Technical Brief
Number 31

Mobile Applications for Self-Management of Diabetes

AHRQ
Agency for Healthcare Research and Quality

Effective Health Care Program

Technical Brief

Number 31

Mobile Applications for Self-Management of Diabetes

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Contract Nos. 290-2012-0004-C and -290-2017-0000-3C

Prepared by:
Scientific Resource Center
Portland, OR

Investigators:
Stephanie Veazie, M.P.H.
Kara Winchell, M.A.
Jennifer Gilbert, M.D., M.P.H.
Robin Paynter, M.L.I.S.
Ilya Ivlev, M.D., Ph.D.
Karen Eden, Ph.D.
Kerri Nussbaum, M.S.
Nicole Weiskopf, Ph.D.
Jeanne-Marie Guise, M.D., M.P.H.
Mark Helfand, M.D., M.P.H.

AHRQ Publication No. 18-EHC010-EF
May 2018

Key Messages

Purpose of Review

This review evaluates the efficacy, usability, and features of commercially available mobile applications (apps) for diabetes self-management.

Key Messages

- Although hundreds of apps for diabetes self-management are commercially available, we only identified health outcomes studies on 11 apps.

- Of the 11 apps, studies showed only 5 were associated with clinically significant improvements in HbA1c, an important clinical test for monitoring diabetes. (For Type 1 diabetes- Glucose Buddy, Diabeo Telesage; For Type 2 diabetes- Blue Star, WellTang, Gather Health)

- None of the studies showed patient improvements in quality of life, blood pressure, weight, or body mass index. More rigorous and longer-term research studies could determine whether apps help people manage their diabetes and reduce complications.

- Studies had methodological issues: they were short (2-12 months); inconsistent in reporting of randomization, allocation, masking, and drop-out analysis; and often used co-interventions that hindered interpretation of results. None of the included studies are considered to be high quality.

This report is based on research conducted by the Scientific Resource Center under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract Nos. 290-2012-0004-C and 290-2017-00003-C). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

This report is made available to the public under the terms of a licensing agreement between the author and the Agency for Healthcare Research and Quality. This report may be used and reprinted without permission except those copyrighted materials that are clearly noted in the report. Further reproduction of those copyrighted materials is prohibited without the express permission of copyright holders.

AHRQ or U.S. Department of Health and Human Services endorsement of any derivative products that may be developed from this report, such as clinical practice guidelines, other quality enhancement tools, or reimbursement or coverage policies may not be stated or implied.

Persons using assistive technology may not be able to fully access information in this report. For assistance contact epc@ahrq.hhs.gov.

Suggested citation: Veazie S, Winchell K, Gilbert J, Paynter R, Ivlev I, Eden K, Nussbaum K, Weiskopf N, Guise J-M, Helfand M. Mobile Applications for Self-Management of Diabetes. Technical Brief No. 31. (Prepared by the Scientific Resource Center under Contract Nos. 290-2012-0004-C and 290-2017-00003-C.) AHRQ Publication No. 18-EHC010-EF. Rockville, MD: Agency for Healthcare Research and Quality; May 2018. Posted final reports are located on the Effective Healthcare Program search page.
DOI: https://doi.org/10.23970/AHRQEPCTB31.

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Center (EPC) program, sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

This EPC evidence report is a Technical Brief. A Technical Brief is a rapid report, typically on an emerging medical technology, strategy or intervention. It provides an overview of key issues related to the intervention—for example, current indications, relevant patient populations and subgroups of interest, outcomes measured, and contextual factors that may affect decisions regarding the intervention. Although Technical Briefs generally focus on interventions for which there are limited published data and too few completed protocol-driven studies to support definitive conclusions, the decision to request a Technical Brief is not solely based on the availability of clinical studies. The goals of the Technical Brief are to provide an early objective description of the state of the science, a potential framework for assessing the applications and implications of the intervention, a summary of ongoing research, and information on future research needs. In particular, through the Technical Brief, AHRQ hopes to gain insight on the appropriate conceptual framework and critical issues that will inform future research.

AHRQ expects that the evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

If you have comments on this Technical Brief, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

Gopal Khanna, M.B.A.
Director
Agency for Healthcare Research and Quality

Stephanie Chang, M.D., M.P.H
Director
Evidence-based Practice Center Program
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Arlene S. Bierman, M.D., M.S.
Director
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Elise Berliner, Ph.D.
Task Order Officer
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Jasmine Bihm, Dr. P.H., M.P.H.
Task Order Officer
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Acknowledgements

The authors gratefully acknowledge the following individuals for their contributions to this project: Ian Anderson, James Case, Lily Cook, Makalapua Motu'apuaka, Ryan McKenna, Ed Reid, and Leah Williams.

Key Informants

In designing the guiding questions, the authors consulted several Key Informants with diverse experiences and perspectives in diabetes prevention and management, public health, and mobile health evaluation. Key Informants were not involved in the analysis of the evidence or the writing of the report. Therefore, guiding questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the authors work to balance, manage, or mitigate any conflicts of interest. The list of Key Informants who provided input to this report follows:

Ann Albright, Ph.D., R.D.*
Director of the Division of Diabetes Translation at the Centers for Disease Control and Prevention
Atlanta, GA

Melanie Bird, Ph.D.*
Clinical Policies Strategist for the American Academy of Family Physicians
Leawood, KS

Tiffani Bright, Ph.D.
Senior Staff fellow, Center for Evidence and Practice Improvement Division of Health IT
Agency for Healthcare Research and Quality
Rockville, MD

Dave Crosbee
Managing Director, Xcertia
Las Vegas, NV

W. Douglas Evans, Ph.D.*
Professor of Prevention and Community Health & Global Health
The George Washington University
Washington, DC

Judith Fradkin, Ph.D.*
Director, Division of Diabetes, Endocrinology,
and Metabolic Diseases, National Institute of
Diabetes and Digestive and Kidney Diseases
Bethesda, MD

Shannon Haffey, M.H.S.A.
Director of Systems and Payer Strategies
American Medical Association
Chicago, IL

Michael Hodgkins, M.D.
Chief Medical Information Officer
American Medical Association
Chicago, IL

Kate Kirley, M.D., M.S.
Director of Diabetes and Cardiovascular Disease
Prevention
American Medical Association
Chicago, IL

*Key Informants who also served as Peer Reviewers

Peer Reviewers

Prior to publication of the final evidence report, the SRC sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

Steven Findlay, M.P.H.
Independent Health Policy Analyst
Washington, DC

Andrew Holtz, M.P.H.
Independent Health Journalist
Portland, OR

Sharon A. Watts, DNP, FNP-BC, CDE
Clinical Nurse Advisor, Metabolic Syndrome &
Diabetes FAC for VHA Office of Nursing Services, Northeast Ohio VA Medical Center
Cleveland, OH

Mobile Applications for Self-Management of Diabetes

Structured Abstract

Background. While hundreds of mobile applications (apps) for diabetes self-management are commercially available, patients lack information on which apps are effective in improving diabetes-related outcomes.

Purpose. Examine the evidence, usability, and features of commercially available mobile apps for self-management of type 1 and type 2 diabetes.

Methods. We searched Ovid/Medline and the Cochrane Database of Systematic Reviews for systematic reviews and technology assessments, and selected five recent, high-quality systematic reviews of highest relevance. We also conducted searches online and through Ovid/Medline, CINAHL, Embase, and ClinicalTrials.gov to identify additional, recently published primary studies. We used predetermined criteria to identify eligible studies, then extracted study-level data. We conducted quality assessments, extracted technical specifications and costs, and evaluated the usability of each app.

Findings. We identified 15 studies/analyses evaluating 11 unique apps: six apps for type 1 diabetes and five for type 2 diabetes. Two apps had multiple tiers of access (free and paid), which resulted in the evaluation of features of 13 apps. Common features of apps include the ability to track blood glucose, HbA1c, medications, physical activity, and weight. Studies were 2-12 months long. For type 1 diabetes, patients had clinically significant improvement in HbA1c if they used either of two apps and statistically significant improvement using one additional app. For type 2 diabetes, patients using any of three apps experienced clinical and statistical improvement in HbA1c. Patients using two apps for type 1 diabetes experienced improvements in hypoglycemic episodes. Patients did not experience improvements in quality of life, blood pressure, weight, or body mass index outcomes, regardless of the app or type of diabetes. The quality of studies was variable. Study design and presentation made it difficult to distinguish the effect of the app and the effect of additional interactions with study personnel or health care providers. Of the eight apps available for usability testing, three apps (two for type 1 and one for type 2 diabetes) were scored by researchers as “acceptable,” two apps (type 1 diabetes) as “marginal,” and three apps (one for type 1 and two for type 2 diabetes) as “not acceptable.”

Implications. Some apps for diabetes self-management may improve outcomes in the short-term, but the effect cannot be distinguished from the concomitant effect of additional support from a health care provider. More rigorous and longer-term evaluations are needed to determine how these apps affect weight, blood pressure, quality of life, and complications of diabetes.

Contents

Background 1
Diabetes Treatment and Self-Management 1
Mobile Health (mHealth) 2
History of Nomination 2
Objective and Guiding Questions 2
Methods 4
Discussions with Key Informants 4
PICOTS 5
Search Strategies 6
Study Selection 6
Study-Level Data Extraction 6
Risk of Bias/Quality Assessment 7
App Features and Usability Testing 8
Data Presentation 9
Peer Review and Public Commentary 9
Findings 10
Results of Literature Searches 10
Description of Included Studies and Apps 10
Type 1 Diabetes 10
Overall Summary 10
Description of Apps 14
Glucose Buddy 14
Diabetes Manager 15
Dbees 15
Diabetes Diary 16
Diabetes Interactive Diary (also called Il Diario Interattivo per il Diabete, or DID) 17
Diabeo Telesage (also called Diabeo) 18
Type 2 Diabetes 20
Overall Summary 20
Description of Apps 23
BlueStar Diabetes 23
mDiab 24
NexJ Connected Wellness Platform—Health Coach + [NexJ] 25
Gather Health 26
WellTang 26
Risk of Bias/Quality Assessment 27
Discussion 30
Limited Statistical Efficacy of Commercially Available Apps 30
Limited Clinical Efficacy of Commercially Available Apps 30
Study Findings May Be Generalizable to Most Diabetes Patients 31
Variation in Usability Scores 31
Limited Evidence to Detect Patterns between Cost, Features, and Efficacy 32
Short Duration of Studies 32
Methodological Issues with Available Evidence 32
Limitations 33

Rapid Review Limitations 33
Limitations from Lack of Access to Apps 33
Limitations in Usability Assessment 34
Next Steps 34
Future Research Needs 34
Implications for Clinicians and Patients 35
Evidence Should Be Available in App Stores 35
Patient-Centered Decision Tools 35
References 37

Tables

Table 1. Features, usability, and significant outcomes for apps for type 1 diabetes 12
Table 2. Features, usability, and significant outcomes for apps for type 2 diabetes 21

Figures

Figure 1. Risk of bias and overall quality for individual studies for type 1 and type 2 diabetes.. 28
Figure 2. Risk of bias across studies for type 1 and type 2 diabetes..... 29

Appendixes

Appendix A. Search Strategies
Appendix B. Inclusion and Exclusion Criteria for Primary Research Studies
Appendix C. Study Details
Appendix D. System Usability Scale

Background

More than 30 million Americans have some form of diabetes mellitus, which includes type 1 diabetes, type 2 diabetes, and gestational diabetes.[1] Patients with diabetes have prolonged periods of high blood glucose, which results from insufficient levels of insulin or an inadequate cellular response to insulin. In the United States, type 2 (insulin-resistant) diabetes comprises approximately 90 to 95 percent of all patients with diabetes, while type 1 (insulin-insufficient) diabetes accounts for 5 percent. The Centers for Disease Control and Prevention (CDC) reports that in 2012, diabetes cost $245 billion in related complications, medical costs, and lost wages.[1] Diabetes was the seventh leading cause of death in the United States in 2015.[1]

Uncontrolled blood glucose elevation can cause microvascular complications, including nephropathy (kidney problems), neuropathy (nerve problems), retinopathy (eye problems), and macrovascular complications such as hypertension and hyperlipidemia.[2] These complications can culminate in kidney failure, adult onset blindness, and lower limb amputations.[2]

Overall, racial and ethnic minorities are at higher risk than non-Hispanic whites for microvascular complications for both type 1 or type 2 diabetes.[3] In addition, type 2 diabetes is more prevalent among certain racial and ethnic minorities including African American, Hispanic/Latino, American Indian, Asian American, or Pacific Islander.[2]

The American Diabetes Association (ADA) recommends using HbA1c as a measurement of glycemic control for both diagnosis and treatment of diabetes;[4] it is an important intermediate outcome in the treatment of diabetes. Diabetes can be diagnosed by either a HbA1c $\geq$ 6.5 percent or fasting plasma glucose (FPG) $\geq$ 126 mg/dL or a 2-hour plasma glucose value after a 75-gram oral glucose tolerance test $\geq$ 200 mg/dL. A 0.5 percent reduction in HbA1c is considered clinically significant, as diabetes-related complications are directly proportional to HbA1c.[5]

Diabetes Treatment and Self-Management

Management of diabetes varies depending on the type and severity of diabetes. For type 1 diabetes patients, insulin is a life-long treatment, with a wide spectrum of doses including multiple dose injections or insulin pumps (also known as continuous subcutaneous insulin infusion). Management also includes monitoring glycemic control and controlling blood pressure and cholesterol.[6] Optimal glycemic control requires self-monitoring glucose levels multiple times daily and modifying insulin, diet, or physical activity as needed. The National Institutes of Health (NIH)-funded Diabetes Control and Complications Trial of type 1 patients and a related longitudinal follow-up study showed tight glycemic control reduced microvascular and macrovascular complications.[7]

For type 2 diabetes patients, management is often initially focused on lifestyle changes (diet and physical activity) and may include the use of oral hypoglycemic medications. Sometimes type 2 diabetes patients use insulin in addition to or in place of other medications to obtain optimal glycemic control.[6]

For decades, diabetes self-management has been considered a cornerstone of diabetes care and is believed to play an important role in preventing micro and macrovascular complications. Components of self-management include diabetes education; healthy eating, physical activity, medication, and device usage; monitoring and using patient-generated data to adjust behavior and medication doses; preventing, detecting, and treating acute and chronic complications; coping with psychosocial issues; and problem solving.[8]

Mobile Health (mHealth)

Increasingly, clinicians, pharmacists, and patients have started to use mHealth ("mobile and wireless technologies to support the achievement of health objectives"[9]) to assist with diabetes self-management. mHealth is typically patient-facing and is available on personal mobile devices. mHealth overlaps with telehealth and telemedicine; however, these broader terms include all information and communication technologies to improve clinical care as well as public health, health administration, and health-related education.[10-12] In this report, we define mHealth for diabetes as any Web site or application delivered through a mobile device (i.e., mobile phone, tablet, or watch) for the purpose of diabetes self-management. For the purposes of this report, "apps" includes both Web sites and applications.

In 2017, there were more than 318,000 mobile health applications available to consumers worldwide.[13] Diabetes apps accounted for 16% of the total number of disease-specific apps available to consumers, second only to mental health apps.[13] Diabetes apps vary in the functions they provide, including tracking blood glucose measurements, nutrition database and carbohydrate tracking, physical activity and weight tracking, sharing data with clinicians or peers, social support, messaging, and reminders.[14] Theoretically, the use of these features could help patients adhere to diet, exercise, and medication management plans, which could lead to improved diabetes-related outcomes.

There is considerable variability in how mobile apps are designed and used in care. Some apps only provide a single function, while others provide a group of functions. Mobile apps can be delivered as a stand-alone app, through an app and Web site combination, or through a Web site alone. Availability of apps also varies by the types of device and operating systems required (i.e., platform). Some, but not all, apps are configured for multiple devices and operating systems. Mobile apps vary in the extent to which they connect to other aspects of patient care. For example, some apps are designed to be used within an online patient portal, where patients and clinicians can exchange messages or other health information, while others connect to the patient's electronic medical record (EMR). Some connect directly to US Food and Drug Administration (FDA)-approved medical devices, such as blood glucose meters, which automatically upload information to the application.

History of Nomination

Mobile apps for diabetes self-management was nominated to the AHRQ Effective Health Care (EHC) program by a managed care pharmacist. The nominator was interested in the effectiveness of mHealth for diabetes self-management to inform the use of mHealth in clinical practice as well as third-party payer coverage policies. In early 2017, the AHRQ Scientific Resource Center (SRC) identified several systematic reviews that could potentially address the questions from the nomination.[15, 16] However, these reviews and others typically apply one of two strategies: they look exclusively at the published literature and include apps that are not available to consumers, or they review features of commercially available apps and do not consider whether the apps have evidence of clinical efficacy. We determined that a marriage of these two strategies could address both research and consumer needs.

Objective and Guiding Questions

Our objective was to synthesize and present evidence on commercially available apps for diabetes self-management, including evidence of efficacy and information about app function,

cost, and usability to help decisionmakers (patients, clinicians, and professional societies) make informed choices. In addition, this product serves as a potential prototype for future rapid AHRQ products. The following questions guided the literature search and inclusion/exclusion criteria.

1. Which specific mHealth technologies for diabetes self-management have been researched?

2. What are the characteristics (e.g., interoperability, functions, acceptability/usability, or connection to electronic health records) of these specific mHealth technologies?

3. What patient outcomes are associated with the use of these specific mHealth technologies?

4. What are the harms and costs associated with these specific mHealth technologies?

Methods

We followed established AHRQ processes for Technical Briefs, including interviewing key informants, soliciting additional unpublished materials to inform our review through a Federal Register notice, and utilizing peer and public review. Because AHRQ Technical Briefs focus on emerging and rapidly changing technologies, strength of evidence assessments are not typically conducted, and we did not evaluate strength of evidence in this review. We used rapid review methodology instead of traditional systematic review methodology to search for and synthesize evidence. A rapid review is similar to a systematic review, except that it restricts or eliminates certain methodological steps so that it can be completed on a shortened time frame. Decisions about which steps should be restricted or eliminated depend on the context of the health care intervention, the availability of high-quality systematic reviews, and discussion of what steps are necessary to ensure confidence in the results.

Our methods are based on an AHRQ methods paper, which outlines strategic steps that can be taken to produce a review on a rapid timeline.[17] This rapid review limited the number of databases searched; relied on existing systematic reviews to identify primary studies; performed a gap search for additional primary studies; performed single review of abstracts, titles, and full text papers; and performed single data extraction and risk of bias assessment, which were both checked for accuracy by a second reviewer. In addition, because we knew there were several recent, high-quality systematic reviews that address the overall effect of mobile apps on diabetes outcomes, we decided to focus on interpreting the evidence on specific, commercially available apps or Web sites optimized for mobile use for patients. While there are many systematic reviews on mobile apps for diabetes self-management, patients may have a difficult time using evidence from systematic reviews to decide whether and which app to use in care.

This draft report was sent to all key informants and selected peer reviewers who did not serve as key informants; it was also posted to the EHC Web site for public comment.

Discussions With Key Informants

Nine key informants (KIs) representing diverse perspectives including diabetes prevention and management, public health, and mHealth, provided input on this review (listed on p. v). The intent of KI interviews was to provide context and guidance on areas where a review would make the biggest impact, particularly regarding the public and potential users. KIs provided input on the scope of the review, including the proposed populations, interventions, comparators, outcomes, timing/setting (PICOTS); which characteristics of mHealth are most important in informing decisionmaking; and what type of product would be most useful to decisionmakers.

KIs were generally in agreement about the proposed PICOTS for this review. Overall, they felt that all non-pregnant populations (e.g., individuals with type 1 and type 2 diabetes; children, adults, and older adults; subpopulations such as men/women, race/ethnicity, etc.) were important to examine. There was also agreement about the types of outcomes to examine, with HbA1c, blood glucose, weight loss, improved nutrition, and level of activity most often discussed. KIs believed that the most important characteristics of mHealth (in addition to efficacy) were connection to EMRs, data security, and usability. KIs noted that this rapid review should provide information in a digestible format, either through a patient decision tool or through tables that visually depict the characteristics of technologies and the state of evidence supporting them. However, KIs disagreed on whether mHealth technology for prevention or management was a higher priority for this review, with several noting that both were important.

Two additional themes emerged from conversations with KIs. First, several discussed the importance of examining patient preferences and degree of engagement with apps. Specifically, the effectiveness of an app may depend on whether patients have a high or low comfort level with technology, and whether the app continually engages them. Second, KIs commented that a major challenge of evaluating apps is identifying what the effect of an app is versus the effect of the additional support and care a patient receives with that app, and how to manage expectations accordingly. Often, apps are touted as a silver bullet for diabetes prevention and self-management. In reality, however, they are adjunctive tools that must be combined with other efforts to improve outcomes. It is important to consider the mechanism that is driving changes in outcomes. For example, tracking steps via a pedometer may not affect diabetes-related outcomes unless tracking helps motivate patients to walk more.

Ultimately, discussions with KIs helped to identify the most important aspects of mHealth to examine in this review and to define the most important considerations for interpreting and applying evidence within the topic of this report.

PICOTS

Populations: We focused on non-pregnant adults with type 1 or type 2 diabetes, as KIs noted that both these groups are likely to use mobile health technologies in their self-management. We excluded children, adolescents, pregnant women with diabetes, and patients with gestational diabetes.

Interventions (types of technologies): We included studies of commercially available apps or Web sites delivered through mobile devices (i.e., phone, tablet, or watch) for diabetes self-management. To be included, apps had to provide at least one of the following five features: (1) education; (2) data tracking; (3) communication between participants and providers or coaches; (4) social support or social media; and (5) reminders (except for text message-based appointment reminders because these were not close enough to our conceptualization of diabetes self-management). Though not a requirement for inclusion, we considered the dosage, which we defined as the number of times patients used features of the app. We excluded studies using patients with an artificial pancreas because these are more intensive interventions that require additional safety and regulatory considerations. We also excluded studies of medical devices that do not connect to an app, such as blood glucose meters alone.

Comparators: We included studies that had comparators of usual care or another mobile or nonmobile program for diabetes self-management. The most important factor in our determination of inclusion/exclusion was whether the control group received some form of care. However, we did include registry studies with no comparator.

Outcomes: We included all patient-related outcomes, including but not limited to participant satisfaction; self-efficacy; participant assessments of usability of apps; costs; clinical outcomes such as HbA1c, blood pressure, weight loss, physical activity; quality of life; functionality; incidence of hypoglycemic and hyperglycemic episodes; harms and adverse events; and all-cause death. We excluded provider outcomes, health system outcomes, and technology performance outcomes such as malfunctions and crash statistics.

Timing/Setting: We included all settings and all study lengths. We included articles published in 2008 or later, as this was the first year that mobile apps were available to consumers through Apple and Google Play (formerly Android Market) app stores. We only evaluated the statistical significance of changes in outcomes at the end of the intervention, and did not consider intermediate or follow-up time points.

Study designs: We included randomized controlled trials (RCTs), non-RCTs, or other observational studies that had a comparator. We included registry studies to provide information on harms that may not have been reported in other included studies. We excluded studies if they only examined pre-post differences in a single group. We anticipated that this would result in excluding pilot and feasibility studies that contain detailed information on the usability of apps; however, in order to evaluate the *clinical efficacy* of apps, we focused on comparators that are realistic options for clinical practice.

Language: We included studies in English.

Search Strategies

While this was a rapid review, we took steps to ensure that we captured as many studies as possible that evaluated the desired outcomes for commercially available apps for self-management of diabetes. Specifically, we searched Ovid/Medline and Cochrane Database of Systematic Reviews (CDSR) for systematic reviews or technology assessments published between January 2008 and June 2017. After we examined eligible systematic reviews, we conducted online searches and an additional literature search to find primary research studies in Ovid/Medline, Embase, CINAHL and Clinicaltrials.gov from January 2016 to June 2017. We updated the search for Ovid/Medline and CDSR in December 2017. See Appendix A for all search strategies.

We posted a Federal Register notice about our protocol, to seek additional data and unpublished materials. The notice was posted between August 15 and September 14, 2017. For all included apps, we contacted app developers or original study authors and requested any additional information they would like to provide. For apps that required a payment, subscription, access code, or password, we requested a free trial so we could adequately describe app features and assess usability.

While the rapid review shortcuts we took (e.g., limiting our search, single reviewer, and limiting the scope to only commercially available apps) are consistent with the methods literature on this type of publication,[17] we do not know whether these shortcuts affect the conclusions of the final product.

Study Selection

One reviewer screened titles and abstracts of systematic reviews and technology assessments then examined full text articles for eligibility. Five systematic reviews addressed our guiding questions and met three additional criteria: (1) searched one or more citation databases; (2) applied prespecified inclusion and exclusion criteria; and (3) assessed the quality or risk of bias of identified studies. For primary studies identified from systematic reviews and additional searches, we applied the inclusion and exclusion criteria described in Appendix B.

Study-Level Data Extraction

One investigator extracted details about the study design, population, setting, interventions, comparator, and results. A second investigator reviewed data for accuracy.

For each outcome, we extracted data on difference-in-differences, including p-values and confidence intervals (CI) if available and pre-post-differences in intervention and control groups if not available (Appendix C, Tables C-1 and C-2). We made a determination of "yes" if the study showed a significant between-group difference; "no" if the study showed no significant

between-group differences; and "CND" or "could not determine" if information was insufficient to make a conclusion.

We also extracted data on harms (e.g., hypoglycemic episodes, hospitalization, emergency room [ER] visits) as presented in the studies.

Risk of Bias/Quality Assessment

We developed a risk of bias tool based on AHRQ guidance,[18] which included the following categories:

1. Random sequence generation (selection bias)
2. Allocation concealment (selection bias)
3. If groups were similar at baseline, and if not, if differences were controlled for in analysis (selection bias)
4. If conditions were controlled so effects could be attributed to mobile application (co-intervention bias)
5. If outcomes were prespecified and reported (performance and reporting bias)
6. If participants were analyzed based on originally assigned groups (attrition bias)
7. If attrition was low and adherence high (attrition bias)
8. If outcome assessors and data analysts were masked (detection bias)
9. If reliable measures of outcomes were used consistently across all participants (detection bias, confounding)

As patients know whether they were using an app, and no sham controls were used, we did not include masking of participants or providers in our risk of bias tool. Our rationale was that, while lack of masking of treatment assignment can introduce bias, this bias affected all the studies. Therefore, although we did not formally evaluate the lack of masking of participants and providers in our risk of bias tool, we considered the bias in our overall judgments of risk of bias and study quality.

Co-intervention bias can occur if participants assigned to the mobile app also receive earlier, more intense, or more effective communication with providers than those assigned to the control group. This type of bias is particularly concerning in unmasked trials. Our determination of whether conditions were controlled so effects could be attributed to the mobile application was nuanced. In telehealth interventions, it can be difficult to determine whether additional interactions with providers is a *benefit* of the intervention (i.e., increase in timely communication between provider and participant), a *source of bias* (i.e., the intervention group received considerably more attention that was not controlled for in the control group) or an issue of *limited applicability* (i.e., effect of app is caused by this extra attention, so unless patients have this level of interaction they may not see a benefit). In our determinations, we considered whether the study's design allowed for equitable patient-provider/patient-study personnel interactions between groups, even if one group ended up having more interactions.

Risk of bias assessments were conducted by one reviewer and checked by a second reviewer for accuracy. Disagreements were resolved through discussion. We used the nine items to rate each study as low, moderate, or high risk of bias. We did not use a simple count of strengths or deficiencies, rather, we weighed each bias based on its magnitude and potential consequences. We used risk of bias assessments as proxy measures for study quality; a low risk of bias means a study is likely high quality, a moderate risk of bias means a study is likely moderate quality, and

a high risk of bias means a study is likely low quality. The rationale for each judgment is described in the "Results" section.

Systems such as Grading of Recommendations Assessment, Development and Evaluation (GRADE) look across studies of an intervention to assess consistency, directness, and other aspects of the evidence regarding a specific outcome.[19] We did not rate bodies of evidence in this way because most apps were associated with sparse data. Instead we report the details of the quality assessment and narrative critiques of each study.

App Features and Usability Testing

We searched for and downloaded apps from our identified research studies. We accessed the most recent version of the app available and describe this version in the "Results" section. We did not assess the extent to which the current versions of the apps differ from the version of the app used in the study, but we commented when the study provided additional modules or interventions that the current app doesn't provide. For each free app, we examined app characteristics on all available platforms, including Apple iPhone, Apple iPad, Android phone, and Android tablet. For each app that required a fee or access code for download, we examined app characteristics on an Apple iPad and used information from developer websites and app stores to determine app characteristics on other platforms. We report the following information on app characteristics, when available:

- Available in Apple App Store and/or Google Play
- Logistical specifications (operating system, last date of update, size, country of origin, available languages, customer rating, number of reviews, and cost of initial download)
- Security information ("red flags" in the privacy policy, access to other apps or information from device, ownership of health data, and other relevant security and privacy information)
- Features (diabetes-related health information tracked, feedback provided from app, costs of additional subscriptions or add-ons, and connection to other devices)

We rated each app we could access on the System Usability Scale (SUS) (Appendix D).[20] For apps only available on Android devices, we evaluated usability on an Android phone. For apps only available on Apple devices, or Apple and Android devices, we evaluated usability on an Apple iPad. The SUS is a validated, well-established psychometric instrument that is used to elicit and structure consumer views on the subjective concept of service or product usability. Most frequently it is applied to software programs and other forms of information technology, but it has been broadly adapted. The SUS includes a 10-item Likert Scale that touches on issues including system functionality, learnability, and ease of use.[20] SUS scores range from 0 points to 100 points, [20] We considered all apps with a score of 70 points or higher as having "acceptable" usability; those with a score between 50 and 69 as having "marginal" usability; and apps with a SUS score lower than 50 as having "not acceptable" usability.

Because the SUS is by nature a subjective instrument, we had three reviewers evaluate each app. Scores given in this report represent the average of the three reviewers' scores. The reviewers were all female, ranging in age from 26–53, and all had advanced degrees. None of the reviewers currently have, or have ever had, any type of diabetes. The scores were given after each reviewer used the tool for approximately 15-30 minutes. Use of this tool has many limitations, described in the "Limitations in Usability Assessment" section in "Limitations."

Data Presentation

The first two tables (under the "Type 1 Diabetes" and "Type 2 Diabetes" sections in "Findings") provide information about the important features of each app, the usability score of each app when available, and whether each app has been shown to have a statistically significant effect on any diabetes-related outcomes. The first figure illustrates the risk of bias and overall quality judgements for individual studies, while the second figure shows the frequency of each risk of bias category among all the included studies (under the "Risk of Bias/Quality Assessment" section in "Findings"). In the figures, red represents high risk of bias, yellow means the risk is unclear, and green means the risk of bias is low. Appendix C reports study-level data gathered during the data extraction process. It is organized by study, and aims to provide the reader a detailed look at the information that was considered. While it highlights statistically significant outcomes, all outcomes are reported regardless of significance or whether information was sufficient to assess the risk of bias for that outcome.

Peer Review and Public Commentary

Experts in diabetes and health communication were invited to provide external peer review of this systematic review; AHRQ and an associate editor also provided comments. The draft report was posted on the AHRQ website for 3 weeks to elicit public comment. We addressed all reviewer comments, revising the text as appropriate, and documented everything in a disposition of comments report that will be made available 3 months after the Agency posts the final systematic review on the EHC website.

Findings

Results of Literature Searches

From Ovid/Medline and CDSR searches, we found 143 unique systematic reviews and technology assessments, of which, 74 full text articles were reviewed to identify five relevant systematic reviews.[15, 16, 21-23] These five reviews included 34 unique primary research studies which we evaluated for inclusion. Subsequent literature searches for primary research did not yield any additional studies meeting inclusion criteria but seven additional primary research studies were identified through online searching. Excluding studies that evaluated apps that were not commercially available to download in July 2017 left 14 studies/analyses[24-38] that evaluated 11 unique apps. After reviewing comments from peer and public review, we re-classified one additional study as eligible for inclusion,[38] for a total of 15 studies/analyses.

Two of the 11 apps had two tiers of access (free and paid), resulting in the evaluation of features of 13 apps. We included both Apple and Android versions of the apps.[39-48] For one app, we received an access code from the developer so we could evaluate the app's features and usability. Two of these apps were not available for download in the United States, but were included because users of this report with access to foreign app stores may find the evidence helpful. For more information on the searches, please see Appendix A.

Description of Included Studies and Apps

Fifteen studies/analyses met the strict inclusion/exclusion criteria (Appendix B) designed to answer our four guiding questions. Because KIs emphasized the importance of distinguishing between apps designed for and studied in type 1 and type 2 diabetes, we organized our findings not by guiding question, but, first by type of diabetes, then by specific app. For each app, we present the following information:

1. App features (e.g., on which device the app is available, what the app does, cost, etc.)
2. App usability (using the SUS, presented as an average of three scores given by researchers involved in this report)
3. Summary of the evidence from the study or studies that evaluated the app
4. Study quality

Type 1 Diabetes

Overall Summary

For type 1 diabetes we identified eight publications[24-27, 30-32, 36] of seven studies evaluating six commercially available mobile applications (Glucose Buddy,[43, 44, 49] Diabetes Manager,[41] Dbees,[50] Diabetes Diary,[51] Diabetes Interactive Diary,[52] and Diabeo Telesage[40, 53]). Please see Table 1 for detailed descriptions of apps (including app name, platform, cost, what it tracks, what feedback it provides, usability, evidence of effectiveness, and quality of associated studies), and Appendix C, Table C-1 for a detailed description of each study.

Of the six apps, three (Dbees,[50] Diabetes Diary,[51] and Diabetes Interactive Diary[52]) were free to download, one (Diabetes Manager[41]) required a download fee, one (Diabeo Telesage[40, 53]) required a paid subscription, and one (Glucose Buddy) had two tiers of access: one (Glucose Buddy[44, 49]) is free and the other (Glucose Buddy Pro[43]) costs $1.99. One app (Diabetes Diary[51])

had an additional blood glucose meter module, Diastat, that was examined in the study that is not currently available through the app.[32]

Of the eight publications we identified, seven were RCTs[24-27, 30-32] and one was a subgroup analysis of an included RCT.[36] Only the Diabetes Interactive Diary[52] was evaluated in more than one study.[30, 31] Participants in the seven studies ranged in mean age from 33 to 40 years old. Duration of diabetes in the intervention groups ranged from 16 to 25 years, while baseline HbA1c ranged from 7.8 to 8.78 percent. Study duration and length of time that participants used the apps ranged from 8 weeks to 6 months. Only three studies reported app "dosage."[27, 30, 31] The main outcomes evaluated were HbA1c,[24-27, 30-32, 36] quality of life,[24, 25, 27, 30, 31] and hypoglycemic events.[24, 26, 30-32]

Table 1. Features, usability, and significant outcomes for apps for type 1 diabetes

Name of App	Platform	Cost	What does the app track?	What feedback does the app provide to patients?	Does this app have a privacy/security policy?	Usability (out of 100)	Patients who used the app saw improvement in which outcomes?*	Can I trust the results?
Glucose Buddy[44, 49]	Apple (iPhone, iPad, iPod Touch)	Free	BG | C/F | Rx | Ex | Wt	• Medication reminders • BG measurement reminders • Diabetes education	App has privacy policy. Developer has access to records and personally identifiable information and can share information with third-party contractors. Developer cannot guarantee security of personal information. Apple version of app recently changed to a new developer and they implemented a new policy.	72.3	• HbA1c	The study was *moderate* quality.[27]
	Android (tablet and phone)	Free			Privacy policy has not been updated since 2012, but the developer maintains they have no access to records or personally identifiable information. Developer can share information only if user creates an account.			
Glucose Buddy Pro (GB+)[43]	Apple (iPhone, iPad, iPod Touch)	$1.99	BG | HbA1c | C/F | Rx | Ex | Wt	• Medication reminders • BG measurement reminders • Diabetes education	App has privacy policy and has access to records and personally identifiable information. Developer can share information with third-party contractors. Developer cannot guarantee security of personal information. Apple version of app recently changed developers and implemented a new policy.	65.8	• HbA1c	
Diabetes Manager[41]	Apple (iPhone, iPad, iPod Touch)	$4.99	BG | HbA1c | C/F	• Insulin dose suggestions • HbA1c calculations	Could not determine if app has a privacy policy.	68.5	• HbA1c	The study was *low* quality.[26]
Dbees[50, 54]	Apple** (iPhone, iPad, iPod Touch)	Free	BG | C/F | Rx | Ex | Wt	• Medication reminders • BG measurement reminders • Dietary calculator • Forum for diabetes education	App has a privacy policy. Developer will not sell information but will use information for internal purposes in order to keep the app functioning.	Unable to assess.	• Participants found this app to be useable	The study was *moderate* quality.[25]
	Android (tablet and phone)	Free				65		

Name of App	Platform	Cost	What does the app track?	What feedback does the app provide to patients?	Does this app have a privacy/security policy?	Usability (out of 100)	Patients who used the app saw improvement in which outcomes?*	Can I trust the results?
Diabetes Diary[51]	Android (tablet and phone) Pebble Smart watch	Free	BG | C/F | Rx | Ex | Wt	• Nutrition Database	App does not have a privacy policy.	16	• Out-of-range hypoglycemic and hyperglycemic episodes	The study was *low* quality.[32]
Diabetes Interactive Diary (DID+)[52]	Available on Android platforms, but unavailable in the United States	Free to download. Unsure if any additional costs.	BG | C/F | Rx | Ex	• Nutrition database • EMR connection	Could not determine if app has a privacy policy.	Unable to assess.	• Triglycerides • Treatment satisfaction • Severe (grade 2) hypoglycemic episodes	The studies were *moderate* quality.[30, 31]
Diabeo Telesage[40, 53]	Available on Apple and Android platforms, but unavailable in the United States	Free, but requires prescription & subscription.	Features unclear	• Self-adjusting insulin calculator • Connection to health team via automated patient data monitoring	Could not determine if app has a privacy policy.	Unable to assess.	• HbA1c	The study was *moderate* quality.[24]

BG = blood glucose; C/F = carbohydrates/food; EMR = electronic medical record; Ex = exercise; HbA1c = hemoglobin A1c; Rx = prescriptions/medication; Wt = weight

*****The "Patients who used the app saw improvement in which outcomes?" column shows significant between-group outcomes and study-reported satisfaction/usability only.

**Not currently supported by IOS 11.

Description of Apps

Glucose Buddy

App features. Glucose Buddy (version 3.7 for Apple and 1.0 for Google Play) is available for free on Apple[44] and Android[49] operating systems. Glucose Buddy Pro (version 5.13) is only available from the Apple App Store and costs $1.99.[43] Both Apple apps were bought by a new developer and were updated in January 2018. These apps are very large (153.4 MB each). The Android app is only 8.62 MB and has not been updated since 2012. All three apps provide users with the ability to track blood glucose, HbA1c, meals and carbohydrates, medication, and physical activity; provide medication and glucose measurement reminders; and assist with HbA1c calculation. Only Glucose Buddy Pro allows users to track weight and blood pressure and display it graphically, though using the "notes" feature on Glucose Buddy could help to log these changes. The user interfaces of Glucose Buddy and Glucose Buddy Pro are almost identical, and whenever a user of Glucose Buddy chooses an option that is only available on Pro, the app prompts the user to upgrade. This allows for an easy transition from one app to another, if the user chooses to upgrade.

Glucose Buddy has a 4.8/5 Apple App Store rating (3,301 reviews) and a 4.4/5 Google Play rating (13,891 reviews). Glucose Buddy Pro scored a 4.8/5 (1,694 reviews) on the App Store. The developer of Glucose Buddy and Glucose Buddy Pro (Apple) has a privacy policy that addresses the use of cookies, collection of personal information, and personal information is used. The developer has access to records and personally identifiable information and can share information with third-party contractors. The developer cannot guarantee security of personal information. Glucose Buddy (Android) privacy policy has no red flags, and the developer explicitly states that the developer has no access to records or any personally identifiable information.

App usability. Out of a possible 100, Glucose Buddy scored a 72.3 and Glucose Buddy Pro scored a 65.8. According to the usability scales, Glucose Buddy has "acceptable" usability, and Glucose Buddy Pro has "marginal" acceptability, which are generally consistent with reviews in both app marketplaces.

Summary of evidence. A 6-month 2013 RCT (n=72)[27] in Australia evaluated the efficacy of Glucose Buddy (of note, we could not determine if the study evaluated "Glucose Buddy" or "Glucose Buddy Pro). Participants had a mean duration of diabetes of nearly 19 years. Thirty-eight percent of participants used an insulin pump. The intervention group used Glucose Buddy, which allowed participants to manually enter data including blood glucose levels, insulin other medication dosages, diet, and physical activity. Participants received personalized feedback on their data from a certified diabetes educator at a minimum of one text message per week. The control group received usual care which included a visit to primary care diabetes health care practitioner every 3 months, and did not have any feedback from the certified diabetes educator. The intervention group demonstrated no statistically significant improvement in quality of life, self-care activities (e.g., diet, exercise, glucose testing), or diabetes-related self-efficacy. The interaction effect between the intervention and control group for HbA1c at 9 months (6 months of intervention and 3 months follow-up) was clinically and statistically significant (difference-in-difference = -1.39%; $p<.001$). The effect of HbA1c should be interpreted with caution because of the significant differences between intervention and control groups at baseline.

Study quality. This study was moderate quality, due to a lack of information on the allocation concealment and a high attrition rate (26 percent). Also, the intervention group received text

messages from a certified diabetes educator while the control group did not. Therefore, the results of this study are applicable when Glucose Buddy is used in combination with text messages from a diabetes educator. If this additional support affected some outcomes, the effects of Glucose Buddy by itself are less certain.

Diabetes Manager

App features. Diabetes Manager (version 3.2, $4.99) is available on Apple operating system.[41] The app was last updated in April 2016. This 26.7 MB app can track blood glucose, HbA1c, meals/carbohydrates, receive insulin dose suggestions, and receive HbA1c calculations. This app has a generic food database, which allows users to select their meals and automatically import carbohydrate and other nutrition information. In addition to English, the app is available in German and Portuguese. Diabetes Manager has a 3.25/5 rating (10 reviews) in the App Store. We were unable to access the developer's privacy policy statement.

App usability. Out of a possible 100, Diabetes Manager scored a 68.5, which is at the upper end of "marginal" usability. This is consistent with App Store reviews of this app.

Summary of evidence. A 6-month 2017 RCT (n=100)[26] from the United States evaluated the efficacy of Diabetes Manager. Participants had a mean duration of diabetes of nearly 25 years in the intervention group and 22 years in the control group. Both groups had a similar percentage of participants who were overweight (body mass index [BMI]=27). The intervention group included Diabetes Manager combined with the iBGStar System in which a blood glucose meter connects to a participant's iPhone. When the iBGStar System is used with the Diabetes Manager app, the patient's phone functions as a blood glucose meter. The intervention group had communication every 7 to 14 days with a provider via email, text, or phone. The control group was provided with an Accu-Chek Nano Glucometer and training. Participants in the control group did not have regular scheduled communication with providers, but were encouraged to contact providers as needed. The intervention was shown to statistically reduce HbA1c (difference-in-difference = -0.35%; p=0.04), but did not meet the threshold for a clinically significant reduction (0.5 percent). The app demonstrated no significant reduction in weight or hypoglycemic events.

Study quality. This study was low quality due to inconsistent reporting of outcomes as well as lack of information on randomization and allocation concealment. In addition, providers contacted participants in the intervention group using the app every 7 to 14 days, while the control group did not have regularly scheduled contact with providers. Therefore, the results of this study are applicable when Diabetes Manager is used in addition to scheduled contact with providers every 7 to 14 days. If this additional support affected some outcomes, then the effects of Diabetes Manager by itself are less certain.

Dbees

App features. Dbees (version 0.9.5 in the Apple App Store and 0.9.51 in Google Play, free) is available on Apple and Android operating systems.[50,54] However, a graphical error will not allow login credentials to be entered on either an iPhone or an iPad, therefore we were unable to use this app on Apple devices. The Apple app was last updated in 2012, so it is unknown if this function will be fixed in the near future. This app is also not supported by the most recent Apple software (IOS 11). The Android app does not have this graphical error, so we were able to use it. This app is the smallest of all of the apps we evaluated, at 1.68 MB. Users must first create an account online and enter basic information about their diabetes before they are able to use the mobile app. Once users log into the app, they can track their blood glucose, meals and

carbohydrates, medication, physical activity, and weight. Dbees has a 2.7/5 rating in the Android marketplace. A privacy policy is available on the Dbees Web site, and there are no clear data security issues.

App usability. We were only able to evaluate the Android app due to the graphical error on the Apple app. The Android app's setup takes considerably longer than the other examined apps. We scored this app as 65 out of 100 on the usability scale. Other researchers scored this app slightly higher (77) using the same scale.[25] Their scores indicate "acceptable" usability, while our researchers' scores indicate "marginal" usability. Our "marginal" usability score is consistent with Android marketplace ratings of the app.

Summary of evidence A 3-month 2015 RCT (n=72)[25] conducted in the Netherlands evaluated the efficacy of Dbees. Participants had a mean duration of diabetes of nearly 17 years and two-thirds (66 percent) were on an insulin pump. Participants had important comorbidities including retinopathy (25 percent) and neuropathy (19 percent). The intervention group used the Dbees app and personal Web portal that allowed manual entry of participant self-care data, including blood glucose, carbohydrate intake, medication, and physical exercise. The control group used a standard paper diary. The study did not demonstrate significant changes in HbA1c, quality of life, or diabetes emotional distress.

Study quality. This study was moderate quality due to a lack of clarity on randomization and insufficient detail about the difference in planned interactions with research staff between the group that used the app and the control group.

Diabetes Diary

App features. Diabetes Diary (version 1.7, free) is available on the Android operating system.[51] The app was last updated in June 2017. This 25.11 MB app can track blood glucose, meals/carbohydrates, physical activity, and weight. Like the Diabetes Manager app, this app has a generic food database that allows users to select their meals and automatically import carbohydrate and other nutrition information. Along with English, the app is available in Norwegian and Czech. Diabetes Diary has a 4.5/5 rating (40 reviews) on Google Play. This app has a privacy policy that discusses data security and how information will be used, and while there are no clear red flags, this app will request access to photos and Bluetooth connections.

App usability. Out of a possible 100, this app only scored 16 on the SUS, which is "not acceptable" according to our usability scale. This is not consistent with ratings on Google Play. This may be due to the limited scope of the SUS, and the relatively brief time SUS reviewers interacted with the app.

Summary of evidence. A 2015 RCT (n=30)[32] from Norway of stepped wedge design with two endpoints at 8 and 10 weeks evaluated the efficacy of Diabetes Diary with an additional data driven feedback module for blood glucose self-management, Diastat. Participants had a mean HbA1c of 8.2 percent. Both intervention and control groups used the Diabetes Diary in this RCT. The intervention group used the Diabetes Diary with the Diastat feedback module for blood glucose management, while the control group used the Diabetes Diary app without the Diastat feedback module. Out-of-range blood glucose events, defined as blood glucose outside range 72-270 mg/dL, were found to be significantly reduced in the Diastat intervention groups (median out-of-range events over 2 weeks: -14.5 percent [95% CI -18.0 to -9.0; $p< 0.001$]). We could not determine the effect of Diastat on HbA1c because the between-group difference-in-differences was not provided.

Study quality. This study was low quality based on incomplete information about randomization and lack of information about allocation concealment. In addition, there were insufficient details about the difference in planned interactions between the research staff and intervention and control groups.

Diabetes Interactive Diary (also called Il Diario Interattivo per il Diabete, or DID)

App features. Diabetes Interactive Diary (DID) (version 1.1.3) is available in the Google Play store (free),[52] but is unavailable to download in the United States. The app was last updated in June 2017. Per the developer's Web site,[55] this 40 MB Italian app can track blood glucose, diet, physical activity, and medication use. The app uses a photographic database of food to receive real time information about each meal's nutritional value and carbohydrate values, and then provides meal-based insulin dose suggestions. Using MyStar Connect, DID can also send information directly to a physician via the patients' EMR. The Google Play store has 15 reviews for this app, averaging 3.7 out of 5. While the developer has a general privacy policy which addresses data maintenance, use of cookies, and user's rights, we could not identify a policy specifically attached to this app.

App usability. Because the app was unavailable to download in the United States, we were unable to provide a usability score.

Summary of evidence. The efficacy of DID was evaluated in two RCTs in Italy.[30, 31] The 6-month 2010 RCT (n=130)[30] was composed of participants with type 1 diabetes on multiple daily injections of short- and long-acting insulin analogs or an insulin pump. Participants had a mean duration of diabetes more than 8 years and nearly one-fifth (19 percent) of both intervention and control groups were on an insulin pump. The intervention group received the DID, while the control group received standard education from their providers. The intervention group was found to have significant change in treatment satisfaction as measured by the World Health Organization Diabetes Treatment Satisfaction Questionnaire (WHO-DTSQ) (p=0.04). Within the lipid profile, only triglycerides (TG) were statistically significantly improved (p=0.04) but this result should be interpreted with caution since intervention and control groups were statistically different at baseline. No significant improvement was found for total cholesterol (TC), high density lipoprotein (HDL), or low-density lipoprotein (LDL). All other outcomes did not demonstrate significant changes between intervention and control groups, including HbA1c, quality of life, weight change, self-reported mild hypoglycemia, and fasting blood glucose (FBG).

The 6-month 2013 RCT (n=127)[31] was composed of participants with type 1 diabetes on a basal bolus regimen of insulin. Participants with all other insulin regimens, including insulin pumps, were excluded. Participants had a mean duration of diabetes of more than 16 years in the intervention group compared with 15 years in the control group. This study used the same intervention as in the 2010 study described above, and the control group received standard education**.** The intervention group was shown to have statistically significant improvement in grade 2 hypoglycemic episodes, but no improvement in all other outcomes (quality of life, HbA1c, FBG, mean amplitude of glucose excursions, blood pressure, lipids [TC, TG, HDL, LDL], grade 1 hypoglycemic episodes, and diabetes treatment satisfaction). Grade 1 hypoglycemic episodes symptomatic or asymptomatic blood glucose levels of less than 60 mg/dl where the patient does not receive assistance, whereas grade 2 episodes involved coma, seizure, or significant neurologic impairment or requiring assistance. Grade 2 hypoglycemic episodes

were significantly reduced compared with the control group [Incidence Risk Ratio 0.14 ([95% CI 0.07 to 0.29]).

Study quality. Both the 2010 and 2013 studies were moderate quality. First, there were potential applicability concerns because research personnel interaction varied between intervention and control groups. In both studies, participants in the intervention groups attended a course with the physician and/or dietitian on the use of DID composed of a maximum of three visits during a maximum period of 2 weeks. Participants in the control groups did not receive this additional interaction with a physician and/or dietitian. Thus, the results of this study are applicable when DID is used in concert with a 2-week course with a physician or dietitian. If this additional support affected some outcomes, then the effects of DID by itself are less certain. Second, we could not identify protocols for either study so the studies lacked prespecified outcomes.

Diabeo Telesage (also called Diabeo)

App features. This app is available in both the Apple App Store (version 2.11.2, free)[40] and the Google Play store (version 2.11.2, free),[53] but is unavailable to download in the United States. The app was last updated in May 2017, but the app size is not reported. This French app requires a prescription by a physician and must be activated by that physician. Per the Diabeo Telesage Web site,[56] the app includes a self-adjusting insulin calculator, a digital diary for long- and short-acting insulin, and easy access to the user's healthcare team through automated patient data monitoring. The privacy policy created by the developer contains no major concerns.

App usability. Because the app was unavailable to download in the United States, we were unable to provide a usability score.

Summary of evidence. The efficacy of Diabeo was studied in a 6-month RCT (n=180)[24] in France. Participant mean age was 33.8 years. Of note this population had diabetes that was difficult to control despite intense insulin therapy. Participants had HbA1c of greater or equal to 8 percent and a basal bolus regimen for a minimum of 6 months. Participants had a mean duration of diabetes greater than 16 years, and nearly one-third (37 percent) had an insulin pump. The study included three intervention arms: Diabeo software alone, Diabeo software with teleconsultations every 2 weeks, and control group of paper logbooks. In teleconsultations both participants and physicians reviewed data on a smart phone or computer monitor while physicians provided motivation and advice on insulin doses.

The intervention group of Diabeo showed a significant decrease in HbA1c over 6 months, but did not demonstrate significant improvements in quality of life. HbA1c was shown to have a statistically significant reduction when Diabeo software was used alone compared with control (-0.67 percent [95% CI 0.35 to -0.99] $p \leq 0.001$) and a greater reduction when Diabeo software was used with teleconsultations compared with control (-0.91 percent [95% CI 0.60 to -1.21] $p \leq 0.001$). For major hypoglycemic episodes (defined as those requiring third-party assistance), authors reported three episodes in each intervention arm and one in the control arm.

Diabeo was also evaluated in a subgroup analysis of high and low system use.[36] High system users and low system users were based on the median percentage of informed meals, where high system users had greater than the median rate of Diabeo use. Informed meals were defined as meals for which the Diabeo system proposed an insulin dose based on pre-meal blood glucose or FBG, physical activity, and expected carbohydrate consumption. There was no statistically significant reduction in HbA1c between the two user groups (p=0.879). No other outcomes were examined.

Study quality. This study was moderate quality based on concerns related to randomization and inclusion of participants who did not meet inclusion criteria. In addition, the study does not provide sufficient detail to determine if the two intervention groups, Diabeo alone and Diabeo with teleconsultation, received more interaction with research personnel than the control group.

Type 2 Diabetes

Overall Summary

For type 2 diabetes, we identified seven publications[28, 29, 33-35, 3737] of six studies evaluating five commercially available apps (BlueStar Diabetes [BlueStar],[39, 57] mDiab,[45, 46, 58, 59] Health Coach +,[47, 60] Gather Health,[42, 61] and WellTang,[48]). Please see Table 2 for further description of apps, and Appendix C, Table C-2 for a detailed description of each study.

Of the five apps, one (WellTang[48]) was free to download, three (Health Coach +,[47, 60] Gather Health,[42, 61] and BlueStar[39, 57]) required a paid subscription or access code, and one (mDiab) had two tiers of access: mDiab Lite[45, 58] and mDiab.[59] Because two apps (Health Coach+[47, 60] and Gather Health[42, 61]) required a subscription and one (WellTang[48]) was not available in English, we were only able to download and test the usability of two apps (mDiab[45, 46, 58, 59] and BlueStar[38,48]).

Participants in the six studies ranged in mean age from 48 to 55 years old, mean duration of diabetes from 6.63 to 11 years, and mean baseline HbA1c from 8.59 to 9.86 percent depending on the study group. Study duration and length of time that participants used the apps ranged from 2 to 12 months. Of the seven publications, six were RCTs[28, 29, 33-35, 38] and one[37] was a subgroup analysis of an included RCT. Each app was only evaluated in one study (excluding subgroup analyses), except BlueStar which was evaluated in 2008 and again in 2011. Only one study reported app "dosage."[34] Main outcomes examined included HbA1c,[28, 29, 33-35, 37] blood pressure,[29, 35, 37] lipids,[29, 35, 37] and hypoglycemic events.[29, 35, 37]

Table 2. Features, usability, and significant outcomes for apps for type 2 diabetes

Name of App	Platform	Cost	What does the app track?	What feedback does the app provide to patients?	Does this app have a privacy/security policy?	Usability (out of 100)	Patients who used the app saw improvement in which outcomes?*	Can I trust the results?
BlueStar Diabetes[39, 57]	Apple (iPhone, iPad, iPod Touch)	Free to download, but requires an access code	BG | HbA1c | C/F | Rx | Ex | Wt	• Dietary advice • Medication reminders • BG level alerts • Diabetes education • Connection to EMR • Connects to wearables	App has privacy policy. App tracks user's actions, but the data is generally secure and safeguards exist to prevent third parties from taking data without permission.	85	• HbA1c • Increase in medication dosage • Satisfaction with provider care • Self-entered medication errors identified by app • Participants were satisfied with the app.	The studies were *low* quality.[29, 38]
	Android (tablet and phone)	Free to download, but requires an access code	BG | HbA1c | C/F | Rx | Ex | Wt					
mDiab Lite[45, 58]	Apple** (iPhone, iPad, iPod Touch)	Free	BG | HbA1c | C/F | Rx	• BG level alerts • HbA1c calculation • Diabetes education	App does not have a privacy policy.	47.5	• Evidence did not show improved outcomes. • Participants were satisfied with app and found it be usable.	The study was *low* quality.[33]
	Android (tablet and phone)	Free	BG | HbA1c | C/F | Rx | Ex | Wt	• BG measurement reminders • BG level alerts • HbA1c calculation				
mDiab[46, 59]	Apple (iPhone, iPad, iPod Touch)	$5.99	BG | HbA1c | C/F | Rx | Ex | Wt	• Medication reminders • BG measurement reminders • BG level alerts • HbA1c calculation	App does not have a privacy policy.	48.3		
	Android (tablet and phone)	$5.33						
NexJ Health Coach +[47, 60]	Apple (iPhone, iPad, iPod Touch)	Free, but requires prescription & subscription	BG | HbA1c | C/F | Rx | Ex | Wt	• Medication reminders • Diabetes education	App has privacy policy. App tracks user's actions, but data is generally secure and safeguards exist to prevent third parties from taking data without permission.	Unable to assess.	• Evidence did not show improved outcomes.	The study was *moderate* quality.[34]
	Android (tablet and phone)	Free, but requires prescription						

		& subscription						
Gather Health[42, 61]	Apple (iPhone, iPad, iPod Touch)	Free, but requires prescription & subscription	BG | HbA1c | Rx | Ex | Wt	• Dietary advice • Medication reminders • BG measurement reminders • BG level alerts • HbA1c calculations • Diabetes education	Developer reserves the right to share, sell, transfer, license, and/or covey some or all the information collected on the platform including drug administration patterns and tests conducted with another business entity for any reason whatsoever, without disclosing the user's identity or contact details.	Unable to assess.	• HbA1c	The study was *low* quality.[28]
	Android (tablet and phone)	Free, but requires prescription & subscription						
WellTang[48]	Apple (iPhone, iPad, iPod Touch), however the app downloads in Mandarin and we were unable to change it to English	Free to download. Unsure if any additional costs	BG | HbA1c | C/F | Rx | Ex | Wt	• Connects the patient's phone, wearables, and glucose monitor to physician • Diabetes education	Could not determine if app has a privacy policy.	Unable to assess.	• HbA1c • Fasting blood glucose • 2-hour post-breakfast blood glucose • Diabetes knowledge • Self-care behaviors • Participants were satisfied with app.	The study was *moderate* quality.[35]

BG = blood glucose; C/F = carbohydrates/food; EMR = electronic medical record; Ex = exercise; HBA1c = hemoglobin A1c; Rx = prescriptions/medication; Wt = weight

* The "Patients who used the app saw improvement in which outcomes?" column shows significant between-group outcomes and study-reported satisfaction/usability only.

**Not currently supported by IOS 11.

Description of Apps

BlueStar Diabetes

App features. BlueStar Diabetes (BlueStar) (free to download but requires an access code from a member of the care team to use the app) is available on Apple (version 4.0.1)[39] and Android (version 4.0.1)[57] operating systems. In 2010, an earlier version of BlueStar (then called DiabetesManager) received 510(k) clearance as a Class II medical device, with a prescription required for the use of coaching messages.[62] In 2017, the FDA cleared BlueStar, including coaching messages, as a non-prescription device due to its low risk. A prescription was required for its in-app insulin calculation feature.[63]

The Apple app is 51.6 MB and the Android app is 29.86 MB. Users can track blood glucose, HbA1c, carbohydrates/food, prescriptions, exercise, and weight. The platform also provides dietary advice, medication reminders, glucose measurement reminders, glucose level alerts, diabetes education, connection to wearables (specifically Fitbit, Jawbone, and Misfit fitness trackers), and a connection to the user's EMR or patient portal using Human API integration software. The security statement in the privacy policy has ensured that encryption mechanisms are in place to protect user data, although the developer can use personal health information for treatment, payment and operations purposes. In 15 reviews, the app averages 4.5/5 stars in the Apple App Store and 4.2/5 from 86 reviews in Google Play.

App usability. Out of a possible 100, BlueStar scored 85, which is considered "acceptable" usability. This was the highest usability score of the apps that were used. This is consistent with the Apple App Store and the Google Play reviews.

Summary of evidence. The efficacy of BlueStar was examined in a 3-month RCT (n=30)[38], a 12-month RCT (n=163)[29] and an associated subgroup analysis (n=118)[37] that examined differences by age. Studies were conducted in the United States. Participants in both RCTs had similar baseline characteristics (mean age 51-52.8 years old; mean diabetes duration 7.6-8.2 years; mean HbA1c 9.0-9.5 percent).

In the 2008 RCT,[38] the intervention group received the BlueStar app (then called DiabetesManager System) along with a Bluetooth-enabled blood glucose monitor. In the intervention group, participants used the BlueStar app to label blood glucose measurements that were synced to their phone, entered carbohydrates and medications, and received feedback on nutrition, lifestyle, state of change, and self-management skills based on their entered information. The app also suggested medication changes, which were sent to both the participant and physician. The physician could then recommend a change in medication. The control group received usual care, which included receiving a blood glucose meter and instructions to send logbooks to their physician every 2 weeks. The intervention group had greater improvements in HbA1c than control (difference of -1.35%; $p<0.04$). Intervention group participants were also more likely to have increase in medication dosage ($p=.002$), to have self-entered medication errors identified by app ($p=.002$), and be satisfied with care ($p=.004$). There were no differences between groups in new depression diagnoses, self-reported improved knowledge of food choices or confidence in diabetes control. Cumulative scores for the Diabetes Self-Care Activities scale were not reported, so we could not determine whether there were differences between groups. Study authors report that "at least 91%" of the intervention group were satisfied with specific components of the app and that 53% had medication errors identified by the app.

In the 2011 RCT,[29] there were three intervention groups. All groups used the BlueStar app, which included access to virtual case managers. In the coach only (CO) group, providers could

receive data if participants shared it. In the coach primary care physician (PCP) portal (CPP) group and coach PCP portal with decision support (CPDS) group, providers were trained to access data through an online portal. In the CPDS group, providers also received quarterly reports summarizing participant progress and relevant evidence-based guidelines. Control participants received usual care by providing physicians with blood glucose readings and logbooks. The intervention group with the most intensive support (CPDS) had clinically and statistically significantly improved HbA1c compared with the control group (difference of -1.2 percent; p=0.001) but no changes on other outcomes including blood pressure, lipids, diabetes distress, diabetes symptoms, or depression. The CO group also had a clinically and statistically significant difference in HbA1c (-0.9 percent; p=.027) but the CPP group did not (p=.40) compared with control. Hospitalizations, ER visits, and hypoglycemic events were infrequent in all groups, and there were no deaths. The subgroup analysis[37] found that both those <55 versus ≥55 years old in the CPDS group had improved HbA1c compared with control; there were no significant differences by age.

Study quality. We rated both RCTs as low quality due to methodological issues. In the 2008 RCT, there were baseline differences in diabetes duration between intervention and control groups that weren't accounted for, data from drop-outs were not included in analyses, cumulative scores for the Diabetes Self-Care Activities scale were not reported and other measures of patient self-efficacy and satisfaction with the app were not validated. In the 2011 RCT, there were issues in recruiting and retaining participants, rates of attrition ranged from 10 to 40 percent depending on the group, and authors noted that the IRB required that participants be re-consented.

mDiab

App features. mDiab Lite (free)[45, 58] and mDiab (Apple-$5.99/Android-$5.33)[46, 59] are available on Apple (lite-version 1.3; regular-version 1.4.1) and Android (lite-version 1.0; regular-version 1.1) operating systems. Of note, mDiab Lite is not supported by the most recent Apple software (IOS 11). mDiab Lite has not been updated since 2014, but mDiab was last updated in July 2017. mDiab Lite is 5.0 MB on Apple devices and 1.68 MB on Android devices. mDiab is 4.9 MB on Apple devices and 16 MB on Android devices, making them among the smallest of the diabetes self-management apps analyzed. For both mDiab Lite and mDiab, the user can track blood glucose, HbA1c, medication, physical activity, and weight. With mDiab, the user can also set alarms to receive medication and glucose measurement reminders. Much like Glucose Buddy, the user interfaces for mDiab Lite and mDiab are almost identical, and selecting a feature that is only available in mDiab will result in a message asking the user if they want to upgrade. However, not all features are available through a simple upgrade. Functions like direct connection between physician and user and data synchronization with the mDiab database are only available after the user requests access from the app developers. In addition to English, the apps are also available in French and German. mDiab Lite has one review in the Apple App Store and has a 5/5-star rating. Six Google Play reviewers gave mDiab Lite a 4.5/5 rating. mDiab has only one review in the App Store and has a 1/5-star rating. Three Google Play reviewers gave mDiab an average of 4.3/5.

App usability. Out of a possible 100, mDiab Lite scored a 47.5 and mDiab scored a 48.3. They both fall into the "not acceptable" usability category. This is much lower than the Apple App Store and Google Play reviews. This may be due to the limited scope of the SUS, and the relatively brief time SUS reviewers spent with the app.

Summary of evidence. The efficacy of mDiab was tested in a 2-month RCT (n=40) in the Democratic Republic of Congo.[33] Of note, we could not determine whether the study tested the mDiab Lite or mDiab. RCT participants were on average 53.3 years old, and had a mean baseline HbA1c of 8.67 percent in the intervention group versus 8.59 percent in the control group. The intervention group used the app as described in "App features" and could connect with doctors via the mobile app or short message service (SMS) as well as use a Web-based health portal. The control group received usual care without the app or Web-based portal. The amount of time each group spent with physicians or study staff was not reported. Although authors reported a greater reduction in HbA1c in the intervention group than control, they did not provide sufficient detail to determine if results were significant. The study also reported that the glucose variability (standard deviation of HbA1c) was lower in the intervention group than controls at follow-up, but again, the detail was insufficient to determine if results were significant. The study also reported that intervention group gave a score of 7/10 or higher on three survey measurements related to usability and design (7), efficiency and therapy satisfaction (7.43), and acceptance and appreciation of intervention (8.65). However, it was not clear if these tools were valid or reliable, and the questions that comprised the third measure were not described in the article.

Study quality. This study was low quality due to a lack of information on randomization and allocation concealment, lack of information on how drop-out data was analyzed, and limited information on whether baseline characteristics (besides HbA1c) and relevant diabetes therapy were similar between groups. The health care context of the Democratic Republic of Congo is also considerably different than the United States, so applicability may be limited. Findings should also be interpreted with caution because authors examined HbA1c and usability/satisfaction without looking at harms.

NexJ Connected Wellness Platform—Health Coach + [NexJ]

App features. NexJ Connected Wellness Platform—Health Coach + [NexJ] (free) is available on Apple (version 2.1)[47] and Android (version 2.5)[60] operating systems. The Apple version was last updated in June 2016 and the Android version was last updated in August 2017. This app requires a prescription from a doctor to create an account. The cost of this Canadian-developed program is not publicly available. We were unable to use the app (which is 3.1 MB in size), but per its Web site, it allows the user to track blood glucose, HbA1c, meals and carbohydrates, medication, physical activity, and weight. The app also provides medication reminders and is set up to connect to smart watches and the user's health record or user portal. To keep the user's sensitive medical data safe, the developer has many physical, logical, and procedural safeguards in place. There are no reviews for this app on the Apple App Store, but Google Play has five reviews giving the Health Coach + app a 5/5 score.

App usability. Because this app requires a prescription, we were unable to use it or provide a usability score.

Summary of evidence. The efficacy of the NexJ was examined in a 6-month RCT in Canada among those from a lower socioeconomic status community (n=97).[34] RCT participants were on average 53.1 years old in the intervention group and 53.3 years in the control group, and had baseline HbA1c levels of 8.69 percent in intervention and 8.89 percent in control group. Intervention participants used the app to manually enter health data and communicate with a health coach via secure messaging, scheduled phone contact, or during in-person meetings (mean total contact: 38 minutes/week). Control participants received health coach support without access to a mobile app. There were no significant differences between groups in the reduction in

HbA1c. The remaining data on weight, waist circumference, BMI, life satisfaction, depression, anxiety, quality of life, and affect were presented as pre-post differences within groups and as between-group differences at baseline and follow-up. Calculations on the difference in difference were not presented so we could not determine if there was a significant change in outcomes in the intervention group compared with controls.

Study quality. This study was moderate quality due to high rates of attrition in the intervention group (28 percent).

Gather Health

App features. Gather Health (free) is available on Apple (version 1.6.3)[42] and Android[61] operating systems (version 1.6.3). The Apple version was last updated in January 2016 and the Android version was last updated in March 2016. This app requires a "prescription" from a doctor to create an account. The cost of this program is not publicly available, but their Web site states that "custom work may incur additional fees" above the base price.[64] We were unable to use the 21.7 MB app, but according to their Web site, users are able to track blood glucose, HbA1c, medication use, physical activity, and weight. Gather Health also provides dietary advice, medication reminders, glucose measurement reminders, glucose level alerts, HbA1c calculations, and diabetes education to its users. We could not determine if the app connects to an EMR, however the security statement in the privacy policy says, "Data will be encrypted on your device and when sent to your doctors and other care team members."[64] One Apple user gave the app a 5/5 review, and the average of 95 android users was 4.3/5.

App usability. Because this app requires a prescription, we were unable to use it or provide a usability score.

Summary of evidence. The efficacy of Gather Health was tested in a 6-month RCT (n=91) in India.[28] RCT participants were on average 48.4 years old, with a median diabetes duration of 10 years, and a mean baseline HbA1c of 9.3 percent. Both intervention and control groups received free visits, laboratory tests, test trips, and lancets, but the intervention group received the app and a mobile phone plan stipend. Per the Clinicaltrials.gov protocol for this study, providers would not contact control group participants between regular visits, though they would respond to queries directed at them. Intervention group participants would enter in medication and BG testing goals, receive automated reminders, and data would be regularly reviewed by study staff. Data on reduction in HbA1c were analyzed according to three different methods; there was a clinical and statistical significant improvement in HbA1c in the intervention compared with control through analysis of only follow-up data (difference-in-differences: -0.7 percent; p=0.02) and last observation carried forward (p=0.045), but not imputation from treatment arm means (p=0.06).

Study quality. This study was of low quality due to a lack of information on randomization and allocation concealment, and considerably more interaction with study staff in the intervention than the control group. Findings should also be interpreted with caution because authors examined HbA1c without looking at harms.

WellTang

App features. While WellTang (free) is available in the Apple App Store (version 4.6.0),[48] it is only accessible by scanning a QR code on the WellTang Web site unless the user has a Mandarin keyboard.[65] Scanning the code will take the user to the App Store where the app can be downloaded. The 72 MB app was last updated in June 2017. While the Apple App Store claims

the app is available in English, we could only download it in Mandarin, and we were unable to translate the application into English. According the Web site (translated by Google Translate), the WellTang app can help users track their blood glucose, HbA1c, meals and carbohydrates, medication use, physical activity, and weight.[65] It also provides users with diabetes education. This app can also connect users and their phones, "wearables," and glucose-measuring devices to their physicians so that care teams can monitor a user's progress and adjust treatment plans when necessary. It is important to note that we were unable to read the privacy policy, and are unsure of any data security issues that may be present. Because we were unable to use the app, there may be additional functionality not listed here. Five reviewers ranked the app as 4/5 in the Apple App Store.

App usability. Because the app was not available in English, we were unable to rate its usability.

Summary of evidence. The efficacy of WellTang was tested in a 3-month RCT (n=100) from China.[35] Due to the setting of the study, results should be interpreted with caution. RCT participants were on average 54 years old in the intervention group and 53.5 years in the control group. Participants had a mean diabetes duration of 6.65 years in intervention and 6.63 years in control, and had a baseline HbA1c of 9.86 percent in intervention and 9.76 percent in control. The intervention group used the WellTang app by self-entering health data and could ask questions and receive feedback from the study team usually within a day, while the control group received usual care from physicians who reviewed blood glucose readings, logbooks, and adjusted medication regimens to targeted goals once a month. The intervention group had significantly improved HbA1c (intervention changed -1.95 percent while control changed -0.79 percent from baseline; $p<0.001$), fasting blood glucose ($p<0.01$), 2-hour post-breakfast blood glucose ($p<0.01$), diabetes knowledge ($p<0.01$) and self-care behaviors ($p<0.01$) but no differences in blood pressure, LDL, weight, BMI, or waist or hip circumference. No participants changed the type of medication they were taking, but there were more medication dosage changes in the intervention group (significance not reported). Hypoglycemic events were infrequent in both groups. Additionally, 84 percent of intervention participants were satisfied with the app.

Study quality. This study was moderate quality due to a lack of information about allocation concealment, missing information on the number participants who dropped out of the control group, and no information on how drop-out data was analyzed.

Risk of Bias/Quality Assessment

Study quality varied for both type 1 and type 2 diabetes. Studies examining Diabetes Interactive Diary,[30, 31] Diabeo Telesage,[24] Glucose Buddy,[27] Dbees,[25] Health Coach +,[34] and WellTang,[35] were of moderate quality. Studies on Gather Health,[28] Diabetes Manager,[26] BlueStar,[29, 38] Diabetes Diary,[32] mDiab,[33] were of low quality. Common methodological issues included a lack of information about randomization and allocation concealment, more potential for interaction with study personnel in the intervention than the control groups, high rates of attrition, and a lack of information on how drop-out data were analyzed. Few studies reported whether providers or personnel were masked. Details on study quality for individual studies (Figure 1) and across studies (Figure 2) are presented below. For each criterion, red represents high risk of bias, yellow represents unclear risk of bias, and green represents low risk of bias. The overall assessment of study quality is presented at the bottom of each column.

Figure 1. Risk of bias and overall quality for individual studies for type 1 and type 2 diabetes

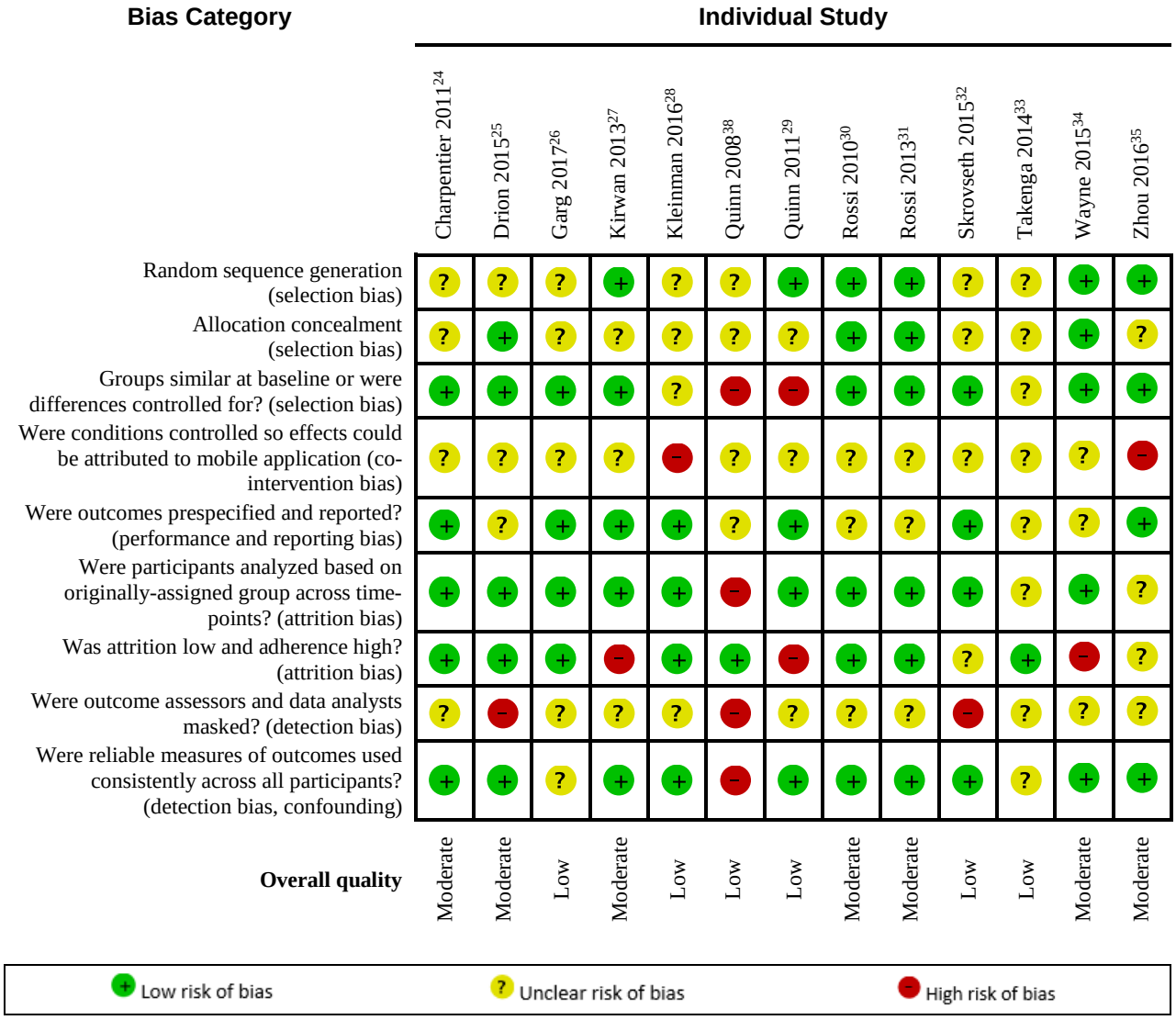
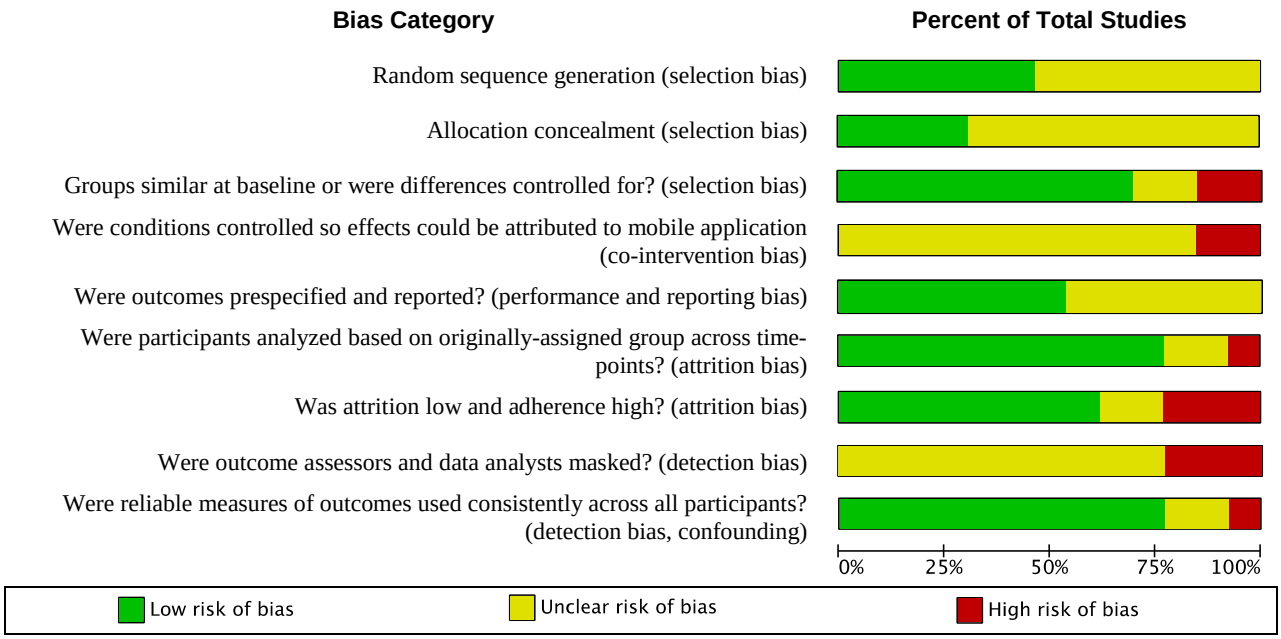


Figure 2. Risk of bias across studies for type 1 and type 2 diabetes



Discussion

This review provided a critical examination of three components of commercially available apps for diabetes self-management: (1) available features, (2) usability, and (3) clinical efficacy, including harms. This review bridges the gap between systematic reviews examining all types of mHealth (including apps that are proprietary or otherwise unavailable to consumers) and reviews that only examine features or usability of commercially available apps. Other mHealth researchers have explored several of these components in a single review, such as summarizing evidence on commercially available apps;[66] or summarizing evidence on all mHealth technologies and analyzing these technologies' adherence to clinical recommendations, features, and potential risk to patients.[16] This review builds on previous work by assessing the usability of apps that are currently commercially available. Our goal was to synthesize relevant information in a consumer-friendly way to both provide guidance to those currently making choices about which app to use, and to highlight research gaps that need to be addressed. Our focus on both evidence and user experiences is aligned with the goals of leaders in mHealth and diabetes fields, including the Digital Diabetes Congress[67] and Xcertia.[68]

Limited Statistical Efficacy of Commercially Available Apps

Our results highlight that relatively few apps available through app stores have evidence of efficacy, which is consistent with findings of other systematic reviews.[15, 16] For example, we did not find evidence for many of the apps that appear first when searching Google and Apple app stores, such as Diabetes: M, Diabetic Diet, MySugr, Blood Glucose Tracker, Sugar Sense, Diabetes and Blood Glucose Tracker, Carb Manager, or Diabetes In Check. Of the eight apps we identified as available for download in English in the United States, use of five apps (Glucose Buddy, Diabetes Manager, Diabetes Diary, Gather Health and BlueStar) demonstrated improvement in at least one outcome compared to controls, including HbA1c,[26-29, 37, 38] and out-of-range hypo and hyperglycemic episodes. Use of one app (BlueStar) was associated with an increase in medication dosage, identification of self-entered medication errors, and satisfaction with care. One app was only available in the United States in Mandarin (WellTang).[35,48] Use of this app demonstrated improvement in HbA1c, fasting blood glucose, 2-hour post-breakfast blood glucose, diabetes knowledge, and self-care behaviors.[35] Two additional apps[40, 52, 53] were not available in the United States; use of these apps demonstrated an improvement in HbA1c[24, 36] and triglyceride levels,[30, 31] as well as a reduction the number of severe (grade 2) hypoglycemic episodes.[30, 31]

Limited Clinical Efficacy of Commercially Available Apps

We found a clinically meaningful reduction in HbA1c of at least 0.5 percent in studies of five apps when compared with usual care. Of the five apps, two were for type 1 diabetes (Diabeo Telesage and Glucose Buddy) and three were for type 2 diabetes (BlueStar, WellTang, and Gather Health). Of note, we could not determine the effect of two apps (Diabetes Diary or mDiab) on HbA1c due to lack of information on between-group difference-in-differences. These findings demonstrate that only a few commercially available apps have clinical evidence supporting improved glycemic control.

Study Findings May Be Generalizable to Most Diabetes Patients

Findings from these short-term studies may be generalizable to most patients with type 1 and type 2 diabetes.

Study participants with type 1 diabetes were on average 33 to 40 years old with a diabetes duration of 16 to 25 years, making them comparable to the typical adult with type 1 diabetes who is usually diagnosed as a child, adolescent, or young adult.[69] However, participants may have had more severe diabetes than typical type 1 diabetes patients, as measured by insulin pump usage. Nationally 20 percent of type 1 patients are estimated to use an insulin pump.[70] Four studies with type 1 participants reported insulin pump usage ranging from 19 to 66 percent, while two studies of type 1 participants excluded participants with insulin pumps. In addition, multiple studies involved participants on complex management regimens (e.g., multi-day injections) including insulin pumps, which may have increased interest in using an app for self-care management.

Study participants with type 2 diabetes were on average 48 to 55 years old, which falls within the most diagnosed demographic for diabetes of ages 45 to 64.[71] Participants had an average diabetes duration of 6.6 to 11 years, which may have made them more likely to use a patient tool—like an app—for self-care management.

Older adults comprise an important subpopulation of patients with diabetes. The percentage of adults with type 2 diabetes increases with age, with the highest prevalence (25.2 percent) among those aged 65 years or older.[1] Although type 2 diabetes participants in our studies were on average 48 to 55 years old, older adults should be evaluated in future studies, as more than 40 percent of this group now owns smartphones.[72]

Variation in Usability Scores

We were only able to give usability scores to eight apps that we could download and access. Of these eight apps, we rated two of the apps as "acceptable" (Glucose Buddy and BlueStar), three as "marginal" (Glucose Buddy Pro, Diabetes Manager, and Dbees), and three as "not acceptable" (mDiab Lite, mDiab, and Diabetes Diary). These results suggest that consumers may have a difficult time using these apps. However, usability is subjective, and unless a consumer can download and test all the evidence-based apps, they may not be able to tell which app is best suited for them.

It is also important to note that the apps we evaluated do not have the same pleasing aesthetics as some of the more popular diabetes apps in the app stores. Because we did not identify published evidence on some of the more popular apps, we did not formally evaluate them in this review. However, other researchers that evaluated the usability of commercially available apps had similar findings. A 2014 systematic review of currently available diabetes apps found that usability for those 50 years and older was "moderate to good" for apps offering a narrow range of functions but "considerably worse" for apps offering more functions.[73] Another 2016 study examining 4 popular diabetes apps found that there was "wide variability" in the ease of entering blood glucose, one of the easiest tasks to complete of those examined.[74]

Limited Evidence To Detect Patterns between Cost, Features, and Efficacy

Our discussions with experts drew attention to the fact that decisionmakers want information on the relationship between costs, features, and efficacy of mobile apps. For example, do apps that require a fee or paid subscription result in larger benefits in outcomes? Are there specific features of apps that lead to improved health outcomes, and others that do not? Unfortunately, because we identified relatively few studies on commercially available apps, study quality was variable, and we could not empirically assess the features and usability of several apps, we could not make any judgements about the relationship between cost, features and efficacy.

Short Duration of Studies

Studies ranged from 2 to 12 months, which is relatively short compared with the lifelong duration of diabetes. It is unclear whether these apps impact long-term outcomes, including microvascular and macrovascular complications.

Methodological Issues With Available Evidence

Our risk of bias assessments revealed that there is lack of consistency in how researchers are reporting their mHealth studies. Limited information on randomization, allocation, masking, and analysis of drop-outs are common methodological problems in studies of health care interventions. However, other methodological issues specific to mHealth made it difficult to interpret and apply findings.

In general, the RCTs we identified were inconsistent in what they considered to be a positive effect of an app (i.e., pre-post differences, between-group differences, or both). In some cases, this was because the main purpose of the study was to see if both groups had a change from baseline. For example, the study on NexJ[34] was interested in whether a health coaching intervention was efficacious both with and without an app, so pre-post differences for both groups were presented. Still, study authors calculated the difference-in-difference between groups for HbA1c.

Study design also made it difficult to determine what effect could be attributed to the app and what was attributable to the additional interactions with study personnel or providers. For example, the 2011 RCT[29] on BlueStar included multiple intervention groups with varying degrees of support by providers, but the main comparison was between the most intensive intervention versus usual care, so it was impossible to determine what was the effect of that additional support. For several studies, the intervention group had the ability to message providers or study staff and get an immediate response while usual care participants had to go through standard channels like phone calls or monthly appointments. In these cases, the control group did not provide a sufficient degree of attention control so it is not clear whether the app or the extra attention was causing the effect. This makes it difficult to interpret and apply findings across health care contexts where patients may not have as much support.

Additional issues that came up in several studies included inconsistent or missing information on how much participants used apps (i.e., the “dosage” of the intervention), limited information on the content of diabetes education provided by the app or provider, and not examining potential harms.

Most of the systematic reviews we included in this review commented that there is a lack of rigorous research on apps for diabetes.[15, 21-23] Our conversations with KIs revealed that there are

many advocacy, research, and professional groups working to create guidance on both the reporting of mHealth studies, and on the interpretation of what constitutes an "effective" app. During our research, we identified tools to standardize mHealth reporting, such as the CONSORT-EHEALTH checklist.[75] These tools attempt to standardize the level of detail included in studies so that the results can be interpreted in a meaningful way; however, it does not appear that these tools have been consistently used even though the checklist was published in 2011, before a majority of the studies were published.

Limitations

In addition to limitations caused by the variable quality of identified studies, there were three major limitations in this review: limitations created by the type of report, limitations caused by the lack of access to some of the commercially available apps, and limitations in how usability was assessed.

Rapid Review Limitations

We identified our list of potentially relevant studies from five recently published systematic reviews as well as hand-searching. As a result, we may have missed eligible studies. Also of note, although we took steps to critically assess the potential for bias in these studies, we did not consider every potential area for bias. Specifically, we did not evaluate primary and secondary outcomes as specified by study authors. Therefore, we could not tell if these outcomes were selectively reported.

Limitations From Lack of Access to Apps

We focused on commercially available apps accessible by the general public; however, defining "commercially available" became difficult. Of the 13 apps we evaluated, only 10 were available on Apple platforms and 10 available on Android platforms. Of the 10 Apple apps, we were unable to download one because it was only available for download from the French Apple App Store. This means we could not provide first-hand usability scores and consumer details about the app and had to rely on second-hand, potentially biased sources, mainly the developer Web sites. So, while we included the app because it was a commercially available app with evidence, it is unavailable to use in the United States.

On the Apple platform we were able to download three apps that we could not subsequently log into. The Android platform had two apps that were unavailable from the United States Google Play Store, and three that we could not log into. There was one app that we were able to download on an Apple device, but it was not in English. For this app, we based our assessment of features on potentially biased information from the developer.

Due to limited funding, our evaluation of three paid apps' characteristics (Diabetes Manager, mDiab, and Glucose Buddy Pro) was only conducted on one platform, an Apple iPad. Therefore, we were unable to report any discrepancies in features and functions across platforms.

Finally, it is likely the versions of apps we assessed may have been different from the versions of apps that were studied, as most (7 out of 13) apps had been updated since the studies were published.

Limitations in Usability Assessment

Our SUS results may not generalize to the diabetes population. The SUS is typically administered to large numbers of actual users of apps- in this case, people with diabetes. Because none of our reviewers had diabetes, they may not have represented the experiences and preferences of people with diabetes. In addition, each app was assessed by only three reviewers.

In addition, reviewers had limited exposure to the app and were bound by the scope of the questions. This scoring tool consists of only 10 questions, available in Appendix D, and was designed to be a "quick and dirty" evaluation tool to assign a score to a process that is descriptive, nuanced, and subjective in nature.[76]

We were also unable to examine all characteristics of apps that are important to patients. Most notably, we did not examine technology performance outcomes such as malfunctions or crash statistics. While reliability is an important consideration for patient decisionmaking, we were unable to address this characteristic in this review.

Next Steps

Future Research Needs

First, there is a need for longer-term studies (more than 1 year) on apps for diabetes. Diabetes is a chronic condition and the risk of serious complications increases over time. These complications can take several months to years to develop, and are some of the most important outcomes for studies to address. Therefore, longer-term studies are necessary to tell whether an app has an impact on the development of these complications. In addition, longer-term studies are important in determining whether patients continue to engage with these apps, or if they eventually lose interest. Longer-term studies could also help determine if the beneficial effects of apps on short-term outcomes hold up over time.

It is particularly difficult to assess long-term outcomes in studies of apps, since apps are constantly changing. In longer-term studies, or multiple studies of one app, it is critical to report the app version, timing of updates, and any significant changes to features or content. This helps to determine if the results can be applied to the most recently updated app and current health care context. Researchers should also consider study designs other than RCTs to answer questions pertaining to long-term outcomes. An example is a cohort study where the outcomes of those who use an app versus those who do not are tracked over several years. Interviews and surveys could be used to ask why patients continue to use an app or not, and how patients' interest in an app changes over time.

Second, researchers should consistently include harms in studies of diabetes apps, particularly hypoglycemic episodes. Ideally, studies would separate hypoglycemic episodes by severity, distinguishing between self-reported mild episodes and those that require medical assistance. It is important to report mild and severe hypoglycemic episodes for both shorter and longer-term studies.

Third, researchers who use RCT methodology should carefully consider how much interaction with study personnel and providers each group receives, and control for these interactions as much as possible (i.e., attention control). This would help ensure that the findings represent the effect of the app, not of the additional support. Future researchers should also consider head-to-head comparisons of multiple apps. This study design would provide adequate

attention control, and would be more patient-centered, as many patients know they want to use an app in care but do not know which one is most appropriate for them.

Fourth, researchers should consider evaluating the most popular apps from app stores- and conversely- making researched apps available to patients. As previously discussed, relatively few commercially available apps are supported by evidence, so patients do not know how these apps will affect their diabetes-related outcomes. Patients and physicians need evidence on the apps that are currently available to them if they are to make informed decisions on which app to use in care.

Last, there is a need for a broader research and dissemination agenda on diabetes apps. Depending on the privacy policy, app developers can collect enormous amounts of information on which apps are being downloaded and used, how use changes over time, and how patient data changes over time. A registry that connects this information to other data sets, such as medical record data, would provide a wealth of knowledge that could move this field forward. This type of study is not likely to be funded by individual app developers; therefore, there is a need for collaboration between app developers, researchers and consumers to develop this registry and update it as apps change over time.

Implications for Clinicians and Patients

Although there is limited evidence that commercially available mobile apps improve diabetes-related outcomes, patients are downloading and using them anyway. Strong evidence can help people make informed choices, but when evidence is limited, patients who use these apps are essentially experimenting on themselves. Considering this, clinicians should consider asking their patients if they use apps in their self-management, and determine if the information provided by these apps adheres to current guidance for diabetes self-management. Patients should be aware that there is little evidence supporting the effectiveness of these apps, and should be wary of claims that these apps will improve their outcomes if not supported by evidence.

Evidence Should Be Available in App Stores

As previous researchers have noted, information on which apps have been studied is not readily available to patients through app stores. The result is that patients could potentially be using apps that either do not impact health outcomes or actually cause harms. This is a huge problem for all health apps, and there should be greater efforts by app developers and app stores to present this information to users.

Patient-Centered Decision Tools

mHealth for diabetes is an important topic for researchers, patients, providers, health systems, and professional groups. There have been efforts by many different research and professional groups to summarize the evidence on this topic. There is now a need to interpret and apply the current findings in a patient-facing way. This could take the form of patient-centered decision tools that help patients judge and select apps based on their personal needs and preferences as well as evidence of efficacy. These types of tools could help patients by describing which apps have evidence of efficacy and which ones do not, and indicating which outcomes may improve as a result of using the apps. Tailoring this information to patient preferences and needs, and updating the tools as more research is published, could empower

patients as they navigate the vast amount of information available on these apps, and direct them to the apps that are most likely to improve their health outcomes.

References

1. Centers for Disease Control and Prevention. National Diabetes Statistics Report (2017). Estimates of diabetes and its burden in the United States. 2017. http://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf. Accessed October 11, 2017.
2. Centers for Disease Control and Prevention. Diabetes; 2015. http://www.cdc.gov/diabetes/basics/index.html. Accessed May 1, 2017.
3. American Diabetes Association. Promoting health and reducing disparities in populations. Diabetes Care. 2017;40(Supplement 1): S6-S10. DOI: 10.2337/dc17-S004. PMID: 27979888.
4. American Diabetes Association. Standards of medical care in diabetes-2017 Abridged for primary care providers. Clin Diabetes. 2017;35(1):5-26. DOI: 10.2337/cd16-0067. PMID: 28144042.
5. Sherwani SI, Khan HA, Ekhzaimy A, et al. Significance of HbA1c test in diagnosis and prognosis of diabetic patients. Biomarker insights. 11:95-104. DOI: 10.4137/BMI.S38440. PMID: 27398023.
6. National Institute of Diabetes, Digestive and Kidney Diseases. Managing diabetes. 2016. http://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes. Accessed May 4, 2017.
7. Nathan DM. The diabetes control and complications trial/epidemiology of diabetes interventions and complications study at 30 years: Overview. Diabetes Care. 2014;37(1):9-16. DOI: 10.2337/dc13-2112. PMID: 24356592.
8. Beck J GD, Blanton L, Bollinger ST, Butcher MK et al. National Standards for Diabetes Self-Management Education and Support. 2017 http://professional.diabetes.org/sites/professional.diabetes.org/files/media/2017_national_standards_for_dsmes_public_comment.pdf. Accessed May 12, 2017.
9. World Health Organization. mHealth: New horizons for health through mobile technologies. 2011. http://www.who.int/goe/publications/goe_mhealth_web.pdf. Accessed January 10, 2017.
10. U.S. Department of Health and Human Services, Federal Office of Rural Health Policy. Telehealth Programs. Nov 2015. https://www.hrsa.gov/rural-health/telehealth/index.html. Accessed February 6, 2018.
11. World Health Organization. Telemedicine: opportunities and developments in member states. 2010. http://www.who.int/goe/publications/goe_telemedicine_2010.pdf. Accessed January 10, 2018.
12. van Dyk L. A review of telehealth service implementation frameworks. Int J Environ Res Public Health. 2014;11(2):1279-98. DOI: 10.3390/ijerph110201279. PMID: PMC3945538.
13. IQVIA Institute for Human Data Science. The Growing Value of Digital Health. Nov 2017. Available at: http://www.iqvia.com/institute/reports/the-growing-value-of-digital-health. Accessed January 10, 2018.
14. Ristau RA, Yang J, White JR. Evaluation and evolution of diabetes mobile applications: Key factors for health care professionals seeking to guide patients. Diabetes Spectrum. 2013;26(4):211. https://doi.org/10.2337/diaspect.26.4.211.
15. Kitsiou S, Pare G, Jaana M, et al. Effectiveness of mHealth interventions for patients with diabetes: An overview of systematic reviews. PloS one. 2017;12(3):e0173160. DOI: 10.1371/journal.pone.0173160. PMID: 28249025.
16. Wu Y, Yao X, Vespasiani G, et al. Mobile app-based interventions to support diabetes self-management: A systematic review of randomized controlled trials to identify functions associated with glycemic efficacy. JMIR mHealth and uHealth. 2017;5(3):e35. DOI: 10.2196/mhealth.6522. PMID: 28292740.
17. Hartling L, Guise JM, Kato E, et al. AHRQ Comparative Effectiveness Reviews. EPC methods: An exploration of methods and context for the production of rapid reviews. Rockville (MD): Agency for Healthcare Research and Quality (US); 2015.

18. Viswanathan M, Ansari MT, Berkman ND, et al. Assessing the risk of bias of individual studies in systematic reviews of health care interventions. Agency for Healthcare Research and Quality Methods Guide for Effectiveness and Comparative Effectiveness Reviews. Mar 2012. AHRQ Publication No. 12-EHC047-EF. Available at: www.effectivehealthcare.ahrq.gov/. PMID: 22479713

19. Berkman ND, Lohr KN, Ansari MT, et al. Grading the strength of a body of evidence when assessing health care interventions: An EPC update. J Clin Epidemiol. 2015 Nov;68(11):1312-24. DOI: 10.1016/j.jclinepi.2014.11.023. PMID: 25721570.

20. Bangor A, Kortum P, Miller J. Determining what individual SUS scores mean: Adding an adjective rating scale. J Usability Stud. 2009;4(3):114-23.

21. Hou C, Carter B, Hewitt J, et al. Do mobile phone applications improve glycemic control (HbA1c) in the self-management of diabetes? A systematic review, meta-analysis, and GRADE of 14 randomized trials. Diabetes Care. 2016;39(11):2089-95. DOI: 10.2337/dc16-0346. PMID: 27926892.

22. Cui M, Wu X, Mao J, et al. T2DM Self-Management via Smartphone Applications: A Systematic Review and Meta-Analysis. PLoS ONE [Electronic Resource]. 2016;11(11):e0166718. DOI: 10.1371/journal.pone.0166718. PMID: 27861583.

23. Holmen H, Wahl AK. Tailored communication within mobile apps for diabetes self-management: A systematic review. J Med Internet Res. 2017;19(6):e227. DOI: 10.2196/jmir.7045. PMID: 28645890.

24. Charpentier G, Benhamou PY, Dardari D, et al. The Diabeo software enabling individualized insulin dose adjustments combined with telemedicine support improves HbA1c in poorly controlled type 1 diabetic patients: A 6-month, randomized, open-label, parallel-group, multicenter trial (TeleDiab 1 Study). Diabetes Care. 2011;34(3):533-539. DOI: 10.2337/dc10-1259. PMID: 21266648.

25. Drion I, Pameijer LR, van Dijk PR, et al. The effects of a mobile phone application on quality of life in patients with type 1 diabetes mellitus: A randomized controlled trial. Diabetes Sci Technol. 2015;9(5):1086-1091. DOI: 10.1177/1932296815585871. PMID: 25963412.

26. Garg SK, Shah VN, Akturk HK, et al. Role of mobile technology to improve diabetes care in adults with type 1 diabetes: The remote-T1D study iBGStar(R) in type 1 diabetes management. Diabetes Ther. 2017;8(4):811-819. DOI: 10.1007/s13300-017-0272-5. PMID: 28555339.

27. Kirwan M, Vandelanotte C, Fenning A, et al. Diabetes self-management smartphone application for adults with type 1 diabetes: randomized controlled trial. J Med Internet Res. 2013 Nov 13;15(11):e235. DOI: 10.2196/jmir.2588. PMID: 24225149.

28. Kleinman NJ, Shah A, Shah S, et al. Impact of the gather mHealth system on A1C: Primary results of a multisite randomized clinical trial among people with type 2 diabetes in India. Diabetes Care. 2016;39(10):e169-70. DOI: 10.2337/dc16-0869. PMID: 27493133.

29. Quinn CC, Shardell MD, Terrin ML, et al. Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. Diabetes Care. 2011;34(9):1934-42. DOI: 10.2337/dc11-0366. PMID: 21788632.

30. Rossi MC, Nicolucci A, Di Bartolo P, et al. Diabetes interactiveDiary: a new telemedicine system enabling flexible diet and insulin therapy while improving quality of life: an open-label, international, multicenter, randomized study. Diabetes Care. 2010;33(1):109-15. DOI: 10.2337/dc09-1327. PMID: 19808926.

31. Rossi MC, Nicolucci A, Lucisano G, et al. Impact of the "Diabetes Interactive Diary" telemedicine system on metabolic control, risk of hypoglycemia, and quality of life: a randomized clinical trial in type 1 diabetes. Diabetes Technol Ther. 2013;15(8):670-9. DOI: 10.1089/dia.2013.0021. PMID: 23844569.

32. Skrovseth SO, Arsand E, Godtliebsen F, et al. Data-driven personalized feedback to patients with type 1 diabetes: A randomized trial. Diabetes Technol Ther. 2015;17(7):482-9. DOI: 10.1089/dia.2014.0276 PMID: 25751133.

33. Takenga C, Berndt RD, Musongya O, et al. An ICT-based diabetes management systemtested for health care delivery in the african context. Int J Telemed Appl. 2014;2014:437307. DOI: 10.1155/2014/437307. PMID: 25136358.

34. Wayne N, Perez DF, Kaplan DM, et al. Health coaching reduces HbA1c in type 2 diabeticpatients from a lower-socioeconomic status community: A randomized controlled trial. J Med Internet Res. 2015;17(10):e224. DOI: 10.2196/jmir.4871. PMID: 26441467.

35. Zhou W, Chen M, Yuan J, et al. Welltang - A smart phone-based diabetes management application - Improves blood glucose control in Chinese people with diabetes. Diabetes Res Clin Pract. 2016 Jun;116:105-10. DOI: 10.1016/j.diabres.2016.03.018. PMID: 27321324.

36. Franc S, Borot S, Ronsin O, et al. Telemedicine and type 1 diabetes: is technology per se sufficient to improve glycaemic control? Diabetes Metab. 2014;40(1):61-6. DOI: 10.1016/j.diabet.2013.09.001. PMID: 24139705.

37. Quinn CC, Shardell MD, Terrin ML, et al. Mobile Diabetes Intervention for Glycemic Control in 45- to 64-Year-Old Persons With Type 2 Diabetes. J Appl Gerontol. 2014;35(2):227-43. DOI: 10.1177/0733464814542611. PMID: 25098253.

38. Quinn CC, Clough SS, Minor JM, et al. WellDoc mobile diabetes management randomized controlled trial: change in clinical and behavioral outcomes and patient and physician satisfaction. Diabetes Technol Ther. 2008;10(3):160-8. DOI: 10.1089/dia.2008.0283. PMID: 18473689.

39. BlueStar Diabetes. Apple App Store. 2018. https://itunes.apple.com/us/app/bluestar-diabetes/id700329056?mt=8. Accessed January 22, 2018.

40. Diabeo Telesage. Apple App Store. Sanofi. 2017. https://itunes.apple.com/fr/app/diabeo-telesage/id595993009?l=en&mt=8. Accessed January 22, 2018.

41. Diabetes Manager. Apple App Store. iTenuto Soft. 2016. https://itunes.apple.com/us/app/diabetes-manager/id368455341?mt=8. Accessed January 22, 2018.

42. Gather Health. Apple App Store. 2016. https://itunes.apple.com/us/app/gather-health/id909621891?mt=8. Accessed January 22, 2018.

43. Glucose Buddy Pro. Apple App Store. Azumio Inc. 2018. https://itunes.apple.com/us/app/glucose-buddy-pro-diabetes-managing-logbook-w-blood/id533299240?mt=8. Accessed January 22, 2018.

44. Glucose Buddy. Apple App Store. Azumio Inc. 2018. https://itunes.apple.com/us/app/glucose-buddy-diabetes-logbook-manager-w-syncing-blood/id294754639?mt=8. Accessed January 22, 2018.

45. mDiab Lite. Apple App Store. Infokom GmbH. 2014. https://itunes.apple.com/us/app/mdiab-lite/id604866236?mt=8. Accessed January 22, 2018.

46. mDiab. Apple App Store. Infokom GmbH. 2017. https://itunes.apple.com/us/app/mdiab/id608181716?mt=8. Accessed January 22, 2018.

47. NexJ Health Coach +. Apple App Store. NexJ Health Inc. 2016. https://itunes.apple.com/ca/app/nexj-health-coach/id1047247250?mt=8. Accessed January 22, 2018.

48. WellTang. Apple App Store. 2017. https://appsto.re/us/aDAoR.i. Accessed January 22, 2018.

49. Glucose Buddy. Google Play. Azumio, Inc. 2012. https://play.google.com/store/apps/details?id=com.skyhealth.glucosebuddyfree&hl=en. Accessed January 22, 2018.

50. Dbees. Freshware. Amazon App Store. 2012. https://www.amazon.com/gp/product/?ie=UTF8&ASIN=B004XWHBIU&ref=mas_ty. Accessed January 22, 2018.

51. Diabetes Diary. Google Play. 2017. https://play.google.com/store/apps/details?id=no.telemed.diabetesdiary&hl=en. Accessed January 22, 2018.

52. Diabetes Interactive Diary. Google Play. Meteda. 2017. https://play.google.com/store/apps/details?id=it.meteda.did. Accessed January 22, 2018.

53. Diabeo Telesage. Google Play. Sanofi. https://play.google.com/store/apps/details?id=com.sanofi.fr.diabeo&hl=en. Accessed January 22, 2018.

54. Dbees. Freshware. Apple App Store. 2012. https://itunes.apple.com/us/app/dbees-com-diabetes-under-control/id408492591?mt=8. Accessed January 22, 2018.

55. Diabetes Interactive Diary. 2017. www.meteda.it/en/product/did-diario-interattivo-del-diabete/. Accessed January 22, 2018.

56. Diabeo Telesage. 2017. http://www.sanofi-diabete.fr/la-recherche-avance/lengagement-de-sanofi-diabete-dans-la-telemedecine/introduction&prev=search. Accessed January 22, 2018.

57. BlueStar Diabetes. Google Play. WellDoc, Inc. 2017. https://play.google.com/store/apps/details?id=com.welldoc.platform.android&hl=en. Accessed January 22, 2018.

58. mDiab Lite. Google Play. Infokom GmbH. 2013. https://play.google.com/store/apps/details?id=com.infokom.mdiab.lite&hl=en. Accessed January 22, 2018.

59. mDiab. Google Play. Infokom GmbH. 2014. https://play.google.com/store/apps/details?id=com.infokom.mdiab&hl=en. Accessed January 22, 2018.

60. NexJ Health Coach +. Google Play. NexJ Health. 2017. https://play.google.com/store/apps/details?id=com.connectedwellness.HealthCoachPlus&hl=en. Accessed on January 22, 2018.

61. Gather Health Family Diabetes. Google Play; 2016. https://play.google.com/store/apps/details?id=com.gatherhealth.gatherdm&hl=en. Accessed January 22, 2018.

62. U.S. Food and Drug Administration. Letter to WellDoc regarding DiabetesManager 510(k) Clearance. 2010. https://www.accessdata.fda.gov/cdrh_docs/pdf10/K100066.pdf. Accessed January 24, 2018.

63. U.S. Food and Drug Administration. Letter to WellDoc regarding BlueStar 510(k) clearance. 2017. https://www.accessdata.fda.gov/cdrh_docs/pdf16/k162532.pdf. Accessed January 24, 2018.

64. Gather Health. 2017. https://www.gatherhealth.com. Accessed January 22, 2018.

65. WellTang. 2017. http://www.welltang.com/. Accessed January 22, 2018.

66. Drincic A, Prahalad P, Greenwood D, et al. Evidence-based mobile medical applications in diabetes. Endocrinol Metab Clin North Am. 2016;45(4):943-65. DOI: 10.1016/j.ecl.2016.06.001. PMID: 27823614.

67. Klonoff DC, Kerr D, Wong JC, et al. Digital diabetes congress 2017. J Diabetes Sci Technol. 2017;11(5):1045-1052. doi: 10.1177/1932296817723037. PMID: 28786320.

68. Xcertia. mHealth app guidelines; 2017. http://www.xcertia.org/the-guidelines/. Accessed January 24, 2018.

69. MedlinePlus. Type 1 diabetes. 2016. https://medlineplus.gov/ency/article/000305.htm. Accessed October 3, 2017.

70. Pickup JC. Point: Are insulin pumps underutilized in type 1 diabetes? Yes. Diabetes Care. 2006;29(6):1449-52. DOI: 10.2337/dc06-0011. PMID: 16732043.

71. Centers for Disease Control and Prevention. National diabetes statistics report. 2017. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf. Accessed October 11, 2017.

72. Anderson M, Perrin A. Tech adoption climbs among older adults. Pew Research Center; 2017. http://www.pewinternet.org/2017/05/17/tech-adoption-climbs-among-older-adults/. Accessed October 11, 2017.

73. Arnhold M, Quade M, Kirch W. Mobile applications for diabetics: A systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older. J Med Internet Res. 2014;16(4):e104. DOI: 10.2196/jmir.2968. PMID: PMC4004144.

74. Sarkar U, Gourley GI, Lyles CR, et al. Usability of commercially available mobile applications for diverse patients. J Gen Intern Med. 2016. 31(12):1417-26. DOI: 10.1007/s11606-016-3771-6. PMID: PMC5130945.

75. Eysenbach G. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. J Med Internet Res. 2011;13(4):e126. DOI: 10.2196/jmir.1923. PMID: 22209829.

76. Brooke J. SUS-A quick and dirty usability scale. Usability evaluation in industry. 1996;189(194):4-7.

Appendix A. Search Strategies

Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present
Update Search Date: December 5, 2017
Searched by: Information Specialist

#	Searches
1	*Diabetes Mellitus/ or *Diabetes Mellitus, Type 1/ or *Diabetes Mellitus, Type 2/ or (diabet* or T2DM or T1DM or T2D or T1D or NIDDM or IDDM).ti.
2	*disease management/ or (dh or dt or th).fs. or (monitor* or self-monitor* or manag* or self-manag* or control* or self-control* or self-care or educat* or self-educat*).ti,ab.
3	exp *telemedicine/ or exp *"online systems"/ or exp *internet/ or "cell phones"/ or smartphone/ or "text messaging"/ or exp *"mobile applications"/ or (tele* or mobile* or mhealth* or m-health* or ehealth* or e-health* or digital* or online* or Internet* or web or web-based or technology* or app or apps or application* or applet* or SMS or text or text-messag* or cellphone* or cell-phone* or phone* or smartphone* or iphone* or ipad* or android* or email* or virtual* or game or game-* or gaming or social media or social network* or Facebook* or Skype* or Twitter* or Snapchat* or Instagram* or LinkedIn*).ti.
4	(Accu-Check or BlueStar or DBEES or Dexcom or Dario or Diabeo or "Diabetes:M" or "Diabetes+Me" or DiabetesConnect or "Diabetes Diary" or "Diabetes Interactive Diary" or "Il Diario Interattivo per il Diabete" or "Diabetes and Blood Glucose Tracker" or "Diabetes in Check" or "Diabetes Kit Blood Glucose Logbook" or "Diabetes Manager" or "Diabetes Pal" or "Diabetes Under Control" or DiaTouch or "Gather Health" or Glooko or "Glucose Blood Sugar Tracker & Diabetes Companion" or "Glucose Buddy" or "Glucose Companion" or "Glucose Wiz" or GlucOracle or Health2Sync or HeartSquare or "Health Coach+" or "Health Coach +" or Lazysugar or LibreLink or mDiab or "Mobile Diab" or myBG or mySugr or "NexJ Connected Wellness Platform" or "Noom Coach" or Omada or "OneTouch Reveal" or "One Drop for Diabetes Management" or "Open Diabetes" or Sugarmate or "Sugar Sense" or "Sugar Streak" or Track3 or WellDoc or WellTang or “LibreLink”).tw,kf.
5	and/1-3
6	4 or 5
7	limit 6 to english language
8	limit 7 to yr="2008 -Current"
9	limit 8 to (comment or editorial or letter or news)
10	8 not 9

#	Searches
11	(((comprehensive* or integrative or systematic*) adj3 (bibliographic* or review* or literature)) or (meta-analy* or metaanaly* or "research synthesis" or ((information or data) adj3 synthesis) or (data adj2 extract*))).ti,ab. or (cinahl or (cochrane adj3 trial*) or embase or medline or psyclit or (psycinfo not "psycinfo database") or pubmed or scopus or "sociological abstracts" or "web of science").ab. or ("cochrane database of systematic reviews" or evidence report technology assessment or evidence report technology assessment summary).jn. or Evidence Report: Technology Assessment*.jn. or ((review adj5 (rationale or evidence)).ti,ab. and review.pt.) or meta-analysis as topic/ or Meta-Analysis.pt.
12	and/10-11
13	(201709* or 201710* or 201711* or 201712*).dc.
14	and/12-13
15	10 not 12
16	limit 15 to ("all adult (19 plus years)" or "young adult (19 to 24 years)" or "adult (19 to 44 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)" or "aged (80 and over)")
17	remove duplicates from 16
18	(201709* or 201710* or 201711* or 201712*).dc.
19	17 and 18

EBM Reviews - Cochrane Database of Systematic Reviews 2005 to November 29, 2017, EBM Reviews - Health Technology Assessment 4th Quarter 2016, EBM Reviews - NHS Economic Evaluation Database 1st Quarter 2016
Update Search Date: December 5, 2017
Searched by: Information Specialist

#	Searches
1	*Diabetes Mellitus/ or *Diabetes Mellitus, Type 1/ or *Diabetes Mellitus, Type 2/ or (diabet* or T2DM or T1DM).ti.
2	*disease management/ or (dh or dt or th).fs. or (monitor* or self-monitor* or manag* or self-manag* or control* or self-control* or self-care or educat* or self-educat*).ti,ab.

3	exp *telemedicine/ or exp *"online systems"/ or exp *internet/ or exp *"cell phones"/ or exp *"mobile applications"/ or (tele* or mobile* or mhealth* or m-health* or ehealth* or e-health* or digital* or online* or Internet* or web or web-based or technology* or app or apps or application* or applet* or SMS or text or text-messag* or cellphone* or cell-phone* or phone* or smartphone* or email* or virtual* or game or game-* or gaming or social media or social network* or Facebook* or Skype* or Twitter* or Snapchat* or Instagram* or LinkedIn*).ti.
4	and/1-3
5	(Accu-Check or BlueStar or DBEES or Dexcom or Dario or Diabeo or "Diabetes:M" or "Diabetes+Me" or DiabetesConnect or "Diabetes Diary" or "Diabetes Interactive Diary" or "Il Diario Interattivo per il Diabete" or "Diabetes and Blood Glucose Tracker" or "Diabetes in Check" or "Diabetes Kit Blood Glucose Logbook" or "Diabetes Manager" or "Diabetes Pal" or "Diabetes Under Control" or DiaTouch or "Gather Health" or Glooko or "Glucose Blood Sugar Tracker & Diabetes Companion" or "Glucose Buddy" or "Glucose Companion" or "Glucose Wiz" or GlucOracle or Health2Sync or HeartSquare or "Health Coach+" or "Health Coach +" or Lazysugar or LibreLink or mDiab or "Mobile Diab" or myBG or mySugr or "NexJ Connected Wellness Platform" or "Noom Coach" or Omada or "OneTouch Reveal" or "One Drop for Diabetes Management" or "Open Diabetes" or Sugarmate or "Sugar Sense" or "Sugar Streak" or Track3 or WellDoc or WellTang or “LibreLink”).ti,ab.
6	or/4-5
7	remove duplicates from 6
8	(201709* or 201710* or 201711* or 201712*).up.
9	7 and 8

EMBASE.com
Date Searched: July 6, 2017
Searched by: Information Specialist

#25 #4 AND #24 AND ([cochrane review]/lim OR [systematic review]/lim OR [meta analysis]/lim) AND [2016-2017]/py 95
#24 #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 427,051
#23 'patient care planning'/de OR 'patient monitoring'/de OR 'case management'/de OR 'home care'/de OR 'home monitoring'/de 171,470
#22 'ambulatory monitoring'/de 10,597
#21 'physiologic monitoring'/de 3,111
#20 'disease management':ab,ti 15,941
#19 remote NEAR/3 (consult* OR monitor*) 4,056
#18 telemetr*:ab,ti OR tele+metr*:ab,ti OR telemed*:ab,ti OR tele+med*:ab,ti OR telehealth*:ab,ti OR tele+health*:ab,ti OR telecare:ab,ti OR tele+care:ab,ti OR telehome:ab,ti OR tele+home:ab,ti OR telemonit*:ab,ti OR tele+monit*:ab,ti OR teleconsult*:ab,ti AND ortele+consult*:ab,ti OR teleconferenc*:ab,ti OR tele+conferenc*:ab,ti OR telecommunicat*:ab,ti OR tele+communicat*:ab,ti OR telenurs*:ab,ti OR tele+nurs*:ab,ti

OR teleservic*:ab,ti OR tele+servic*:ab,ti OR videoconferenc*:ab,ti OR video+conferenc*:ab,ti AND ortelemanagement:ab,ti OR tele+management:ab,ti OR telephon*:ab,ti OR phone*:ab,ti OR web+based:ab,ti OR internet+based:ab,ti OR website:ab,ti OR web+site:ab,ti 160,484
#17 'wireless communication'/de 3,602
#16 'video conferencing'/de 2,475
#15 'text messaging'/de 2,714
#14 'telephone'/de 31,538
#13 'interactive voice response system'/de 502
#12 'mobile phone'/de 12,825
#11 'telemetry'/exp 22,249
#10 'telemonitoring'/de 1,949
#9 'teleconsultation'/de 7,714
#8 'telemedicine'/de 16,428
#7 'telehealth'/exp 30,319
#6 'teleconference'/de 1,035
#5 'telecommunication'/de 22,683
#4 #1 OR #2 OR #3 927,578*
#3 iddm:ab,ti OR niddm:ab,ti OR mody:ab,ti OR t1dm:ab,ti OR t2dm:ab,ti OR t1d:ab,ti OR t2d:ab,ti 62,538
#2 diabet*:ab,ti 754,565
#1 'diabetes mellitus'/exp 799,907

EBSCO CINAHL
Date Searched: July 6, 2017
Searched by: Information Specialist

#	Search Terms	Search Options
S26	**S12 AND S15 AND S20 AND S25**	**Limiters – Published Date: 20160101-20171231 Exclude MEDLINE records**
S25	S21 OR S22 OR S23 OR S24	
S24	TI (intervention*)	
S23	(MH "Meta Analysis")	
S22	((MH "Systematic Review")) OR (TX (systematic review))	
S21	TX (MEDLINE)	
S20	S16 OR S17 OR S18 OR S19	
S19	TX disease management	
S18	TX remote N3 (cosnult* or monitor*)	

#	Search Terms	Search Options
S17	TX (telemetr* or tele-metr* or telemed* or tele-med* or telehealth* or tele-health* or telecare or tele-care or telehome or tele-home or telemonit* or tele-monit* or teleconsult* or tele-consult* or teleconferenc* or tele-conferenc* or telecommunicat* or tele-communicat* or telenurs* or tele-nurs* or teleservic* or tele-servic* or videoconferenc* or video-conferenc* or telemanagement or tele-management or telephon* or phone* or web-based or web?based or internet-based or internet?based or websit ...	
S16	(MH "Telecommunications") OR (MH "Interactive Voice Response Systems") OR (MH "Teleconferencing") OR (MH "Telecommuting") OR (MH "Telehealth") OR (MH "Telemedicine") OR (MH "Remote Consultation") OR (MH "Telenursing") OR (MH "Telephone") OR (MH "Text Messaging") OR (MH "Videoconferencing") OR (MH "Wireless Communications")	
S15	S13 OR S14	
S14	(MH "Patient Care") OR (MH "Case Management") OR (MH "Disease Management") OR (MH "Home Health Care") OR (MH "Ambulatory Care")	
S13	(MH "Monitoring, Physiologic") OR (MH "Blood Glucose Monitoring") OR (MH "Blood Glucose Self-Monitoring") OR (MH "Telemetry") OR (MH "Nursing Assessment")	
S12	S8 NOT S11	
S11	S9 OR S10	
S10	TX (diabet* insipidus)	
S9	(MH "Diabetes Insipidus+")	
S8	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7	
S7	TX ((typ* I or typ* II) N6 diabet*)	
S6	TX ((typ* 1 or typ* 2) N6 diabet*)	
S5	TX (insulin* depend* or insulin?depend*)	
S4	TX (non insulin* depend* or noninsulin* depend* or non insulin?depend* or noninsulin?depend*)	
S3	TX (IDDM or NIDDM or MODY or T1DM or T2DM or T1D or T2D)	
S2	TX diabet*	
S1	(MH "Diabetes Mellitus") OR (MH "Diabetes Mellitus, Type 1") OR (MH "Diabetes Mellitus, Type 2") OR (MH "Glucose Metabolism Disorders") OR (MH "Pregnancy in Diabetes") OR (MH "Diabetes Mellitus, Gestational") OR (MH "Prediabetic State")	

Appendix B. Inclusion and Exclusion Criteria for Primary Research Studies

Category	Criteria
Populations	**INCLUDE:** Entire included population are adults (18+ years old) diagnosed with type 1 or type 2 diabetes; or effects for this population can be distinguished (ie, through a subgroup analysis) **EXCLUDE:** Children, adolescents, pregnant women, those with pre-diabetes or risk factors for diabetes, or gestational diabetes
Interventions	**INCLUDE:** Commercially available Web site, program, or app delivered through a mobile device (ie, phone, tablet or watch) for the purpose of diabetes self-management. Interventions must include at least one of the following components: 1. Education 2. Data tracking 3. User-provider communication 4. Social support/social media 5. Reminders (with the exception of appointment reminders) **EXCLUDE:** Medical devices that do not connect to a mobile phone or tablet (ie, blood glucose meter); artificial pancreas; texting interventions
Comparators	**INCLUDE:** Usual care or other mobile or nonmobile program for diabetes self-management; no comparator but part of a registry study
Outcomes	**INCLUDE:** All patient outcomes **EXCLUDE:** Provider outcomes, health care system outcomes, technology performance outcomes (eg, bugs and crash statistics)
Timing/Setting	**INCLUDE:** Any setting; any study length; only studies published after 2008
Study Designs	**INCLUDE:** Randomized controlled trials, nonrandomized controlled trials, or other observational study with a comparator; a subgroup analysis of these studies; or a registry study **EXCLUDE:** Pre-post studies without a comparator
Language	**INCLUDE:** English

Appendix C. Study Details

Table C-1. Study details for apps for type 1 diabetes

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome effect size [95% CI] & P-value	Outcome Measurement Details
Glucose Buddy Kirwan 2013[1] 6 months Moderate quality Australia	Number: 72 Age: Mean 35.2 Diabetes severity: Duration of diabetes (years) 18.94 Mean HbA1c: 8.78% Insulin pump: 38% Key I/E criteria: Treated with multiple daily injections or insulin pump.	With Glucose Buddy, ppts manually enter BG levels, insulin dosages, other medications, diet (food item in grams), and physical activity (minutes). Ppts view data on customizable graph and information reviewed weekly by certified diabetes educator (CDE). Ppts sent minimum of one personalized text message per week by CDE.	Usual care which includes visit to primary care diabetes health care practitioner every 3 months.	HbA1C (%)	Yes (but significant differences at baseline so interpret with caution)	p < 0.001 from baseline to 9 months (6 months of intervention with 3 months follow-up) I group from 9.08 to 7.80% vs. C group from 8.47 to 8.58%	NA
				Diabetes – related self efficacy	No	p>0.05	Diabetes Empowerment questionnaire (DES-SF)
				Self-care behaviors	No	p>0.05	Summary of Diabetes Self Care Activities, 6-item measured which authors included 4 items: general diet, specific diet, exercise, and glucose testing
				Quality of Life	No	p>0.05	Diabetes Quality of Life
Diabetes Manager Garg 2017[2] 6 months Low quality				HbA1C (%)	Yes	–0.51 in intervention vs -0.16 in control (p=0.04)	NA
				Hypoglycemic events	No	21.5 ± 15.5 in intervention vs 25.5 ± 31.0 in control (p=0.48)	Not defined

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome effect size [95% CI] & P-value	Outcome Measurement Details
United States	Number: 100 Age: Mean I group 38; C group 39 Diabetes severity: Duration of diabetes (years) I group 25; C group 22 Mean HbA1c (%): I group 8.0; C group 7.7 Comorbidities BMI: I group 27.1; C group 27.3 (both overweight) Key I/E criteria: Excluded ppts with history of severe hypoglycemia in last 6 months	The iBGStar system is a BG meter that attaches to an iPhone as a peripheral device. Using the iBGStar with the Diabetes Manager App, a user's iPhone can function as a blood glucose meter. The Diabetes Manager App provides personal feedback on SMBG by allowing ppts to filter and dynamically interact with log book data, graph trends, and view statistics. Provider communicated every 7-14 days throughout study (email, text, home) All subjects (I and C groups) had similar clinic and phone visits for 3 months, with a 3-month extension, for a total of 8 required visits—a screening visit, 4 in-clinic visits, and 3 phone calls.	Self-monitoring of blood glucose with Accu-Chek Nano. Training on their use was provided at baseline and reinforced at week 1. Ppts encouraged to contact provider as needed	Hypoglycemia fear	No	–1.37 ± 9.9 in intervention vs –3.9 ± 12.5 in control (p=0.32)	hypoglycemia fear score
Dbees Drion 2015[3] 3 months Moderate quality Netherlands		Intervention was offered as an application and a personal web portal linked to application and consisted of a digital diabetes diary which could manually enter diabetes-related self-care data: blood	Standard paper diary	HbA1C (mmol/mol)	No	median between group differences (IQR) –2 (–6,5)	NA
				Usability	Yes (int. only)	I group rated as 77 out of 100	SUS
				Quality of Life	No	median between group differences (IQR): Physical component: 0 (–1,1) Mental component: –1 (–7,5)	RAND-36 health survey

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome effect size [95% CI] & P-value	Outcome Measurement Details
	Number: 63 Age: Median 33 Diabetes severity: Duration of diabetes (years) 17 Mean HbA1c (mmol/mol): 62 Insulin pump: 66% Comorbidities retinopathy 25% nephropathy 2% neuropathy 19% Key I/E criteria: Treated with multiple daily injections, continuous subcutaneous insulin infusion, or continuous intraperitoneal insulin infusion.	glucose values, carbohydrate intake, medication, physical exercise, and notes into the application.		Diabetes emotional distress	No	median between group differences (IQR): –1 (–4,2)	Problem Areas in Diabetes (PAID) questionnaire
Diabetes Diary Skrovseth 2015[4] 8 weeks (1st intervention group)/ 10 weeks (2nd intervention group) Low quality Norway	Number: 30 Age: Mean 39.70 Diabetes severity: Mean HbA1c: 8.2% Key I/E criteria: T1DM > 1 year (insulin pumps were included) Excluded if had "severe complications attributed to their diabetes that would render participation unethical or medically challenging"	This intervention was Diabetes Diary with an additional data-driven feedback module for BG self-management, Diastat Bluetooth enabled phone connected to BG meter. Diastat included last BG measurement, last insulin recording and last carbohydrate registration.	Diabetes Diary app without the Diastat feedback module	HbA1C (%)	CND	-0.60% from baseline to 8 weeks p< 0.001 (no between group difference-in-differences reported)	NA
				Combined hypoglycemic and hyperglycemic events*	Yes	Median out-of range (OOR) events over 2 weeks: -14.5 (95% CI -18.0 to -9.0; p< 0.001)	OOR events –combine BGs outside range 72-270 mg/dl

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome effect size [95% CI] & P-value	Outcome Measurement Details
Diabetes Interactive Diary Rossi 2010[5] 6 months Moderate quality Italy	Number: 130 Age: Mean I group 35.4; mean C group 36.1 Diabetes severity: Duration of diabetes (years) I group 17.1; C group 15.8 Mean HbA1c (%): I group 8.2; C group 8.4 Insulin pump: I group 19%; C group 19% Comorbidities: retinopathy: I group 29%; C group 21% nephropathy: I group 5%; C group 3% symptomatic neuropathy: I group 9%; C group 3% lower limb complications: I group 0%; C group 3% Key I/E criteria: Multiple daily injections of short- and long-acting insulin analogs or continuous subcutaneous insulin infusion; self-monitoring BG minimum 3 times/day	The Diabetes Interactive Diary (DID) is a carbohydrate/insulin bolus calculator, an information technology device, and a telemedicine system based on the communication between a health care professional (physician or dietitian) and a participant via text messages. It supports participants in managing the CHO counting through a food atlas and in recording the self-monitoring blood glucose (SMBG) measurements. DID suggests the daily carbohydrate intake, and automatically calculates the most appropriate insulin dose to be injected at each meal. All the recorded data are sent to the physician via SMS and clinic sends personalized recommendations (insulin doses, activity) to participant's mobile phone.	Standard education	HbA1C (%)	No	–0.4 ± 0.9 in intervention vs. –0.5 ± 1 in control (p=0.68)	NA
				Lipids	Triglycerides (mg/dl)- Yes Total cholesterol (mg/dl)- No HDL (mg/dl) - No LDL(mg/dl)- No	Triglycerides: –10.7 ± 56.1 in intervention vs –8.2 ± 43.4 in control (p=0.04) Total cholesterol: –3.6 ± 32.3 in intervention vs 2.7 ± 28.9 in control (p=0.33) HDL: 1.6 ± 8.5 in intervention vs 4.8 ± 10.3 in control (p=0.14) LDL: –3.4 ± 29.1 in intervention vs 0.3 ± 27.6 in control (p=0.79)	NA
				Blood pressure (mmHg)	No	SBP: –0.8 ± 8.6 in intervention vs –0.7 ± 11.5 in control (p=0.71) DBP: –1.3 ± 6.5 in intervention vs –1.1 ± 7.6 in control (p=0.89)	NA
				Diabetes treatment satisfaction	Yes	3.4 ± 4.2 in intervention vs 1 ± 4 in control (p=0.04)	World Health Organization-Diabetes Treatment Satisfaction Questionnaire
				Weight (kg)	No	0.7 ± 3.6 in intervention vs 1.5 ± 2.3 in control (p=0.22)	NA
				Quality of Life	No	Physical component score p=0.77 Mental component score: p=0.14	SF-36

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome effect size [95% CI] & P-value	Outcome Measurement Details
				Severe hypoglycemic episodes	No	No episodes	Requiring assistance
				Self-reported mild hypoglycemia	No	2 episodes I group; 2 episodes C group; p=0.93	No definition provided
Diabetes Interactive Diary Rossi 2013[6] 6 months Moderate quality Italy	Number: 127 Age: Mean I group 38.4; mean C group 34.3 Diabetes severity: Duration of diabetes (years) I group 16.2; C group 15.0 Mean HbA1c (%): I group 8.4; C group 8.5 Comorbidities: retinopathy: I group 16 %; C group 19% symptomatic neuropathy: I group 2%; C group 2% "other chronic complications": I group 17%; C group 16% Key I/E criteria: basal-bolus regimen with insulin analogs, self-monitored BG measurements at least 3 times a day. Excluded ppts treated with NPH insulin or soluble regular insulin, insulin pump, or insulin regimens other than basal bolus.	Same as above	Standard education	HbA1C (%)*	No	–0.49 ± 0.11 in intervention vs –0.48 ± 0.11 in control (p=0.73)	NA
				Fasting Blood Glucose (mg/dl)	No	–1.66 ± 12.26 in intervention vs –32.28 ± 11.76 in control (p=0.07)	NA
				Glucose variability	No	5.36 ± 6.60 in intervention vs –5.47 ± 6.40 in control (p=0.24)	Mean Amplitude of Glucose Excursions
				Blood pressure (mmHg)	No	SBP: –0.72 ± 1.51 in intervention vs –2.00 ± 1.45 in control (p=0.54) DBP: –2.00 ± 0.94 in intervention vs 0.16 ± 0.91 in control (p=0.47)	NA
				Lipids	No	Total cholesterol (mg/dl): 3.74 ± 4.36 in intervention vs –0.63 ± 4.21 in control (p=0.47) HDL(mg/dl): 1.09 ± 1.60 in intervention vs –0.25 ± 1.57 in control (p=0.71) LDL (mg/dl): 8.27 ± 4.39 in intervention vs 5.08 ± 4.37 in control (p=0.61) Triglycerides (mg/dl): 0.39 ± 3.82 in intervention vs –6.23 ± 3.73 in control (p=0.22)	NA
				Weight (kg)	No	0.38 ± 0.38 in intervention vs 0.28 ± 0.36 in control (p=0.85)	NA

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome effect size [95% CI] & P-value	Outcome Measurement Details
				Diabetes treatment satisfaction	No	0.89 ± 0.89 in intervention vs 1.97 ± 0.88 in control (p=0.39)	Diabetes Treatment Satisfaction Questionnaire
				Grade 1 hypoglycemia	No	Incidence Risk Ratio: 1.08 (1.00-1.16)	Symptomatic or asymptomatic BG < 60 mg/dl not requiring medical assistance
				Grade 2 hypoglycemia	Yes	Incidence Risk Ratio 0.14 (0.07-0.29)	Coma, seizure or significant neurologic impairment or required assistance
				Quality of Life	No	1.30 ± 1.36 in intervention vs -–0.91 ± 1.35 in control (p=0.25)	Diabetes Specific Quality of Life Scale
Diabeo Charpentier 2011[7] 6 months Moderate quality France	Number: 180 Age: Mean 33.8 Diabetes severity: Duration of diabetes 16.4 years; Insulin pump 37% Comorbidities: retinopathy 30% nephropathy 12% clinical neuropathy 11% Key I/E criteria: HbA1c≥ 8% and treated with basal bolus insulin for minimum 6 months	Diabeo software on smartphone includes prandial insulin dose advisor which accounts for self-monitored BG, carbohydrate counts and planned physical activity. Software recommends adjustments in carbohydrate-to-insulin ratio, long acting insulin dose or pump basal rate. Smartphone with Diabeo software automatically uploads from phone to secure Web Site available to providers and ppts. [2 intervention groups: Group 2- Diabeo software alone and Group 3- Diabeo software and teleconsultations]	Group 1 (control) ppts kept paper logbooks and attended two follow-up hospital clinic visits (3 and 6-months)	HbA1C (%)	Yes	Group 1 vs Group 2: –0.67% [0.35, 0.99] p≤ 0.001 Group 1 vs Group 3: –0.91% [0.60, 1.21] p≤ 0.001 Group 2 vs Group 3: 0.24% [–0.08, 0.56] p = 0.417	NA
				Quality of life	No	NR, p= 0.1271	Diabetes Quality of Life
				Quality of life	No	Disinhibited eating subset, NR, p=0.7872 Psychological distress subset, NR, p=0.2447 Barriers to activity subset, NR, p=0.5906	Diabetes Health Profile Questionnaire
				Major hypoglycemic episodes	CND	G1- 3 episodes; G2-3 episodes; G3-1 episode	Requiring third-party assistance
				Minor hypoglycemic episodes	CND	Intervention group did not differ from control at study end (4.6 ± 4.0).	Symptomatic, non-severe self-reported by ppt within 14 days before baseline and endpoint visits

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome effect size [95% CI] & P-value	Outcome Measurement Details
Diabeo Franc 2013[8] ***subgroup analysis of Charpentier 2011[7] which is Moderate quality France	Ppts of Charpentier study divided into Diabeo system high users and system low users based on median percentage of informed meals (informed meal defined as meal which Diabeo system proposed an insulin dose based on pre-prandial BG or fasting BG, physical activity, and expected carbohydrate consumption) Age: median [25-75th percentile]: high user 33 vs low user 25 Diabetes severity Duration of diabetes median [25-75th percentile]: high user 17 vs low user 14 Insulin pump: NR Comorbidities: NR	(same as above)	(same as above)	HbA1C (%)	No	High system users: decrease HbA1C of 0.5 % for both intervention groups (Group 1 vs Group 2 and Group 3) Low system users: decrease in HbA1C of 0.8% for both intervention groups (Group 1 vs Group 2 and Group 3)	NA

BG=blood glucose; C=control; CND=could not determine; DBP=diastolic blood pressure; HDL=high-density lipoprotein; I=intervention; I/E=inclusion/exclusion; LDL=low-density lipoprotein; NA=not applicable; NR=not reported; PHQ=patient health questionnaire; ppts=participants; SBP=systolic blood pressure; SMBG=self-monitored blood glucose; SUS=System Usability Scale

Table C-2. Study details for apps for type 2 diabetes

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome results	Outcome Measurement Details
BlueStar Diabetes Quinn 2008[9] 3 months Low quality United States	Number: 30 ppts Age: mean 51.04 Diabetes severity: Diabetes duration: 11 years (intervention) vs. 7.6 years (control) Baseline HbA1c: 9.51 % (intervention) vs. 9.05% (control) Comorbidities: BMI (kg/m$^{2.}$) 34.07 (intervention) vs. 34.58 (control) 62% hypertension 54% hyperlipidemia 4% coronary artery disease 31% microvascular complications	Intervention ppts were given app with Bluetooth-enabled blood glucose meter. All ppts used mobile phones to label BG from blood glucose meter and enter carbohydrates & medications. Based on BG values, ppts received positive feedback or instructions to test BG or emailed questions to determine the root of problem. All suggested medication changes were sent to ppts and their physicians. Ppts received feedback related to nutrition, lifestyle, state of change and self-management skills and were referred to a diabetes educator if more help was needed.	Usual care (UC): control ppts were given BG meter and asked to send BG logbooks every 2 weeks to physician. Physicians followed usual standards of care for patients' diabetes management.	HbA1c (%)	Yes	Intervention group decreased 2.03% vs. control group decreased 0.68% (p <0.04)	NA
				Increase in medication dosage	Yes	Intervention group 84.6% vs. control group 23.3% (p= 0.002)	NA
				Self-entered medication errors identified by app	Yes	Intervention group 53.4% vs. control group 0% (p =0.002)	NA
				New depression diagnosis	No	Intervention group 9% vs. control group 20% (p=0.37)	NA
				Self-care behaviors	CND	Cumulative score for tool not reported.	Summary of Diabetes Self Care Activities, 5-domain measurement including diet (specific and general), exercise, glucose testing, smoking, and foot care.
				Improved knowledge of food choices	No	Intervention group 91% vs. control group 50%, p=0.062	Self-reported control issues survey (developed by authors)
				Self-reported satisfaction with provider care	Yes	Intervention group 100% vs. control group 37.5%, p=0.004	Self-reported control issues survey (developed by authors)
				Confidence about diabetes control	No	Intervention group 100% vs. control group 75%, p=0.167	Self-reported control issues survey (developed by authors)

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome results	Outcome Measurement Details
				Satisfaction with app	Yes (intervention only)	"At least 91%" of users were satisfied with specific components of app	Survey questions of patient satisfaction (feedback messages, cell phone use, medical team approach, and time saving)
BlueStar Diabetes Quinn 2011[10] 12 months Low quality United States	Number: 163 ppts Age: mean 52.8 Diabetes severity: Diabetes duration: 8.2 years Insulin pump: None Baseline HbA1c: 9.4% Comorbidities: 76.1% of ppts obese (BMI>30 kg/m$^{2)}$ Mean PHQ-9 of 5.2 indicating minimal to mild depression 63.2% hypertension 58.3% hypercholesterolemia	Intervention ppts were split into 3 groups: coach only (CO), coach PCP portal (CPP), and coach PCP portal with decision support (CPDS). All ppts used mobile phones to record BG, carbohydrates, & medications and received algorithm-derived educational and motivational messages. Virtual case managers intermittently reviewed data and provided feedback, and participants could reach out to case managers. In the CO group, providers could receive data from participants if they shared it. In the CPP and CPDS group, providers were trained on accessing data through an online portal and in the CPDS group, providers also received quarterly reports summarizing	Usual care (UC): providers reviewed ppts blood glucose (BG) meter readings and BG logbooks when made available by ppts, and providing care accordingly	HbA1c (%)	Yes for CPDS and CO, No for CPP	CPDS-UC: favors intervention, difference of -1.2% [-.5 to -1.9%] P=.001 CO-UC: favors intervention, p=.027 CPP-UC: no difference, p=.40	NA
				Blood pressure	No	SBP: NR, p>.05 DBP: NR, p>.05	NA
				Lipid profile	No	LDL: NR, p>.05 HDL: NR, p>.05 Triglycerides: NR, p>.05 Total cholesterol: NR, p>.05	NA
				Hypoglycemic events	CND	"Infrequent in all groups"	Not defined
				Health care utilization	CND	Hospitalizations: "Infrequent in all groups." 1 ppt hospitalized twice in for reasons not reported in the study ER visits: "Infrequent in all groups"	NA
				Death	No	No deaths in either group	NA
				Diabetes Distress	No	NR, p>.05	Diabetes Distress Scale
				Diabetes symptoms	No	NR, p>.05	Self-Completion Patient Outcome Instrument
				Depression	No	NR, p>.05	PHQ-9
				Adverse events	No	None reported.	NA

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome results	Outcome Measurement Details
		participants' progress and relevant evidence-based guidelines.					
BlueStar Diabetes Quinn 2014[11]*subgroup analysis for Quinn 2011 which is low quality 12 months United States	Number: 118 ppts Age: 60% of intervention vs 52% of control were <55 years old Diabetes severity: Diabetes duration: For those <55 years old, mean diabetes duration was lower in intervention than control (6.8 vs. 8.9 years). For those ≥55 years old, mean diabetes duration was higher in intervention than control (10.3 vs. 9.2 years). Insulin pump: none HbA1c: For those <55 years old, HbA1c was 9.9% for both intervention and control. For those ≥55 years old, HbA1c was 9.8% in intervention vs. 8.4% in control. Comorbidities: 61% hypertension 59% hypercholesterolemia 8% coronary artery disease 12% microvascular complication	CPDS above.	Same as above.	HbA1c (%)	Yes, for younger and older ppts	Younger (<55 years): −1.0% [−1.8, −0.2] P=.02. Older (≥55 years): −1.4% [−2.3, 0.6] P =.001.	NA
mDiab Takenga 2014[12] 2 months Low quality Democratic Republic of Congo		Ppts can input data using their mobile devices (Android, iPhone, and iPads) and/or web-based applications. App collects information on blood glucose, insulin intake, sports done with duration,	Conventional therapy without the use of telemedicine system	HbA1c (%)	CND	Intervention group decreased from 8.67% to 6.89%. Control group increased from 8.59% to 8.6%.	NA
				Usability and design	Yes (intervention only)	Mean 7 out of 10 (intervention only)	5 questions assessing ppt perceptions how often they successfully used the

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome results	Outcome Measurement Details
	Number: 40 Age: Mean 53.3 in intervention; mean 53.35 in control Diabetes severity: Diabetes duration: NR Insulin pump: NR Baseline HbA1c: Mean 8.67% for intervention vs. 8.59% for control Comorbidities: NR	BP measurements, body weight and size, via manual entry or syncing with blood glucose meter. Doctors send therapy plans, instructions, and recommendations to mobile app or email/SMS. App connects to a web-based health portal which can be accessed by users, doctors, and hospital and system administrators					system, how easy it was to use the system and how they would evaluate the input, output, visualization and design of the application
				Efficiency and therapy satisfaction	Yes (intervention only)	Mean 7.43 out of 10 (intervention only)	2 questions assessing ppt perceptions on whether app motivated them to control BG levels and whether feedback from doctors helped.
				Acceptance and appreciation	Yes (intervention only)	Mean 8.65 out of 10 (intervention only)	NR (article says this measurement was based on 2 questions but doesn't say what those were)
				Glucose variability (mg/dL)	CND	Standard deviation at follow up was 33 in intervention and 48.16 in control.	Standard deviation of mean BG
NexJ Health Coach + Wayne 2015[13] 6 months Moderate Quality Canada	Number: 138 ppts Age: mean 53.2 Diabetes severity: Diabetes duration: NR Insulin pump: NR Baseline HbA1c: 8.69% in intervention vs. 8.89% in control Comorbidities: NR	App supports ppts in health-related goal setting and progress monitoring. Ppts manually enter data, communicate with health coach at any time via secure messaging, and schedule phone contact and/or in-person meetings through app.	Ppts received health coach support in selecting and progressing toward goals without access to a study-provided mobile phone or software. Ppts received health coach support in selecting and	HbA1c (%)	No	Intent-to-treat analysis: Intervention-control difference of -0.152; P=0.48 Per protocol analysis: Intervention-control difference of .055; p=.83	NA
				Weight (kg)	CND	Intervention group lost 1.22 (.35-2.08) kg, control group gained .45 (-1.33 to .44) kg.	NA
				Waist circumference (cm)	CND	Intervention group lost 2.23 (.53-3.93) cm, control group gained .122 (-1.89 to 1.64) cm.	NA

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome results	Outcome Measurement Details
			progressing toward goals without access to a study-provided mobile phone or software.	BMI (kg/m^2)	CND	Intervention group lost .21 (-.24 to .66), control group lost .21 (-.68 to .25) kg/m^2.	NA
				Life satisfaction	CND	Intervention group increased by 3.72 (1.50-5.94) and control group increased by 3.77 (1.3-6.24).	Satisfaction with Life Scale
				Depression & anxiety	CND	Depression: Intervention group decreased by 1.81 (-2.81 to -.82) and control group decreased by 1.7 (-2.73 to -.67). Anxiety: Intervention group decreased by 1.12 (-2.29 to .05) and control group decreased by 1.5 (-2.73 to -.27).	Hospital anxiety and depression scale
				Quality of life	CND	Physical: Intervention group increased by 2.69 (.21 to 5.17) and control group increased by 2.92 (.24 to 5.6). Mental: Intervention group increased by 2.48 (-1.1 to 6.05) and control group increased 2.82 (-1.05 to 6.69).	SF-12
				Affect	CND	Negative affect: Intervention group decreased by 2.03 (-4.87 to .8). Control group decreased by .57 (-3.55 to 2.41). Positive affect: Intervention group increased by 1.6 (-1 to 4.2). Control group increased by .44 (-2.3 to 3.18)	Positive and Negative Affect Schedule (PANAS)

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome results	Outcome Measurement Details
Gather Health Kleinman 2016[14] 6 months Low Quality India	Number: 91 ppts Age: Mean 48.4 Diabetes severity: Diabetes duration: Median 10 years Insulin pump: NR Baseline HbA1c: Mean 9.3% Comorbidities: NR	System supports self-management, facilitates participant–provider communication, and enables treatment changes between visits using participant's mobile phone apps and provider web portals and mobile phone apps.	Usual care consisting of free visits, laboratory tests, and test strips and lancets	HbA1c	Yes	Using only ppts who had follow-up data, intervention group decreased 1.5% and control group decreased 0.8% (P=0.02). Using all participants and last observation carried forward, the difference was still significant (P=0.045). Using all participants and imputation from treatment arm means, the difference was not significant (P=0.06).	NA
WellTang Zhou 2016[15] 3 months Moderate Quality China		App provided information on diet, exercise, medicine, blood glucose monitoring, and summaries of the latest guidelines (knowledge). Participants could enter their self-care data (blood glucose values, carbohydrate intake, medications, and other diabetes management information) which was transferred to secure servers to	Physicians reviewed blood glucose readings, logbooks, and adjusted medication regimens to targeted goals once a month	Satisfaction	Yes (intervention only)	84% satisfaction rate	1 item where 1 means satisfied and 0 means not satisfied with the use of the application.
				HbA1c (%)*	Yes	Intervention group changed -1.95% and control group changed -.79% from baseline, P < 0.001	NA
				Fasting blood glucose (mmol/L)	Yes	-1.89 ± 2.61 in intervention vs. -0.95 ± 1.54 in control (P < 0.01)	NA
				2-hour post-breakfast blood glucose (mmol/L)	Yes	-4.39 ± 4.43 in intervention vs. -2.81 ± 2.69 control (P < 0.01).	NA

App Name Author & Year Length of Study ROB Assessment	Participants	Intervention	Comparator	Outcome	Significant improvement in intervention vs. comparator	Outcome results	Outcome Measurement Details
	Number: 100 ppts, including 18 with type 1 and 82 with type 2 diabetes Age: mean 55 years in intervention vs. 53.5 in control Diabetes severity: Diabetes duration: mean of 6.65 years in intervention vs. 6.63 in control Insulin pump: NR Baseline HbA1c: 9.86% in intervention vs. 9.76% in control Comorbidities: 40% Hypertension 20% Hyperlipidemia 12% Coronary artery disease	generate into computer-generated logbooks (self-management). Participants could ask questions and receive feedback from study team on blood glucose, target goals, and individualized medication regimens (communication).		Blood pressure (mmHg)	No	SBP: Intervention group decreased from 134.2 ± 19.7 to 132.2 ± 19.2 vs. control decreased from 134.2 ± 20.2 to 133.6 ± 15.5 (P>.05) DBP: Intervention group decreased from 76.8 ± 11.5 to 75.8 ± 11.1 vs. control decreased from 77.1 ± 11.4 to 76.8 ± 11.3 (P>.05)	NA
				LDL-C (mmol/L)	No	Intervention group decreased from 2.42 ± 0.81 to 2.34 ± 0.57 vs. control decreased from 2.48 ± 0.80 to 2.43 ± 0.64 in (P >.05).	NA
				Weight (kg)	No	Intervention group decreased from 62.4 ± 12.8 to 62.2 ± 11.0 vs. control increased from 62.5 ± 12.8 to 62.7 ± 12.1 (P>.05).	NA
				BMI (kg/m^2)	No	Intervention group decreased from 23.04 ± 4.09 to 23.01 ± 3.58 vs. control increased from 23.01 ± 4.04 to 23.10 ± 3.81 (P>.05).	NA

BG=blood glucose; CND=could not determine; DBP=diastolic blood pressure; HDL=high density lipoprotein; I/E=inclusion/exclusion; LDL=low-density lipoprotein; NA=not applicable; NR=not reported; PHQ=Patient Health Questionnaire; ppts=participants; SBP=systolic blood pressure

Full References of Included Studies

1. Kirwan M, Vandelanotte C, Fenning A, et al. Diabetes self-management smartphone application for adults with type 1 diabetes: randomized controlled trial. J Med Internet Res. 2013;15(11):e235. DOI: 10.2196/jmir.2588. PMID: 24225149

2. Garg SK, Shah VN, Akturk HK, et al. Role of mobile technology to improve diabetes care in adults with type 1 diabetes: The remote-T1D study iBGStar(R) in type 1 diabetes management. Diabetes Ther. 2017;8(4):811–819. DOI: 10.1007/s13300-017-0272-5. PMID: 28555339.

3. Drion I, Pameijer LR, van Dijk PR, et al. The effects of a mobile phone application on quality of life in patients with type 1 diabetes mellitus: A randomized controlled trial. Diabetes Sci Technol. 2015;9(5):1086-1091. DOI: 10.1177/1932296815585871. PMID: 25963412.

4. Skrovseth SO, Arsand E, Godtliebsen F, et al. Data-driven personalized feedback to patients with type 1 diabetes: A randomized trial. Diabetes Technol Ther. Jul 2015;17(7):482-489. DOI: 10.1089/dia.2014.0276. PMID: 25751133.

5. Rossi MC, Nicolucci A, Di Bartolo P, et al. Diabetes interactive diary: A new telemedicine system enabling flexible diet and insulin therapy while improving quality of life: an open-label, international, multicenter, randomized study. Diabetes Care. Jan 2010;33(1):109-115. DOI: 10.2337/dc09-1327. PMID: 19808926.

6. Rossi MC, Nicolucci A, Lucisano G, et al. Impact of the "Diabetes Interactive Diary" telemedicine system on metabolic control, risk of hypoglycemia, and quality of life: A randomized clinical trial in type 1 diabetes. Diabetes Technol Ther. Aug 2013;15(8):670-679. DOI: 10.1089/dia.2013.0021. PMID: 23844569.

7. Charpentier G, Benhamou PY, Dardari D, et al. The Diabeo software enabling individualized insulin dose adjustments combined with telemedicine support improves HbA1c in poorly controlled type 1 diabetic patients: A 6-month, randomized, open-label, parallel-group, multicenter trial (TeleDiab 1 Study). Diabetes Care. Mar 2011;34(3):533-539. DOI: 10.2337/dc10-1259. PMID: 21266648.

8. Franc S, Borot S, Ronsin O, et al. Telemedicine and type 1 diabetes: Is technology per se sufficient to improve glycaemic control? Diabetes Metab. Feb 2014;40(1):61-66. DOI: 10.1016/j.diabet.2013.09.001. PMID: 24139705.

9. Quinn CC, Clough SS, Minor JM, et al. WellDoc mobile diabetes management randomized controlled trial: Change in clinical and behavioral outcomes and patient and physician satisfaction. Diabetes Technol Ther. Jun 2008;10(3):160-168. DOI: 10.1089/dia.2008.0283. PMID: 18473689.

10. Quinn CC, Shardell MD, Terrin ML, et al. Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. Diabetes Care. Sep 2011;34(9):1934-1942. DOI: 10.2337/dc11-0366. PMID: 21788632.

11. Quinn CC, Shardell MD, Terrin ML, et al. Mobile diabetes intervention for glycemic control in 45- to 64-year-old persons with type 2 diabetes. J Appl Gerontol.. Feb 2014;35(2):227-243. DOI: 10.1177/0733464814542611. PMID: 25098253.

12. Takenga C, Berndt RD, Musongya O, et al. An ICT-based diabetes management system tested for health care delivery in the African context. Int J Telemed Appl. 2014;2014:437307. DOI: 10.1155/2014/437307. PMID: 25136358.

13. Wayne N, Perez DF, Kaplan DM, et al. Health coaching reduces HbA1c in type 2 diabetic patients from a lower-socioeconomic status community: A randomized controlled trial. J Med Internet Res. Oct 05 2015;17(10):e224. DOI: 10.2196/jmir.4871. PMID: 26441467.

14. Kleinman NJ, Shah A, Shah S, et al. Impact of the Gather mHealth system on A1C: Primary results of a multisite randomized clinical trial among people with type 2 diabetes in India. Diabetes Care. Oct 2016;39(10):e169-170. DOI: 10.2337/dc16-0869. PMID: 27493133.

15. Zhou W, Chen M, Yuan J, et al. Welltang - A smart phone-based diabetes management application - Improves blood glucose control in Chinese people with diabetes. Diabetes Res Clin Pract. Jun 2016;116:105-110. DOI: 10.1016/j.diabres.2016.03.018. PMID: 27321324.

Appendix D. System Usability Scale

Below are the statements that were used to evaluate the usability of apps in this report.

1. I think that I would like to use this product frequently.
2. I found the product unnecessarily complex.
3. I thought the product was easy to use.
4. I think that I would need the support of a technical person to be able to use this product.
5. I found that the various functions in this product were well integrated.
6. I thought that there was too much inconsistency in this product.
7. I would imagine that most people would learn to use his product very quickly.
8. I found the product very awkward to use.
9. I felt confident using the product.
10. I needed to learn a lot of things before I could get going with this product.