



The role of telenursing in the management of Diabetes Type 1: A randomized controlled trial



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ABSTRACT

Background: Diabetes Mellitus type 1 (T1DM) is a chronic disease that requires patients' self-monitoring and self-management to achieve glucose targets and prevent complications. Telenursing implicates technology in the interaction of a specialized nurse with patients with chronic diseases in order to provide personalized care and support.

Objective: To evaluate the effect of telenursing on T1DM patients' compliance with glucose self-monitoring and glycemic control.

Design: Randomized controlled study.

Settings: Outpatient Department of Diabetes, Endocrinology and Metabolism of a University Hospital in Northern Greece.

Methods: Ninety-four T1DM patients were recruited and randomized in two groups by a random number generator. The intervention group (N = 48) was provided with telenursing services. A specialized nurse made a weekly contact via telephone motivating patients to frequently measure blood glucose and adopt a healthy lifestyle. The control group (N = 46) received standard diabetes advice and care in the clinic. The primary outcome was the effect of the intervention in glucose control and glucose variability. The secondary outcome was the effect on frequency of self-monitoring. SPSS 20.0 was used for data analysis.

Results: The two groups did not differ in age, sex, physical activity or initial HbA1c. In the intervention group, blood glucose significantly decreased at the end of the study in all predefined measurements, compared to control group: morning (93.18 ± 13.30 mg/dl vs. 105.17 ± 13.74 mg/dl, $p < 0.005$), pre-prandial (114.76 ± 9.54 mg/dl vs. 120.84 ± 4.05 mg/dl, $p < 0.005$), post-prandial (193.35 ± 25.36 mg/dl vs. 207.84 ± 18.80 mg/dl, $p < 0.005$), and HbA1c decreased significantly over time in the intervention group ($8.3 \pm 0.6\%$ at the beginning of the study vs. $7.8 \pm 1\%$ at the end of the study, $p = 0.03$). In the intervention group there were also fewer omitted glucose measurements than in the control group.

Conclusions: Patients in the intervention group achieved better glucose control and more frequent self-monitoring than patients in routine care in the clinic. The findings of our study indicate that telenursing can motivate T1DM patients to better control their disease.

What is already known about the topic?

- T1DM is a chronic disease associated with complications. The appropriate treatment in combination with patients' self-management contributes to prevention of these complications.
- Several studies have shown that telemedicine plays important role

in the management of diabetes, whereas some studies had conflicting results.

- Telenursing uses technology in order to offer nursing care and support to patients with chronic disease.

Abbreviations: DM, diabetes mellitus; T1DM, diabetes mellitus type 1

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What this paper adds

- Telenursing can provide nursing support through technology means in patients with T1DM, leading to their better glycemic control.
- Through telenursing, specialized staff can counsel and motivate patients through cost-effective means -telephone- and result in improvement of patients' compliance to self-monitoring.
- The role of nurse and the systematic and personalized care achieved by telenursing is crucial for the management of T1DM.

1. Introduction

Diabetes Mellitus (DM) is a chronic metabolic disorder complicated by long-term microvascular and macrovascular complications leading to high morbidity and mortality rates (Deckert et al., 1978). Its prevalence increases globally and tends to be rising in epidemic proportions. IDF Diabetes Atlas in 2015 suggests that 415 million adults in the world have DM and it is estimated that 642 million adults will have DM by 2040. DM of type 1 (T1DM), although less common, seems to be increasing by approximately 3% per year (International Diabetes Federation, 2015). In Greece, there are only a few studies about DM prevalence, conducted mostly in adults and elderly people with DM of type 2 (T2DM). Most of them are regional, small epidemiological studies. There is one large study conducted in general population about two decades ago (from 1996 to 1999), which estimated only self-reported data (Tentolouris et al., 2009). According to these studies, the prevalence of DM varied between 3.1–9.5%, depending on design and population (Gikas et al., 2008; Katsilambros et al., 1993; Lionis et al., 1996; Melidonis et al., 2006; Panagiotakos et al., 2005; Papazoglou et al., 1995; Tentolouris et al., 2009). In 2016, Liatis et al. studied the prevalence of both DM types in Greece based on prescribed pharmacological treatment and showed that the prevalence of T2DM was 7% and of T1DM was 0.24% (Liatis et al., 2016). Data about overall T1DM epidemiology in Greece are limited and based on decades-old studies, that report an incidence of T1DM in the whole country (1992) of 6.25 persons per 100,000 and in Athens of 9 persons per 100,000 (Bartsocas, 1998; Dacou-Voutetakis et al., 1995). Further studies also reported a T1DM incidence of 6.1 persons per 100,000 in Crete and of 4.6 persons per 100,000 in northern Greece (Green et al., 1992; Mamoulakis et al., 2003).

Studies have shown that strict glycemic control can reduce microvascular complications in both T1DM and T2DM and when applied early in the course of the disease, it can decrease the risk of macrovascular complications. In the case of T1DM, the Diabetes Control and Complications Trial (DCCT) and the Stockholm Diabetes Intervention Study (SDIS) have shown that intensive diabetes management prevents and decreases the development of microvascular complications. (Diabetes Control and Complications Trial Research Group et al., 1993; Reichard et al., 1988; Stratton, 2000) Lifestyle changes and proper self-management of the disease constitute an essential part of the treatment strategy, as it is evident from treatment guidelines (American Diabetes Association, 2017).

Self-management focuses on behavioral changes that an individual must adopt to optimize disease management. Self-management in DM includes self-monitoring of blood glucose, and handling of physical activity, exercise, nutrition and medication (McGowan, 2005). Studies have shown that self-monitoring of blood glucose is important to achieve glycemic goals in T1DM, by helping with titration of insulin and avoidance of extreme variations in blood glucose levels (Karter et al., 2001; Tattersall and Gale, 1981).

Patients with T1DM, especially young adults, in Greece as well as worldwide, find several difficulties in the management of their disease and need more structured education and support to achieve better glycemic control. Studies show that glycemic control in T1DM remains a challenge worldwide. The T1DM Exchange study examined glycemic levels among large numbers of T1DM patients in USA and indicated that

only 17% of young adults with age 18–25 and 30% with age 25–30 met ADA criteria and achieved HbA1c < 7% (Beck et al., 2012). There is only one study including data from adult T1DM patients (> 25 years old) in Greece, which shows that mean HbA1c at the study time is 7.6% (McKnight et al., 2015). Glycemic control in T1DM is strongly associated with frequent monitoring (Miller et al., 2013). However, it seems that several factors impair the adherence of adults, especially young, in diabetes management. The transition from childhood into adulthood seems to be a possible reason. Adults are burdened with many changes in lifestyle and in health care, they are found in an unstable period with difficulties in work environment, inflexible working hours, financial instability and adjustment in a new lifestyle model away from their families. Young adults with T1DM need closer surveillance, motivation and psychological support, which can be provided in flexible hours and in remote areas in order to effectively manage of their disease (Monaghan et al., 2015). Health care providers play an important role for DM patients' compliance to self-management (Shrivastava et al., 2013). Nurses seem to provide significant support to patients in order to effectively manage their disease (Mulder et al., 2015; Tshiananga et al., 2012). However, adult T1DM patient care in Greece is physician based and specialized nurses do not interact with patients in an outpatient setting. On top of that, the infrequency of patients' visits to health services, lack of time, distance and high cost could be potential barriers. Telemedicine or telenursing interventions could possibly benefit these patients.

Telemedicine is defined as the transmission of medical information from one site to another via electronic media in order to improve disease management. Telemedicine is a general term that includes a growing variety of applications and services like two-way video, email, smart phones, wireless tools and other forms of telecommunications technology. Telenursing is the use of technology to “deliver nursing care and conduct nursing practice” (American Telemedicine Association, 2001). Telemedicine and telenursing in DM provide health services, including transmission of blood glucose measurements and delivery of advice and support from a DM healthcare provider. This form of indirect communication may lead to enhancement of the patient-doctor or patient-nurse relationship and may reduce visits to the clinic. Although it cannot replace personal contact and physical examination, it may help DM patients achieve their glycemic targets and may prove a form of cost-effective health care (Bellazzi et al., 2002).

Several studies have suggested that telemedicine plays a crucial role in motivating self-monitoring of blood glucose as well as improving self-management of DM patients (Fountoulakis et al., 2015; Montori et al., 2004; Salzsieder et al., 2007). There are also some studies that did not prove any difference compared to conventional treatment (Hanauer et al., 2009; Landau and Boaz, 2012; Greenwood et al., 2014). The role of telenursing in the field of T2DM has been examined by Borhani et al. and the results suggested that this method improved glycemic control in participants (Borhani et al., 2013). In Greece, Fountoulakis et al. also indicated that telemonitoring positively affects insulin-treated DM patients (Fountoulakis et al., 2015). However, telenursing studies in T1DM patients are lacking in Greece.

The aim of this study was to investigate whether telenursing positively affects disease management in young adult T1DM patients by assessing the effect on blood glucose control as well as on the frequency of glucose measurements.

2. Methods

2.1. Study setting and participants

This randomized controlled study was conducted among adult T1DM patients, recruited from the outpatient department of Diabetes, Endocrinology and Metabolism of a University Hospital in Northern Greece.

The inclusion criteria for the study were: 1) Diagnosis of T1DM for

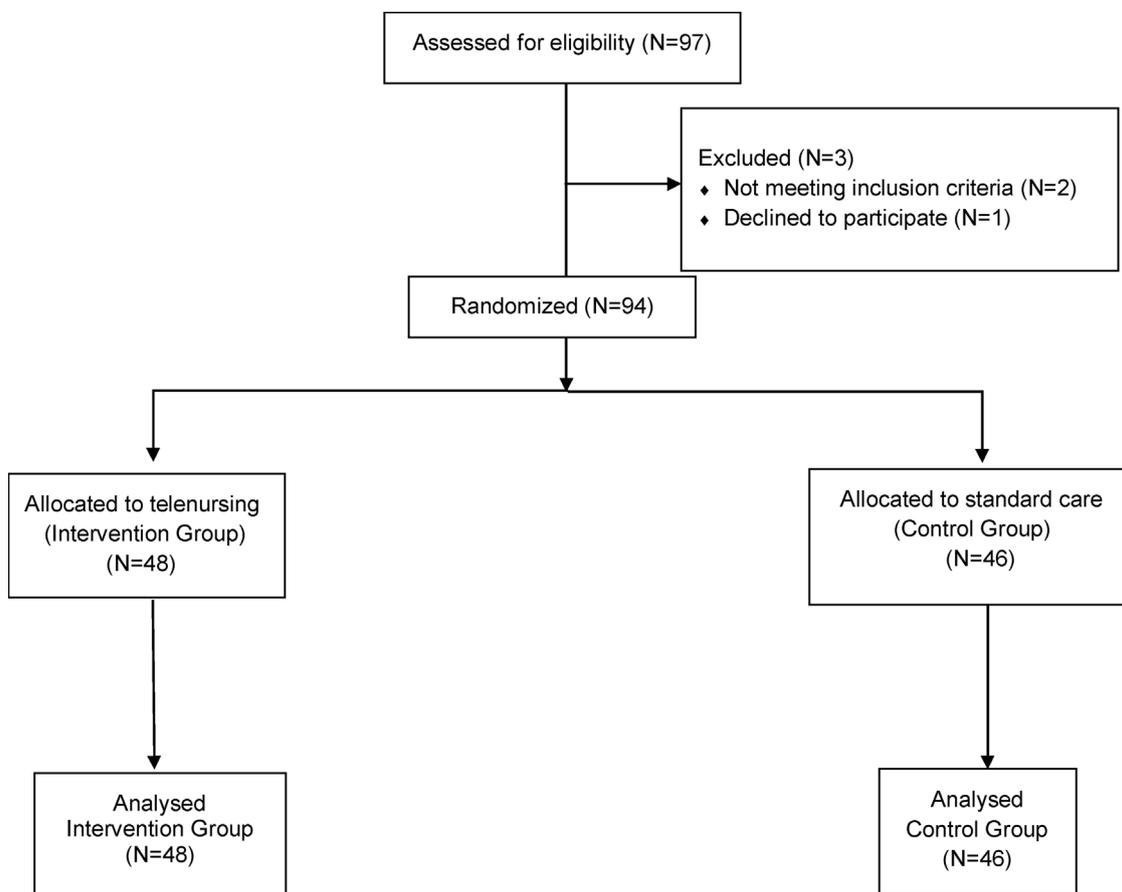


Fig. 1. Flow diagram of the study.

at least one year, 2) Age 18–39 years, 3) Patients on multiple daily injections of insulin (MDI). The exclusion criteria were: 1) Patients on insulin pump, 2) Patients on continuous glucose monitors (CGM).

A total of 94 patients participated in the study. They were randomized in two groups by a random number generator and sealed envelopes. Intervention group consisted of 48 patients, while control group included 46 patients who received standard clinical care (Fig. 1). Power analysis was used for the calculation of sample size. It was an “a priori” power analysis performed by G*Power 3.0.10 program based on data of Fountoulakis et al. published study (Fountoulakis et al., 2015). Patient written consent was obtained from all participants according to guidelines of ethical committee of Aristotle University of Thessaloniki. The study fulfilled the Principles of the declaration of Helsinki.

2.2. Intervention and procedure

Recruitment started on January and the follow up was terminated on August of the same year. Patients in both groups attended a 3-h educational program in which they received information about DM self-monitoring and self-care, diet, exercise, optimal glucose targets and insulin self-titration. All participants were requested to record their glucose values three times a day (morning, midday pre-prandial, afternoon post-prandial) seven days a week for three months. All participants were encouraged to write down their glucose values on a diary.

The patients in the intervention group were requested to transmit these values to a DM specialized nurse. The ways of transmission were three: via USB connected to the glucose meter, via e-mail or telephone calls. They received telephone calls every Thursday (10–12 A.M.) for 5–15 min from the coordinator-nurse (M Med Sci degree in Diabetes Care). During this time, patients discussed possible problems in their

disease management, potential reasons for omitted measurements, self-titration or hypoglycemia guidelines. The nurse also advised them on maintaining a healthy lifestyle and motivated them to increase the frequency of glucose measurements and comply with physician’s advice on insulin treatment. The recommendations were based on the individual’s data input and on patients’ needs.

The patients in the control group were advised to transmit their data via USB connected to the glucose meter or via e-mail or otherwise collect them for review at the end of the study. There was no telephone interaction in the control group. After three months, all patient data were reviewed in the outpatient clinic.

2.3. Measures and outcomes

The primary outcome was the measurement of morning (fasting), pre-prandial and post-prandial glucose level, as well as HbA1c. At the beginning of the study, blood sample was collected for HbA1c measurement. This procedure was followed again 3 months later. Patients were provided with CE certified brand glucose meters in order to measure their blood glucose three times a day.

2.4. Data analysis

Statistical analysis was performed using SPSS 20.0 for Windows (SPSS Inc., Chicago, IL, USA). Between groups comparisons were performed by *t*-test for normally distributed values and Mann-Whitney for non-normally distributed ones. The tests that were used to evaluate the differences within the groups were Paired *T*-test and Wilcoxon (Non parametric Test). Fisher’s Exact Test was used for analysis of demographic variables at baseline. A *p* value < 0.05 was considered as statistically significant.

Table 1
Baseline Sociodemographic Characteristics of study participants.

Variables	Intervention Group (N = 48)	Control Group (N = 46)	P
Ages in years ^a	26.35 (± 7.36)	27.63 (± 7.25)	0.39
Duration of diabetes in years ^a	15.78 (± 3.62)	15.53 (± 3.40)	0.73
Sex			0.84
Male	25	22	
Female	23	24	
Physical Activity			0.30
Yes	22	16	
No	26	30	
Living Condition			0.33
Alone	11	7	
With parents	20	16	
With housemate	17	23	
Family Condition			< 0.001
Unmarried	36	37	
Married	6	6	
Divorced	6	3	
Professional Condition			0.81
Student	16	13	
Non- working	15	17	
Working	17	16	
Morning blood glucose (mg/dl) ^b	120.01 ± 25.69	107.18 ± 12.69	0.03
Pre-prandial blood glucose (mg/dl) ^b	148.23 ± 16.24	120.66 ± 9.39	< 0.001
Post-prandial blood glucose (mg/dl) ^b	248.30 ± 11.71	220.92 ± 18.63	< 0.001
HbA1c (%) ^b	8.3 ± 0.6	8.1 ± 1.2	0.25

^a Age and duration of diabetes are presented as mean (± SD).

^b Initial glucose per-day time in Month 1 and initial HbA1c (Mean value ± SD).

3. Results

3.1. Population

Table 1 shows the baseline demographic data of all patients. There is no statistically significant difference regarding age, sex, duration of diabetes and physical activity ($p = 0.39$, $p = 0.84$, $p = 0.73$, $p = 0.30$) between the groups.

3.2. Glycemic control-glucose measurements

The total number of glucose measurements from the patients of both groups was 20140. Analysis of mean glucose values per day-time at the beginning of the study showed that the mean values of glucose measurements in the intervention group were higher than those in control group ($p < 0.05$), while HbA1c did not differ significantly between the two groups (Table 1).

During the period of the study, analysis of the average values of glucose per month and per daytime has revealed that there has been a significant improvement in the glucose level in the intervention group. The morning glucose measurements were significantly higher in the intervention group compared to control group in Month 1 (120.01 ± 25.69 mg/dl vs. 107.18 ± 12.69 mg/dl, $p = 0.03$). Despite these results, the mean morning glucose levels in Month 3 were lower in the intervention group than the control group (93.18 ± 13.3 mg/dl vs. 105.17 ± 13.74 mg/dl, $p < 0.001$). In month 2, the difference was not significant ($p = 0.36$) (Fig. 2).

In addition, regarding the midday pre-prandial measurements in Month 1 and in Month 3, there was a statistically significant difference between the two groups ($p < 0.001$). In particular, during Month 1,

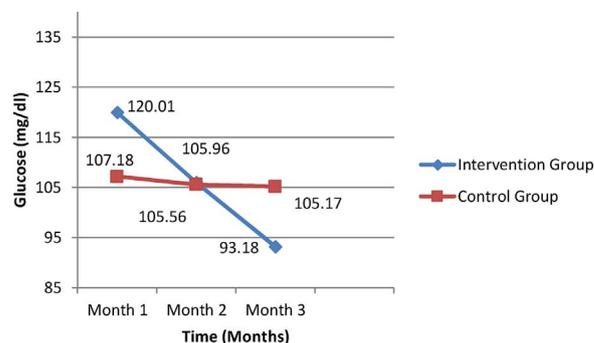


Fig. 2. Morning mean values of blood glucose over time in the two groups.

the mean pre-prandial glucose levels in the intervention group was 148.23 ± 16.24 mg/dl and in control group was 120.66 ± 9.39 mg/dl ($p < 0.001$). In Month 2, the difference was not significant ($p = 0.36$). In Month 3, the mean pre-prandial glucose levels in the intervention group and in the control group was 114.76 ± 9.54 mg/dl and 120.84 ± 4.05 mg/dl respectively ($p < 0.001$). This indicates that while the patients in the intervention group started with worst pre-prandial glucose values compared to the control group, they were improved at the end of intervention program (Fig. 3).

Moreover, the mean post-prandial glucose value in the intervention group was higher in Month 1 compared to the control group (248.30 ± 11.71 mg/dl vs. 220.92 ± 18.63 mg/dl, $p < 0.001$). In Month 2, the difference was not significant ($p = 0.56$). In Month 3, glucose levels in the intervention group were decreased in comparison with control group (193.35 ± 25.36 mg/dl vs. 207.84 ± 18.80 mg/dl, $p = 0.04$) (Fig. 4).

3.3. HbA1c

HbA1c did not differ between the groups at the beginning of the study. The HbA1c in the intervention group improved importantly at the end of the study ($8.3 \pm 0.6\%$ vs. $7.8 \pm 1\%$, $p = 0.03$), whereas in the control group the decrease in HbA1c was not statistically significant ($8.1 \pm 1.2\%$ vs. $7.9 \pm 0.8\%$, $p = 0.15$).

3.4. Frequency of glucose measurements

Analyzing the total number of omitted measurements, it was obvious that the subjects of the control group missed a greater number of measurements (69.7%) per day than the patients of the intervention group (54.1%), $p < 0.001$.

4. Discussion

T1DM is a chronic disease that requires adoption of lifestyle patterns and acquisition of treatment strategy skills (i.e. insulin titration)

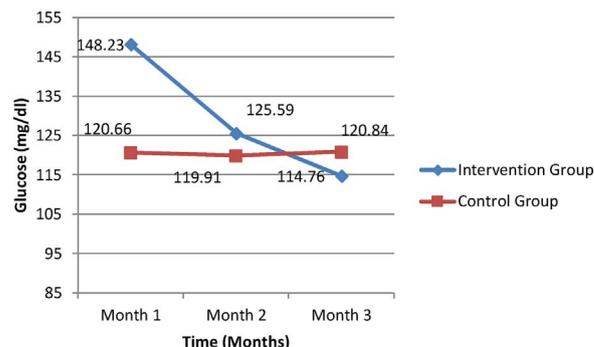


Fig. 3. Pre-prandial mean values of blood glucose over time in the two groups.

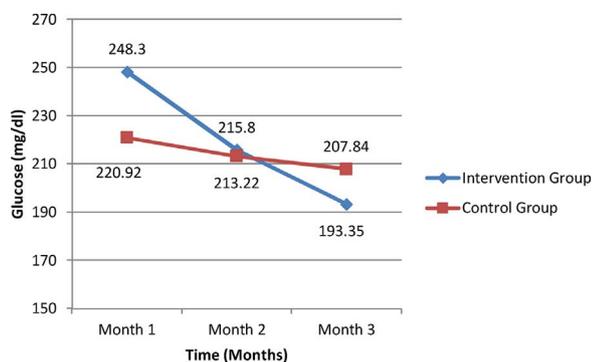


Fig. 4. Post prandial mean values of blood glucose in the two groups.

aiming to minimize the risk of complications on target organs (Chiang et al., 2014; Diabetes Control and Complications Trial Research Group et al., 1993). T1DM patients need special care and frequent outpatient visits in order to control their blood glucose and achieve the desired glucose targets (Chiang et al., 2014). They are often discouraged due to lack of motivation, inadequate information and excessive cost – especially when they have to travel from remote areas (Monaghan et al., 2015; Zgibor and Songer, 2001). Telecommunications and technology seem to play an important role in supporting DM patients' management and care.

The purpose of this study was to evaluate the efficacy of telenursing (weekly phone call intervention by a DM nurse) on the frequency of glucose measurements and the improvement of blood glucose variation in young T1DM adults (age 18–39). This age group has been chosen, as studies have shown that young adults are prone to poor glycemic control (Beck et al., 2012). Possible reasons for deterioration in diabetes management in this group are the transition of childhood to adulthood and the need of adjustment in a new unstable environment under working conditions away from family (Monaghan et al., 2015). The study findings indicated that this kind of communication via telephone resulted in increased patients' compliance as well as in better glycemic control. The intervention group achieved less glycemic variability than the control group, although initial mean glucose values were higher. In addition, they seemed to omit less glucose measurements during the three months of the study. At the first stage of analysis, the average of total morning, pre-prandial and post-prandial glucose values per month indicated that the pre-prandial glucose values of patients in intervention group were higher in the beginning of the study compared to those in the control group. An exploratory analysis revealed that the average of glucose values per time and per month was different between the two groups. The intervention group showed improvement in glucose values between the baseline point and the 3-month visit, as compared with the control group. As far as patients' compliance is concerned, we noticed a trend in enhanced adherence to self-monitoring in the intervention group. The average of missing glucose measurements was lower in the intervention group compared with the control group.

Several studies have been conducted investigating the improvement of glycemic control through telemedicine by using various technologies. The results of the studies are various and conflicting. Some previous telemedicine studies have used more complicated ways of intervention such as e-mail and SMS cell phone text messaging reminders or internet-based blood glucose monitoring (Hanauer et al., 2009; Landau and Boaz, 2012). In these studies, telemedicine was associated with no significant effects on glycemic control in T1DM patients. A potential explanation lies on the complexity of the intervention system indicated by the percentage of patients characterized as non-compliant (11/40 participants in the first study and 12/36 participants in the second study). In our study, the simplicity of phone call interaction may have contributed to patients' compliance. In addition, our results are in contrast to those of Howells et al. reporting no improvement in the

glycemic control of T1DM patients who participated in an one-year telemedicine program via telephone (Howells et al., 2002). This difference may be attributed to the short duration of our study intervention that may have resulted to better compliance. However, even in this negative outcome study, there are findings indicating increased self-efficacy in these patients.

On the other hand, there are many studies suggesting that telemedicine and telemonitoring can result in amelioration of glycemic levels. In agreement with our study, Montori et al. reported that patients participating in a telemedicine group achieved lower levels of HbA1c after six months (Montori et al., 2004). Nevertheless, their meta-analysis concluded that telecare leads to insignificant reduction of blood glucose levels. A Greek study by Fountoulakis et al. in both type 1 and type 2 DM insulin treated patients also resulted in HbA1c improvement as well as in better glycemic control (Fountoulakis et al., 2015). Moreover, in accordance with our results, telemedicine intervention in a clinical trial in patients with DM type 1 and 2 decreased HbA1c levels by approximately 0.62% within 3 months (Salzsieder et al., 2007).

The intervention effect was estimated with mean difference in the change of glucose values between the intervention and control group. It is known that blood glucose monitoring is critical for diabetes outcomes and estimates the treatment effect. Moreover, it provides a measure of blood glucose variability that cannot be estimated by HbA1c values alone. The frequency of glucose measurements is related to patient's adherence and the glucose values is a valuable indicator of glycemic control (Guilfoyle et al., 2011). Therefore, the evaluation of this factor renders the results of our study more reliable.

The choice of telephone calls as a mean of intervention offers a direct communication with a nurse or a healthcare provider. This is important for patients with a chronic disease like T1DM as it contributes to better adherence and improvement on psychological outcomes (Krishna and Boren, 2008). The use of text messaging was not preferred because it does not offer the flexibility of direct exchange of information between the patient and the professional. Moreover, in this study the use of phones is a cost-effective way of providing high quality health care to patients especially in those who do not have easy access to healthcare providers. Furthermore, it can be applied in every country (developing or developed) and in patients with low socioeconomic status (Suksomboon et al., 2014). The use of phone does not demand a high educational level and patients' acquaintance with technology.

This brief phone call intervention for just three months was effective in improving blood glucose values and patient adherence with less measurements missing. These results support a telenursing role. However, the short duration of the study is the main limitation, as it is unknown whether patients' compliance would be affected by longer-term follow up. Furthermore, another limitation of our study is that the two groups, although very similar, were not matched for fasting glucose at baseline. Despite this, the intervention group had worse glucose levels at the beginning of the study but ended up with remarkable improvement. These higher glucose levels at baseline may indicate that intervention group patients had less self-management abilities and adherence compared to those of the control group. However, they presented with significant improvement that may have resulted from the close monitoring by the intensive followed up through telenursing. Glycemic control in both groups was not optimal (HbA1c > 8%). Intervention studies have shown that DM patients with poor glycemic control benefit the most from self-management or self-care interventions (Cheng et al., 2017; Murphy et al., 2017; Tricco et al., 2012; Welch et al., 2010). Telecare studies have produced evidence that the impact of telemedicine is higher in patients with inadequate glycemic control (Lee et al., 2017; Marcolino et al., 2013). Piette et al. has shown that automated calls in combination with nurse telephone follow up were more effective in T2DM patients with higher baseline HbA1c (Piette et al., 2001). However, the small number of participants in our study did not allow further subgroup analysis based on baseline glucose

values or HbA1c.

Another limitation of this study is that by design it did not aim to record changes in physical activity levels. A modification in lifestyle (diet and physical activity level) can improve glycemic control (Bohn et al., 2015). Patients with T1DM may deal with several barriers to exercise such as fear of hypoglycemia, low confidence, lack of time and motivation (Lascar et al., 2014). In our study, although the nurse has advised participants to maintain a healthy lifestyle and to be physically active, levels and kind of physical activity were not recorded during the intervention. It is possible that this encouragement to maintain a certain lifestyle may have influenced the results and it has not been recorded. Overall, this study in this particular population and with the aforementioned limitations, has shown that T1DM patients can benefit from the addition of a weekly phone call interaction from a specialized nurse to their usual outpatient follow up making their care strategy more efficacious.

Additional research should be conducted, in order to determine whether telecare could substitute regular outpatient care for patients with limited access to healthcare providers. Moreover, further studies are needed to examine the long-term impact of telenursing and phone call intervention on glucose control in T1DM and evaluate the influence of co-factors such as diet and exercise. Further studies are also necessary to establish the efficacy of different kinds of intervention (like internet-based interaction) on similar or larger patient groups. As technology continues to advance, it will be crucial for healthcare providers to incorporate such innovations in the effort to optimize glycemic control in patients with T1DM.

Conflicts of interest

None.

Funding

None.

Ethical approval

Ethical Committee of Aristotle University of Thessaloniki.

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