A Review of the Scientific and Medical Literature 2011–2016

How Effective Are Digital Health Tools in the Management of Diabetes?

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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 is a trend to translate to approximately 385 million diabetes worldwide.1 This prevalence is expected to grow to 7.7%, with an estimated population of approximately 439 million by 2030.2

• The prevalence of diagnosed diabetes in the US increased between 1988 and 2014.3

• The estimated direct and indirect costs in the US attributed to diagnosed diabetes were $245 billion in 2012.4

• In 2010, there were 85.6 million adults that were attributed to diabetes in the US. This daily cost is higher than the cost due to AIDS and cancer combined.5

• 25%–45% of all diabetic patients do not meet hemoglobin A1C (HBA1C) glycemic, lip 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 management problems and developing strategies to mitigate these problems.

• Digital health technologies can be deployed to address and augment these management goals in a cost-effective manner.

RATIONAL

• A variety of digital health tools have been developed and deployed in recent years. Such tools include digital self-management platforms; patient engagement platforms designed to prevent diabetic complications; direct patient care delivery platforms such as telemedicine and patient response applications.

• It is unclear how effectively 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’, ‘in-silico’, ‘technology’, ‘mobile’, and ‘rando’.

• 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 PubMed 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 (73%) 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%
  - Where applicable, raw counts and percentages for categorical variables and means, medians and ranges for continuous variables were derived and reported.

• Most studies were of short duration (3 months–1 year). No study reviewed exceeded a range: 30–567 patients).

• The majority of studies included small sample sizes (mean = 147 patients; median = 109 patients; range: 35–547 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 reported hemoglobin A1C levels, an indicator of glycemic control, as an endpoint.

• Of these, 63% of studies showed no change or only modest improvement in HBA1C levels. A total of 38% showed a reduction in HBA1C outcomes by the intervention and control arms in terms of absolute change in HBA1C levels from baseline to the end of the study. The breakdown of such studies with HBA1C intervention comparison was the intervention and control groups as baseline and end of study is as follows (Figure 4):

  - 21.1% (6/28) 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 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 1.31% (median = 1.2% range: 1.0%–1.75%).

  - For patients that had a ≤ 1% change in HBA1C, it was a mean reduction of 0.34% (median = 0.33% range: 0.25%–0.50%).

• There was no clearly discernible pattern of which type of digital health intervention yielded the greatest improvement in glycemic outcomes.

• A qualitative review of these findings seems to indicate that studies with larger sample sizes tended to show greater improvements in HBA1C levels.

• There also appears to be significant shrinkage affect 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.

CONCLUSIONS

• Three quarters of the studies reviewed were associated with digital health technologies that were used to prevent or manage diabetes or diabetes management. More than half of the studies reviewed were short of 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 effectiveness of these digital health technology tools.

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REFERENCES


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