL, LDL), physical (body mass index, blood pressure), and psychological parameters (Patient Health Questionnaire-9 [PHQ-9], Diabetes Distress Scale [DDS] questionnaires and Martín-Bayarre-Grau [MBG] questionnaire for self-perceived therapeutic adherence) were recorded for all patients. This registry was performed at the beginning of the intervention and 3, 6, 12, and 18 months after the trial initiation. All drugs were evaluated according to their labeling and/or recommended prescription.

Intervention protocol

The NIT addressed physical, emotional, and social counseling and support strategies using specific and empathic language and communication skills. The main objectives of the intervention were to promote treatment adherence, educate on healthy living behaviors, address needs and concerns on an individual basis (Aikens & Piette, 2009), conduct motivational interviewing and simple cognitive-behavioral therapy strategies, as indicated by (Rollnick &

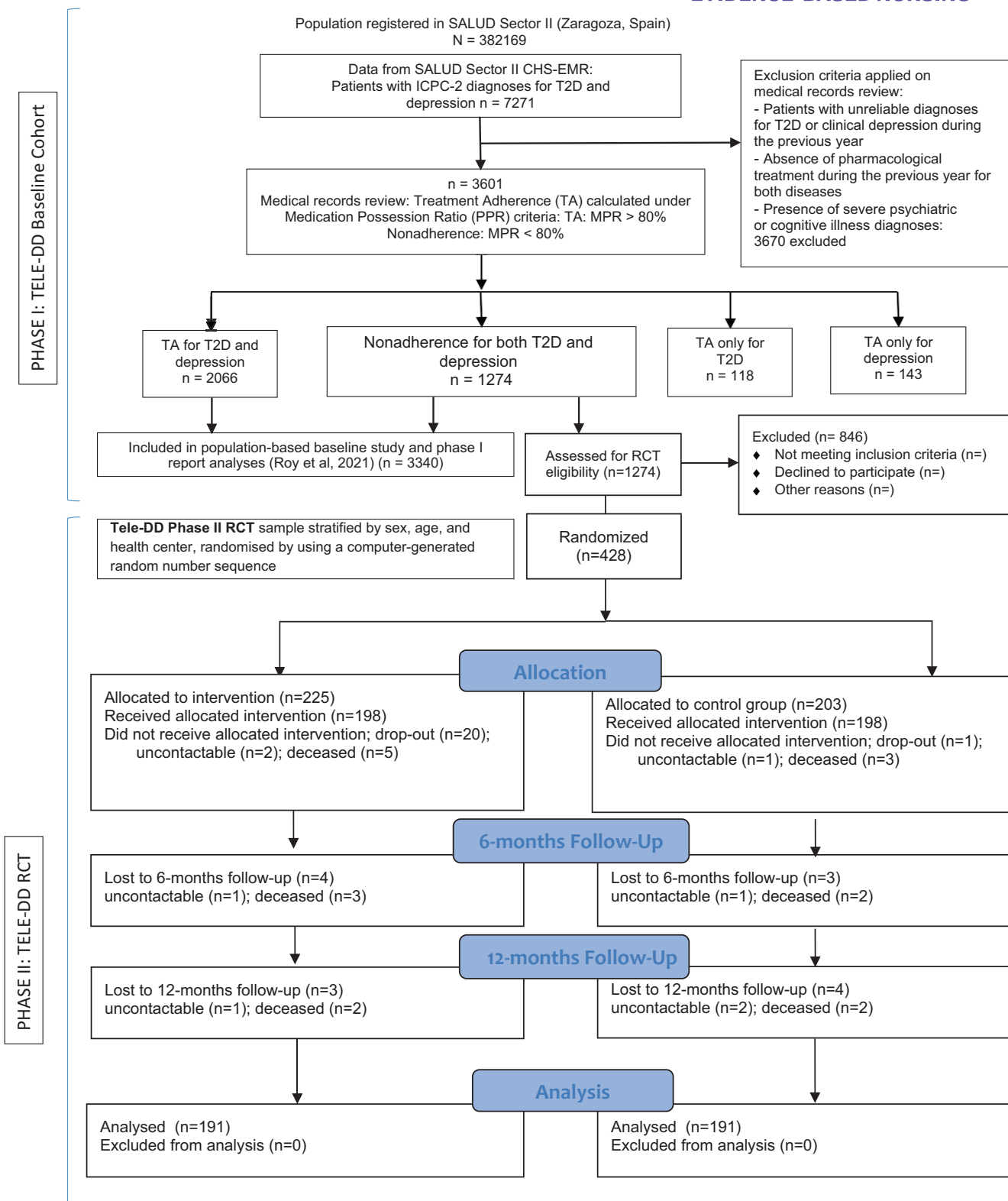
Miller, 2013), and enhance the QOL and biopsychosocial well-being of patients, in any case.

Standardization and training of the nursing intervention team (NIT)

There were 24 (12 per group) practitioner nurses, for an $n=191$ sample size per group, belonging to the 23 health centers. To ensure uniformity and validity of the intervention, the characteristics of each call and intervention were established and agreed upon by the research team and clinical directors through a previously designed standardization process. Four 2-hour training and standardization seminars were conducted to synchronize and review the protocol and for proper scripting of the phone calls, including sessions representing archetypal comorbidities of depression and DM. Common guidelines on patient attitudes and motivation and appropriate language for their use were agreed upon. In this regard, the NIT received training in motivational interviewing characterized by a patient-centered counseling approach designed to support individuals during behavioral change and increase the patient's ability to resolve issues of self-management, adherence, and emotional distress (Sacco et al., 2009). Through training, the collaborating nurses acquired skills to act and help patients in the resolution of problems that arose in the survey (Safren et al., 2014).

Questionnaires and study variables

Treatment adherence was studied through the patient self-perceived therapeutic adherence MBG questionnaire validated and adapted for populations with DM and CD (Martínez et al., 2011). It includes questions related to timely intake of drugs, diet, visits to the health center, physical activity, and self-management. The variables studied were: Physical Activity ("yes, I do physical activity"), when the patient said they walked 1 hour or more per day, which could be at various intervals and during 3 alternate days per week; and Diet ("yes, I do"), compliance with the indications provided by the health professionals who usually monitor the patient's disease was assessed. To calculate the score obtained by each patient, a value of 0 was assigned to the column *Never*, 1 to *Seldom*, 2 to *Sometimes*, 3 to *Almost always*, and 4 to *Always*, with 48 being the maximum score. Those patients who obtained between 38 and 48 points were considered "total adherence," 18 to 37 points were "partial adherence," and those who obtained between 0 and 17 points were "non-adherence." The questionnaire provided a Cronbach's alpha of 69%, five components were defined, and a total explained variance of 63%. A qualitative assessment of patient satisfaction was included, as well as additional issues or skills, which should be addressed in psychoeducational and intervention training. At the same time, the nurses carried out a subjective assessment of the evolution of patient adherence, as perceived by the professional, through the interviews. It was graded using a Likert-type scale from 1 to 5, with 1 corresponding to a rating of the



Lozano del Hoyo et al. (2022)

FIGURE 1 Flow diagram demonstrating the TELE-DD Project population data cohort (phase I) and RCT sample randomization, allocation, and follow-up (phase II).

patient is not adherent at all and 5 corresponding to the patient is very adherent. Comparison of this assessment by the professional and the patient's responses on self-adherence proved to be of great value.

The difficulty encountered by the professionals in carrying out the patient surveys was also assessed, with a dichotomous response ("yes/no" encountered difficulty).

Statistical analysis

Descriptive data were calculated for all variables included, with frequencies, percentages, means, and standard deviation, according to the type of variable. To analyze the changes that occurred in the dependent variable *Self-perception of adherence to treatment* after the measurements were carried out, the mean and standard deviation of each of the dimensions were calculated, obtaining their frequency of change before and after the intervention. Parametric Student's *t*-tests and ANOVA, with Tukey's HSD test, were used when the variable data followed a normal distribution, and the nonparametric Mann-Whitney *U* and Wilcoxon tests when there was no normality on measures. A statistical significance of $p < .05$ (two tails) was established for all contrast tests performed and a confidence interval (CI) of 95%. SPSS statistical software for Windows, version 26.0, was used.

Ethical considerations

The prospective cohort study was reviewed and approved by the Health Care Quality Unit and authorized by the Clinical Ethics Research Committee (protocol code: PI17-0167). It was designed following the ethical standards indicated in the Declaration of Helsinki and its subsequent modifications. The data collected were kept segregated from identifiable data, under the precepts established in the current legislation on personal data protection contained in the Organic Law 15/1999, of 23 December, on the Protection of Personal Data, always maintaining the standards of good clinical practice. Patient safety and data confidentiality were fully guaranteed (Rebers et al., 2016). Before starting the study, all participants signed the informed consent form in the context of a prospective cohort study following the Reporting Observational Studies in Epidemiology (STROBE) guidelines for reporting social and psychological observational studies (Von Elm et al., 2007).

RESULTS

Therapeutic adherence

According to the MBG Self-Assessment of Therapeutic Adherence Questionnaire, at baseline 38.45% (27.6% of the CG and 49.3% of the IG) of patients in both groups were considered total adherence, 60.8% partial adherence (71.4% of the CG and 50.2% of the IG), and 0.7% non-adherence (1% of the CG and 0.4% of the IG; Table 1). Patients reported always taking their medication within the established time in 77.8% of the cases, performing physical activity as a treatment for their pathology in 24.8%, complying with diet-related indications in 31.1%, and using reminders for the correct taking of medication in 55.4% of the cases. A total of 82.7% expressed discussing with health professionals how to comply with their treatment. A total of 75.2% of the IG felt that treatment adherence would increase because of this telephone intervention and that a

notification system would be useful when medication was not collected from the pharmacy (91.4%).

The results of the MBG adherence survey of the two groups (IG and CG) were compared throughout the intervention, and it was found that both the percentages of non-adherence and partial adherence in the CG were always higher than those in the IG, and the percentages of total adherence in the IG were higher throughout the study. These differences between the two groups were most evident in month 18. It is important to highlight that 27.1% of the self-perceived adherence rates increased in the IG, while 1.1% increased in the CG.

Healthy lifestyle habits were assessed, giving patients the possibility of recording them (Table 2). Perception regarding patients' QOL in CG increased slightly among patients who reported feeling well after 18 months (67% month 0; 69% month 18). However, in the IG, the proportion of patients who perceived feeling well increased considerably (67.1% at month 0; 100% at month 18; Figure 2). Regarding dietary care, the proportion of patients who claimed to take care of their diet in CG increased slightly between month 0 and month 18 (60%–69%). In this case, there was also a clear increase in the affirmative response in the IG (65.3% in month 0; 97.9% in month 18; Table 2). The proportion of patients doing physical activity in the CG remained between 41%–49%, but in the IG there was a clear increase in the affirmative response, which increased from 48.4% at month 0 to 88.5% at month 18. When comparing the proportion of patients between groups (IG, CG) we found significant differences in month 0, but there were significant differences in the remaining months (Table 2).

The NIT quantified difficulties encountered while conducting the interviews; difficulties included patients' cooperation and understanding. The study nurses indicated that it was "not difficult" or "a bit difficult" (83% of the cases). On the other hand, the NIT response profiles in both groups were very similar in months 0 and 12, with some differences in months 6 and 18. Variations in the affirmative responses between groups were more than 10% (Table 3).

DISCUSSION

Our findings showed that treatment adherence is an essential link between the prescription of a drug and its success, but many patients find it difficult to adequately follow the therapeutic recommendations, constituting a global problem of great magnitude in this specific illness's comorbidity.

Our results also confirmed that a lack of adherence to treatment leads to poorer outcomes and higher healthcare costs (Jha et al., 2012) since complications resulting from poor control have repercussions for the healthcare system and the general population. The benefits and efficacy of treatments proportionally decrease in non-adherent patients (Poveda, 2014), appearing as a strong association between medication nonadherence and negative clinical outcomes such as rehospitalization, morbidity, and mortality (Smith et al., 2006). Previous research suggests that many factors can

TABLE 1 MBG Therapeutic adherence questionnaire values between the intervention and control groups at 0, 6, 12, and 18 months of follow-up.

| | Control group | | | Intervention group | | | p value |
|----------|---------------|-------------------|-----------------|--------------------|-------------------|-----------------|---------|
| | Non-adherence | Partial adherence | Total adherence | Non-adherence | Partial adherence | Total adherence | |
| | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | |
| Month 0 | 2 (1.0%) | 145 (71.4%) | 56 (27.6%) | 1 (0.4%) | 113 (50.2%) | 111 (49.3%) | <.001 |
| Month 6 | 29 (14.6%) | 131 (66.2%) | 38 (19.2%) | 3 (1.5%) | 55 (27.8%) | 140 (70.7%) | <.001 |
| Month 12 | 24 (12.4%) | 100 (51.5%) | 70 (36.1%) | 5 (2.6%) | 49 (25.1%) | 141 (72.3%) | <.001 |

TABLE 2 Descriptive analysis about healthy lifestyle habits between the intervention and control groups at 0, 6, 12, and 18 months of follow-up.

| | Control group | | Intervention group | | p value |
|--|---------------|-------------|--------------------|-------------|---------|
| | n (%) | n (%) | n (%) | n (%) | |
| | No | Yes | No | Yes | |
| Are you feeling well? | | | | | |
| Month 0 | 64 (31.5%) | 139 (68.5%) | 74 (32.9%) | 151 (67.1%) | .763 |
| Month 6 | 64 (32.3%) | 134 (67.7%) | 36 (18.2%) | 162 (81.8%) | .001 |
| Month 12 | 63 (32.5%) | 131 (67.5%) | 10 (5.1%) | 185 (94.9%) | <.001 |
| Month 18 | 59 (30.9%) | 132 (69.1%) | 0 (0.0%) | 191 (100%) | <.001 |
| Do you take care of diet? | | | | | |
| Month 0 | 70 (34.5%) | 133 (65.5%) | 78 (34.7%) | 147 (65.3%) | .968 |
| Month 6 | 75 (37.9%) | 123 (62.1%) | 24 (12.1%) | 174 (87.9%) | <.001 |
| Month 12 | 76 (39.2%) | 118 (60.8%) | 26 (13.3%) | 169 (86.7%) | <.001 |
| Month 18 | 60 (31.4%) | 131 (68.6%) | 4 (2.1%) | 187 (97.9%) | <.001 |
| Do you perform physical activity? | | | | | |
| Month 0 | 104 (51.2%) | 99 (48.8%) | 116 (51.6%) | 109 (48.4%) | .947 |
| Month 6 | 114 (57.6%) | 84 (42.4%) | 44 (22.2%) | 154 (77.8%) | <.001 |
| Month 12 | 113 (58.2%) | 81 (41.8%) | 43 (22.1%) | 152 (77.9%) | <.001 |
| Month 18 | 102 (53.4%) | 89 (46.6%) | 22 (11.5%) | 169 (88.5%) | <.001 |

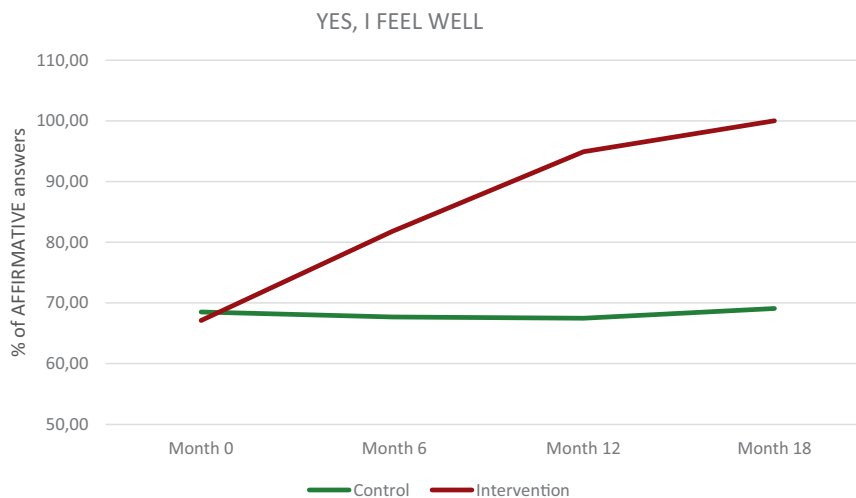


FIGURE 2 Evolution of the perception of Quality of Life in intervention group (IG) and control groups (CG).

TABLE 3 Descriptive analysis of the Nursing Intervention Team's opinion on treatment adherence.

| | Control group | | | | | Intervention group | | | | | p value |
|------------|---------------------|----------------|--------------------|----------------|-------------------|---------------------|----------------|--------------------|----------------|-------------------|---------|
| | Not at all n (%) | A bit n (%) | Some-What n (%) | A lot n (%) | Complete n (%) | Not at all n (%) | A bit n (%) | Some-what n (%) | A lot n (%) | Complete n (%) | |
| Adherence | | | | | | | | | | | |
| Month 0 | 5 (2.5%) | 18 (8.9%) | 42 (20.7%) | 68 (33.5%) | 70 (34.5%) | 6 (2.7%) | 18 (8.0%) | 44 (19.6%) | 71 (31.6%) | 86 (38.2%) | .950 |
| Month 6 | 4 (2.0%) | 11 (5.6%) | 46 (23.2%) | 67 (33.8%) | 70 (35.4%) | 2 (1.0%) | 8 (4.0%) | 27 (13.6%) | 62 (31.3%) | 99 (50.0%) | .024 |
| Month 12 | 6 (3.1%) | 16 (8.2%) | 38 (19.6%) | 62 (32.0%) | 72 (37.1%) | 2 (1.0%) | 5 (2.6%) | 29 (14.9%) | 51 (26.2%) | 108 (55.4%) | .002 |
| Month 18 | 4 (2.1%) | 14 (7.3%) | 39 (20.4%) | 63 (33.0%) | 71 (37.2%) | 2 (1.0%) | 5 (2.6%) | 8 (4.2%) | 49 (25.7%) | 127 (66.5%) | <.001 |
| Difficulty | | | | | | | | | | | |
| | | No | Yes | No | Yes | No | Yes | No | Yes | | |
| Month 0 | | 175 (86.2%) | 28 (13.8%) | 195 (86.7%) | 28 (13.8%) | 195 (86.7%) | 30 (13.3%) | 195 (86.7%) | 30 (13.3%) | 890 | .890 |
| Month 6 | | 165 (83.3%) | 33 (16.7%) | 193 (97.5%) | 33 (16.7%) | 193 (97.5%) | 5 (2.5%) | 193 (97.5%) | 5 (2.5%) | <.001 | <.001 |
| Month 12 | | 162 (83.1%) | 32 (16.5%) | 162 (83.5%) | 32 (16.5%) | 162 (83.5%) | 33 (16.9%) | 162 (83.5%) | 33 (16.9%) | .910 | .910 |

influence the lack of adherence to treatment in type 2 DM. According to Rolnick et al. (2013), the characteristics of our sample are factors that contribute to non-adherence to treatment. Other studies (Kang et al., 2018) with higher rates of non-adherence include the cost of drugs as a main cause of lack of adherence. However, in Spain this is not considered to be a confounding factor since most of the pharmacological treatments for DM and CD are largely financed (Lozano del Hoyo et al., 2022).

The results of the patients' self-perception of their treatment adherence in this study are surprising. At the beginning of the trial, more than half of the patients did not recognize their lack of adherence, neither when asked directly, nor when the MBG questionnaire was administered. However, outcome variables such as HbA_{1c}, LDL-cholesterol, and computerized electronic prescription medication withdrawal data indicated otherwise (Lozano del Hoyo et al., 2022; Roy et al., 2021).

Several options have been considered as an explanation for the discordance of results. It could be that patients did not integrate the knowledge and indications provided by healthcare professionals, i.e., there is an alteration in the perception of correct self-care (Mann et al., 2009). In some cases, it could be a patient's eagerness to please the health personnel who treat them that motivates them to modify their answers, or a memory bias since, on some occasions, they are asked to recall events from 2 or 3 weeks ago or further in time. However, multiple studies agree that literacy, and most specifically health literacy, is directly related to the degree of diabetes knowledge and that these suboptimal beliefs are potentially modifiable and are logical targets for educational interventions (Gonzalez et al., 2016). In our study, the improvement in clinical parameters observed in the IG confirmed the increased adherence to treatment reported by patients at the end of the trial (Lozano del Hoyo et al., 2022).

Prior research based on behavioral change interventions has attempted to promote medication adherence (Brown & Bussell, 2011). However, factors influencing behavior are complex and unique to the individual, requiring numerous multifactorial strategies. A systematic review carried out by Nieuwlaat et al. (2014) showed this difficulty, concluding that self-perception of the disease and acceptance to follow a treatment do not always lead to great improvements in adherence and treatment outcomes.

Finally, our results showed that more frequent contact using telephone or digital resources was effective in improving therapeutic adherence. The increased interaction with patients from the IG has been reflected in the significant improvement in the results of very adherent patients by having a positive effect on the evolution and prognosis of both comorbid diseases confirmed by the clinical variables reported in the phase 2 of the study (Lozano del Hoyo et al., 2022). However, while establishing the benefits of telephonic interventions, we also recognize that face-to-face visits cannot be entirely replaced by telephone consultations as the absence of visual cues or the inability to conduct physical examinations limits the understanding and the relationship between professionals and patients.

Our study has several limitations. On one hand, the choice of a method for assessing adherence to treatment carries an implicit limitation that we must assume. The decision to use the medication possession ratio (MPR) in Phase I (Roy et al., 2021) of the TELE-DD study while prescribed in the last 365 days, and extracted from the electronic prescription format, was used in 100% of the territory studied, guaranteed the least possible limitation, as it was the method most widely used due to its greater precision. However, using this method imposed difficulties for comparing treatment adherence data with phase II where the MBG was used instead, as being more specific for individual and clinical assessment. Nevertheless, because Moreno Juste et al. (2019) also used the MPR system and obtained 72.4% of adherent patients to antidiabetic drugs in a population over 65 years of age, we decided to use a similar approach to identify individuals who were non-adherent to the pharmacological treatment for either disease, as they did not even collect their prescriptions from the pharmacy.

On the other hand, as the aims of the study did not include questions regarding the QOL of the patients in all its dimensions, no validated QOL questionnaire was used.

Based on our results, future studies should focus on longer longitudinal assessments to gauge the sustainability of the intervention's effects on treatment adherence and health outcomes. Qualitative exploration of patient perceptions and interventions targeting health literacy could offer deeper insights into adherence behaviors. On the other hand, comparative studies evaluating different intervention modalities and cost-effectiveness analyses would help identify optimal strategies for diverse patient populations. Finally, integrating digital health tools and assessing their impact on adherence could enhance intervention effectiveness in chronic disease management.

Linking evidence to action

- **Patient Acceptance:** To achieve greater acceptance of participation in the project by patients, it is recommended to publicize the study and present the team and those responsible for it in the most common means of communication of the population to which the project is directed.
- **Standardized Work:** Control of the intervention objectives as well as the homogenization of the methodology used in the telephone calls was achieved through the coordination and scheduling of periodic meetings of the group of nurses who carry out the intervention.
- **Maintenance of Participation:** To maintain patient participation, it is important to personalize the dates and times of the calls according to the patient's availability and that the next appointment is planned at the end of each interview.
- **Continuity of Self-Care:** Positive support and personalized and consensual attention with the patients achieve patient fidelity and therapeutic adherence by the individual's own decision, which we consider essential for the continuity of self-care.

CONCLUSIONS

Despite the limitations of our study, psychoeducational interventions based on motivational interviewing with periodic follow-up have proven effective in improving clinical, psychological, and self-perceived health outcomes. Furthermore, the success of the intervention in these parameters is directly related to improvements in nutrition, physical activity, and overall physical and psychological well-being of the patients. Our results demonstrate that adherence to pharmacological and non-pharmacological treatments enhances the effectiveness of health care and, most importantly, supports holistic care that integrates physical, psychological, and social well-being.

The training of the NIT and the standardization of telephonic interventions have provided practitioner nurses with a framework to tailor each intervention to the educational needs of each patient. This individualized approach fosters strong bonds between nurses and patients, creating an empowering environment for self-care. Given the positive outcomes observed in the intervention group of the TELE-DD study, similar protocols could be developed and combined with individual or group face-to-face education. Telephonic interventions are notably more cost-effective and environmentally sustainable. Therefore, further studies are needed to assess the acceptance and effectiveness of this type of intervention based on patient profiles.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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REFERENCES

- Aikens, J. E., & Piette, J. D. (2009). Diabetic patients' medication underuse, illness outcomes, and beliefs about antihyperglycemic and antihypertensive treatments. *Diabetes Care*, 32(1), 19–24. <https://doi.org/10.2337/dc08-1533>
- American Diabetes Association. (2018). 6. Glycemic targets: Standards of medical care in diabetes-2018. *Diabetes Care*, 41(Suppl 1), S55–S64. <https://doi.org/10.2337/dc18-S006>
- Beydoun, M. A., & Wang, Y. (2010). Pathways linking socioeconomic status to obesity through depression and lifestyle factors among young US adults. *Journal of Affective Disorders*, 123(1–3), 52–63. <https://doi.org/10.1016/j.jad.2009.09.021>
- Brown, M. T., & Bussell, J. K. (2011). Medication adherence: WHO cares? *Mayo Clinic Proceedings*, 86(4), 304–314. <https://doi.org/10.4065/mcp.2010.0575>
- Fadini, G. P., Morieri, M. L., Longato, E., & Avogaro, A. (2020). Prevalence and impact of diabetes among people infected with SARS-CoV-2. *Journal of Endocrinological Investigation*, 43(6), 867–869. <https://doi.org/10.1007/s40618-020-01236-2>
- Ferrera, N. V., Moine, D. H., & Yañez, D. C. (2010). Hipertensión arterial: Implementación de un programa de intervención de control y adherencia al tratamiento en un Centro de Atención Primaria de la

- Salud de la ciudad de Paraná. *Revista de la Federación Argentina de Cardiología*, 39(3), 194–203.
- Gonzalez, J. S., Tanenbaum, M. L., & Commissariat, P. V. (2016). Psychosocial factors in medication adherence and diabetes self-management: Implications for research and practice. *American Psychologist*, 71(7), 539–551. <https://doi.org/10.1037/a0040388>
- Ho, P. M., Rumsfeld, J. S., Masoudi, F. A., McClure, D. L., Plomondon, M. E., Steiner, J. F., & Magid, D. J. (2006). Effect of medication nonadherence on hospitalization and mortality among patients with diabetes mellitus. *Archives of Internal Medicine*, 166(17), 1836–1841. <https://doi.org/10.1001/archinte.166.17.1836>
- Hoerger, T. J., Segel, J. E., Gregg, E. W., & Saaddine, J. B. (2008). Is glycaemic control improving in U.S. adults? *Diabetes Care*, 31(1), 81–86. <https://doi.org/10.2337/dc07-1572>
- Inzucchi, S. E., Bergenstal, R. M., Buse, J. B., Diamant, M., Ferrannini, E., Nauck, M., Peters, A. L., Tsapas, A., Wender, R., Matthews, D. R., & American Diabetes Association (ADA), & European Association for the Study of Diabetes (EASD). (2012). Management of hyperglycemia in type 2 diabetes: A patient-centered approach: Position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care*, 35(6), 1364–1379. <https://doi.org/10.2337/dc12-0413>
- Jha, A. K., Aubert, R. E., Yao, J., Teagarden, J. R., & Epstein, R. S. (2012). Greater adherence to diabetes drugs is linked to less hospital use and could save nearly \$5 billion annually. *Health Affairs*, 31(8), 1836–1846. <https://doi.org/10.1377/hlthaff.2011.1198>
- Kang, H., Lobo, J. M., Kim, S., & Sohn, M.-W. (2018). Cost-related medication non-adherence among U.S. adults with diabetes. *Diabetes Research and Clinical Practice*, 143, 24–33. <https://doi.org/10.1016/j.diabres.2018.06.016>
- Kumar, A., Arora, A., Sharma, P., Anikhindi, S. A., Bansal, N., Singla, V., Khare, S., & Srivastava, A. (2020). Is diabetes mellitus associated with mortality and severity of COVID-19? A meta-analysis. *Diabetes and Metabolic Syndrome*, 14(4), 535–545. <https://doi.org/10.1016/j.dsx.2020.04.044>
- Lozano del Hoyo, M. L., Rodrigo, M. T. F., Urcola-Pardo, F., Monreal-Bartolomé, A., Ruiz, D. C. G., Borao, M. G., Alcázar, A. B. A., Casbas, J. P. M., Casas, A. A., Funcia, M. T. A., & Delgado, J. F. R. (2022). The TELE-DD randomised controlled trial on treatment adherence in patients with type 2 diabetes and comorbid depression: Clinical outcomes after 18-month follow-up. *International Journal of Environmental Research and Public Health*, 20(1), 328. <https://doi.org/10.3390/ijerph20010328>
- Mann, D. M., Ponienman, D., Leventhal, H., & Halm, E. A. (2009). Predictors of adherence to diabetes medications: The role of disease and medication beliefs. *Journal of Behavioral Medicine*, 32(3), 278–284. <https://doi.org/10.1007/s10865-009-9202-y>
- Martínez, J. W., Perea, J. A. V., Jaramillo, J., Betancur, A. M. Q., & Calderón, V. (2011). Validación del cuestionario de adherencia al tratamiento anti hipertensivo Martín Bayarré Grau. *Revista Médica de Risaralda*, 17(2), 101–105. <https://doi.org/10.22517/25395203.7595>
- Moreno Juste, A., Gimeno Miguel, A., Poblador Plou, B., González Rubio, F., Aza Pascual-Salcedo, M. M., Menditto, E., & Prados Torres, A. (2019). Adherencia al tratamiento de hipertensión arterial, hipercolesterolemia y diabetes en población anciana de una cohorte española. *Medicina Clínica*, 153(1), 1–5. <https://doi.org/10.1016/j.medcli.2018.10.023>
- Nieuwlaat, R., Wilczynski, N., Navarro, T., Hobson, N., Jeffery, R., Keepanasseril, A., Agoritsas, T., Mistry, N., Iorio, A., Jack, S., Sivaramalingam, B., Iserman, E., Mustafa, R. A., Jdraszewski, D., Cotoi, C., & Haynes, R. B. (2014). Interventions for enhancing medication adherence. *Cochrane Database of Systematic Reviews*, 2014(11), CD000011. <https://doi.org/10.1002/14651858.CD000011.pub4>
- Nouwen, A., Adriaanse, M. C., Van Dam, K., Iversen, M. M., Viechtbauer, W., Peyrot, M., Caramlau, I., Kokoszka, A., Kanc, K., De Groot, M., Nefs, G., Pouwer, F., & the European Depression in Diabetes (EDID) Research Consortium. (2019). Longitudinal associations between depression and diabetes complications: A systematic review and meta-analysis. *Diabetic Medicine*, 36(12), 1562–1572. <https://doi.org/10.1111/dme.14054>
- Polonsky, W. H., Capehorn, M., Belton, A., Down, S., Alzaid, A., Gaman, V., Nagel, F., Lee, J., & Edelman, S. (2017). Physician-patient communication at diagnosis of type 2 diabetes and its links to patient outcomes: New results from the global IntroDia® study. *Diabetes Research and Clinical Practice*, 127, 265–274. <https://doi.org/10.1016/j.diabres.2017.03.016>
- Poveda, J. L. (2014). *Entrevista al Dr. Jose Luis Poveda*. Fundación ECO para la Excelencia y Calidad en la Oncología. [Entrevista]. <https://fundacioneco.es/entrevista-al-dr-jose-luis-poveda/>
- Powers, M. A., Bardsley, J., Cypress, M., Duker, P., Funnell, M. M., Fischl, A. H., Maryniuk, M. D., Siminerio, L., & Vivian, E. (2015). Diabetes self-management education and support in type 2 diabetes: A joint position statement of the American Diabetes Association, the American Association of Diabetes Educators, and the academy of nutrition and dietetics. *Journal of the Academy of Nutrition and Dietetics*, 115(8), 1323–1334. <https://doi.org/10.1016/j.jand.2015.05.012>
- Rebers, S., Aaronson, N. K., Van Leeuwen, F. E., & Schmidt, M. K. (2016). Exceptions to the rule of informed consent for research with an intervention. *BMC Medical Ethics*, 17(1), 9. <https://doi.org/10.1186/s12910-016-0092-6>
- Rollnick, S., & Miller, W. R. (2013). *Motivational interviewing: Helping people for change* (3rd ed.). Guilford Press.
- Rolnick, S. J., Pawloski, P. A., Hedblom, B. D., Asche, S. E., & Bruzek, R. J. (2013). Patient characteristics associated with medication adherence. *Clinical Medicine and Research*, 11(2), 54–65. <https://doi.org/10.3121/cm.2013.1113>
- Roy, J. F., Lozano Del Hoyo, M. L., Urcola-Pardo, F., Monreal-Bartolomé, A., Gracia Ruiz, D. C., Gómez Borao, M. M., Artigas Alcázar, A. B., Martínez Casbas, J. P., Aceituno Casas, A., Andaluz Funcia, M. T., García-Campayo, J., & Fernández Rodrigo, M. T. (2021). The TELE-DD project on treatment nonadherence in the population with type 2 diabetes and comorbid depression. *Scientific Reports*, 11(1), 8889. <https://doi.org/10.1038/s41598-021-87410-9>
- Ruiz de Adana, M. S., Alhambra-Expósito, M. R., Muñoz-Garach, A., Gonzalez-Molero, I., Colomo, N., Torres-Barea, I., Aguilar-Diosdado, M., Carral, F., Serrano, M., Martínez-Brocca, M. A., Duran, A., Palomares, R., & Diabetes Group of SAEDYN (Andalusian Society of Endocrinology, Diabetes, and Nutrition). (2020). Randomized study to evaluate the impact of telemedicine care in patients with type 1 diabetes with multiple doses of insulin and suboptimal HbA1c in Andalusia (Spain): PLATEDIAN study. *Diabetes Care*, 43(2), 337–342. <https://doi.org/10.2337/dc19-0739>
- Ryu, S. (2012). Telemedicine: Opportunities and developments in member states: Report on the second global survey on ehealth 2009 (global observatory for eHealth series, volume 2). *Healthcare Informatics Research*, 18(2), 153–155. <https://doi.org/10.4258/hir.2012.18.2.153>
- Sacco, W. P., Malone, J. I., Morrison, A. D., Friedman, A., & Wells, K. (2009). Effect of a brief, regular telephone intervention by paraprofessionals for type 2 diabetes. *Journal of Behavioral Medicine*, 32(4), 349–359. <https://doi.org/10.1007/s10865-009-9209-4>
- Safren, S. A., Gonzalez, J. S., Wexler, D. J., Psaros, C., Delahanty, L. M., Blashill, A. J., Margolina, A. I., & Cagliero, E. (2014). A randomized controlled trial of cognitive behavioral therapy for adherence and depression (CBT-AD) in patients with uncontrolled type 2 diabetes. *Diabetes Care*, 37(3), 625–633. <https://doi.org/10.2337/dc13-0816>
- Saydah, S. H. (2004). Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. *JAMA*, 291(3), 335. <https://doi.org/10.1001/jama.291.3.335>
- Smith, S. C., Allen, J., Blair, S. N., Bonow, R. O., Brass, L. M., Fonarow, G. C., Grundy, S. M., Hiratzka, L., Jones, D., Krumholz, H. M., Mosca,

- L., Pasternak, R. C., Pearson, T., Pfeffer, M. A., & Taubert, K. A. (2006). AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease: 2006 update: Endorsed by the National Heart, Lung, and Blood Institute. *Circulation*, 113(19), 2363–2372. <https://doi.org/10.1161/CIRCULATIONAHA.106.174516>
- Von Elm, E., Altman, D. G., Egger, M., Pocock, S. J., Gøtzsche, P. C., & Vandenbroucke, J. P. (2007). The strengthening the reporting of observational studies in epidemiology (STROBE) statement: Guidelines for reporting observational studies. *The Lancet*, 370(9596), 1453–1457. [https://doi.org/10.1016/S0140-6736\(07\)61602-X](https://doi.org/10.1016/S0140-6736(07)61602-X)
- Zhou, F., Yu, T., Du, R., Fan, G., Liu, Y., Liu, Z., Xiang, J., Wang, Y., Song, B., Gu, X., Guan, L., Wei, Y., Li, H., Wu, X., Xu, J., Tu, S., Zhang, Y., Chen, H., & Cao, B. (2020). Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: A retrospective cohort study. *The Lancet*, 395(10229), 1054–1062. [https://doi.org/10.1016/S0140-6736\(20\)30566-3](https://doi.org/10.1016/S0140-6736(20)30566-3)
- Zoppini, G., Fedeli, U., Schievano, E., Dauriz, M., Targher, G., Bonora, E., & Corti, M. C. (2018). Mortality from infectious diseases in diabetes. *Nutrition, Metabolism, and Cardiovascular Diseases*, 28(5), 444–450. <https://doi.org/10.1016/j.numecd.2017.12.007>

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