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Effects of Telehomecare Interventions on the Management and Complications of Diabetes Mellitus: Protocol for a Systematic Review and Meta-Analysis

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ABSTRACT

Background: Diabetes is one of the most serious health challenges of the 21st century. The number of adults with diabetes has roughly tripled in the last 20 years. The increased burden of chronic diseases and scarce health resources compel healthcare systems to make modern patients more self-sufficient by requiring them to play a more active part in the treatment and management of their disease. Tele-home-care is a method of distance intervention through the transmission of electronic data for follow-up, education, prevention, clinical decision-making, and treatment modulation that has a high potential for the population with diabetes. Previous studies have not systematically evaluated the effects of different features of long-distance caregiving on diabetes at different stages of disease severity.

Objectives: The present study describes a protocol for a systematic review and meta-analysis for summarizing the evidence comparing telehomecare interventions on diabetes management and its complications.

Methods: PubMed, Scopus, ISI Web of Science, Cochrane databases, HTA (Health Technology Assessment), NHS EED (NHS Economic Evaluation Database), DARE (Database of Abstract of Reviews of Effects), Embase, and SID will be searched using medical subject heading (MeSH) keywords. Controlled clinical trials in patients with type 1 diabetes, type 2 diabetes, and gestational diabetes will be selected based on predefined eligibility criteria. The risk of bias in studies will be checked using the JADAD score. The mean difference and its standard deviation will be calculated to be used as effect size. A random-effects meta-analysis was performed to pool the results. Subgroup analysis and meta-regression will be conducted to explore the possible sources of heterogeneity.

Conclusion: The systematic review and meta-analysis provided by the results of a systematic review can be useful to endocrinologists, physicians, public health policymakers, and the general population.

Keywords: Tele-homecare, Diabetes, Systematic review, Meta-analysis

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Introduction

Diabetes is one of the most important health challenges of the 21st century. The number of adults with diabetes has more than tripled in the last 20 years *[1]*. Diabetes is a serious and long-term disease that has a major impact on the lives and well-being of patients, families, and communities around the world *[2]*. It causes life-threatening health complications such as cardiovascular disease, nephropathy, and retinopathy. According to data from the International Diabetes Federation Atlas ninth edition, 463 million adults are currently living with diabetes. Without adequate measures to fight the epidemic, 578 million people will have diabetes by 2030, which will increase to 700 million by 2045. Diabetes has the potential to cause numerous debilitating health complications that can affect the quality of life and lead to early death. The complications often result from uncontrolled or poorly managed diabetes *[1]*.

Over the past decades, there has been a rapid advance in science and technology that has altered the course and structures of modern healthcare systems. The burden of chronic diseases is increasing all over the world, compelling modern healthcare systems to pay more attention to the management and care of chronic diseases. As a result, more and more health resources are spent on chronic care. This requires considerable costs while health resources are progressively limited. The increased burden of chronic diseases and the scarce health resources compel healthcare systems to make modern patients more self-sufficient by requiring them to play a more active part in the treatment and management of their disease *[3]*.

Telehomecare (THC) is a remote intervention through the transmission of electronic data for follow-up, training, prevention, clinical decision-making, and treatment settings that has a high potential for the diabetes population. Analysis of the available data suggests that adherence to THC programs allows the active patient to participate in the care process and encourages empowerment *[4]*. Therefore, paying attention to the needs of patients with diabetes, distance care, and other studies have evaluated the effectiveness of a type of remote care intervention in diabetes management compared to routine care and reported an outcome *[5-8]*. To date, systematic and meta-analytical studies to examine all aspects of HTA have not been performed with the original HTA model approach. Therefore, this research provides a more comprehensive study of the management and complications of diabetes mellitus by THC interventions. The present study is a protocol for a systematic review and meta-analysis and is reported based on the PRISMA-P guidelines *[9]*.

Materials and Methods

Study eligibility

Participants

Primary studies conducted on patients with diabetes, including type 1 and 2 diabetes and gestational diabetes will be included.

Intervention

Telehomecare, which includes telemonitoring, use of reminder systems and decision aid, tele-education, and teleconsultation (tele-visit), will be defined as intervention.

Comparisons

Eligible comparators will be usual care.

Outcomes

The following outcomes will be considered in primary studies: control of serum FBS level, control of blood glucose level, control of serum HbA1c level, mortality reduction, the effect of remote care on prevention of kidney failure, prevention of stroke, prevention of amputation, prevention of retinopathy (retinal damage), prevention of diabetic foot, prevention of cardiovascular disease in diabetes patients, prevention of diabetes neuropathy,

reduction of costs, frequency of hospitalization, quality of life improvement.

Types of studies

Eligible studies include randomized controlled trials (RCTs), cluster RCTs, controlled clinical trials (CCTs) or non-randomized cluster trials, and intermittent time series.

Search strategy

The primary studies will be identified through searching PubMed, Google Scholar, Scopus, ISI web of science, CRD Cochrane databases, HTA, EED, DARE, EMBASE, and SID using medical subject heading (MeSH) and non-MeSH keywords. The search strategies used to find the related papers in different databases are provided in Supplementary Table 1. After finalizing the search, two independent reviewers will select the related studies according to eligibility criteria. In the first step, the titles/abstracts will be screened and all potential publications will be selected. The researchers will retrieve full texts in the second step and select the related studies. The final lists of the included studies selected by the two authors will be combined with a clear reason for excluding non-eligible studies. A third reviewer will be consulted in case of disagreement. The reference lists of related articles will also be checked to find other potentially relevant articles. In addition, relevant journals such as the Journal of Telemedicine and Telecare, Telemedicine, and e-health will be hand-searched.

Data collection and analysis

Selection of studies

A summary of the search, selection, and inclusion of studies will be reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines.

Data extraction and management

HD and MD will extract data separately and double-check for final confirmation. A pre-designed form will be used for data extraction. Three types of data will be extracted including participants' characteristics, intervention details, and outcome measures.

1.**Participants' characteristics**

Studies performed in patients with type 1 and 2 diabetes and gestational diabetes will be included. If a study is conducted on patients with chronic diseases in general, but the results of people with diabetes are specifically mentioned, it will also be included. The criteria used for diagnosing diabetes will be recorded in the data collection form. Moreover, mean age, duration of diabetes, presence of other comorbidities and complications at the time of admission, and management method (medication, insulin), if reported, will be recorded in the data collection form.

2. Intervention details

Telehomecare, in addition to telemonitoring, use of reminder systems and decision aid; teleeducation; and teleconsultation (tele-visit)

3. Outcome measures

Control of serum FBS level, control of blood glucose level, control of serum HbA1c level, mortality reduction, the effect of remote care on prevention of kidney failure, prevention of stroke, prevention of amputation, prevention of retinopathy (retinal damage), prevention of diabetic foot, prevention of cardiovascular disease, prevention of diabetes neuropathy, reduction of costs, frequency of hospitalization, and quality of life improvement will be measured.

Dealing with missing data

In case of insufficient or missing data, the authors of the eligible articles will be contacted at least twice, one week apart. If they cannot be contacted, the available data will be analyzed and the effects of missing data will be reported in the results and discussed by comparing the results with the results of the systematic reviews.

Risk of bias assessment

Two reviewers will independently assess the risk of bias for the selected studies using the JADAD "risk of bias" assessment score, which evaluates sequence generation, allocation concealment, blinding, incomplete outcome data, loss to follow-up, and selective outcome reporting *[10]*. In evaluating the quality of articles based on the quality criteria of the newcomer, the articles receive a score ranging from 0 to 7 points, with a higher score indicating higher quality .*[11]* Although quality will not be considered as a case study, it will be taken into account in the conclusion for considering the results of studies.

Data analysis

The mean changes in the quantitative outcomes of the study (such as HbA1c, FBS, and odds ratio (OR) for complications) in the intervention and control groups will be calculated to determine the difference as the effect size. In this study, a random-effects model that considers the diversity between studies will be applied. The Stata software version 12 (Stata Corp, College Station, TX) will be used to analyze the data. P values less than 0.05 will be considered significant.

Assessment of heterogeneity

Statistical heterogeneity will be tested using the Cpchran's Q test test and I-squared (I^2) statistic (0% to 40%: might not be important; 30% to 60%: may represent moderate heterogeneity; 50% to 90%: may represent substantial heterogeneity; 75% to 100%: considerable heterogeneity). If high levels of heterogeneity exist among the trials (I2 >=50% or Cochran's Q test, P < 0.1), the study design and characteristics in the included studies will be checked to explain the source of heterogeneity by subgroup analysis or sensitivity analysis *[12]*.

Subgroup analysis and sensitivity analysis

Subgroup analysis will be performed to evaluate whether the intervention(s), individuals' health status, and other trial characteristics explain the possible heterogeneity between studies. Additionally, sensitivity analysis will also be performed by excluding studies one by one from the meta-analysis.

Publication bias

In order to assess publication bias, it will be determined whether the RCT protocol was published before the recruitment of patients or not. In the presence of a small sample bias, the random effects estimate of the intervention is more beneficial than the fixed effect estimate. Publication bias will be assessed using Begg's funnel plots and Egger's and Begg's asymmetry tests *[9]*.

Discussion

This systematic review will compare the effect of telehomecare interventions on diabetes mellitus control and its complications. Overall, the systematic review outlined in this protocol will try to identify, assess, and synthesize using meta-analytic methods available in the evidence of the effects of Tele-homecare on type 1 and 2 diabetes and gestational diabetes control and their complications. This systematic review will evaluate which diabetes telehomecare interventions classified by their functionalities are the most effective in the management of patients with diabetes, according to both clinical and resource utilization outcomes. Telehomecare intervention is reported to be effective in the management of several chronic conditions such as diabetes mellitus, chronic heart failure, chronic obstructive pulmonary disease, and etc. *[4]*. This systematic review examines all aspects of HTA with the HTA core model approach, thus providing a more comprehensive review of the management and complications of diabetes mellitus by THC interventions. We believe that the results will be essential for policy-making regarding the use of tele-homecare in diabetes management. This evidence can be useful to endocrinologists, clinicians, public health policy-makers, patients, and the general population.

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All authors read and approved the final manuscript.

Authors' contribution

HD conceived the study. HD and FF designed the search strategy. MM and HD wrote the first draft of the manuscript. MM and AD revised the manuscript. All authors read and approved the final version of the manuscript.

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Conflict of interest

There is no conflict of interest between the authors.

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