Complete Title: Audio Care for Managing Diabetes: A Rapid Review

Brief Title: Audio Care for Diabetes

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# Abstract

Background

Diabetes is a chronic condition afflicting many in the United States. The impact of audio care on the health of individuals with diabetes is unclear; it is particularly important to understand its effects among those at risk for disparities—many of whom may only be able to access telehealth services via telephone.

Objectives

We compared the effectiveness of audio care, as a replacement or a supplement to usual care, for managing diabetes.

Design

We used rapid review methods to synthesize available evidence.

Studies

We searched for English-language articles from the last 10 years reporting randomized controlled trials (RCTs) of adults diagnosed with diabetes.

Outcomes

We abstracted data on clinical outcomes (including A1c), patient-reported health and quality-of-life, health care access and utilization, care quality and experience, and patient safety.

Results

We included 22 RCTs of participants with diabetes. Evidence for replacing in-person care with audio care was limited but trended toward a favorable impact. Supplemental audio care had minimal impact on A1c (pooled mean difference A1c -0.08% (n=3,659 [95% confidence interval [CI]: -0.27% to 0.11], *I2* = 58.7%), although stratified results trended toward interventions performing more favorably in individuals with A1c ≤ 9% and in interventions with at least monthly contact. There were no differences between the pooled mean difference in A1c for studies conducted in populations at risk for disparities and those not at risk.

Conclusions

This small evidence base reveals some promise for managing diabetes with audio care, either through replacing in-person or video visits or supplementing care. However, more high-quality evidence is needed, particularly for evaluating replacement care and in populations at risk for disparities.

Keywords

Telehealth, Audio Care, Diabetes, Access to Care

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# Background

Throughout the COVID-19 public health emergency, outpatient and routine health services frequently shifted to telehealth for the management of chronic conditions such as diabetes. Diabetes mellitus affects approximately 8.5% to 11.3% of U.S. adults and about half have poorly controlled blood glucose,1 which can lead to significant morbidity and mortality.2,3 Interventions promoting glycemic control include counseling on diet and exercise, self-management support, medication adherence, and treatment intensification, and may be reasonable to implement through telehealth.4-6 Because nearly 40% of Americans have no access to broadband internet (including many medically and vulnerable individuals) and telephone care may be their sole means of telemedicine access,7 audio interventions could potentially have an outsized impact for this population.8,9 In this review, we examined the impact of audio care on clinical, patient-reported, health care utilization, and safety outcomes in individuals with diabetes, particularly on individuals at risk for health disparities.

# Methods

This review addressed 2 key questions:

1. What are the impacts of audio telemedicine visits compared to in-person or video appointments and other usual care for managing diabetes mellitus in adults?
2. How do the findings vary for patients at risk for health disparities?

A detailed protocol of our rapid review process, which followed recommendations from the Cochrane Rapid Reviews Methods Group,10 was registered on October 6, 2022, and is available on Open Science Framework.11 In brief, we made the following adjustments to standard systematic review methods to accommodate timely synthesis: we limited eligibility to randomized controlled trials (RCTs), omitted grey literature searches, required dual screening for excluded abstracts only, utilized focused data extraction, relied on study-reported statistical significance, and excluded strength-of-evidence assessments.

## Study Selection

We searched PubMed, Embase, and American Psychological Association PsycInfo for English-language articles published in the last 10 years (January 2012–July 2022). Additionally, we manually searched the reference lists of recent relevant systematic reviews.

**Table 1** outlines the prespecified inclusion and exclusion criteria for this review. We included adults with type I and type II diabetes. We included studies comparing audio care to in-person or video-teleconferencing or other usual care. We also included hybrid intervention studies that combined synchronous in-person or video care with audio care compared to the same intervention without the audio component to assess the incremental impact of the audio component.

We used DistillerSR (Evidence Partners) to screen the literature and EndNote (Thomson Reuters) to manage bibliographic records. To exclude a study at the title and abstract stage, we required 2 team members to independently agree the study did not meet the inclusion criteria. Publications promoted for full-text screening were assessed by 2 reviewers and discrepancies resolved through discussion.

## Data Extraction and Risk-of-Bias (RoB) Assessment

We used DistillerSR to abstract information about each included study and the Cochrane tool (Risk of Bias 2.0) to assess risk of bias (RoB) for each outcome.12 One reviewer performed the initial data abstraction and RoB assessment. A second reviewer verified the abstracted data and each RoB rating. Discrepancies were resolved by discussion or a third reviewer.

We characterized the purpose of each intervention as either supplementing usual care with audio (supplement) or replacing usual care with audio (replacement) and the intervention focus as either medication management (MM), behavioral/lifestyle management (BLC), or both. MM included counseling on medication adherence and treatment intensification. We assessed intervention intensity dichotomously as audio intervention contact occurring less than once a month or once a month or more frequently.

## Data Synthesis and Analysis

Data tables display key information on the study designs, populations, interventions, and results. We developed an evidence map to visually summarize the direction and significance of findings across 4 outcome categories: clinical, patient reported, health care utilization, and safety. We summarized the studies narratively and quantitatively only for A1c at 6 and 12 months.13 We employed random-effects models using the inverse variance method of DerSimionian and Laird to generate pooled mean differences.14 Because this was a rapid review and we did not grade the strength of evidence, we restricted meta-analyses only to studies with low or some concerns of RoB to ensure scientific rigor and performed a sensitivity analysis including all studies (**Supplemental Digital Content** **[SDC] Figure 1**). We performed subgroup analyses for glycemic control (A1c < or ≥ 9 based on the Centers for Medicare & Medicaid Services criteria for poorly controlled) and for populations at risk for disparities.

# Results

**Figure 1** is a PRISMA diagram summarizing our study identification and screening process. Of 2,157 unique records, we included 23 publications representing 22 RCTs, 1 of which was a cluster RCT.15 **Table 2** includes key study characteristics and additional detail can be found in **SDC Table 1**. We rated 6 studies as high RoB,15-20 15 as some concerns of bias or low RoB,21-35 and 1 as mixed RoB depending on the outcomes36 (**SDC Table 2**). Studies were primarily rated as high RoB because of concerns in domains of randomization, deviations from intervention, and missing data.

Most studies (20 of 22) provided audio care to supplement existing in-person care.15-17,19-25,27-36 Two studies evaluated the use of audio care to replace other care;18,26 3 trials conducted interventions focused on MM,19,34,36 9 on BLC,16,20,24,26,27,29-31,33 and 10 on both (MM+BLC).15,17,18,21-23,25,28,32,35 Interventions were compared to usual care in most instances,15,16,18-21,23-34,36 but occasionally the comparison was usual care enhanced with education materials.17,22,35,37 Seventeen studies were conducted in individuals with type II diabetes.15,16,20-23,25-31,33-36 Mean baseline A1c was less than 9.0% in 14 studies15,16,18-23,26-29,31,33 and ≥ 9.0% in 8 studies.17,22,24,25,32,34-36 Interventions were delivered most frequently by nurses20,21,23,27,31,32,35,36 or coaches and counselors or educators (CCEs)16,17,26,29,37 and less often by physicians,15,18 registered dieticians,28,33 or other providers.19,25,30 The number of audio intervention contacts ranged from a single scripted telephone call to 27 calls. Among the 13 studies reporting duration, audio interventions lasted from 5 to 60 minutes per call.17,18,23-25,27-31,34-37 Seven studies included contact with individuals less than once a month, while 15 studies involved at least monthly contact. Studies overall randomized 9424 (min: 22 and max: 2378) individuals, with a median sample size of 215 (IQR: 340) participants.

The following sections and evidence map (**Figure 2**) summarize the results by intervention purpose (replacement or supplement) and then by outcome.

## Intervention Purpose: Replace In-Person Care

Only 2 (of 22) studies evaluated the use of audio care to replace in-person visits (661 participants); outcomes from both studies were similar between arms or favored the intervention.18,26 One study (high RoB), conducted in a population with a baseline A1c of 7.3% to 7.7%. The intervention focused on MM and BLC with remote patient monitoring supports and replaced 2 in-person routine care visits with 2 5-minute telephone and computer-based visits with a physician at 3 and 9 months.18 The study found similar effects at 6 months and 12 months between the audio intervention and in-person comparator for glycemic control, blood pressure (BP), lipids, and body mass index (BMI). No hospitalizations for hypoglycemia were reported in either group over the 12-month duration of the study.

The second study included 2 telephone consultations (timing and duration not reported) delivered by certified diabetes educators who adapted a community weight loss program.26 The baseline A1c of the study population ranged from 8.28% to 8.36%. The study found no difference in A1c at 3 months between the audio intervention and standard care (which included nutrition counseling and written materials); however, significant effects, favoring the audio intervention, were reported at 12 months for change in A1c (-0.32% vs. 0.16%, P < 0.001) and weight loss (3.39% vs. 1.79%, P < 0.001). The number of participants experiencing hypoglycemia was significantly higher in the intervention group compared to the standard care group (35% vs. 21%, P < 0.001) at 3 months, although by 12 months the proportion was similar.

Neither study reported patient-reported health, quality of life, health care access, or utilization outcomes.

## Intervention Purpose: Supplement with Audio Care

### Glycemic Control

Twenty studies supplemented usual care with interventions using audio care and reported A1c levels (8763 participants). Most studies (14 of 20) reported no statistically significant difference between audio intervention and the usual care comparator or did not report a statistical test between groups.31,33 Over half of the studies finding no statistically significant differences delivered audio care less than once a month, included study populations with baseline A1c ≥ 9%.22,24,25,32,34,36

Studies that delivered audio interventions monthly or weekly were more likely to show a statistically significant decrease in A1c (P values < 0.05); these interventions were also typically delivered by nurses or counselors, coaches, or educators (CCEs), included study populations with a baseline A1c < 9%, and used other intervention supports, such as remote patient monitoring tools and tailored educational materials.16,17,19,20,28,35 However, among these 6 studies reporting statistically significant decreases in A1c, 4 were rated high RoB,16,17,19,20 whereas among the 14 studies finding no difference only 2 were rated high RoB15,36 (**SDC Table 3**).

Ten of the 15 studies classified as low RoB or some concerns had data available for a meta-analysis examining the impact of supplemental audio interventions on the mean difference in A1c compared to usual care between 6 and 12 months (**Figure 3**). The pooled mean difference in A1c was -0.08% (n = 3659, [95% CI: -0.27% to 0.11%], *I2* = 58.7%). Similar results were obtained including all studies (**SDC Figure 1**). Stratifying by study population baseline mean A1c, interventions including study populations with A1c < 9% had a pooled mean difference in A1c of -0.24% (95% CI: -0.51 to 0.02), while those with an A1c ≥ 9% had a pooled mean difference of 0.08% (95% CI: -0.13 to 0.28). Interventions delivered monthly or more frequently had a pooled mean difference in A1c of -0.17% (95% CI: -0.42 to 0.07), while those delivered less than once a month had a pooled mean difference of 0.10% (95% CI: -0.06 to 0.25) (**SDC Figure 2**). There was no difference in pooled mean difference in A1c by intervention focus (**SDC Figure 3**).

### Other Clinical Outcomes

**Blood pressure.** Twelve studies supplementing usual care with audio care reported BP (5794 participants)15,20-23,27-29,31,32,34,35 (**Figure 2**): 215,20 were rated high RoB, and 1 did not report statistical tests evaluating intervention effects on BP between groups.31 Nine of the 12 studies reported no statistical differences in BP, regardless of intervention focus (4 BLC, 1 MM, 4 BLC+MM). The trial designs were heterogeneous, with audio interventions delivered by different provider types and audio calls administered at different frequency and duration. Nurses21,35 and registered dieticians 28 delivered monthly MM+BLC interventions in the 3 studies finding small statistically significant decreases in systolic and diastolic BP, mean difference ranging from -5 to -7.7 mmHg between 6 to 12 months of follow-up (**SDC Table 3**).

**Lipids.** Twelve studies supplementing usual care with audio care reported lipids (5777 participants, **Figure 2**).15,20-23,27-31,33,34 Two studies did not report statistical tests evaluating intervention effects on lipids,31,33 and 10 studies (2 high RoB)15,20 reported similar effects on lipids when comparing supplemental audio care to usual care. These studies involved a range of intervention foci, contact frequency, and providers.

**Weight.** Seven studies supplementing usual care with audio care reported weight or BMI (1,098 participants, **Figure 2**).16,22,27-30,33 One study did not report statistical tests.33 Four studies reported no statistically significant differences and implemented interventions focused on BLC (2 studies)27,30 or BLC+MM (2 studies)22,28 via a range of intervention contact frequencies and various providers (**SDC Table 3**). Two studies reported statistically significant reduction in weight or BMI (1 high RoB16);16,29 they used BLC interventions delivered either as monthly calls over 3 months16 or multiple calls without a prespecified frequency over 18 months.29 The calls in both were delivered by CCEs16,29 and the studies used other supports such as print materials29 and remote monitoring tools.16,29

### Patient-Reported Health and Quality-of-Life Outcomes

Six of the 20 studies providing audio care as a supplement assessed mental and physical health-related quality of life (2272 participants, **Figure 2**).15,20,21,27,32,37,38 One study did not report a statistical test between groups37,38 (**SDC Table 3**). Two studies found no statistically significant differences between groups, 1 of which focused on both MM and BLC15 and the other on BLC alone.27

Among the 3 studies (1 high ROB20) reporting statistically significant improvements in patient-reported health and quality of life, intervention contact was monthly20,21 or weekly32 and all intervention providers were nurses.20,21,32 One study focused on BLC alone;20 the remaining 2 focused on both MM and BLC.21,32 Two studies included intervention supports using remote patient monitoring tools20,32 and asynchronous communication with study nurses through text, email, or mobile devices.20,32 Comparison groups included in-person visits32 and usual care.20,21

### Health Care Access and Utilization Outcomes

Seven studies reported at least 1 eligible health care access and utilization outcome (5937 participants, **Figure 2**).15,17,20,23,25,34,35

**Medication adherence.** Six studies (2 high RoB)15,17 evaluated medication adherence.15,17,23,25,34,35 Four studies reported no statistically significant differences.17,25,34,35 Two studies evaluating MM + BLC interventions reported significant improvements in medication adherence. One reported improved adherence at 12 months for individuals who received monthly calls with a nurse than for those who received usual care (odds ratio [OR]: 4.4 [95% CI: 1.8 to 10.6], P = 0.0008).23 The second study (high RoB),15 delivered bi-weekly phone call by a physician with improvement in adherence at 4 months but not 12 months.15

**Healthcare visits.** One study (high RoB)20 reported no significant difference in hospital stays or emergency room visits over 12 months between the intervention (BLC delivered monthly or as-needed calls by a nurse) and the usual-care group.

### Harms

Of the 20 studies that evaluated audio care as a supplement to usual care, only 2 reported harms (363 participants); 1 focused on BLC20 and 1 on MM.36 Both interventions were delivered by nurses and at variable frequency. Authors reported 5 hypoglycemic episodes (3 in the intervention group and 2 in the control group), all mild, over 12 weeks in 1 study (61 participants)36 and no hypoglycemic episodes over 12 months in the second study (302 participants, high RoB).20 Statistical significance testing for hypoglycemic episodes was not reported for either study.

## Populations at Risk for Disparities

In 9 of 22 included studies, at least a quarter of study participants were BIPOC,17,23,24,26,32,35,36 older adults,15,24 individuals with limited English proficiency,17,32 individuals with low health or digital literacy,23,35 immigrants and refugees,17 persons with intellectual and developmental disabilities,24 and veterans.22,24,35 Several studies had groups with multiple risks for disparities.17,23,24,32,35,36 Four studies tailored interventions for the study population,17,23,35,36 and no studies described community engagement in intervention design.

Studies including 25% or more participants at risk of disparities tended to have poorer baseline glycemic control; 6 of 9 had a baseline A1c ≥ 9%,17,22,24,32,35 ranging from 7.8% to 11.7% (**SDC Table 4**)**.** In contrast**,** among the other studies, only 2 of 13 studies had a baseline A1c ≥ 9%25,34 and average A1c ranged from 6.8% to 9.8%.

Interventions among populations likely at risk of disparities compared to those less at risk tended to include MM or MM+BLC than BLC alone, involve more frequent audio contact such as weekly or biweekly calls,15,22,24,32,35 and include tailored intervention materials.23,36 However, remote patient monitoring tools and web-based technologies were less commonly a support component for at-risk populations.

Although studies in at-risk populations had favorable outcomes for medication adherence,15,23 there were similar effects between groups for clinical and patient-reported outcomes in studies, with a few exceptions.21,28,29,33 Specifically, we found no difference in the pooled mean difference in A1c when we stratified the meta-analysis by the presence or absence of a population at risk for disparities (**SDC Figure 4**).

## Gaps in Current Evidence

The evidence map provides a visual representation of research gaps (**Figure 2**). Although all studies reported on A1c, there are clear gaps for other clinical outcomes, patient-reported outcomes, health care access and utilization outcomes, patient experience, and patient safety and harms. The literature is dominated by interventions aiming to supplement care with audio interventions, while only 2 studies replaced in-person care with audio visits. The majority of studies was not conducted in populations at risk of disparities.

# Discussion

This rapid review investigated the impact of audio-delivered care interventions to either replace in-person care or supplement usual care for managing diabetes. From the 2 studies in which audio care replaced in-person care, we found limited evidence that the audio care yielded as good or possibly better clinical outcomes, including glycemic control, BP, lipids, and BMI. Among the studies assessing the effects of supplemental audio care, we found minimal impact on A1c and other clinical outcomes, although we identified intervention and population characteristics that may be associated with improved outcomes.

Successful supplemental audio interventions tended to involve more frequent contact with participants, generally at least once a month if not more often, and to have intervention supports such as tailored self-management materials and remote patient monitoring tools. Study populations where outcomes favored the audio intervention tended to have a baseline A1c < 9%, suggesting more research is needed on the optimal intervention design for study populations with very poorly controlled diabetes (≥9%). The pooled results from the meta-analysis trended toward supporting this qualitative finding, although there was a small overlap in CIs (**Figure 3**). Providers of interventions with more favorable results tended to be nurses or CCEs, suggesting advanced practitioners may not be necessary to deploy these interventions successfully. In contrast, studies with similar effects for audio-intervention and control groups across outcomes tended to have less frequent contact with participants (fewer than 1 contact per month), shorter follow-up periods (e.g., 3 months), a range of provider types and enrolled study participants with A1c ≥ 9%. Some of these interventions also targeted conditions other than diabetes, such as hypertension.23

Individuals from populations at risk of disparities were more likely to have poorly controlled diabetes, and there were indications that studies focusing on these populations employed more intense and combined (MM+BLC) interventions. Among the 6 studies using interventions with biweekly or weekly calls, all but 1 targeted a study population at risk of disparities. However, remote patient monitoring tools and web-based technology supports were employed less often in studies focused on populations at risk of disparities, highlighting a need for further study of these tools in vulnerable populations, including providing access to technological resources (e.g., internet access) if needed. Although several studies were tailored for the target population, no studies reported community engagement in intervention design, underscoring another research need.

Although existing systematic reviews of telehealth diabetes care have assessed a broad range of interventions, 2 recent reviews focused on audio care for type II diabetes and had findings consistent with our rapid review.5,6 The 2 reviews included interventions focused on self-management, education, and treatment adherence, often delivered by nurses and counselors. Both reviews reported statistically significant impacts of audio interventions on A1c; however, the meta-analyses included studies with high RoB without reporting sensitivity analyses, so it is unclear if pooled results were skewed. Neither review assessed interventions across purpose (e.g., supplement or replacement in-person or video care with audio care), although most studies appeared to fall within the bounds of audio care supplementing usual care. Furthermore, neither review applied a health equity lens by assessing subgroups at risk for disparities.

This rapid review should be interpreted within the context of several limitations. For supplemental audio care, it is difficult to disentangle the effects of the intervention from the audio modality of the intervention and some studies provided only 3 months of follow-up, which may be too short to evaluate the optimal impact of an intervention.13 Lack of reporting may have affected our ability to adequately characterize aspects of the intervention and comparator and to assess diabetes type (I or II) and intervention intensity. For example, MM was broadly defined as including both adherence counseling and treatment intensification, potentially encompassing a range of intervention activities and the crude measure of intervention intensity (call frequency) does not consider the quality of counseling. Several (5 of 7) studies with high RoB reported favorable outcomes and we did not include them in the meta-analysis. Additionally, there was high heterogeneity of interventions, which was also observed in the meta-analysis results. Finally, this review did not include observational studies which, when explored, may fill identified evidence gaps, particularly around harms. Our review found no evidence of increased risk of harm (hypoglycemic episodes) associated with audio interventions; however, many of the included studies did not report patient safety outcomes.

Future research priorities include more replacement studies (replacing in-person or video care with audio care) to understand if audio care is truly non-inferior, as was suggested by the few examples identified. Standardized reporting on intervention components, providers, and metrics on intervention contact frequency and duration would improve future evaluations and facilitate replication and expansion activities. Higher quality studies with low RoB are needed. Future studies, particularly those with MM interventions, should routinely collect harms data. Finally, more research is needed on audio care delivered to patients with diabetes who are also at risk of disparities; interventions should be designed incorporating input from and tailored for the target population. Individuals at risk of disparities are more likely to only have access to audio-only technology compared to other telehealth modalities and to have limited access to in-person care and, thus, are a particularly important group to consider when designing and evaluating these kinds of interventions.

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