How Effective Are Digital Health Tools in the Management of Diabetes? A Review of the Scientific and Medical Literature 2011–2016

PHS118

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BACKGROUND

- Diabetes is one of the most common chronic conditions worldwide. It is estimated that in 2010, the prevalence rate was 6.4%, which in turn translates to approximately 285 million diabetics worldwide.[1] This prevalence rate is expected to grow to 7.7%, with an estimated population of approximately 439 million by 2030.[1]
- The prevalence of diagnosed diabetes increased by 382% between 1988 and 2014.[2]
- The estimated direct and indirect costs in the US attributed to diagnosed diabetes were $245 billion in 2012.[3]
- In 2010, there were 69,201 deaths that were attributed to diabetes in the US. This death toll is higher that the death toll due to AIDS and breast cancer combined.[2]
- 33%–49% of all diabetic patients do not meet hemoglobin A1C (HBA1C) glycemic, lipid and blood pressure goals.
- Provider treatment goals for diabetes include promoting a healthy patient lifestyle, empowering patient diabetes self-management, prevention of diabetes complications, and identification of patient self-management problems and developing strategies to mitigate those problems.[4]
- Digital health technologies can be deployed to address and augment these management goals in a cost-effective manner.

RATIONALE

- A variety of diabetic digital health tools have been developed and deployed in recent years. Such tools include diabetic self-management platforms; patient engagement platforms designed to prevent diabetic complications; direct patient care delivery platforms such as telemedicine; and patient treatment adherence platforms.
- It is unclear how effective currently deployed digital health tools are in improving diabetic patient outcomes in the 'real world'

OBJECTIVES

- To conduct a comprehensive literature review of published scientific and medical studies of randomized control trials and/or well-designed observational studies that have evaluated the effectiveness of digital health tools over the last 5 years i.e. between 2011 and 2016.

METHODOLOGY

- An open-ended literature search was conducted in PubMed using key terms and medical subject headings (MeSH) such as 'diabetes', 'digital', 'health', 'e-health', 'm-health', 'mobile', and 'randomized', either singularly or in combination between 2011 and 2016.
- Based on this preliminary identification, abstracts from candidate studies were downloaded and reviewed. The following inclusion and exclusion criteria were utilized to further refine and reduce the final set of eligible studies;
  - Inclusion Criteria:
    - Enrolled study patients had to be clinically diagnosed with diabetes Type 1 (T1DM) or Type 2 (T2DM).
    - Only studies with randomized study designs were included
    - Only studies with at least 2 study arms (parallel group design) were included.
    - Only published studies in the English language were included
  - Exclusion Criteria
    - Feasibility evaluations, technological assessments, meta-analyses, and pilot studies < 20 patients were excluded.
    - Studies that had end-points other that diabetes or recognized as potential diabetes-related e.g. blood pressure, lipids, depression, etc., were excluded.
    - Any-non-active intervention trials or studies were excluded i.e. studies that evaluated effectiveness in screening, detection, etc., were excluded.
  - Upon applying the inclusion and exclusion criteria to candidate studies, a final set of studies deemed eligible for review were identified for retrieval. Full text manuscripts of these studies were downloaded and evaluated by the principal investigator (PN) and key findings were notated in a standardized data collection instrument.
  - The retrieval and abstraction was conducted from December 15th 2016 through January 9th 2017.
  - Only basic descriptive statistics were utilized to characterize some of the study findings. Where applicable, raw counts and percentages for categorical variables and means, medians and ranges for continuous variables were derived and reported.
  - All analyses were performed on Microsoft Excel 2010.

RESULTS

Overview:

- In the open-ended literature search using the key words and the MeSH headings as described above, a total of 187 candidate abstracts were identified and retrieved for review.
- Upon application of the selection criteria described above, a final sample of 28 abstracted studies (15%) was considered eligible for the literature review. Full text versions of these articles were downloaded and reviewed. A full bibliography is available from study co-authors upon request.
- The 28 studies reviewed involved the use of various digital health tools to improve patient behavior, impart self-management skills and knowledge, and improve diabetes management. The breakdown is as follows (Figure 1):
  - Diabetes Management/Self-Management: 75%
  - Adherence: 4%
  - Lifestyle Education: 7%
  - Telemedicine/Telehealth: 14%
- 57% of the studies were US based studies whereas the remainder (43%) were conducted outside the US (Figure 2).
- 36% of the studies were conducted in 2016. The number of such published studies have shown an increasing trend over the past few years (Figure 3)
- The majority of studies involved small sample sizes (mean = 167 patients; median = 109 patients; range: 30–567 patients).
- Most studies were of short duration (3 months–1 year). No study reviewed exceeded a period of 1 year from randomization.

Glycemic Outcomes:

- A total of 19 studies out of 28 (68%) had captured hemoglobin A1C levels, an indicator of glycemic control, as an end-point.
- Of these, 63.2% of studies showed no change or only modest improvement in hemoglobin A1C (HBA1C) outcomes between the intervention and control study arms in terms of absolute change in HBA1C levels from baseline to the end of the study. The breakdown of studies with HBA1C measurement between the intervention and control groups at baseline and end of study is as follows (Figure 4):
  - 21.1% (4/19) showed no change in the absolute difference between the change from baseline of HBA1C between the two study arms
  - 42.1% (8/19) showed a reduction of < 1% in the absolute difference between the change from baseline of HBA1C between the two study arms
  - 36.8% (7/19) showed a reduction of ≥ 1% in the absolute difference between the change from baseline of HBA1C between the two study arms
- The average absolute difference in percent reduction change from baseline and end of study across intervention and control groups is as follows:
  - For patients that had a < 1% change in HBA1C, it was a mean reduction of 0.34% (median = 0.33%; range = 0.20%–0.50%)
  - For patients that had a ≥ 1% change in HBA1C, it was a mean reduction of 1.31% (median = 1.2%; range = 1.0%–1.7%).
- There was no clearly discernible pattern of which type of diabetic digital health intervention yielded the greatest improvement in HBA1C.
- A qualitative review of these findings seems to indicate that studies with larger sample sizes tended to be associated with modest reductions in HBA1C.
- There also appears to be a significant placebo effect among the control arms of these studies as the majority of studies reviewed also showed a reduction in HBA1C in the control arm between baseline and the end of the study.

Figure 1: Distribution of Type of Diabetic Digital Health Intervention

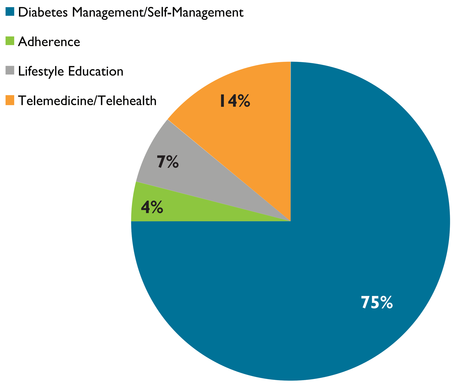


Figure 2. Distribution by Geography of Diabetic Digital Health Studies

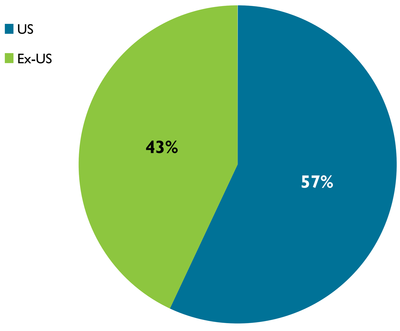


Figure 3. Distribution of Diabetic Digital Health Studies by Year

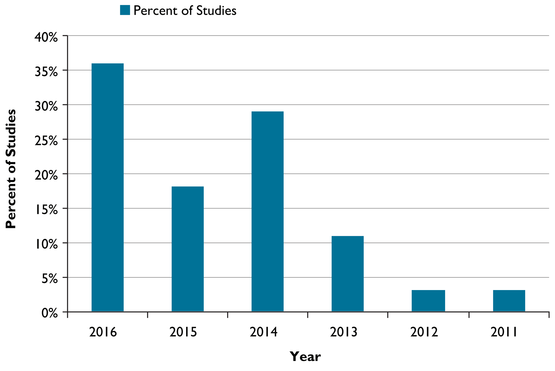
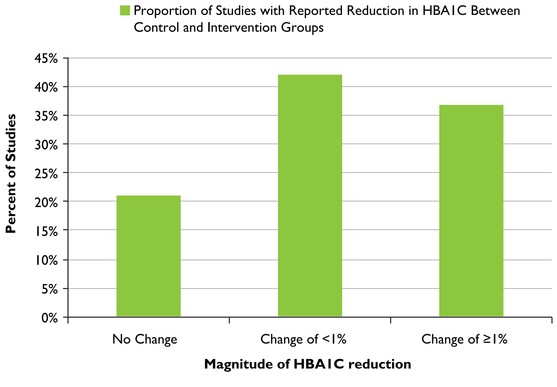


Figure 4. Distribution of Diabetic Digital Health Studies with Reported HBA1C Changes



CONCLUSIONS

- Three quarters of the studies reviewed were associated with digital health technologies that were focused on patient self-management or diabetes management. Most of the studies reviewed were of short duration (≤ 1 year) and had modest sample sizes. Consequently, these studies had low statistical power to detect clinically meaningful changes in glycemic outcomes as well as other study end-points.
- Almost two-thirds of the studies reviewed showed no change or only very modest change (< 1%) in HBA1C levels when the degree of HBA1C % reduction (from baseline to end of study) was compared between the control and intervention arms of these studies.
- Studies with much larger sample sizes and a longer duration of follow-up should be conducted to more precisely evaluate the clinical effectiveness of these digital health technology tools.

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FUNDING

- This study was funded by Sygeny Ltd, Finland.