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Original Article

Feasibility of an Activity Control System in Patients with Type 2 Diabetes: Results from a Non-Randomised Controlled Pilot Study

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Highlights

Teaching Points:

- The study was undertaken because diabetes mellitus is a highly prevalent condition that requires close monitoring and aimed to answer whether the AI2EPD home activity monitoring system is feasible, specifically focusing on its impact on therapeutic adherence in the treatment of people with Type 2 Diabetes Mellitus (DM2).
- Participants found the AI2EPD system easy to use, safe, and highly acceptable.
- Patients went from having a high risk of complications to a moderate risk, showing positive trends in lifestyle and disease management, although these changes cannot be attributed to the intervention, since no significant between-group clinical benefit was demonstrated.
- Across the six monitored activities, participants reported higher levels of compliance than those recorded by the monitoring system; this implies a potentially significant limitation when relying exclusively on self-reported measures of therapeutic adherence, highlighting the need to complement them with objective measurement tools.

Clinical relevance:

Using a non-invasive intelligent remote monitoring system at home is a feasible approach that could help improve therapeutic adherence, aid clinical decision-making and reduce healthcare costs in patients with DM2.

Abstract

Objective

Diabetes mellitus (DM) is a disease that requires continuous, active management by the patient, encompassing lifestyle and activities of daily living (ADL). There is limited evidence and a scarcity of devices that monitor ADL in patients with DM using artificial intelligence-based technology. This study evaluates the feasibility of the AI2EPD home activity monitoring system, focusing on therapeutic adherence in the treatment of people with DM2.

Methods

A pilot-controlled study was conducted. Vibration and motion sensors were placed in the home, and physical activity bracelets were worn, together with an Artificial Intelligence web system. The following scales were used for evaluation: System Usability Scale (SUS), Morisky-Green Test, Charlson Comorbidity Index (CCI), Spanish version of the Summary of Diabetes Self-Care Activities Measure (SDSCA-Sp), Diabetes Knowledge Questionnaire (DKQ-24), International Physical Activity Questionnaire (IPAQ), and EuroQol 5D.

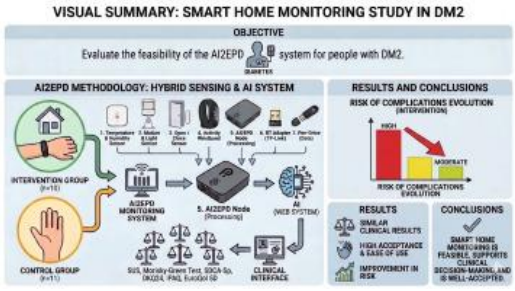
Results

Twenty-one participants were included (10 in the intervention group and 11 in the control group). The clinical results were similar for both groups. The intervention group found the system easy to use and safe, indicating high acceptance. No clinical benefit attributable to the intervention was demonstrated. The only statistically significant within-group improvement in HbA1c was observed in the control group; however, given the pilot nature of the study and the multiple exploratory comparisons, this finding should be interpreted with caution.

Conclusions

The use of the AI2EPD intelligent remote monitoring system in the home was feasible and well accepted by participants. Exploratory findings regarding therapeutic adherence and clinical outcomes warrant further evaluation in adequately powered studies.

Graphical abstract



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Section snippets

INTRODUCTION

Diabetes mellitus (DM) poses a challenge for every healthcare system in the world. More than half a billion people worldwide live with DM, and it is estimated that over the next 30 years, that figure will rise to 1,3 billion; it is most prevalent among

people aged 65 and over, with a rate of more than 20% of the total[1]. Globally, almost all cases (96%) were type 2 DM (DM2)[2]; however, the incidence and prevalence of type 1 DM are also increasing1, 2, 3.

Its increasing prevalence is due to …

Study design

Open-label, controlled pilot study to evaluate the feasibility of using a home activity monitoring system (AI2EPD) in the management of patients with DM2, through the placement of sensors in the home and activity identification bracelets. Motion, presence, and vibration sensors were used, along with Bluetooth beacons and a specific AI web system, to monitor the therapeutic objectives agreed upon with the patients25, 26. …

AI2EPD System

The system consists of 2 main components: fog and cloud layers. The “Fog” …

RESULTS

All patients (n=21) were evaluated at baseline and at 6 months, at the end of the intervention, with no loss to follow-up during the study (Figure 2). The 21 study subjects were recruited between December 2022 and January 2023 and were followed for 6 months. The 10 patients in the intervention group (IG) had a mean age of 64,6 years (SD: 8,49), and the 11 in the control group (CG) had a mean age of 62,5 years (SD: 11,7). Table 2 shows the baseline characteristics of the patients included in the …

DISCUSSION

This research was primarily a feasibility study of remote activity monitoring in patients with DM2, in which the potential to detect changes in clinical variables such as weight, waist circumference, lipid profile, or HbA1c was also preliminarily evaluated. The results from this controlled pilot study provide valuable information on the feasibility of using smart home activity-monitoring systems to manage these patients. No clinical trials with similar characteristics were found for comparison …

CONCLUSIONS

The treatment of patients with DM requires ongoing monitoring of biomarkers, lifestyle and behavioural habits, and therapeutic adherence, along with patient empowerment to support active participation in this process.

In recent years, new technologies have been integrated to monitor these individuals; however, there remains a gap in the study of telemonitoring of their daily activities, as well as in the feasibility and adherence to these systems.

Through the AI2EPD System, Artificial …

Ethical considerations

Patient confidentiality was preserved in accordance with applicable laws and regulations. Specifically, all actions complied with Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of natural persons regarding the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

Informed consent was obtained from each and every participant in the study, and all …

Conflict of Interest Statement

No potential conflict of interest was reported by the authors. …

Authors Contributions

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE): Substantial contributions to the conception and design, acquisition of data, or analysis and interpretation of data; drafting the article; or revising it critically for important intellectual content. …

Funding

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Clinical Trial Registration

The protocol for the entire process, including the information and methodology used, was registered in ClinicalTrials, with the registration number: NCT04380844 (https://clinicaltrials.gov/study/NCT04380844?id=NCT04380844&viewType=Card&rank=1 ↗). …

Patient consent statement

All participants were informed about the research and the characteristics of participation in it and freely agreed by signing an information sheet and an informed consent. …

Data availability statement

The research data has been presented in the manuscript. Further information is available upon request from the corresponding author. …

Declaration of Interest Statement

☒ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☐ The author is an Editorial Board Member/Editor-in-Chief/Associate Editor/Guest Editor for this journal and was not involved in the editorial review or the decision to publish this article.

☐ The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: …

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