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International Interdepartmental Master of Science Programme in

LIFESTYLE MEDICINE

The effect of smartphone-based-interventions on health-related quality of life of adults with type 2 diabetes mellitus- A systematic review

by

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I certify that I am the author of this thesis and that any assistance I have had in its preparation is fully acknowledged and referenced in the following text. I have also cited any sources from which I have used data, ideas or words, whether they are quoted exactly or paraphrased. I also certify that this thesis was prepared by me personally specifically for the requirements of obtaining a Master's degree in Lifestyle Medicine by the University of Thessaly. I declare that I will respect co-authorship rights in any linked scientific publication and/or presentation stemming from this thesis, in accordance to my signed affirmation, and in respect of the principles of ethics in research. Likewise, I declare I will recognize any funding sources and will acknowledge my affiliation to the University of Thessaly during the preparation of this work in any future presentation.

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Abstract

Background: Previous systematic reviews have primarily focused on examining the influence of smartphone-based interventions mainly on the metabolic or clinical parameters among adults with type 2 diabetes. However, there is still not enough evidence in the literature regarding the assessment of these interventions on health-related quality of life (HRQoL). Considering the significant negative influence of type 2 diabetes on HRQoL in adults, understanding the benefits of smartphone-based interventions in improving the HRQoL of individuals with type 2 diabetes is crucial. Therefore, this systematic review aims to analyze existing literature to fill this gap by examining the effect of smartphone-based interventions on the HRQoL of adults diagnosed with type 2 diabetes.

Objectives: To review the effect of smartphone-based self-management interventions on health-related quality of life of adults with type 2 diabetes mellitus.

Methods: A systematic search of a database (PubMed) was conducted. Studies published in English from January 2014 to February 2024 were considered. Only randomized controlled trials (RCTs) of smartphone-based self-management interventions for patients with type 2 diabetes mellitus that reported any of the study outcomes were included. The main author screened the studies, extracted data and assessed the quality of the studies.

Results and conclusion: Smartphone interventions for type 2 diabetes may improve health-related quality of life (HRQoL), but more research is needed. Within-group improvements in HRQoL were observed in all studies, but between-group comparisons showed mixed results. Future research should focus on improving intervention design and long-term sustainability of effects.

Keywords: Type 2 diabetes, health related quality of life, smartphone apps, mobile applications, mhealth interventions

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Περίληψη

Εισαγωγή: Οι προηγούμενες συστηματικές ανασκοπήσεις έχουν επικεντρωθεί κυρίως στην εξέταση της επίδρασης των επεμβάσεων με smartphone κυρίως στις μεταβολικές ή κλινικές παραμέτρους μεταξύ ενηλίκων με σακχαρώδη διαβήτη τύπου 2. Ωστόσο, δεν έχει γίνει εκτενής έρευνα σχετικά με την αξιολόγηση αυτών των επεμβάσεων στην ποιότητα ζωής (HRQoL). Λαμβάνοντας υπόψη τη σημαντική αρνητική επίδραση του σακχαρώδους διαβήτη τύπου 2 στην ποιότητα ζωής που σχετίζεται με την υγεία στους ενήλικες, η κατανόηση των οφελών των επεμβάσεων που βασίζονται σε smartphone στη βελτίωση της ποιότητας ζωής που σχετίζεται με την υγεία των ατόμων με σακχαρώδη διαβήτη τύπου 2 είναι κρίσιμη. Επομένως, αυτή η συστηματική ανασκόπηση στοχεύει στην ανάλυση της υπάρχουσας βιβλιογραφίας για να καλύψει αυτό το κενό εξετάζοντας το αποτέλεσμα των επεμβάσεων που βασίζονται σε smartphone στην ποιότητα ζωής που σχετίζεται με την υγεία των ενηλίκων που έχουν διαγνωσθεί με σακχαρώδη διαβήτη τύπου 2.

Σκοπός: Να γίνει αξιολόγηση της επίδρασης των επεμβάσεων αυτοδιαχείρισης μέσω smartphone στην ποιότητα ζωής των ενηλίκων με σακχαρώδη διαβήτη τύπου 2.

Μεθοδολογία: Έγινε συστηματική αναζήτηση σε μία βάση δεδομένων (PubMed). Συμπεριλήφθηκαν μελέτες που δημοσιεύτηκαν στα αγγλικά από τον Ιανουάριο του 2014 έως τον Φεβρουάριο του 2024. Συμπεριλήφθηκαν μόνο τυχαιοποιημένες ελεγχόμενες μελέτες (RCTs) επεμβάσεων αυτοδιαχείρισης σε smartphone για ασθενείς με σακχαρώδη διαβήτη τύπου 2 που ανέφεραν οποιοδήποτε από τα αποτελέσματα της μελέτης. Ο κύριος συγγραφέας εξέτασε τις μελέτες, εξήγαγε τα δεδομένα και αξιολόγησε την ποιότητα των μελετών.

Αποτελέσματα και συζήτηση: Οι επεμβάσεις μέσω εφαρμογών κινητού τηλεφώνου στα άτομα με σακχαρώδη διαβήτη τύπου 2 ενδέχεται να βελτιώσουν την ποιότητα ζωής τους, ωστόσο απαιτείται περισσότερη έρευνα για να μπορεί να γενικευτεί το συμπέρασμα. Παρατηρήθηκε βελτίωση στην ποιότητα ζωής των ατόμων που χρησιμοποίησαν τις εφαρμογές, σε όλες τις συμπεριλαμβανόμενες μελέτες. Ωστόσο οι συγκρίσεις μεταξύ των ομάδων δεν έδειξαν ξεκάθαρα αποτελέσματα. Γι’ αυτό το λόγο είναι ανάγκη να γίνει περισσότερη έρευνα η οποία θα επικεντρωθεί στη μελέτη της ποιότητας ζωής καθώς και

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στη σχεδίαση εφαρμογών που θα στοχεύουν όχι μόνο στη βελτίωση των κλινικών παραμέτρων των νοσούντων, αλλά και στη βελτίωση της ποιότητας υγείας τους.

Λέξεις -κλειδιά: Type 2 diabetes, health related quality of life, smartphone apps, mobile applications, mhealth interventions

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List of abbreviations

App – Application

AQoL-8D - Assessment of Quality of Life-8 Dimensions

BMI - Body Mass Index

CDC - Centers for Disease Control and Prevention

CI - Confidence Interval

COPD - Chronic Obstructive Pulmonary Disease

CT - Clinical Trial

CVD - Cardiovascular Disease

DM - Diabetes Mellitus

DPP-4 - dipeptidyl-peptide 4 inhibitors GLP-1 and GLP-1/GIP Receptor Agon

EQ-5D – EuroQol five-dimensional questionnaire

EQ-5D-5L - EuroQol five-dimensional questionnaire with five levels

EQ-VAS - EuroQol Visual Analogue Scale

GLP-1 - Glucagon-like peptide-1 receptor agonists

GLP-1/GIP Glucagon-like peptide-1/ Gastric inhibitory polypeptide receptor agonists

HRQoL - Health-Related Quality of Life

IDF - International Diabetes Federation

ITG - Intervention Group

mHealth - Mobile Health

MDC – My Diabetes Coach

N - Number of participants

NIH - National Institutes of Health

OGTT - Oral Glucose Tolerance Test

P - Probability

PICO - Population, Intervention, Comparator, Outcome

PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-analyses

QoL - Quality of Life

RAND-36 - RAND 36-Item Health Survey

RCT - Randomized Controlled Trial

RoB2 - Risk of Bias 2 (Cochrane Library tool)

SD - Standard Deviation

SDMD - Shared Decision-Making Dashboard

SF-36 - Short Form (36) Health Survey

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SGLT-2 - Sodium-glucose cotransporter 2 inhibitors

SMSS - Self-Management Support System

T2D - Type 2 Diabetes

WHO-5 - World Health Organization-Five Well-Being Index

WHO-QOL-Bref - World Health Organization Quality of Life-Bref

WLC - Wait List Control Group

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1. Introduction

In the 21st century, diabetes has emerged as a prominent global health concern. The increasing prevalence of diabetes is leading to significant economic consequences for healthcare systems worldwide (1,2).

Type 2 diabetes is the main subtype (90%) among all cases of diabetes mellitus. A sedentary and unhealthy lifestyle plays a significant role in this development. This condition is associated with various chronic complications, including macrovascular, microvascular and additional conditions. In addition, episodes of hypoglycaemia , fear of hyperglycaemia and sedentary lifestyle are common. These lead to a lower HRQoL comparing to the general population (3,4) .

Health-related quality of life examines the impact of an individual's physical and mental well-being on their daily functioning and overall contentment with life (5). QoL has become highly emphasized in recent years as an important healthcare outcome. With an increasing prevalence of chronic diseases and the focus of health care expanding from “adding years to life” to “adding life to years”, there is a growing interest in assessments of the quality of life in healthcare (6).

There is already evidence in the literature showing the impact of chronic conditions on the health-related quality of life of individuals (7–9).

There are different reasons why people with type 2 diabetes may experience a lower HRQoL compared to the general population. Diabetes-related complications may have a negative physical impact, such as pain, discomfort, immobility, and fatigue, as well as psychological impact, including frustration and distress for individuals (8,10–12) .

Treating type 2 diabetes should involve a comprehensive approach that incorporates both lifestyle modifications and medication. Self-management techniques, such as having healthier dietary choices, increasing physical activity, and aiming for weight reduction can also improve blood sugar control and reduce the reliance on medication and its associated side effects (13,14). Prioritizing healthy lifestyle habits may lead to an effective control of the condition and therefore to an improvement of overall well-being of the patients with type 2 diabetes (15).

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Digital life interventions have been widely used in the last years to help people with chronic diseases manage their condition effectively and achieve optimal health outcomes (16) .

Research evidence suggests that computer-based interventions, telemonitoring, online coaching, used individually, are effective on individuals with type 2 diabetes, providing sustained support, self-management-resources and wider access to diabetes education (17–19).

In recent years there is an increased utilization of smartphone applications that have a notable impact on self-management for type 2 diabetes (20,21). Most of these apps have several similar features including self-monitoring, education, reminders and communication (22,23).

Many systematic reviews and meta-analyses have already shown the effect of the smartphone applications on clinical outcomes for patients with type 2 diabetes (24–26). Thus, existing reviews were not yet able to evaluate the effectiveness of smartphone-based technologies on psychosocial outcomes, like health-related quality of life. Several reviews have been conducted but were not designed to examine primarily the HRQoL. There is a need to analyze evidence on this outcome parallel with clinical outcomes.

As such, the current review aims to examine whether smartphone-based interventions can contribute to the health-related quality of life in patients with type 2 diabetes.

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2. Aims – Significance

This systematic review aims to examine whether smartphone-based interventions can contribute to the health-related quality of life in patients with type 2 diabetes. Due to the rapid pace of technological development and the evolving design of modern smartphone-based interventions, it is crucial to estimate the effect of these tools on psychosocial outcomes among individuals with type 2 diabetes. By evaluating the impact of these interventions on HRQoL, the evidence synthesized can then be used to guide further research on the management of type 2 diabetes mellitus.

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3. Literature Review

According to the Centers for Disease Control and Prevention (CDC), chronic diseases are conditions that persist for 1 year or more, require continuous medical care, and often lead to restriction of everyday activities (27).

Smoking, a sedentary lifestyle as well as unhealthy dietary habits are the main risk factors. Additional factors like genetics, healthcare system, and environmental factors also contribute to the burden of chronic disease nowadays (28,29).

Metabolic disorders also show an increasing prevalence over the last few years (30). These are a subtype of chronic conditions that are caused when the normal metabolic processes are disrupted. The most prevalent metabolic disorders are diabetes mellitus, obesity, dyslipidemia, osteoporosis, and metabolic syndrome, while diabetes stands as the most common (31).

Diabetes mellitus stands as the most common metabolic disorder, and it is characterized by chronic hyperglycemia. The main factors contributing to its onset are insulin resistance, deficient insulin secretion and action caused by impaired function of Langerhans islets' b-cell. Additionally, increased hepatic glucose production (liver), and decreased peripheral (muscle) glucose utilization are also considered to be responsible for the development and progression of diabetes mellitus (32).

Diabetes has become a growing health issue globally in the 21st century. It is estimated that its prevalence will significantly increase by 2030 and 2045. According to the International Diabetes Federation Diabetes Atlas, diabetes impacts around 10.5% of adults aged between 20 and 79, with almost half going undiagnosed (1).

Due to its increasing prevalence, there are already relevant economic consequences for healthcare systems worldwide. In 2022, the United States experienced a total economic burden of $412.9 billion, representing a significant increase from previous assessments (2). Financial pressure due to global diabetes-related expenditures is expected to worsen by 2030, posing a significant challenge for healthcare systems and individuals (33).

Diabetes mellitus (DM) manifests in three main forms: type 1, type 2 and gestational diabetes.

Type 1 diabetes, also known as insulin-dependent, is caused by autoimmune destruction of the insulin-producing β-cells of the pancreas, triggered by environmental factors such as toxins and viruses. It represents 10% of all diabetes cases. Childhood-onset of the disease is more prevalent, although it may also manifest for the first time in young adults (34). It

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is characterized by insulin deficiency and requires daily administration of insulin. Regular blood glucose monitoring and a healthy lifestyle are also crucial for the effective management of the condition (35).

T2D represents the main subtype (90%) among all diagnosed cases. Insulin resistance is the main characteristic of type 2 diabetes, resulting in the body's inadequate response to insulin. Over time, this can eventually depress the pancreas' function, leading to reduced insulin secretion and, consequently, elevated levels of blood glucose. Type 2 diabetes is also known as adult-onset diabetes due to its higher prevalence among older adults. Risk factors that contribute to its onset include sedentary lifestyle, obesity, impaired glucose tolerance as well as genetic factors. However, recently it is also frequently seen in younger individuals and children (36). According to the International Diabetes Federation, socio-economic disparities, access to health care, and cultural practices may also impact the risk of developing youth-onset diabetes, underlying the variety of factors that can play a role in its emergence (1).

Gestational diabetes occurs during pregnancy, and it is caused by placenta-produced hormones that can lead to pathological insulin resistance. This type of diabetes can lead to complications that affect both the mother and the baby. Women with gestational diabetes also have a greater risk of developing type 2 diabetes after delivery (37).

Common signs of diabetes mellitus include increased thirst and urination, increased appetite, fatigue, blurred vision, and unexplained weight loss. While symptoms tend to be mild and develop over the years in type 2 diabetes, in type 1 diabetes the initial symptoms can manifest and progress within a few days and be life-threatening (35).

Various tests are used to diagnose diabetes. The main tests are fasting plasma glucose (FPG), the A1C test, which shows glycemic control over the last 3 months, the random plasma glucose test, the glucose challenge test, and the oral glucose tolerance test (OGTT) (38).

As diabetes progresses, it can lead to a variety of complications over time. Diabetes-related complications are more frequent in individuals with type 2 diabetes and contribute significantly to morbidity and mortality. They are classified as microvascular and

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macrovascular, with microvascular having a higher prevalence. Microvascular complications consist of retinopathy, nephropathy, and neuropathy, while macrovascular complications include cardiovascular diseases, stroke, and peripheral vascular disease. Diabetic neuropathy and peripheral vascular disease contribute to the development of foot ulcers, known as foot syndrome, which can lead to lower limb amputation (3,39,40). Research evidence has shown that improvements in glycemic control can reduce the risk of chronic diabetes-related complications. Furthermore, patients with type 2 diabetes are likely to experience acute complications, like episodes of hypoglycemia. Hypoglycemia is associated with psychological stress and reduced productivity. Episodes of hypoglycemia may worsen the adherence of the patients to the medication and, therefore, result in poorer control of the disease (41). These can have a negative impact on the quality of life of patients with type 2 diabetes (4).

Health-related quality of life focuses on how a person's physical, mental, and social health affects their daily activities and overall satisfaction with life (5).
Each domain of HRQoL can be influenced by an individual's encounters, beliefs, anticipations, and outlooks (42). Interest in HRQoL emerged when the World Health Organization redefined health to encompass not only the absence of disease and infirmity, but also the presence of physical, mental, and social well-being (43).

Various questionnaires can measure HRQoL. They are designed to determine the self-reported health status of individuals across each domain of health separately. Questionnaires are classified as generic and disease-specific and vary in length and complexity. Each focus on specific domains and uses a unique scoring system. Nonetheless, all these questionnaires focus on patients' perceptions and offer valuable information about the impact of different interventions on an individual's health-related Quality of Life (42).

Chronic diseases significantly impact the physical, mental, and social health of individuals, leading to a lower quality of life. Similarly, the quality of life is negatively affected in patients with type 2 diabetes and even more so in those with poorly controlled type 2 diabetes (7).

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A sedentary and unhealthy lifestyle significantly contributes to the development of Type 2 diabetes. Treating type 2 diabetes should involve a comprehensive approach that incorporates both lifestyle modifications and medication. Self-management techniques, such as having healthier dietary choices, increasing physical activity, and aiming for weight reduction can also improve blood sugar control and reduce the reliance on medication and its associated side effects (13,14). However, inadequate self-management can lead to disease progression and the need for medication. There are various medications that can be used to regulate blood sugar levels. The most commonly used oral antidiabetic drugs include metformin, dipeptidyl-peptide 4 inhibitors (DPP-4), Sodium-glucose cotransporter 2 inhibitors (SGLT-2), sulfonylureas, and thiazolidinediones. Injected drugs include GLP-1 and GLP-1/GIP Receptor Agonists and insulin. Metformin is often the first-line therapy for managing type 2 diabetes because of its widespread availability, affordability, ease of administration, favorable tolerability, and proven efficacy. However, over recent years, GLP-1 and SGLT inhibitors have also been widely used as monotherapy or in combination with metformin, especially in individuals who have comorbidities like heart failure, kidney damage, or even obesity. If monotherapy proves insufficient, combination therapy of oral antidiabetic drugs or, finally, insulin injections may be required (36,44).

In recent decades, technology has undergone considerable development. Computers play a crucial role in various aspects of our daily routines, such as shopping, travel, and healthcare. In medicine, technology was predominantly used for diagnostic and treatment procedures, enhancing the quality of clinical care. Additionally, patient records have been transitioned to electronic medical records, simplifying clinical practice (45).

According to NIH, telemedicine is defined as the use of communication technologies to improve health care from a distance. There is widespread global interest in telemedicine because of its potential to enhance the convenience, quality, safety, and cost-effectiveness of healthcare systems through teleconsultations, remote patient monitoring, and telehomecare (46).

Digital interventions can involve wearable devices and various digital platforms, such as computer-based interventions, short message services, and videoconferencing (45). Wearable devices like smartwatches and physical activity trackers can support behavior

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change by allowing users to monitor their own health data (36). Furthermore, most digital interventions have several common features, including offering educational information to enhance patients' understanding of their own disease. In addition, personalized feedback, progress monitoring, and adherence support are key features of the interventions that lead to a significant improvement in the self-management of chronic diseases. Personalized coaching is also a crucial component of online interventions, often provided through virtual assistants and online consultations between patients and healthcare providers (22,47,48).

Research has demonstrated the impact of these interventions on managing various chronic conditions including type 2 diabetes (22). Evidence has shown that use of digital interventions is associated with optimal glycemic outcomes (49,50).

In recent years, there has been a growing trend towards using smartphone applications as a tool for the self-management of chronic diseases. Mobile phones are widely accessible and user-friendly compared to computers, which could potentially lead to significant improvements in disease self-management (51).

As seen in the literature, smartphone-based interventions have the potential to empower patients, resulting in improved clinical and metabolical outcomes. In recent years, numerous studies have also evaluated the impact of these interventions on HRQoL, except for clinical outcomes. However, there is still insufficient evidence into the connection between improvements in clinical outcomes and psychosocial outcomes as well as into the impact of the interventions on the HRQoL.

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4. Methodology

A systematic review (and meta-analysis) was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines and the Cochrane Handbook.

Screening of studies for eligibility, data extraction, risk of bias assessment, and assessment of quality of evidence were performed by the main author.

4.1. Searching and Selection Processes

The research strategy was performed using the PICO model (Population: adults with type 2 diabetes, Intervention: smartphone applications for diabetes self-management, Comparator: conventional interventions without any smartphone health program(s) Outcome: health-related Quality of life.

An electronic database (PubMed) was systematically searched for studies published from 01 January 2014 until 23 February 2024. The search algorithm is shown in the Supplementary Materials. A supplementary search for relevant studies was conducted from the reference list of the screened manuscripts.

4.2. Inclusion criteria

The eligibility of retrieved records was screened according to the following criteria: 1) adults (>18y) with type 2 diabetes 2) intervention focused on smartphone applications as a major component 3) lifestyle modification (e.g., physical activity and healthy diet) was provided via apps; 4) primary or secondary outcome related to health-related quality of life, measured with widely-used questionnaires available 5)Randomized Controlled Trials. No restrictions were applied on language, sample size, follow-up duration, setting or comparator.

4.3. Exclusion criteria

Studies were excluded if : 1) focused on prediabetes, type 1 diabetes, gestational diabetes ,2)recruited both people at high risk and diagnosed with type 2 diabetes mellitus, and did not show the results separately for each group; 3)included participants with severe comorbidities and disability 3) did not include a smartphone as part of the intervention 4)outcome as disease-specific quality of life 4)were Protocols and ongoing RCTs; 5) published before 2014**;**

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4.4. Risk of bias assessment

For the eligible RCT, Risk of Bias 2 (RoB2) Cochrane library tool to assess their risk of bias (52) was used. The main author performed the risk of bias assessment in all eligible papers.

4.5. Data Extraction Strategy

Data were extracted from the eligible studies as follows: (a) first author surname and year of publication, (b) Number of participants, mean age of participants when available (d) Characteristics of the intervention (e) Characteristics of comparator (f) Outcomes (primary, secondary). The main author extracted data from all eligible papers. The extracted data can be found in the results.

4.6. Data Synthesis and Presentation

A thorough review of the literature was conducted by independently assessing the titles and abstracts of identified citations. Articles generated by automation tools and those deemed clearly irrelevant were excluded. Subsequently, the full text of the remaining articles was carefully reviewed to determine their eligibility for inclusion. Additionally, the reference lists of included studies and relevant review papers were examined to ensure comprehensive coverage and identify any potentially missed articles.

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5. Results

5.1. Results of Searching and Selection Processes

The searching procedure retrieved 479 publications, of which 395 were removed because they were recorded before 2014 and because they were marked as ineligible by automation tools. From the remaining 84 records that were screened, 51 publications were excluded because they were duplicated, irrelevant to our research question and research criteria, or were not randomized controlled trials. From the remaining 33 publications that were completely assessed for eligibility, 22 were excluded as non-eligible, and 4 were excluded because they were not randomized controlled trials. Finally, 7 publications were eligible and included in the current systematic review. The screening of the reference lists of these 7 eligible papers, revealed no more eligible publications. 6 more publications were also found and selected through research procedure. 10 studies were included in the systematic review of the whole research procedure.

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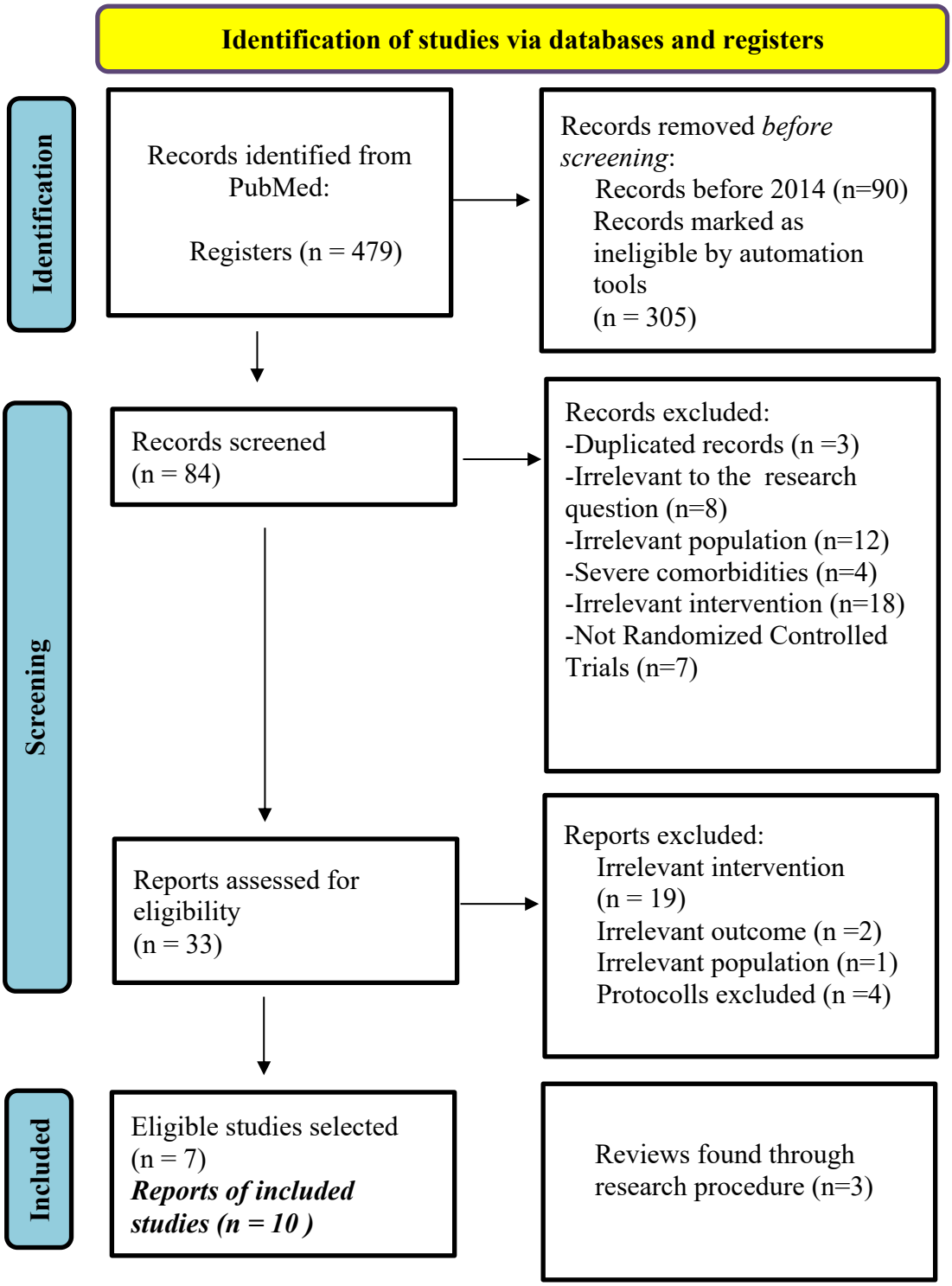
Figure 1: Prisma Flow Diagram



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5.2. Characteristics of Included Studies

All of the included studies in the current systematic review were RCTs. All studies referred to Type 2 diabetes patients. One of the included studies also included type 1 diabetes patients but the outcome was assessed separately for these patients. Overall, the included studies in the current systematic review involved **1721 type 2 diabetes patients and 108 type 1 diabetes patients.**

All studies used widely used questionnaires to assess health-related quality of life. 2 RCTs used WHO-QOL-Bref-questionnaires, 4 RCTs used EQ-5D-5L and the other RCTs used RAND-36, AQoL-8D Scale, WHO-5-Well Being Index and Icelandic health-related Quality of life (53–58).

The data of all eligible studies were extracted as mentioned in the Methodology part.

Table 1. Data Extraction

First author-publication year	Participants characteristics	Intervention	Control group	Outcomes	Results
Hummel, 2022	N=166 (108 men, 58 women) Overall mean age: 60,2 (SD 11,4) Participants from a geographically diverse network of primary care centers and one specialty clinic, encompassing populations of varying socioeconomic background **Intervention group:** Baseline: n= 93 3 months : n=72 6 months: n=58 **Control group:** Baseline**:** n=88 3 months: n=76	Smartphone app DiaCert 3-month intervention The application was used to improve physical activity of the patients. Daily step-tracking, individual goal setting, progress monitoring, positive feedback messages, and the possibility to adjust goals individually	Routine care	Primary outcome: physical activity Secondary outcomes: **Health related Quality of Life (RAND-36),** HbA1c, body weight, serum lipids, blood pressure Follow up at 3 and 6 months	Significant improvement in three of the health concept scores: role limitations due to physical health problems, role limitations due to emotional problems and emotional well- being after 3 months of intervention **No significant difference after 6 months** Within-group differences, favoring the intervention group

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	6 months: n=71				
Heald, 2023	Intervention group: n= 115 Control group: n= 82 Mean age of the active treatment group: 61,1 Mean age of the control group: 65,2	6 month-intervention. Digital health planning and app access for diabetes self-management included daily lifestyle prompts, educational content and self-management tools. Trials conducted in primary care	Standard diabetes care from their General Practitioner	Primary Outcome: Health outcomes (HbA1c, BMI) Secondary and other outcomes: **Health related Quality of life (EQ-5D-5L),** Patient Engagement Follow-up at 6 months	Improvement in their self-measured QoL score in the control group. No information about statistical significance of the result. EQ-VAS score increasing by 8.2% on average in the intervention group. For those patients in the control group, their EQ-VAS score changed on average by - 2.8% indicating a reduction in patients' self-measured standard of their health. Within-group differences favoring the intervention group.
Gong, 2020	N=187 Mean age of the participants: 55-58 Mean HbA1c: 7,3% **Intervention group n=93** **6 months:** Clinical data: n=80 Psycho-behavioral data: n=67 **12 months:** Clinical data: n=79 Psycho-behavioral data: n=66 Patients in the intervention group were slightly younger (*P*=.04) and had lower depression scores (*P*=.004) at baseline. Also the people in the intervention arm were less likely to have been Admitted to	MDC Application 12 month-intervention The program includes: the MDC app, printed user guide, the MDC website, an optional blood glucose meter with Bluetooth capability for blood glucose monitoring and a small number of brief, structured interactions with a program coordinator, primarily for technical assistance. MDC delivers personalized support, monitoring, and	Usual care	Primary outcomes: Health related Quality of life **(AQoL-8D),** HbA1c Follow up at 6 months and 12 months.	Statistically significant between-arm difference at 12 months in the change in HRQOL. (components of physical health and mental health)

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	hospital in the past 6 months. **Control group N=94** **6 months:** Clinical data : n=84 Psycho-behavioral data: n=77 **12 months:** Clinical data: n=83 Psycho-behavioral data: n=79	motivational coaching via an embodied conversational agent, *Laura*, through a series of modules covering blood glucose monitoring, healthy eating, physical activity, medication taking, and foot care.			
Sunil Kumar, 2019	Intervention group: n= 150 Mean age: 55,73±10,45 years Control group: n= 150 Mean age: 73,56±11,27 years Age, family status, Education level – baseline imbalance, favor to intervention group Participants were attending the outpatient department of a tertiary care hospital in southern India.	Diabetes basic care plus DIAGURU mobile application, that aimed to optimize diabetes self-management (blood glucose self-monitoring, food intake, advise, goal tracking) 6-month intervention	Usual diabetes care	Primary outcome: Health related Quality of Life (WHO QOL BREF questionnaire)	Statistically significant improvement in scores of quality of life in all the domains in patients in the intervention group Within-group differences, favoring the intervention group.

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Kim, 2019	**Intervention group:** *n* = 90 Mean age: 60.0 ± 8.4 years Diabetes duration: 13,2 ± 8 years HbA1c: 7,7% **Control group:** *n* = 82 Mean age: 56,7±9,1 year Diabetes duration: 12,5±7,3 years HbA1c: 7,8% **the mDiabetes group was older than that of the pLogbook group (P = 0.027)** Participants were classified into four groups, based on antidiabetic treatment (A: lifestyle, B: oral antidiabetic medication with low risk of hypoglycemia, C: oral antidiabetic medication with risk of hypoglycemia, D: insulin users) Participants were recruited from three teaching hospitals.	***Intervention with mDiabetes application.*** The 24- week intervention included blood glucose self-monitoring, food intake, setting specific goals, receiving feedback messages, activity tracker, bulletin board that allowed users to communicate with each other.	pLogbook group Standard diabetes care and glucose monitoring using a logbook.	Primary outcome: HbA1c difference between 2 groups after 24 weeks Secondary outcomes: HbA1c difference after 12 weeks, Health related quality of life using **WHOQOL Bref**	Statistically significant increase of quality of overall health (1 component) in the mDiabetes group compared to the baseline. Also graphic showed a significant increase in between-group differences. Within-group percentage of change available only for mDiabetes group: 15%
Boels	**Intervention group:** *n* = 114 Mean age: 58.6±8.2 years Diabetes duration: 14,9 ±8.3 years Treatment in secondary care: 63,5%	6-month intervention. Diabetes self-management education and support delivered with a smartphone app and text messages, focused on dietary habits, physical activity, glucose control, prevention of	Standard diabetes care	Primary outcome: HbA1c at 6 months Secondary outcomes: **Health Related Quality of Life (EQ-5D5L Questionnaire, SF-36)** HbA1c <=7% without any hypoglycemic	No statistically significant differences The study population had a higher HbA1c level and was less satisfied with the diabetes treatment. The study population had been using insulin for many years, but still fails to reach good glycemic control and is

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	Control group: *n* = 115 Mean age: 59.7±6.8 years Diabetes duration: 14,3 years Treatment in secondary care: 58,3% **>50% in both groups have microvascular complications and all the patients are on insulin –therapy. HbA1c baseline for both groups > 8 %**	hypoglycemia, using behavioral triggers. Intervention was customized to participant's preferences, the patients could choose the topics that they would work on, the frequency of the text messages they would receive and the duration of the intervention (whether they would prolong the intervention with another 3 months after the first 6 months)		event, BMI, glycemic variability, dietary habits	less satisfied with the treatment. Intervention was designed for patients in primary care, but the majority was from secondary care. Within-group differences favoring the intervention group

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Hilmarsdottir, 2021	N=37 **Intervention group:** *n* = 15 **Control group:** *n* = 15 Mean age: 51.2 ± 10.6 years (25-70) Participants recruited from hospital-based endocrinology clinic 30 participants completed the trial (19% dropout) Participants who dropped out were older (P=0,04) and had more diagnosed diseases (P=0,02) and higher triglycerides. (P<0,001)	6-month smartphone-based intervention provided diabetes self-management education and support, focusing on dietary habits, physical activity, glucose control, and hypoglycemia prevention. Participants customized their intervention, choosing topics, message frequency, and duration. The digital lifestyle program aimed to enhance healthy behaviors through goal setting, self-monitoring, and tasks completion in nutrition, physical activity, and stress management. The app facilitated registration of tasks and competition among users. Main categories included nutrition, physical activity, stress management, and clinic monitoring	Standard care	HbA1c, diabetes distress, anxiety and depression, **Health related Quality of Life (Icelandic Quality of life Scale)**	No significant differences within and between the groups Baseline mean score of HrQol > 48 – (50 highest score) Within-group differences favoring the intervention group
Ruissen, 2023	**Intervention group:** Type 1 diabetes, n=52 Mean age: 44.6±13.9 years **Type 2 diabetes: n=50**	POWER2DM 37-week intervention The system comprises a web-based shared decision-making	Usual diabetes care	Primary outcome: HbA1c Secondary outcomes: **QoL (WHO-5 Well-Being Index)**, diabetes self-	No significant differences. System usage by participants with type 2 diabetes was significantly lower than that by participants with type 1 diabetes. No within-group difference

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	Mean age: 57.8±8.6 Duration of diabetes: 11,9 ± 7,6 years **Control group:** Type 1 diabetes: n=48 Mean age: 45.3±11.5 **Type 2 diabetes**: **n=54** Mean age: 56.2±7.2 Duration of diabetes: 12,1 ± 7,6 years 36.3% of the participants were female Almost 50% of the type 2 diabetes patients in both groups were on insulin-therapy	dashboard (SDMD) used during clinical consultations and a self-management support system (SMSS) available as a mobile app and webpage. SDMD visualizes medical, behavioral, and psychological data, aiding individuals and healthcare professionals in understanding and addressing potential barriers to self-management. SMSS enables goal setting, progress tracking, and support provision. Participants used a blinded continuous glucose monitor for two weeks at the study's start and end, with clinical data collected at baseline and throughout the study to guide personalized treatment goals.		management, glycemic profiles obtained using continuous glucose monitoring devices, hypoglycemia awareness	

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Christensen, 2022	**Intervention group:** *n* = 75 **Control group:** *n* = 53 Mean age of patients:56 years Mean HbA1c: 7,4%	6-month intervention with LIVA 2.0 app, setting goals for diet, exercise, sleep, etc., based on individual needs. Using LIVA 2.0, patients recorded daily goals and communicated with their coach. Weekly coaching, adjusted biweekly after three months, aimed to maintain motivation. Meetings were rescheduled if patients were unwell, ensuring most sessions were completed. Behavior-change techniques included goal setting, action planning, and feedback on performance	Diabetes program in municipalities	Primary outcome: mean body weight Secondary outcome: Quality of life **(EQ-5D-5L)** HbA1c BMI and hip waist ratio, lipids, systolic and diastolic blood pressure, exercise, and diet habits Baseline and 6 months	No statistically significant differences in changes from baseline to six months EQ-5D-5L Within-group differences, favoring the intervention group. Loss to follow up about 25% of the participants.
Agarwal, 2019	**Intervention group:** n= 110 Mean age: 51,5 ±10,6 Baseline mean HbA1c: 8,89% **Control group:** n= 113 Mean age: 52,1 ±10,7 Baseline mean HbA1c: 9,03% Poorly controlled diabetes No baseline differences between participants characteristics	6-month smartphone-based intervention The app was preloaded onto a Samsung smartphone with internet connectivity through cellular data and Wi-Fi. Patients in the intervention group inputted T2DM management details like baseline health,	Wait-list control Group. Standard diabetes care for 3 months and then received the intervention for 3 months	Primary outcome: HbA1c in 3 months Secondary outcomes: Problem Areas in Diabetes Summary of Diabetes Self-Care Activities **Health related Quality of Life (Euro-Qol-5D)** in 3 months	No significant difference No intervention effect was found on secondary outcomes measuring diabetes self-efficacy, quality of life, and health care utilization behaviors. **Low usage of the app overall, with almost half of intervention group users having minimal engagement with the app**. Many app features were poorly utilized, including diet and exercise tracking.

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	Participants were attending Diabetes Education Programm	daily blood glucose, exercise, and food intake. Using this data, the app sent real-time personalized messages targeting motivation, behavior, and education. It aligned with behavior change models and facilitated data transfer to clinicians through Smart Visit reports for diabetes management overview.			Within-group differences favoring the intervention group

5.3. Risk of Bias Assessment Outcomes

For the randomization process, eight of the eligible RCTs displayed a low risk of bias and two of them had some concerns; for intervention assignment, four RCTs demonstrated some concerns, four demonstrated a low risk of bias, and the remaining two had a high risk of bias. For missing data, two RCTs showed a high risk of bias and the rest demonstrated a low risk of bias, while for the measurement of outcome eight of the eligible RCTs displayed some concerns and the other 2 high risk of bias. For the reported results three RCTs displayed a high risk of bias, three a low risk of bias and the other four demonstrated some concerns.

The risk of bias outcomes can be found in Table 1 , while a summary of the risk of bias can be found in Figure 1 .

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Table 1. Risk of bias assessment outcomes. Key: +: low (green color), ?: some concerns (yellow color), −: high (red color), N: not applicable (blue color).

Unique ID	Study ID	Experimental	Comparator	Outcome	Weight	D1	D2	D3	D4	D5
1	36528609	DiaCert	usual care	Health Related Quality of	1	+	+	+	!	+
2	33151154	MDC Program	Routie diabetes self care	Health related Quality of	1	+	+	+	-	+
3	30377185	mDiabetes app	pLogbook	Health related Quality of	1	+	!	+	!	!
4	32680441	Sidekick Health app	Standard care	Health-related Quality of	1	+	+	-	!	!
5	36014930	LIDA app	standard diabetes care	Health related Quality of	1	+	-	+	!	-
6	37775611	e-health system	usual care group	health related quality of	1	+	+	+	!	-
7	32755831	mobile application DIAGUR	usual care	health related quality of	1	!	!	+	!	!
8	30632972	Immediate-Treatment-Gro	Wait-List-Control	Health Related Quality of	1	+	!	-	-	-
9	37079268	digital health planning	usual care	Health related quality of	1	!	-	+	!	!
10	BMJDR-2019-000981	combined self-managemen	usual care	Health related quality of	1	+	!	+	!	+

+ Low risk

! Some concerns

- High risk

D1 Randomisation process

D2 Deviations from the intended interventions

D3 Missing outcome data

D4 Measurement of the outcome

D5 Selection of the reported result

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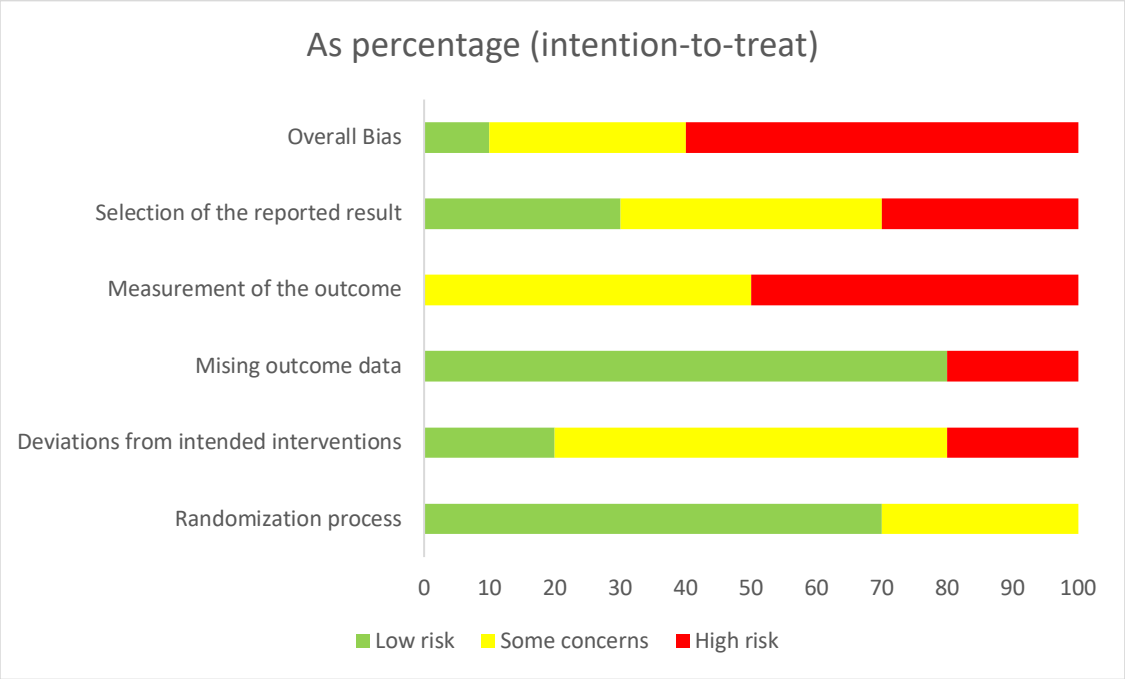
Figure 1. Summary of risk of bias



5.4. Narrative Data Synthesis Results

To adequately synthesize the evidence, a table and a heat-map was created (Table 3). Most of the eligible studies included in the current systematic review examined patients with type 2 diabetes; only one study included patients with type 1 diabetes as well; the results were separated.

Table 3 . Narrative data synthesis outcomes and heat-map for the eligible studies

Hummel, 2022	Overall mean age: 60,2 (SD 11,4) No baseline imbalance between participants characteristics	Smartphone application that was used to improve physical activity of the patients. 3-month intervention	Significant improvement in three of the health concept scores; role limitations due to physical health problems, role limitations due to emotional problems and emotional well- being after 3 months of intervention No significant difference after 6 months

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			Within-group difference in 3 months **Intervention group/ Control group** Physical functioning= 0,85% / -3,25% Social functioning: 7,2% / -10,6% Role physical: 8,7% / -10,6% Role emotional: 9% / -4,38% Emotional well-being: 5% / -,2,23% Energy/fatigue: 7,5% / 1,84% Pain: No change observed / 1,63% General health: 2,8% / 4,8% Health change: 10,3% / 1,94%
Heald, 2023	Intervention group: n= 115 Control group: n= 82 Mean age of the active treatment group : 61,1 Mean age of the control group: 65,2	6 month-intervention. Digital health planning and app access for diabetes self-management that included daily lifestyle prompts, educational content and self-management tools. Control group received only standard diabetes care from their GP *HRQOL was not a primary outcome*	Improvement in their self-measured QoL score in the active intervention group , whereas EQ-VAS score in the control group changed on average by - 2.8% indicating a reduction in patients' self-measured standard of their health No information about statistical significance of the results. Within-group percentage of change in 6 months: Intervention group: 8,2% Control group: -2.8%
Gong, 2020	Intervention group: n=93 Control group: n=94 Mean age of the participants: 55-58	12-month intervention that offers personalized diabetes management support through mobile app that integrates behavior change theories and is personalized based on clinical targets and user responses, blood glucose self-monitoring, activity tracker. Control group received usual diabetes care.	Compared with baseline, the intervention resulted in an increase in the score of the physical health and mental health. There were significant between-arm differences in the mean change of mental health subscore at 6 months as well as the mean change of physical health subscore at 12 months
Sunil Kumar, 2019	Intervention group: n=150 Control group: n= 150 Mean age of the participants in the	6-month intervention. Additionally to the diabetes basic care, patients allocated to the intervention arm were given an android Smartphone application named 'Diaguru', that aimed to optimize	Statistically significant improvement in scores of quality of life in all the domains in patients in the intervention group, compared with that of patients in the control group.

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	intervention group was 55.73 (SD 10.45) Mean age of the participants in the control group : 73.56 (SD 11.27)	diabetes self-management (blood glucose self monitoring, food intake, advise, goal tracking)	Within-group percentage of change: Intervention group: Domain 1: 12,5% Domain 2: 26% Domain 3: 23,2% Domain 4: 12,5 % Control group: Domain 1: 0% Domain 2: 0% Domain 3: -6% Domain 4: -6 %
Kim, 2019	Intervention: *n* = 90 Mean age: 60.0 ± 8.4 Control group: *n* = 82 Mean age: 56.7 ± 9.1 Mean age of the participants in the intervention group older than control group (p= 0.027)	24-week intervention that included blood glucose self-monitoring, food intake, setting specific goals, receiving feedback messages, activity tracker, bulletin board that allowed users to communicate with each other	The patients in the mDiabetes group were more satisfied with their overall health after 24 weeks of intervention compared with the baseline. Between group differences were also statistically significant. Therefore, mDiabetes was well tolerated and possibly increased the quality of life in some aspects. Within-group percentage of change for mDiabetes group: 15%
Boels, 2019	Intervention: *n* = 114 Control group: *n* = 115 Mean age of the participants in the intervention group: 58.6±8.2	6-month intervention Diabetes self-management education and support delivered with a smartphone app and text messages, focused on dietary habits, physical activity, glucose control, prevention of hypoglycemia, using behavioral triggers. Intervention was customized	No statistically significant difference on the health-related quality of life. The study population had a higher HbA1c level and was less satisfied with the diabetes treatment. Study population that had been using insulin for many years, but still fails to reach good glycemic control and is less satisfied with the treatment.

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	Control group: 59.7±6.8	to participant's preferences (choice of topics, frequency, duration of intervention and whether they would prolong it for another 3 or 6 months)	Percentage of change: **Intervention group: 1,33% (95%CI)** Control group: -2,56% (95%CI)
Hilmarssdottir, 2021	Intervention: *n* = 15 Control group: *n* = 15 Mean age of the participants: 51.2 ± 10.6	6-month based intervention that provided diabetes self-management education and support, focusing on dietary habits, physical activity, glucose control, and hypoglycemia prevention. Participants customized their intervention, choosing topics, message frequency, and duration. The digital lifestyle program aimed to enhance healthy behaviors through goal setting, self-monitoring, and tasks completion in nutrition, physical activity, and stress management. The app facilitated registration of tasks and competition among users. Main categories included nutrition, physical activity, stress management, and clinic monitoring	No significant difference. Baseline mean HrQoL. = 48 (Max score 50) HRQoL-score and depression were unchanged. Within-group percentage of change: **Intervention group: 0,21%** Control group: -0,86%
Ruissen, 2023	Patients with Type 1 and 2 Diabetes **Intervention:** Type 1 diabetes, n=52 Mean age : 44.6±13.9 **Type 2 diabetes:** n=50 Mean age: 57.8±8.6	37-week intervention that includes a web-based shared decision-making dashboard (SDMD) used during clinical consultations and a self-management support system (SMSS) available as a mobile app and webpage. SDMD visualizes medical, behavioral, and psychological data, aiding individuals and healthcare professionals in understanding and addressing potential barriers to self-management. SMSS enables goal setting,	Overall scores for QoL (WHO-5) did not change in either the POWER2DM or the usual care group Overall, system usage by participants with type 2 diabetes was significantly lower than that by participants with type 1 diabetes No percentage of change within the groups

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	Control group: Type 1 diabetes: n=48 Mean age: 45.3±11.5 **Type 2 diabetes**: n=54 Mean age: 56.2±7.2	progress tracking, and support provision. Participants used a blinded continuous glucose monitor for two weeks at the study's start and end, with clinical data collected at baseline and throughout the study to guide personalized treatment goals	
Christensen, 2022	Intervention: *n* = 75 Control group: *n* = 53 Mean age of patients:56 years	6-month intervention with LIVA 2.0 app, setting goals for diet, exercise, sleep, etc., based on individual needs. Using LIVA 2.0, patients recorded daily goals and communicated with their coach. Weekly coaching, adjusted biweekly after three months, aimed to maintain motivation. Meetings were rescheduled if patients were unwell, ensuring most sessions were completed. Behavior change techniques included goal setting, action planning, and feedback on performance	Intervention effect on Quality of life and mental well-being was not seen. Magnitude/percentage of change within-groups: **Intervention group: 6,17% (95%CI; 2,47-6,17%)** Control group: 1,3% (95%CI; -3,9-5,19%)
Agarwal, 2019	Mean age of the participants: 51-52	6-month intervention. The app was preloaded onto a Samsung smartphone with internet connectivity through cellular data and Wi-Fi. Patients in the intervention group inputted T2DM management details like baseline health, daily	There was no statistical significant difference in patient-reported general health status (measured by EQ-5D) at 3 months between intervention arms. EQ5D VAS: ITG: Baseline (Mean+SD): 64,6 +_ 21,6

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		blood glucose, exercise, and food intake. Using this data, the app sent real-time personalized messages targeting motivation, behavior, and education. It aligned with behavior change models and facilitated data transfer to clinicians through Smart Visit reports for diabetes management overview. The control group received standard diabetes care for 3 months and then received the intervention for 3 months.	3 months: 70,5 +- 20,8 **Percent of change in mean values: 9.14%** **Percent of change in SD: -3,7%** WLC: Baseline: 67,2 +-16,8 3 months: 68,3 +- 18,6 Percent of change in mean values: 1.64% Percent of change in SD: 10,7% Overall, there was low app utilization among ITG participants with a mean number of log-in days of 42.4 (SD 52.1) over 26 weeks, of which 46.4% (51/110) of participants used the app for 10 days or less.

***e**.g. green color represents a positive effect or association (significant between-group difference) ; orange color represents no association*

All included RCTs included participants with similar mean ages. Five of the included studies demonstrated a significant improvement in health-related quality of life following the digital intervention, while the remaining studies showed no significant difference. One of the RCTs included a 3-month intervention that aimed to improve physical activity and has shown a significant improvement in three of the health concept scores – role limitations to physical health problems, role limitations due to emotional problems and emotional well-being. These results did not remain after 6 months.
Another RCT showed that a smartphone application that was used for 12 months and offered personalized diabetes management through blood glucose monitoring, activity tracker, behavior change theories, and personalized target resulted in a statistically significant between-arm difference in the mean change in HRQoL at 12 months. A statistically significant improvement in mental health subscore was already seen in 6 months.

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Similar to another 6-month digital intervention that offered personalized diabetes management through blood glucose monitoring, individualized goals showed a significant improvement in the patient's overall health.

Another RCT showed that a similar six-month intervention significantly improved health-related quality of life. This specific intervention might have led to this result because of an imbalance in the participant characteristics that favor the intervention group.

Another RCT in the UK showed that a personalized care plan with an app that focused on diabetes education, self-management and daily lifestyle prompts demonstrated an improvement in the QoL-score of the patients after 6 months, whereas for the control group, the QoL decreased. There was no information about the statistical significance of this result.

Over 50% of the participants of an RCT had microvascular complications, and all the patients of this RCT were on insulin–therapy with a diabetes duration of over 15 years. This RCT showed no significant improvement in the health-related quality of life.

Two of the RCTs that showed no significant improvement of the HRQOL showed an overall low usage of the application.

It was also noticed that an RCT in Iceland was about a smartphone app that included management of nutrition, physical activity, stress, and clinic monitoring in order to help to improve HRQOL on patients with type 2 diabetes. This intervention showed no significant improvement in the HRQOL. The baseline mean HRQOL was also high, and the number of participants was small.

Based on the eligible papers reviewed, it is evident that the intervention had a positive effect on the patients. The studies consistently demonstrated within-group differences in the intervention groups, indicating improvements in the health-related quality of life. Conversely, the control groups either showed negative changes or less change compared to the intervention groups. This pattern suggests that the intervention was effective in producing favorable outcomes for the patients compared to standard or no treatment. Overall, the findings underscore the importance and effectiveness of the interventions studied in improving patient outcomes and healthcare delivery.

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6. Discussion

6.1. Summary of Main Findings

The aim of the current systematic review was to examine the effect of smartphone applications on improving health-related quality of life in patients with type 2 diabetes. Overall, we cannot make robust conclusions based on the available evidence. The narrative data synthesis for controlled trials showed no clear results. Half of the RCTs favored the intervention, and the other half showed no significant difference or improvement. Although statistically significant between-group differences were not generally found, it was generally demonstrated that there were within-group differences in the intervention group, which were not observed in the control group.

6.2. Completeness and Applicability of Evidence

Although an intervention effect was not found in all the eligible studies, a within-group difference in the outcome was observed in the intervention group across all studies. The self-management aspects of the interventions likely caused the within-group differences in our outcome. All included studies incorporated interventions with education and goal setting, and some (59–63) provided personalized coaching and feedback. These interventions likely encouraged self-management by improving knowledge and helping participants develop awareness of behavior modification techniques. This could have led to improved self-care activities, self-efficacy, and ultimately a better Health-related Quality of Life for the intervention group. However, according to Polonsky (64), the impact of feedback can be influenced by the level of participant comprehension, its importance, and whether the recipient acknowledged it. That could be associated with the mixed results on the intervention effect in our review.

This review showed that the magnitude of improvement in HRQoL was also associated with the overall utilization of the smartphone application implemented as the intervention. One of the RCTs(60) demonstrated a dose-response relationship between the intervention’s usage and its effect. Similarly, other studies with generally low usage of the app during the intervention period did not have any impact on the outcome(62,65,66). A decreased adherence to the intervention over time was also seen. As seen in the literature, Hartin’s study(67) on Alzheimer disease's prevention and Goyal’s (68) study on type 1 diabetes' management also emphasized the significance of user's engagement in maximizing the

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effectiveness of a digital intervention for chronic disease management. These findings prove the necessity of improving future interventions' characteristics, emphasizing meeting patients' needs and promoting sustained engagement in the intervention. Further research is needed to evaluate the factors that could contribute in this result.

The impact of digital and smartphone-based interventions on the glycemic control of type 2 diabetes patients is already examined in reviews in the literature. This review found that the intervention may have been less effective on patients with poorly controlled diabetes and diabetes complications. This was also observed in the literature (69) and could be associated with the lower motivation and reduced self-efficacy of the patients, as self-efficacy is closely connected to HRQoL (70). Further research is needed to clarify the association between patients with poorly controlled diabetes and their HRQoL. It should be examined how changes in HRqOL through a more effective intervention could be reached and whether this could influence patients' ability to manage their diabetes and achieve better glycemic control.

Previous studies have examined the impact of computer-based interventions on self-management of chronic diseases (19,71). Literature suggests that participants may favor smartphone-based interventions over computer-based ones (72), leading us to focus on smartphone-based interventions in this review. However, the findings do not provide clear evidence that smartphones are more effective than other forms of digital intervention for chronic disease management. Further research is required to address this gap.

Health-related Quality of life was measured using various reliable and valid scales across the studies. Through the research procedure studies that used infrequently used HRQoL scales or were pilot studies were excluded. (73,74) .

There is not enough evidence in the literature about digital health interventions for chronic diseases in developing countries (75,76). One of the eligible studies was conducted in India and showed a positive intervention effect on the HRQoL. Further studies are needed to confirm generalizability across different socioeconomic factors and development levels.

In line with the research question, other reviews were also found in the bibliography examining smartphone-based interventions on health-related quality of life. Aminuddin et

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al (69) conducted the first meta-analysis examining the effectiveness of smartphone-based interventions on psychosocial outcomes, including health-related quality of life. The findings demonstrated an improvement in HRQoL and various other psychosocial outcomes, such as self-efficacy. Another review (26) found mixed effects on psychological well-being and quality of life. However, the studies included in the review were not primarily focused on the HRQOL, potentially limiting the generalizability of the findings**.**

Encouragingly, research beyond type 2 diabetes also suggests the positive effect of smartphone-based interventions on HRQoL for other chronic conditions, such as heart failure, COPD, osteoarthritis, and chronic pain (77,78). These findings collectively suggest that smartphone interventions are a promising tool for improving HRQoL across chronic diseases.

In contrast to prior research, this systematic review specifically examined the effects of smartphone-based interventions on the health-related quality of life of patients with type 2 diabetes. Although not all of the eligible studies showed an intervention effect, they all reported a change of the outcome in the intervention group that was not seen in the control group. This aligns with the literature (15,79,80) suggesting that small improvements in HRQoL can significantly benefit well-being over time. These results indicate the potential of smartphone interventions to enhance the quality of life in individuals with type 2 diabetes. However, further research, including randomized controlled trials, is needed to strengthen the evidence regarding the specific influence of these interventions on health-related quality of life.

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7. Strengths and Weaknesses of this Work

This systematic review includes some strengths. Firstly, all of the included studies were randomized controlled trials. Secondly, improvement in the HRQoL was observed within the intervention group in all of the eligible studies, showing promise for enhancing psychosocial outcomes and prompting further investigation into the underlying mechanisms. In addition, suitable algorithms, which may have retrieved publications that use alternative keywords to describe the same concept, were used in the search procedure. Risk of bias assessment and data extraction was used; Studies were not excluded based on language.

There were some limitations in this review. First, there was a high overall risk of bias present in most studies. Most studies were unable to blind the participants and outcome assessors. The sample size was small, and a meta-analysis could not be conducted. Furthermore, there were controversial results regarding the intervention effect and the importance of specific intervention components in improving the outcome could not found. Due to the limited duration of the studies included in the review, long-term sustainability of the observed within-group changes was not assessed.

However, the findings displayed potential and may alert the scientific community to undertake further research on the topic, eventually also with interventions with longer follow-up periods.

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8. Conclusions and Future Directions

In conclusion, this systematic review did not find a significant overall effect. However, the findings show that these interventions have the potential to improve the health-related quality of life of individuals with type 2 diabetes.

Further research is needed to understand the effect of smartphone interventions on health-related quality of life for patients with type 2 diabetes mellitus. Randomized controlled trials that focus on the effect of digital self-management interventions on HRQoL should be conducted to improve the quality of evidence and confirm the effectiveness of smartphone-based interventions. Interventions specifically designed to study their effects on HRQoL are also necessary. Enhancing overall well-being and HRQoL is just as important as enhancing clinical outcomes for individuals with type 2 diabetes.

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Appendices

Appendix 1: Supplementary Materials

PubMed Search Algorithm (extracted from Excel)

"17,#12 AND #5 AND #16,,,""(""""smartphone""""[MeSH Terms] OR """"smartphone""""[All Fields] OR """"smartphones""""[All Fields] OR """"smartphone s""""[All Fields] OR (""""mobile applications""""[MeSH Terms] OR (""""mobile""""[All Fields] AND """"applications""""[All Fields]) OR """"mobile applications""""[All Fields] OR (""""smartphone""""[All Fields] AND """"apps""""[All Fields]) OR """"smartphone apps""""[All Fields]) OR ((""""mobile""""[All Fields] OR """"mobiles""""[All Fields]) AND (""""intervention s""""[All Fields] OR """"interventions""""[All Fields] OR """"interventive""""[All Fields] OR """"methods""""[MeSH Terms] OR """"methods""""[All Fields] OR """"intervention""""[All Fields] OR """"interventional""""[All Fields])) OR ((""""mhealth s""""[All Fields] OR """"telemedicine""""[MeSH Terms] OR """"telemedicine""""[All Fields] OR """"mhealth""""[All Fields]) AND (""""intervention s""""[All Fields] OR """"interventions""""[All Fields] OR """"interventive""""[All Fields] OR """"methods""""[MeSH Terms] OR """"methods""""[All Fields] OR """"intervention""""[All Fields] OR """"interventional""""[All Fields])) OR (""""appl plant sci""""[Journal] OR """"apps""""[All Fields]) OR (""""applicabilities""""[All Fields] OR """"applicability""""[All Fields] OR """"application""""[All Fields] OR """"applications""""[All Fields] OR """"applicative""""[All Fields])) AND (""""diabetes mellitus, type 2""""[MeSH Terms] OR """"type 2 diabetes mellitus""""[All Fields] OR """"type 2 diabetes""""[All Fields] OR (""""diabetes mellitus, type 2""""[MeSH Terms] OR """"type 2 diabetes mellitus""""[All Fields] OR """"diabetes mellitus type 2""""[All Fields]) OR ((""""dyn med""""[Journal] OR """"dis mon""""[Journal] OR """"dis manag""""[Journal] OR """"dm""""[All Fields]) AND """"type""""[All Fields] AND """"2""""[All Fields]) OR ((""""dyn med""""[Journal] OR """"dis mon""""[Journal] OR """"dis manag""""[Journal] OR """"dm""""[All Fields]) AND """"type""""[All Fields] AND """"II""""[All Fields])) AND (""""quality of life""""[MeSH Terms] OR (""""quality""""[All Fields] AND """"life""""[All Fields]) OR """"quality of life""""[All Fields] OR (""""health""""[All Fields] AND """"related""""[All Fields] AND

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""""quality""""[All Fields] AND """"life""""[All Fields]) OR """"health related quality of life""""[All Fields] OR (""""hrqols""""[All Fields] OR """"quality of life""""[MeSH Terms] OR (""""quality""""[All Fields] AND """"life""""[All Fields]) OR """"quality of life""""[All Fields] OR """"hrqol""""[All Fields]) OR (""""quality of life""""[MeSH Terms] OR (""""quality""""[All Fields] AND """"life""""[All Fields]) OR """"quality of life""""[All Fields]))"",480,03:36:52"

"16,#13 OR #14 OR #15,,,""""""""quality of life""""[MeSH Terms] OR (""""quality""""[All Fields] AND """"life""""[All Fields]) OR """"quality of life""""[All Fields] OR (""""health""""[All Fields] AND """"related""""[All Fields] AND """"quality""""[All Fields] AND """"life""""[All Fields]) OR """"health related quality of life""""[All Fields] OR (""""hrqols""""[All Fields] OR """"quality of life""""[MeSH Terms] OR (""""quality""""[All Fields] AND """"life""""[All Fields]) OR """"quality of life""""[All Fields] OR """"hrqol""""[All Fields]) OR (""""quality of life""""[MeSH Terms] OR (""""quality""""[All Fields] AND """"life""""[All Fields]) OR """"quality of life""""[All Fields])"","""573,394"",03:36:28"

"15,quality of life,,,""""""""quality of life""""[MeSH Terms] OR (""""quality""""[All Fields] AND """"life""""[All Fields]) OR """"quality of life""""[All Fields]"","""573,251"",03:36:21"

"14,HRQOL,,,""""""""hrqols""""[All Fields] OR """"quality of life""""[MeSH Terms] OR (""""quality""""[All Fields] AND """"life""""[All Fields]) OR """"quality of life""""[All Fields] OR """"hrqol""""[All Fields]"","""573,394"",03:36:15"

"13,Health related quality of life,,,""""""""quality of life""""[MeSH Terms] OR (""""quality""""[All Fields] AND """"life""""[All Fields]) OR """"quality of life""""[All Fields] OR (""""health""""[All Fields] AND """"related""""[All Fields] AND """"quality""""[All Fields] AND """"life""""[All Fields]) OR """"health related quality of life""""[All Fields]"","""573,251"",03:36:12"

"12,#6 OR #7 OR #8 OR #9 OR #10 OR #11,,,""""""""smartphone""""[MeSH Terms] OR """"smartphone""""[All Fields] OR """"smartphones""""[All Fields] OR """"smartphone s""""[All Fields] OR (""""mobile applications""""[MeSH Terms] OR (""""mobile""""[All Fields] AND """"applications""""[All Fields]) OR """"mobile applications""""[All Fields] OR (""""smartphone""""[All Fields] AND """"apps""""[All Fields]) OR """"smartphone apps""""[All Fields]) OR ((""""mobile""""[All Fields] OR """"mobiles""""[All Fields]) AND (""""intervention s""""[All Fields] OR """"interventions""""[All Fields] OR """"interventive""""[All Fields] OR """"methods""""[MeSH Terms] OR

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""""methods""""[All Fields] OR """"intervention""""[All Fields] OR
""""interventional""""[All Fields])) OR (("""""mhealth s""""[All Fields] OR
""""telemedicine""""[MeSH Terms] OR """"telemedicine""""[All Fields] OR
""""mhealth""""[All Fields]) AND ("""""intervention s""""[All Fields] OR
""""interventions""""[All Fields] OR """"interventive""""[All Fields] OR
""""methods""""[MeSH Terms] OR """"methods""""[All Fields] OR
""""intervention""""[All Fields] OR """"interventional""""[All Fields])) OR ("""""appl plant
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"6,SMARTPHONE,,,""""""""smartphone""""[MeSH Terms] OR """"smartphone""""[All Fields] OR """"smartphones""""[All Fields] OR """"smartphone s""""[All Fields]"","""27,321"",03:35:13"

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Appendix 2 :Copyright Statement

Affirmation

The undersigned postgraduate student of the Postgraduate Program "LIFESTYLE MEDICINE" of the University of Thessaly

I declare responsibly that I accept the following terms concerning:

(a) the copyright of my Master's Thesis entitled " **The effect of smartphone-based-interventions on health-related quality of life of adults with type 2 diabetes mellitus-systematic review** "

(b) the management of the research data I will collect in the course of its elaboration:

1. The copyright of the resulting volume of the master's thesis will belong to me. I will follow the instructions for writing, printing and depositing copies of the dissertation in the relevant repositories (in printed and/or electronic form).
2. The management of the dissertation data belongs jointly to me and the Director of Studies/Main Supervisor.
3. Any scientific publication or announcement (posted or oral), or reference derived from the material/data of this work will be made with authors myself, the main supervisor and/or other researchers (such as a member of the three-member advisory committee), depending on their contribution to the research or the writing of the research paper(s).
4. The order of names in scientific publications or scientific announcements will be decided jointly by me and the main supervisor (DOS) of the project before it begins. This decision will be certified in writing between myself and the main supervisor.

Finally, I declare that I am aware of the rules on plagiarism and intellectual property and that I will strictly follow them throughout my studies, I will attend to the educational obligations arising from this MSc, as well as will attend the publication procedures that will arise after the completion of my studies.

28.05.2024

Marietta Yioukka

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