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COST ANALYSIS OF MOBILE TECHNOLOGY AND SUPERVISED EXERCISE TRAINING IN TYPE 2 DIABETES MELLITUS

ORIGINAL ARTICLE

ABSTRACT

Purpose: The aim of this study is to examine the cost analysis of a randomized controlled clinical study in which people with Type-2 Diabetes Mellitus (T2DM) were monitored for 12 weeks of exercise program through supervision, a smartphone application and a smart watch.

Methods: The budget impact was calculated by determining the payments made by the Social Insurance Institution for three different T2DM groups who exercised for 12 weeks through supervised exercise, smartphone application and smart watch, and the cost effectiveness was calculated from a social perspective.

Results: The Quality Adjusted Life Years (QALYs) per Turkish Liras (TL) were 14.863 TL ($1777) per QALY in the supervised exercise group; 6056 TL ($724) in the smartphone apps group, and 7379 TL ($882) in the smartwatch group. In the cost analysis, the change in SWM values was 0.11 in the supervised exercise group; 0.12 in the smartphone application group, and 0.11 in the smart watch group. It was determined that the most cost-effective method was the exercise application method via smartphone.

Conclusion: Cost effectiveness was high for the smartphone application group, medium in the mobile applications group and low in the supervised exercise group, and the results of the study are similar to the literature.

Keywords: Cost-effectiveness, Diabetes, Exercise, Telerehabilitation

TİP 2 DİABETES MELLİTUS'TA MOBİL TEKNOLOJİ VE DENETİMLİ EGZERSİZ EĞİTİMİNİN MALİYET ANALİZİ

ARAŞTIRMA MAKALESİ

ÖZ

Amaç: Bu araştırmanın amacı, Tip-2 Diabetes Mellituslu (T2DM) kişilerin gözetimli egzersiz, akıllı telefon uygulaması ve akıllı saat kullanarak yaptıkları 12 haftalık egzersiz takibinin yapıldığı randomize kontrollü klinik çalışmanın maliyet analizinin yapılmasıdır.

Yöntem: Denetimli egzersiz, akıllı telefon uygulaması ve akıllı saat yoluyla 12 hafta boyunca egzersiz uygulanan üç farklı T2DM grubu için Sosyal Sigortalar Kurumu tarafından yapılan ödemeler belirlenerek bütçe etkisi hesaplanmış ve maliyet etkinliği toplumsal bakış açısıyla hesaplanmıştır.

Sonuç: Türk Lirası (TL) başına Kaliteye Ayarlanmış Yaşam Yıl (KAYY) değerleri denetimli egzersiz grubunda 14.863 TL; akıllı telefon uygulama grubunda 6056 TL, akıllı saat grubunda 7379 TL olarak bulundu. Maliyet etkinliği en yüksek olan yöntemin akıllı telefonla egzersiz uygulama yöntemi olduğu belirlendi. Maliyet analizinde KAYY değerlerindeki değişim denetimli egzersiz grubunda 0,11; akıllı telefon uygulama grubunda 0,12 ve akıllı saat grubunda 0,11 olarak hesaplandı.

Tartışma: Maliyet etkinliği akıllı telefon uygulama grubunda yüksek, mobil uygulamalar grubunda orta ve denetimli egzersiz grubunda en düşük olup çalışmanın sonuçları literatür ile benzerlik göstermektedir.

Anahtar Kelimeler: Maliyet Analizi, Diyabet, Egzersiz, Telerehabilitasyon

INTRODUCTION

Diabetes Mellitus is one of the most important public health issues of the modern world (1), with a worldwide prevalence of over 8.8% (2). Type 2 Diabetes Mellitus (T2DM) is a metabolic disorder, accounting for around 90 to 95% of all diabetes cases (3). Globally, about 415 million people are currently living with T2DM (2) and this proportion of people is predicted to reach around 642 million by 2040 amounting to 10.4% of the world population (2). Looking specifically at Turkey, the diabetes-related death rate was 4.33% in 2019 (4). While the prevalence of T2DM is rapidly increasing all over the world, the economic cost associated with the disease and the treatment caused by the disease are quite high. Moreover, the direct (treatment-related), and indirect (absence from work) burden on people living with T2DM is enormous (4). In terms of the direct cost of care, T2DM is an expensive health condition to manage follow-up as most individuals will access some form of healthcare services for a prolonged period. Approximately 12% of global health expenditure is spent on T2DM care and exceeds $673 billion worldwide. This cost no doubt will increase over time and is predicted to increase 20% by 2040 and reach over $800 billion (2). While the expenditure on diabetes in Turkey was 4.5 billion Turkish Lira (TL) in 2008, it was 3.1 billion TL in 2016 (5).

The current guidelines for the management of T2DM recommend medication and diet to achieve therapeutic glycemic control (6). However, drug therapy and diet alone have been shown to be ineffective and holistic management of T2DM has been proposed (6). The recommendations include, in addition to drug therapy, lifestyle interventions, which include regular physical activity. Physical activity guidelines recommend that people with T2DM do 150 minutes or more of moderate to vigorous-intensity activity. People with T2DM should have resistance exercise in 2 to 3 sessions per week on nonconsecutive days (7). Achieving glycemic control has been shown to enhance general health and quality of life in individuals with T2DM (8,9,10,11). However, the proportion of individuals with T2DM who participate in adequate physical activity is very low (12).

Several ways to improve engagement in physical activity have been recommended. Technologies such as mobile health apps are available in the market to promote and monitor physical activity. Mobile health technologies and apps could be potential ways to engage in physical activity for people living with T2DM (13). As the number of mobile applications for T2DM is increasing, the applications include features known to improve adherence to therapy such as individually tailored programs, reminders, real-time monitoring, the adaptation of exercise activities and performance feedback. In the literature, there is a study showing that mobile technology-supported exercise applications increase the physical activity levels of individuals diagnosed with T2DM (14). According to Liebreich's study, the web-based delivery of physical activity programs ensures promise for behaviour change in this population. The increasing availability of the internet lets such programs reach lots of people while providing momentary feedback (15). Thus, technology plays an important role in the treatment of diabetes.

The use of technology has not only been shown to improve health outcomes and engagement but it is also suggested to be cost-effective. There is limited research supporting the cost-effectiveness of technology-assisted physical activity participation. A systematic review shows incremental cost-effectiveness ratio (ICER) is calculated in the range of $516.33 to $126.23 per QALY in the studies (16). Despite limited studies, the positive economic contribution of mobile applications and technology to the health system should not be ignored.

The diverse forms of involvement, such as text messages, mobile apps, interactive telephones, internet servers, websites, video conferences, and mobile devices, may also explain the influence of mobile health apps to improve physical activity levels. This research is another study examining the cost analysis of a randomized controlled trial, whose clinical phase has been completed. The aim of this study was to assess the cost-effectiveness to deploy smartphone apps and smartwatches for 12 weeks in a clinical trial compared to a traditional supervised program. In addition to this study, treatment costs were calculated over the fees covered by Social Security Institution.

METHODS

Study design

The study was the cost-effectiveness of an assessor-blind randomized clinical trial designed to estimate the extent to which an exercise program delivered through a smartphone and smartwatch compared to a supervised program is effective in achieving glycemic control in individuals with T2DM. The current paper presents a cost-effectiveness analysis of three different exercise delivery methods which are supervised exercise training group (supervised exercise), program delivered through smartphone apps supported exercise training group (smartphone apps), and smartwatch supported exercise training group (smartwatch). Smartphone apps and smartwatches were called intervention groups while supervised exercise programs included a control group of patients. During the interventions, all participants took the same exercise program both duration and exercises. All participants have been informed about the trial and their consent has been taken.

Figure 1 shows the randomization, assessments, and follow-ups of the study participants. In summary, a total of 90 individuals were stratified randomized by age and sex, 1:1 to one of the three groups: supervised exercise, smartphone apps, or smartwatch groups (17). The intervention period was for 3-month with a follow-up at 3-month. The trial was conducted from March to September 2018 at the Fatih Sultan Mehmet Hospital Diabetes and Obesity Center in Istanbul, Turkey. The ethical approval of this study has been obtained from the Marmara University Ethics Committee of Clinical Research. (Approval Date: 06.10.2017 and Approval Number 09.2017, 604)

Outcomes Assessed

Several laboratory tests and therapist-supervised physical assessments were carried out to measure the outcomes of alternative interventions for the trial. The Quality Adjusted Life Years (QALY) were calculated for all groups. The outcomes were assessed at baseline and 3-month follow-up.

Intervention

Control Group

Supervised Exercise Training Group (Supervised Exercise): The control group had a physiotherapist-supervised exercise program for 3 sessions per week for a total of 36 sessions during the 3-month intervention period (17). The duration of each exercise session lasted around 60 minutes including a warm-up, aerobic exercises, resistance exercises, exercises of balance and flexibility and a cool down.

Intervention Groups

(a) Smartphone Apps Supported Exercise Training Group (Smartphone Apps): The participants in this group had smartphone apps installed on their personal cell phones (17). The app was programmed by a physiotherapist to create a personalized exercise program including strengthening, walking, balance, stretching, aerobic exercises, and relaxation. The exercise program lasted for around 60 minutes and was supplemented with training videos. The participants were expected to use the program 3 days per week and 36 times for 3-month. The physiotherapist followed up with the participants once a week through phone calls to troubleshoot and modify exercises, as needed.

(b) Smartwatch Supported Exercise Training Group (Smartwatch): A personal account was registered at www.diabetexercise.com (Marmara University Department of Physiotherapy Rehabilitation Education and Informatics, İstanbul, Turkey) for each participant in the smartwatch-supported exercise group (18,19). The participants in this group participated 3 days per week (a total of 36 times) in a 12-week aerobics, strengthening, and stretching exercise training program through a smartwatch. Exercise programs were defined specifically for each participant via video, and after choosing an exercise from the same platform with a smartphone, exercises were performed between 30 and 60 minutes, which is the exercise time that the patients can tolerate. During the exercise program, patient communication was provided by the physiotherapist through the smartwatch once a week so that the exercises could be corrected and modified as needed.

Data analysis: To answer our research question, we followed Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Checklist recommended by ISPOR which is The Professional Society for Health Economics and Outcomes Research (20). After measuring the cost and effectiveness of alternative interventions, we estimated cost-effectiveness ratios and carried out a budget impact analysis. Measuring the cost and effectiveness of alternatives is essential for all cost-effectiveness studies. Measuring cost and effectiveness dimensions as well as estimating cost-effectiveness and budget impact analysis as described below:

1. Cost dimension: The cost dimension was calculated from therapist-supervised training obtained from the 2019 Social Security Institution Health Practice Statement from the Ministry of Health, Republic of Turkey (21). The costs incurred for the three groups are shown in Table 2.

2. Effectiveness dimension: QALY was used to assess the effectiveness dimension in this study (22). The QALY is an important indicator in the health economy, with a QALY of 0 representing death, and 1 representing perfect health (23). The EuroQol-5 Dimensions is a versatile quality of life instrument which is included dimensions of anxiety/depression, a visual analogue scale, usual activities, mobility, pain/discomfort, and self-care. It is used to calculate QALY (24). There are no population norms for Turkey. Therefore, the referenced values for Germany were used in this calculation (25).

3. Cost-effectiveness dimension: There are different perspectives on cost-effectiveness and the cost was calculated from a societal perspective in this study. Two different Incremental Cost Effectiveness Ratios (ICERs) were calculated to compare the extent of cost-effectiveness for alternatives: ICER for supervised exercise versus smartphone apps, and supervised exercise versus smartwatch (26). The calculated ICER values were compared with the threshold values of the Gross Domestic Product (GDP) per capita. Any treatment cost that is up to three times below the threshold is considered cost-effective (22). According to TURKSTAT data published in 2018, GDP was estimated to be around 45 463 TL ($9 632).

4. Budget effect size: The direct cost incurred for providing treatment to all three groups was extrapolated to the total number of people with T2DM for one year in Turkey. The individual treatment cost was multiplied by the total number of referred people with T2DM to physiotherapy clinics in one year. In order to meet the exercise needs of diabetic patients in physiotherapy clinics, the referral rate was calculated as approximately 2% per (27). While calculating the cost, a family education fee was added for groups using smartwatches and smartphone apps.

Statistical Analysis

Data analysis was carried out using IBM SPSS Statistics, version 22.0 (IBM Corporation, Armonk, New York, USA). The normality of the five dimensions of the EQ-5D-5L was tested using the Kolmogorov-Smirnov test. The obtained cost and effectiveness data were compared by using ANOVA and t-tests for paired and independent samples. A Student t-test was used to compare the groups at a significance level of $p \le 0.05$. Also, a cost analysis was calculated for 28 people in each group.

RESULTS

Cost Analysis Phase of Mobile Health Application Developed in Type 2 Diabetes

According to the results of the trial, there was not any difference between the groups after the inter-

Table 1. Participants Characteristics at Baseline

Characteristics	Supervised Exercise (n=26)		Smartphone Apps. (n=25)		Smartwatch (n=24)	
	Mean	SD/%	Mean	SD/%	Mean	SD/%
Age (years)	51.8	8.0	51.6	7.8	51.4	8.1
Weight (kg)	91.6	17.0	89.5	19.1	90.5	18.9
Height (cm)	164.1	9.6	164.6	8.8	165.4	9.0
BMI (kg/m^2)	33.2	6.9	33.0	6.2	32.1	6.3

SD: Standard Deviation, %: Percentage, BMI: Body Mass Index.

Table 2. 12-Week Cost Amounts of Groups

Assessments, units or equipment	Supervised Exercise	Smartphone Apps.	Smartwatch
Therapist-supervised assessements and training	**Cost in TL per test or assessment**		
Educational information	300 ($35.88)	300 ($35.88)	300 ($35.88)
Home exercise program and family education	NA	156 ($18.66) (13*12 sessions)	156 ($18.66) (13*12 sessions)
Range of motion and flexibility	80 ($9.56)	80 ($9.56)	80 ($9.56)
Six-minute walk test, distance in meters	66 ($7.89)	66 ($7.89)	66 ($7.89)
Supervised strengthening exercises	35 ($4.18)	35 ($4.18)	70 ($8.37)
Relaxation exercises	22 ($2.63)	22 ($2.63)	44 ($5.26)
Balance and coordination training	22 ($2.63)	22 ($2.63)	44 ($5.26)
Walking exercises	20 ($2.39)	20 ($2.39)	40 ($4.78)
Stretching exercise	7 ($0.83)	7 ($0.83)	14 ($1.67)
Exercise therapy in chronic diseases	1080 ($129.1)	NA	NA
Total Cost (TL)	1632 ($195.2)	708 ($84.68)	814 ($95.36)

NA: not applicable (Calculated according to the 2019 dollar rate)

Table 3. Within Group Difference on QALY Scores by Groups

Group	Time points	Mean(SD)	Mean Difference	p
Supervised Exercise (n=28) (n=26)	Baseline 3-month	0.76(0.23) 0.87(0.10)	0.11	0.002*
Smartphone Apps (n=28) (n=25)	Baseline 3-month	0.75(0.22) 0.87(0.13)	0.12	0.001*
Smartwatch (n=28) (n=24)	Baseline 3-month	0.76(0.22) 0.87(0.13)	0.11	0.001*

*p<0.005=Statistically significance (Paired-Samples t-test).

vention programs. Laboratory and physical tests showed similar results in all groups. The clinical results of our study are presented in our published article (17). Table 1 shows participants characteristics at baseline.

Cost Dimension

The costs of activities under three alternatives and total costs were calculated for each participant and they are shown in Table 2. While the cost per person for the supervised exercise was 1632 TL ($195.39), the smartphone apps group was 708 TL ($84.76), and the smartwatch group was 814 TL($97.45).

The Effectiveness Dimension

The scores obtained from the EQ-5D-5L were used to obtain the QALY value. German weights were used in order to obtain the QALY scores for quality of life because Turkey weights for QALY are not available in Turkey to Germany (22). The median QALY values were 0.76 at baseline and 0.87 post-intervention for the supervised exercise training group (Figure 2). The QALY values at baseline for smartphone apps and the smartwatch group increased from 0.75 to 0.87 and 0.76 to 0.87 respectively (Table 3).

Table 4 shows the median values for each dimension of the EQ-5D-5L scale and the mean visual analogue scale for current health status. Mean EQ-5D-5L Index Values for the 3 groups can be seen in the chart.

Cost Effectiveness Dimension

QALY scores were estimated to be 0.11 in the supervised exercise group, 0.12 in the smartphone apps group, and 0.11 in the smartwatch group (Table 3).

Cost-effectiveness analysis provides a measure of

Table 4. The Median Score For Each Item and The Mean Score For Visual Analog Health Status of EQ-5D-5L Across Three Groups

Groups	Time points	Mobility	Self Care	Usual Activities	Pain/ Discomfort	Anxiety/ Depression	Visual Anolag Scale	Mean (SD)
Supervised Exercise	Baseline (n=28)	2.0	1.0	2.0	2.0	1.0	51.03	0.75 (0.03)
	3-month (n=26)	1.0	1.0	2.0	2.0	1.0	66.16	0.88 (0.05)
Smartphone Apps.	Baseline (n=28)	2.0	1.0	2.0	2.0	1.0	57.28	0.74 (0.05)
	3-month (n=25)	1.0	1.0	1.0	2.0	1.0	69.44	0.87 (0.04)
Smartwatch	Baseline (n=28)	2.0	1.0	2.0	2.0	1.0	53.97	0.78 (0.05)
	3-month (n=24)	2.0	1.0	2.0	2.0	1.0	67.72	0.86 (0.05)

Table 5. TL per QALYs For All Groups and Budget Impact Dimension

Group	TL per QALYs ($)	Total cost in millions TL($)	Share of Total Health Expenditures (%)
Supervised Exercise (n=26)	14 863 ($1777)	218 505 ($26 136)	0.108
Smartphone Apps. (n=25)	6 056 ($724)	94 792 ($11 338)	0.047
Smartwatch (n=24)	7 379 ($882)	108 984 ($13 036)	0.054

QALYs: The Quality Adjusted Life Years, TL: Turkish Lira

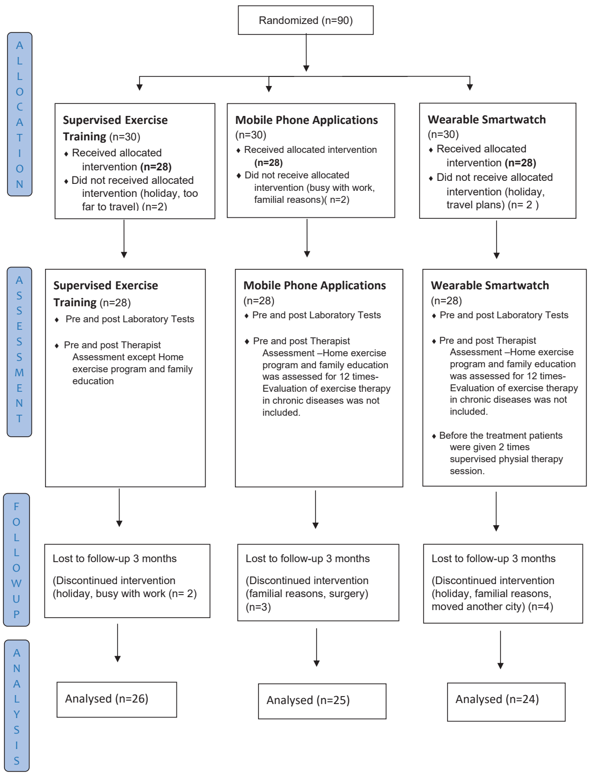

Figure 1. Flow diagram for study participants

Figure 2. Mean EQ-5D-5L index values for the 3 groups

lives saved in health-related units and life-years achieved, as a health-related unit. It is important to monitor the cost and effectiveness of each alternative intervention over time. For this reason, the cost per gained QALY in the past 3-month was calculated, and the results provided are in Table 5 by using the below formula (22).

(Cost of Intervention 2) – (Cost of Intervention 1)

Change in QALY

The cost in TL per gained QALYs in the last 3 months was calculated and they are; 14 863 TL ($1777) per QALY in the supervised exercise group; 6 056 TL ($724) in the smartphone apps group, and 7 379 TL ($882) in the smartwatch group (Table 5).

Across all three treatment groups, the smartphone apps group resulted in the same QALYs but at a lower cost compared to the other two groups.

The net change in costs (between two interventions) divided by the net change in QALYs gives ICER (29). ICER expresses the cost-effectiveness (cost-utility) and is calculated by dividing incremental cost by incremental QALYs. While ICER for smartphone apps was 33 000 in TL ($3947), ICER for smartwatches was 511 250 in TL ($61 154).

Budget Effect Size

According to the IDF, around 6.7 million people with T2DM are living in Turkey (28). Since only 2% of diabetic patients were referred to outpatient physical therapy, total health expenditures were calculated according to this group (27). The total number of people referred to physiotherapy clinics with T2DM in a year was estimated to be 134 thousand. The budget spent on health in 2019 was approximately 201 billion 031 million TL (29). These numbers are multiplied by the individual numbers for each group, respectively, 218 million 505 thousand TL ($ 26 million 136 thousand) for the supervised group, 94 million 792 thousand TL ($ 11 million 338 thousand) on smartphone apps, 108 million 984 thousand TL ($13 million 036 thousand) on the smartwatch. This translates to an approximate expenditure of 0.108% on supervised exercise therapy, 0.047% on smartphone apps, and 0.054% on the smartwatch. Table 5 shows the estimated total annual health expenditures for each group.

DISCUSSION

The aim of this paper was to compare the cost-effectiveness to deploy a smartphone app or smartwatch, versus supervised exercise training for older adults with T2DM in the context of a clinical trial. The changes in QALY values were calculated as 0.11 in the supervised exercise group, 0.12 in the smartphone apps group, and 0.11 in the smartwatch group. For the cost-effectiveness between groups, the smartphone apps group was highly cost-effectiveness followed by mobile applications, while the supervised exercise treatment option was the least.

Approximately 12% of global health expenditures are utilized in the management of T2DM (2). In Turkey, the health expenditure in the management of the T2DM population is close to double, around 23% (5). Technology should be used to reduce costs in healthcare services. Increasingly technology such as mobile applications, and monitoring devices such as smartwatches are commercially available, cost-effective, and timely to meet the needs of a large population. In this randomized controlled clinical trial, glycemic control, muscle strength, physical function, and exercise behaviours of individuals with T2DM were assessed at baseline and after 3-months. Although the overall benefits of the interventions were inconclusive to improve behavioural outcomes, smartphone apps and smartwatches training interventions were non-inferior in improving glycemic control and physical functions compared to supervised exercise training after 3-months of trial exercise training (17).

In this study, the cost-effectiveness analysis was conducted for the 3 intervention groups to compare their net health benefits and cost. EDUC@DOM is a telemonitoring and tele-education program in France. This program was found cost-effective strategy for telemonitoring and tele-education in patients with T2DM (30).

Brun et. al. assessed moderate endurance training on healthcare cost, and fitness in people with T2DM and showed a 50% reduction in the total healthcare expenditure at one year between the exercise intervention and usual care (31). The results of the study conducted with patients with heart failure showed when the total healthcare costs per participant were compared, it was found that the telerehabilitation group was significantly lower than the traditional centre-based program group (32). Our findings showed that the supervised exercise group has the highest cost, while the smartphone app intervention has the lowest cost.

The cost-effectiveness between groups, the smartphone apps group was highly cost-effective followed by mobile applications, while the supervised exercise treatment option was the least. The Feel Diabetes intervention (Feel4Diabetes) was cost-effective in high-income and low to middle-income countries, and cost-saving in the high-income countries under austerity measures following the financial crisis (33).

It should be mentioned that all exercise alternatives enhanced the quality of life in patients deployed in different intervention groups. The estimated costs per gained quality for each intervention were 14.863 TL ($1777) per QALY in the supervised exercise group, 6056 TL ($724) in the smartphone apps group, and 7 379 TL ($882) in the smartwatch group. A study in Australia showed that exercise interventions were estimated to cost around $5.61 (22,16 TL) per QALY for pre-diabetes, and $5.13 (20,26 TL) per QALY for T2DM in 2015. The incremental cost per QALY gained for the combined exercise was $37.87 (149,58 TL) compared with no exercise program (34).

When the economic cost of exercise therapy across the country was calculated, the ratio of supervised exercise therapy in the total health budget was 0.108%, the ratio of smartphone application-assisted exercise therapy was 0.047%, and the rate of exercise therapy supported by smartwatches was 0.054%. According to a study on people with heart failure, exercise therapy had a modest incremental cost-effectiveness ratio of $26,462 (104 524 TL) per QALY and $21,169 (83 617 TL) per life-year in a Brazilian Public Health System (35).

A smartphone app-based diabetes self-management intervention was found to be able to optimize patients' glycemic control and improve participants' self-management performance (36). According to our study, in the comparison of the groups, the smartphone app group was found to be the most cost-effective exercise treatment option. So the next step to continue work in this area will involve developing accessible smartphone apps for android and iOS versions, with features such as language options, interpretable feedback to the users, and including the apps as a part of routine clinical care. Future steps will be to develop policies to uptake the use of smartphone apps to improve glycemic control, physical function, and exercise behaviour for people with T2DM. There is a need to understand the economic burden of diabetes on health systems in order to regulate future policies and practices (37). The development of policies should involve multi-stakeholders such as patient experts, researchers, clinicians, health ministries, and other relevant stakeholders.

This study has some limitations. One of them is the cost-effectiveness was not calculated by considering the patient perspective such as transfer to hospital, accessibility to treatment, and time. It would be useful to conduct a cost-effectiveness analysis from the patient perspective in future studies. The other limitation is QALY scores were assessed for only 3-months. Health-related quality of life coefficients have not been produced for Turkey. Therefore, calculated coefficients for Germany were used in the study.

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