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Review

The Impact of Providing Material Benefits to Improve Access to Food on Clinical Parameters, Dietary Intake, and Household Food Insecurity in People with Diabetes: A Systematic Review with Narrative Synthesis



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ABSTRACT

The high cost of healthy foods makes maintaining a healthy dietary pattern challenging, particularly among people with diabetes who are experiencing food insecurity. The objectives of this study were to: 1) review evidence on the impact of providing material benefits (e.g., food coupons/vouchers, free food, or financial subsidies/incentives) to improve access to food on clinical parameters, dietary intake, and household food insecurity in people with diabetes, and 2) review relevant economic evidence. Six databases were searched from inception to March 2023 for longitudinal studies with quantitative outcomes. Twenty-one studies were included in the primary review and 2 in the economic analysis. Risk of bias was high in 20 studies and moderate in 1 study. The number of randomized controlled trials and non-randomized studies reporting statistically significant improvement, alongside Grading of Recommendations Assessment, Development, and Evaluation (GRADE) certainty of the evidence was: HbA1c: 1/6 and 4/12 (very low), systolic blood pressure: 0/3 and 1/8 (very low), diastolic blood pressure: 0/3 and 1/7 (very low), BMI: 0/5 and 2/8 (very low), body weight: 0/0 and 1/3 (very low), hypoglycemia: 1/2 and 1/2 (very low), daily intake of fruits and vegetables: 1/1 and 1/3 (very low), daily intake of whole grains: 0/0 and 0/2 (very low), overall diet quality: 2/2 and 1/1 (low), and household food insecurity: 2/3 and 0/0 (very low). The 2 studies included in the economic analysis showed no difference in Medicare spending from Supplemental Nutrition Assistance Program participation and cost-savings from medically tailored meals in an economic simulation. Overall, providing material benefits to improve access to food for people with diabetes may improve household food insecurity, fruit and vegetable intake, and overall diet quality, but effects on clinical parameters and whole grain intake are unclear. The certainty of evidence was very low to low by GRADE.

PROSPERO (CRD42021212951)

Keywords: diabetes, HbA1c, dietary intake, food insecurity, material benefits, food subsidies, food vouchers, incentives, interventions, systematic review

Statements of significance

To our knowledge, this is the first systematic review of the impact of providing material benefits to improve food access among adults with diabetes. Findings showed that these interventions may improve food insecurity, fruit and vegetable intake and overall diet quality but effects on clinical parameters and whole grain intake were unclear.

Abbreviations used: GRADE, grading of recommendations assessment, development, and evaluation; RCT, randomized controlled trial; SNAP, Supplemental Nutrition Assistance Program.

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Introduction

A dietary intake pattern that is rich in fruits, vegetables, nuts, legumes, and whole grains is associated with lower HbA1c in patients with diabetes [1,2]. However, the high price of healthy foods is a barrier for people to maintain a healthy dietary pattern, especially for people experiencing household food insecurity [3]. Food insecurity refers to inadequate or insecure access to food due to financial constraints [4]. An estimated 10.5% of households in the United States experienced food insecurity in 2020 [5], and adults with food insecurity are 2 times more likely to have type 2 diabetes mellitus [6]. Because of financial constraints, people experiencing food insecurity often consume less expensive foods, which tend to be energy-dense and nutrient-poor [7]. People experiencing food insecurity often have insufficient material resources to manage other aspects of their health, including paying for prescription medications, which can lead to food-medication trade-offs. Therefore, food insecurity is also associated with lower medication adherence in patients with diabetes [8,9].

As a result of factors such as lower diet quality and barriers to taking medications, people with diabetes and food insecurity experience chronic hyperglycemia more frequently and have higher rates of diabetes complications compared to their food-secure counterparts [10–12]. Increasing access to healthy foods through material benefits may improve glycemia and other clinical parameters by improving adherence to nutritional recommendations and medications [13,14]. A material benefit to improve food access refers to the provision of resources to offset the cost of food, including food coupons/vouchers [15,16], free food [17,18], or financial subsidies/incentives [19,20].

To our knowledge, prior systematic reviews have not examined the impact of providing material benefits to improve access to food in people with diabetes. One systematic review in 2015 broadly reviewed material need support interventions for diabetes prevention and control but only identified 1 study that reported quantitative outcomes pertaining to the effects of a food-based intervention [21,22]. Other systematic reviews have investigated the impact of various types of food-based material support interventions, such as food prescription programs [23, 24], food insecurity interventions [25], or food pantry-based interventions [14]. However, these reviews did not specifically investigate the impact of these interventions on people with diabetes. Given the importance of maintaining a healthy dietary pattern and the high medication costs associated with diabetes, there is a need to review the impact of providing material benefits to improve access to food in people with diabetes.

This study's primary objective was to systematically review evidence on the impact of providing material benefits to improve access to food on clinical parameters, dietary intake, and household food insecurity status in people with diabetes. The secondary objective was to review evidence on the economic impacts of providing material benefits to improve access to food in people with diabetes.

Methods

This systematic review is reported according to the PRISMA and SWiM (Synthesis without Meta-Analysis) [26,27], and the

economic analysis adheres to Cochrane Handbook methods for a "Brief Economic Commentary" [28]. In addition, the review was registered in the PROSPERO (registration no. CRD42021212951) [29].

Information sources

The search strategy was designed in consultation with an experienced librarian and included keywords and subject headings pertaining to diabetes, diet quality or food access, and material benefits. Supplementary Material shows the search criteria for all databases. Embase, MEDLINE, Cochrane CENTRAL, Web of Science, International Health Technologies Assessment Database, and clinicaltrials.gov were searched on March 1, 2023, from their inception. Reference lists from all included articles and relevant review papers were hand searched for additional studies.

Study eligibility

To be included, studies had to be primary research published in English in a peer-reviewed academic journal. Reviews, conference abstracts, and commentaries were excluded. Eligible study designs included any longitudinal study assessing any quantitative outcomes, excluding cross-sectional analyses, ecological studies, case reports, and case series. Studies with any economic data pertaining to a material benefit intervention to improve food access in people with diabetes were included in the economic analysis.

The population was humans of any age with diabetes of any etiological subtype, excluding gestational diabetes. Eligible interventions provided material benefits to improve access to food, which included providing subsidized or free food, financial incentives, vouchers, or food prescription programs that included a direct material benefit to offset the cost of food.

Selection process

All database search results were imported into Covidence [30]. Duplicates were removed, and titles and abstracts were screened against eligibility criteria by 1 reviewer. Two reviewers (KJDS and either SC-R or SMA) independently assessed full texts in duplicate against eligibility criteria. Discrepancies were resolved via consensus with a third reviewer (ES). As per Brief Economic Commentary guidelines, economic studies were reviewed by 1 reviewer (KJDS). Included texts were collated by study and examined for errata.

Data extraction process

Two reviewers (KJDS and either SC-R or SMA) independently extracted data from all included studies using a pilot-tested data extraction form, which included the following categories: study identifiers, study design, statistical methods, participants, comparators, intervention details, adverse outcomes, and study outcomes. The "intervention details" section of the data extraction form included all components of the TIDieR (Template for Intervention Description and Replication) checklist [31]. Study outcomes to extract were determined a priori: HbA1c [percentage (mmol/mol)], the proportion of participants below a specified glycemic threshold (based on each study's designated threshold), systolic blood pressure (mmHg), diastolic blood pressure (mmHg), body weight (kg), BMI (kg/m²), hypoglycemia (based on each study's measurement), daily intake of fruits and/or vegetables (servings/day), daily intake of whole grains (servings/day), overall diet quality (e.g., Healthy Eating Index-2010 [32]), and household food insecurity measured by 1 of the USDA Food Security Survey Modules [33] or the Hunger Vital Sign [34]. In addition, study authors were contacted to provide information on incompletely reported data. Data extraction forms were compared between reviewers, and discrepancies were resolved through consensus or consulting with a third reviewer (ES).

Risk of bias assessment

Two reviewers (KJDS and either SC-R or SMA) independently assessed each included study for risk of bias using the RoB-2 (Risk of Bias-2) tool for randomized studies [35] or the ROBINS-I (Risk of Bias In Nonrandomized Studies – of Interventions) tool for nonrandomized studies [36]. Discrepancies were resolved through consensus or consulting with a third reviewer (ES). The ROBINS-I tool requires a priori identification of important categories of confounding variables. Studies are at higher risk of bias if 1 or more categories are not controlled for. Three categories of important confounding variables were agreed upon: sociodemographic factors, structural social determinants of health, and health-related practices.

Narrative synthesis

Studies were grouped by study designs for each outcome: randomized controlled trials (RCTs) and nonrandomized studies (uncontrolled prepost, controlled prepost, and observational cohort studies). The direction of effect, effect estimates, and 95% CIs were extracted for each outcome. Heterogeneity in reported effects was explored by comparing results between studies with different intervention characteristics (quantity of benefit and duration) and study design. As per Cochrane Handbook recommendations for a Brief Economic Commentary, the economic data are summarized in the discussion section [28].

Certainty assessment

Two reviewers (KJDS and ES) independently assessed the certainty of the evidence. The 5 Grading of Recommendations Assessment, Development, and Evaluation (GRADE) considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) and 3 upgrading criteria (large effect, dose-response gradient, and plausible confounding effect) were used to assess the certainty of the body of evidence as it related to the studies that contributed data to the pre-specified outcomes [37]. Outcomes that were reported without measures of statistical significance were not included in the GRADE assessment.

Results

Study selection

Of 3664 titles and abstracts screened for eligibility, 3368 were deemed ineligible (Figure 1). Of 296 full texts that were assessed, 21 studies were included in the main review, and 2 studies were included in the economic analysis. Two of the included studies were each comprised of 2 manuscripts that were collated together [18,22,38,39]. No errata were identified for included studies. Inter-rater agreement of full-text screening by the 2 reviewers showed substantial agreement with $\kappa = 0.80$ (95% CI: 0.67, 0.94) and 95.81% overall agreement [40]. An explanation of studies that might appear to meet the inclusion criteria but which were excluded is provided in Supplementary Material.

Study characteristics

The 21 included studies were of the following designs: 5 parallel-group RCTs, 1 crossover RCT without a washout period. 1 controlled prepost study, 12 uncontrolled prepost studies, 1 prospective cohort study, and 1 retrospective cohort study (Table 1). Study durations ranged from 8–52 wk. Studies were published between 2013 and 2023. One study took place in Australia [41], and all other studies took place in the United States [15–19,22,42–55]. In addition, 3 studies took place in a rural location [22,47,48], 1 study was in an entire United States state [19], and the other studies took place in an urban location [15-18,41-46,49-55]. Settings included primary care or medical specialty clinics [17,42,51,52], food banks [18,50], public hospitals [41,43,44,45,53], Federally Qualified Health Centers [15,16,22,46–48,55], nonprofit meal provision centers [49], and a nonprofit essential services center [54]. Federally Qualified Health Centers are publicly funded community-based healthcare centers in the United States that provide primary care services to

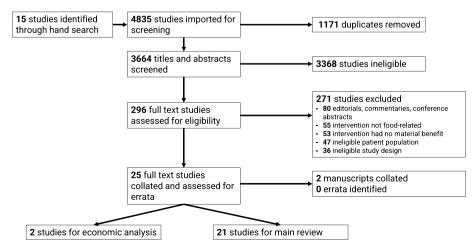


FIGURE 1. Title eligibility.

Description of included studies meeting eligibility criteria for the systematic review

	Author	Program name	Study setting	Participant eligibility criteria	Starting sample size and attrition	Comparator	Outcomes
Parallel- group RCT	Bryce et al. [16] 2021	Fresh Rx	Urban Federally Qualified Health Center	Adults with T2DM and HbA1c >8.0% (63.9 mmol/ mol)	<i>n</i> = 112 16 (14.3%) lost to f/ up	Usual care with a \$10 pharmacy gift card	HbA1c, BMI, BP
	Ferrer et al. [42] 2019	No name listed	Urban primary care clinic	Adults with HbA1c >9% (75 mmol/mol) and FI	n = 58 15 (25.8%) lost to f/ up	Not specified	HbA1c, BMI, Starting the Conversation-Diet score
	Kempainen et al. [43] 2023	FOODRx	Urban public hospital	Adults with T2DM aged 21–70 and FI	n = 281 66 (23.5%) lost to f/ up	Usual care	HbA1c, glycemic threshold ≤9% (74.9 mmol/mol), BMI, FI
	Seligman et al. [18] 2018 Seligman et al. [39] 2022	Feeding America Intervention Trial for Health—Diabetes Mellitus	Urban designated food bank sites	Adults with T2DM, HbA1c ≥7.5% (58 mmol/ mol) and who are food pantry clients	n = 568 145 (25.5%) lost to f/ up	Usual care	HbA1c, glycemic threshold <7.5% (58 mmol/mol), hypoglycemia, F/V intake, FI
	Weinstein et al. [44] 2013	No name listed	Urban public hospital	Adults with T2DM, HbA1c >7% (53 mmol/mol), and BMI >25	n = 79 0 lost to f/up	Usual care	HbA1c, BMI, BP
Crossover RCT	Berkowitz et al. [17] 2019	Community Servings: Food as Medicine for Diabetes	Urban primary care clinics	Adults with T2DM, HbA1c >8.0% (64 mmol/mol) and FI	n = 44 2 (4.5%) lost to telephone f/up 13 (29.5%) lost to in- person f/up	Usual care and a healthy eating brochure	HbA1c, BMI, BP, hypoglycemia, Healthy Eating Index-2010 score, FI
<u>Controlled prepost</u>	Hager et al. [45] 2023	Hartford Healthcare Produce Prescription Program (operated by Wholesome Wave)	Urban clinics situated in a major hospital	People with T1DM or T2DM and HbA1c >6.5% (48 mmol/mol) in the year before the program started and likely to be lower income or have FI based on zip code of residence	n = 786 Data collection was through retrospective chart review; no f/up was required	Usual care	HbA1c, BMI, BP
Uncontrolled prepost	Blitstein et al. [46] 2020	Food for Health	Urban Federally Qualified Health Centers	Adults with T2DM	n = 933 535 (57.3%) lost to f/ up	Pre-intervention participant status	HbA1c
	Bryce et al. [15] 2017	Fresh Rx	Urban Federally Qualified Health Center	Adults with T2DM and HbA1c >6.5% (48 mmol/ mol)	n = 74 9 (12.2%) lost to f/up	Pre-intervention participant status	HbA1c, body weight, BP
	Freedman et al. [22] 2013 Friedman et al. [38] 2014	No name listed	Rural farmers market within a Federally Qualified Health Center	Adults with any diabetes diagnosis who attend a Federally Qualified Health Center	n = 45 1 (2.2%) lost to f/up	Pre-intervention participant status	F/V intake
	Gordon et al. [47] 2022	Wholesome Wave	Rural Federally Qualified Health Centers	Adults with a diabetes diagnosis and HbA1c above normal limits (not further specified)	n = 333 161 (48.3%) lost to f/ up	Pre-intervention participant status	Glycemic threshold ≤9% (74.9 mmol/mol) Note: The study only reported HbA1c for subgroups and did not report HbA1c for the entire sample with complete HbA1c data

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 TABLE 1 (continued)

Author	Program name	Study setting	Participant eligibility criteria	Starting sample size and attrition	Comparator	Outcomes
Harris et al. [48] 2022 Palar et al. [49] 2017	Farmers' Market Voucher Initiative Food = Medicine	Rural Federally Qualified Health Centers Urban nonprofit meal provision center	People \geq 55 y old with diabetes diagnosis with FI Adults with T2DM and/or HIV with income <300% of the United States federal	n = 22 1 (4.5%) lost to f/up n = 29 9 (31.0%) lost to f/up	Pre-intervention participant status Pre-intervention participant status	HbA1c, BMI HbA1c, BMI, glycemic threshold <7% (53 mmol/mol)
Seligman et al. [50] 2015	Diabetes Food Boxes (through Feeding America)	Urban designated food bank sites (Project Open Hand)	poverty line Adults with HbA1c ≥6.5% (48 mmol/mol) or a diabetes diagnosis and using a food pantry or confirmed FI from a clinician	No starting sample size given Final sample size <i>n</i> = 687 42% lost to f/up	Pre-intervention participant status	HbA1c, hypoglycemia, F/V intake
Sharma et al. [51] 2021	A Prescription for Healthy Living (APFHL)	Urban health center	People with HbA1c >7% (53 mmol/mol) with FI	n = 35 (APFHL subgroup) 9 (25.7%) lost to APFHL f/up n = 79 (food prescription subgroup) 24 (30.4%) lost to food prescription f/ up	Pre-intervention participant status	HbA1c, BP, BMI, overa diet quality, whole gra intake
Tester et al. [52] 2021	Food Overcoming our Diabetes Risk (FoodRx)	Urban pediatric obesity specialty clinic	Children (8–17 y) with prediabetes and caregivers residing with child >4 d/ wk living in zip codes with high public health insurance participation. Subgroup of caregivers with T2DM	No starting sample size for caregivers with T2DM Final sample: $n = 47$ households n = 14 caregivers with T2DM Study reported 22% lost to f/up overall. No information on attrition among caregivers with T2DM	Pre-intervention participant status (with T2DM subgroup)	HbA1c, BMI, BP
Veldheer et al. [53] 2021	Veggie Rx	Urban primary care clinic in a community hospital	Adults with T2DM, HbA1c \geq 7.0% (53 mmol/mol), and BMI \geq 25 kg/m²	n = 97 14 (14.4%) lost to f/ up for clinical measurements 43 (44.3%) lost to f/ up for dietary intake survey	Pre-intervention participant status	HbA1c, BMI, BP, F/V intake
Wu et al. [41] 2022	Produce prescription	Urban public hospital	Adults with T2DM for ≥ 6 mo, HbA1c $\geq 8.0\%$ (63.9 mmol/mol) with FI	n = 50 4 (8.0%) lost to f/up for survey questions 5–20 (10–40%) lost to f/up for biometric measurements	Pre-intervention participant status	HbA1c, body weight, BMI, BP, overall diet quality, whole grain intake, FI
York et al. [54] 2020	Farming for Life	Urban nonprofit essential services center (Unity	Latin American adults with T2DM not requiring insulin	<i>n</i> = 23 2 (8.7%) lost to f/up	Pre-intervention participant status	HbA1c, BP, body weig FI

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Author Pogram made Study setting Barticipant eligibility Starting sample size Comparator Outcomest Prospective cohort Xie et al. Produce Prescription Urban Federally Adults receiving SNAP n = 690 (total) Increased program us InAlc, BML, BP Prospective cohort [55] 2021 Programme Unban Federally Adults receiving SNAP n = 690 (total) Increased program us InAlc, BML, BP Prospective cohort [55] 2021 Programme Unbarted Health Center, Subgroup of people with a n = 630 (total) Increased program us InAlc, BML, BP Adults eaving Ows an outpatient medical diabetes diagnosis N information on Increased program us InAlc, BML, BP Attribute services organizations (inbetes) N information on Interescience N information on Interescience Inter	TABLE 1 (continued)							
Xie et al.Produce PrescriptionUrban Federally Cuban FederallyAdults receiving SNAP n = 699 (total)[55] 2021ProgrammeQualified Health Center, an outpatient medical diabetes diagnosisSubgroup of people with a diabetes)= 699 (total) $(55] 2021$ ProgrammeQualified Health Center, an outpatient medical diabetes diagnosisSubgroup of people with a diabetes) $n = 353 (witha diabetes)No information onincome patients, 2 socialservices organizationsNo information onthe number ofparticipants lost to f/up or missing datan = 10,119Young et al.SNAPWest Virginia stateaged 18-64 with diabetesin both SNAP andin both SNAP andin both SNAP andin both SNAP andportones werethrough retrospectiveanalysis)$		Author	Program name	Study setting	Participant eligibility criteria		Comparator	Outcomes
Young et al.SNAPWest Virginia residents $n = 10,119$ Corresponding week[19] 20222022aged 18–64 with diabetesindividuals observedduring a month withenrolled in both SNAP andin both periodsregularly timed SNAPMedicaid0 lost to f/up disbursement (e.g.,furging responding weekfutpdisbursement (e.g.,medicaid0 lost to f/up through retrospectivemedicaidfutpungh retrospectiveanalysis)	Prospective cohort	Xie et al. [55] 2021	Produce Prescription Programme	Urban Federally Qualified Health Center, an outpatient medical clinic serving low- income patients, 2 social services organizations for seniors	Adults receiving SNAP Subgroup of people with a diabetes diagnosis	n = 699 (total) n = 353 (with diabetes) (vith diabetes) No information on the number of participants lost to f/ up or missing data	Increased program use	HbA1c, BMI, BP
	Retrospective cohort	Young et al. [19] 2022	SNAP	West Virginia state	West Virginia residents aged 18–64 with diabetes enrolled in both SNAP and Medicaid	n = 10,119 individuals observed in both periods 0 lost to f/up (outcomes were through retrospective analysis)	Corresponding week during a month with regularly timed SNAP disbursement (e.g., week 1 of January)	Hypoglycemia

HbA1c, glycosylated hemoglobin; BP, blood pressure (includes both systolic and diastolic); f/up, follow-up; F/V, fruit and vegetable; FI, food insecurity; RCT, randomized controlled trial; SNAP, Supplemental Nutrition Assistance Program; T2DM, type 2 diabetes mellitus. Advances in Nutrition 14 (2023) 1067-1084

underserved populations, such as people experiencing homelessness and residents of public housing [56].

All studies were either entirely conducted among adults with diabetes or reported results in a subgroup of adults with diabetes. HbA1c threshold values were frequently used to determine eligibility, with values ranging from HbA1c >6.5% (48 mmol/ mol) to HbA1c >9% (75 mmol/mol) [15-18,41,42,44,45,50,51, 53]. Experiencing food insecurity was an additional eligibility criterion in 7 studies, 4 of which [17,41,42,51] defined food insecurity as >1 positive response on the Hunger Vital Sign [57] and 1 of which included patients who were either currently using a food pantry or were identified by clinics to be experiencing food insecurity (criteria not specified) [50]. Two studies did not specify food insecurity criteria [43,48]. Additional eligibility criteria included: current food pantry client [18,50], patient of a Federally Qualified Health Center [16,22,38,48], patient of a specific healthcare center [43,51], income below 300% of the United States federal poverty line [49], living in a specific zip code known to have high food insecurity rates [45], BMI >22 [44], currently receiving Supplemental Nutrition Assistance Program (SNAP) [19,55], currently enrolled in Medicaid [19], a caregiver of a child with prediabetes [52], or Latin American ethnicity [54]. Study sample sizes were between n = 14 to n =786 for the prospective studies and n = 24,049 for the retrospective study. Participant attrition was >25% in 8 studies [17, 18,42,46,47,49–51]. Five studies had attrition <10% [22,44,45, 48.541.

One controlled prepost study was at moderate risk of bias [45], and 20 studies were at a high risk of bias (Supplementary Figures 3 and 4) [15-19,22,41-44,46-55]. Five of 6 RCTs had a high risk of bias from missing outcome data because of relatively high attrition (range from 14.3-29.5%) [16-18,42,43]. Five RCTs had a high risk of bias from measurement of outcome, which was due to measuring dietary intake through unblinded participant self-report without verification from an objective measure [17,18,42-44]. One RCT also had a high risk of bias from selective reporting due to discrepancies between the methods and reported results for dietary intake measures [44]. All but 1 nonrandomized study [15,19,22,41,46-55] had a high risk of bias because of confounding because they did not control for one or more of the categories of confounding variables. Nonrandomized studies also frequently had high risk of bias because of missing data and measurement of outcomes, which were caused by attrition and use of unblinded self-reported dietary outcome measures, respectively.

Intervention characteristics

There were 22 interventions in the 21 included studies because 1 study investigated 2 separate interventions [51]. Of the 22 interventions, 1 provided a one-time benefit [44], 8 provided a benefit for 12–16 wk [15–17,41,47,48,52,54], 11 provided a benefit for 5–9 mo (Supplemental Table 5) [18,22,42, 43,45,46,49,50,51,53], and 1 provided a benefit for 12 mo [55]. In addition, 1 investigated the impact of a one-time early provision of SNAP benefits [19]. The types of material benefits were fresh produce [42,54], packages containing foods that are recommended for diabetes [18,50,51], vouchers to purchase fruits and vegetables [15,16,22,44–48,53,55], home-delivered meals [17,41,43,52], SNAP [19], or premade meals for pick up at a designated nonprofit center [49]. The quantity of material

benefit that was provided ranged from a one-time \$6 voucher [44] to provide 100% of energy requirements for 6 mo [49]. Six studies provided only a material benefit [17,19,22,48,49,55], and the other studies also included one or more of the following additional components: nutrition or diabetes education [42–47, 51], recipes [41,43], diabetes self-management classes [18,53], ongoing individual check-ins from health promotors or diabetes educators [18,41,42,50], food pantry referrals [46], assistance with SNAP enrollment [46], cooking demonstrations with healthy foods [15,16,52], or a signed dietary prescription [54].

Narrative synthesis of outcomes *HbA1c*

Six RCTs [16–18,42–44], 1 controlled prepost study [45], 10 uncontrolled prepost studies [15,41,46,48–54], and 1 prospective cohort study [55] reported impact on HbA1c (Table 2). One RCT reported a significant improvement in HbA1c [42]. Ferrer et al. [42] randomly assigned 58 adults with HbA1c >9% (75 mmol/mol) and food insecurity to a control group or an intervention group that received 6 mo of biweekly packages containing 10 pounds (lb) of fruits and vegetables and 10 pounds (lb) of canned foods, as well as teaching from a dietitian and health promotor home visits. A significantly lower HbA1c was reported in the intervention group compared to the control group at 6 mo follow-up. The other 5 RCTs did not find any significant differences in HbA1c change or adjusted value at follow-up between intervention and control groups [16–18,43,44].

Twelve nonrandomized studies [15,41,45,46,48-55] reported HbA1c as an outcome, and 4 uncontrolled prepost studies [15,46,51,53] reported significant improvements. Sharma et al. [51] reported HbA1c results separately for 2 different interventions, both of which included food packages. There was no control group that did not receive a food package. The authors reported a significant decrease in HbA1c at 9-mo follow-up after providing 35 people with HbA1c >7% (53 mmol/mol) and food insecurity with 9-mo of biweekly packages of 30 pounds (lb) of fruits, vegetables, and other healthy foods, in addition to 5 2-h culinary medicine-based education sessions. There was no significant change in HbA1c among 79 participants who received the same biweekly food packages but without the education sessions. Veldheer et al. [53] reported a significant decrease in HbA1c at 7-mo follow-up after providing 97 adults with type 2 diabetes, HbA1c \geq 7.0% (53 mmol/mol) and BMI \geq 25 with \$1/ household member/d of vouchers for fresh fruit and vegetables at a designated farmers' market. Blitstein et al. [46] reported a significant decrease in HbA1c at 6-9 mo follow-up after providing 933 adults with type 2 diabetes with 6-9 mo of vouchers for fruits and vegetables (value not specified), group-based nutrition education, food pantry referrals, and assistance with SNAP enrollment. Bryce et al. [15] also reported a significant decrease in HbA1c at 13 wk follow-up after providing 74 adults with type 2 diabetes and an HbA1c >6.5% (48 mmol/mol) with \$10/wk (maximum \$45) to spend on fruits and vegetables from a designated farmers' market as well as cooking demonstrations with healthy foods. One controlled prepost study [45], 6 uncontrolled prepost studies [41,48-50,52, 54], and 1 prospective cohort study [55] reported no improvement in HbA1c.

In summary, 1 RCT [42] and 4 uncontrolled prepost studies [15,46,51,53] reported significant improvements in the HbA1c

outcome, whereas 5 RCTs [16–18,43,44] and 8 nonrandomized studies [41,45,48–50,52,54,55] found no benefit. However, the overall certainty of the evidence was rated as very low by GRADE for no change in HbA1c because of the high risk of bias and inconsistency, indirectness, and imprecision of results (Table 3). Outcomes were downgraded due to indirectness because most studies examined adults with diabetes who also had food insecurity, whereas our review pertains to all adults with diabetes.

Proportion of participants below a specified glycemic threshold

Two RCTs [18,43] and 2 uncontrolled prepost studies [47,49] reported the proportion of participants below a specified glycemic threshold. The RCTs found no significant difference in the proportion of participants with HbA1c <7.5% (58 mmol/mol) [18] or HbA1c \leq 9% [43] (74.9 mmol/mol) between intervention and control groups at 6-mo follow-up. An uncontrolled prepost study by Gordon et al. [47] found a significant increase in the proportion of participants with HbA1c \leq 9% (74.9 mmol/mol) at 12-16 wk follow-up. An uncontrolled prepost study by Palar et al. [49] found no significant difference in the proportion of participants with HbA1c <7% (53 mmol/mol) at baseline compared to 6 mo follow-up. The GRADE certainty of evidence for no change in the proportion of participants below a specific glycemic threshold was rated as very low due to high risk of bias and inconsistency, indirectness, and imprecision of results (Table 3).

Other clinical parameters: blood pressure, BMI, body weight, hypoglycemia

Six RCTs [16–18, 42–44] and 12 nonrandomized studies [15, 19,41,45,48–55] reported one or more other clinical parameter (systolic blood and diastolic blood pressure, BMI, body weight, or hypoglycemia) (Table 2).

A crossover RCT by Berkowitz et al. found that the proportion of participants who self-reported experiencing hypoglycemia over the previous 3 mo was significantly lower at the end of the 12 wk intervention period than at the end of the 12 wk control period [17]. There were no significant differences in systolic blood pressure, diastolic blood pressure, and BMI at the end of the intervention versus control periods.

Five other RCTs [16,18,42–44] reported no significant changes in other clinical parameters. Kempainen et al. [43] and Ferrer et al. [42] both reported no significant difference between intervention and control groups in the change in BMI from baseline to 6 mo follow-up. Bryce et al. [16] reported no difference in blood pressure or BMI at 15-wk follow-up between intervention and control groups. Seligman et al. [18] found that the relative risk of self-reporting \geq 1 hypoglycemic episode was not different between the intervention and control groups at 4 wk follow-up [18]. Weinstein et al. [44] reported that the changes in systolic and diastolic blood pressure and BMI were not significantly different between the intervention and control groups at 12 wk follow-up.

Four uncontrolled prepost studies [41,49,53,54] reported significant improvements in other clinical parameters. Palar et al. [49] found a significant decrease in BMI at 6 mo follow-up. York et al. [54] found significant decreases in systolic and diastolic blood pressure but no change in body weight at 12 wk follow-up. Veldheer et al. [53] found a significant increase in systolic blood pressure and no change in diastolic blood pressure

Clinical parameter results from included studies with point estimates and 95% CI

	Author	Intervention	Clinical parame	ters				
		summary	Change in HbA1c (NGSP % units)	Change in systolic BP (mmHg)	Change in diastolic BP (mmHg)	Change in BMI (kg/m ²)	Change in body weight (kg)	Proportion experiencing hypoglycemia after intervention (%)
<u>Parallel-group</u> <u>RCT</u>	Bryce et al. [16] 2021	15 wk: \$10 vouchers/clinic visit (maximum \$80) for fresh F/V at designated farmers' market, cooking demonstrations with healthy foods	Int: -0.54 (-0.92, -0.16) Ctrl: 0.03 (-0.40, 0.46)	Int: -0.9 (-5.19, 3.39) Ctrl: 1.68 (-2.53, 5.89)	Int: -0.75 (-2.84, 1.34) Ctrl: -0.7 (-2.79, 1.39)	Int: 0.28 (-0.47, 1.03) Ctrl: 0.12 (-2.07, 2.31)		
	Ferrer et al. [42] 2019	6 mo: 10 lb F/V and 10 lb canned food biweekly, dietitian teaching, health promotor home visits	Int: -3.1 (-4.0, -2.1) Ctrl: -1.7 (-2.6, -0.8)			Int: -0.2 (-1.3, 0.9) Ctrl: 0.8 (-0.3, 1.9)		
	Kempainen et al. [43] 2023	24 wk: home- delivered boxes with 30–33 lb of shelf-stable foods tailored to 3 cultural preferences (American, Somali, or Hispanic)	Int: -0.35 Ctrl: -0.11 (no CIs provided) Difference in differences (int-ctrl): -0.24 (-0.56, 0.08)			Int: -0.08 Ctrl: -0.29 (no CIs provided) Difference in differences (int-ctrl): 0.21 (-0.07, 0.49)		
	Seligman et al. [18] 2018 Seligman et al. [39] 2022	6 mo: twice monthly packages of 22 meals of diabetes- appropriate foods, primary care referral, diabetes self- management classes, diabetes educator check-	Int: -0.6 Ctrl: 0.01 (no CIs provided) Adjusted risk difference in HbA1c after intervention: 0.24 (-0.09,0.58)					RR = 1.02 (0.56,1.86)
	Weinstein et al. [44] 2013	ins One-time: \$6 F/V voucher, nutrition group education session	Int: -0.8 (-1.3, -0.2) Ctrl: -0.9 (-1.5, -0.4)	Int: 0.6 (-5.5, 6.7) Ctrl: 3.0 (-4.7, 10.7)	Int: -2.0 (-6.0, 2.0) Ctrl: -1.6 (-6.1, 2.9)	Int: -0.4 Ctrl: -0.5 (no CIs provided)		
<u>Crossover RCT</u>	Berkowitz et al. [17] 2019	12 wk: 5 lunches and 5 dinners/wk of home- delivered complimentary medically tailored meals	¹ Int: 8.0 (7.3, 8.7) ¹ Ctrl: 8.2 (7.6, 8.7)	¹ Int: 133 (127, 140) ¹ Ctrl: 136 (130, 142)	¹ Int: 77 (74, 80) ¹ Ctrl: 78 (75, 81)	¹ Int: 34.2 (31.8, 36.7) ¹ Ctrl: 34.8 (32.5, 37.1)		Int: 47% Ctrl: 64%
<u>Controlled</u> <u>prepost</u>	Hager et al. [45] 2023	6 mo: \$60 vouchers monthly for F/V at local grocery store chain, dietitian-led grocery store tour with food nutritional label teaching, nutrition	6 mo: Int: -0.11 Ctrl: -0.24 Adjusted between- group difference 0.13 (-0.05, 0.32) 9 mo: Int: -0.13	6 mo: Int: -0.93 Ctrl: -4.78 Adjusted between- group difference 3.85 (-0.12, 7.82) 9 mo: Int: -0.41	6 mo Int: -2.61 Ctrl: -1.79 Adjusted between- group difference -0.82 (-2.42, 0.79) 9 mo Int: -2.48	6 mo Int: -0.02 Ctrl: 0.20 Adjusted between- group difference -0.22 (-1.83, 1.38) 9 mo Int: -0.13	ć	ntinued on next need)

(continued on next page)

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TABLE 2 (continued)

	Author	Intervention	Clinical parame	ters				
		summary	Change in HbA1c (NGSP % units)	Change in systolic BP (mmHg)	Change in diastolic BP (mmHg)	Change in BMI (kg/m ²)	Change in body weight (kg)	Proportion experiencing hypoglycemia after intervention (%)
		education class (in-person events canceled without virtual option)	Ctrl: -0.19 Adjusted between- group difference 0.06 (-0.13, 0.25)	Ctrl: -4.44 Adjusted between- group difference 4.03 (-0.34, 8.40)	Ctrl: -1.61 Adjusted between- group difference -0.87 (-2.42, 0.67)	Ctrl: 0.38 Adjusted between- group difference -0.51 (-2.10, 1.08)		
<u>Uncontrolled</u> <u>prepost</u>	Blitstein et al. [46] 2020	6–9 mo: Vouchers (value not specified) for F/V distributed at designated health centers, nutrition group education, food pantry referrals, assistance with SNAP enrollment	-0.2 (-0.4, -0.1)					
	Bryce et al. [15] 2017	13 wk: \$10/wk (maximum \$45) for F/V at a farmer's market, cooking demonstrations with healthy foods	-0.7 (-1.1, -0.3)	0.7 (-2.9, 4.3)	-1.7 (-4.1, 0.7)		0.3 (-0.5, 1.2)	
	Harris et al. [48] 2022	3 mo: \$40 in vouchers monthly for F/V at a designated farmers' market	0.21 (-0.48, 0.90)			0.27 (–0.90, 1.44)		
	Palar et al. [49] 2017	6 mo: twice weekly picked-up meals based on the Mediterranean diet that met 100% of caloric	-0.5 (-1.7, 0.7)			-1.3 (-2.5, -0.1)		
	Seligman et al. [50] 2015	requirements 6 mo: monthly or biweekly prepacked boxes of diabetes- appropriate foods designed to last 1–2 wk, individual and small group education (type of education not specified)	-0.1 (-0.2, 0.02)					Adjusted OR = 0.74 (0.55, 1.01)
	Sharma et al. [51] 2021	APFHL subgroup: 9 mo: 30 lb healthy food boxes biweekly with 5 2-h sessions on culinary medicine education Food prescription subgroup:	APFHL subgroup: -0.96 (-1.82, -0.10) Food prescription subgroup -0.48 (-1.12, 0.15) (not significant)	APFHL subgroup: 0.46 (-7.56, 8.48) Food prescription subgroup: -3.44 (-8.92, 2.04)	APFHL subgroup: -3.02 (-7.55, 1.50) Food prescription subgroup: -0.50 (-3.58, 2.59)	APFHL subgroup: -0.22 (-1.18, 0.74) Food prescription subgroup: 0.01 (-0.61, 0.63)		

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	Author	Intervention	Clinical parame	ters				
		summary	Change in HbA1c (NGSP % units)	Change in systolic BP (mmHg)	Change in diastolic BP (mmHg)	Change in BMI (kg/m ²)	Change in body weight (kg)	Proportion experiencing hypoglycemia after intervention (%)
	Tester et al. [52] 2021	9 mo: 30 lb healthy food boxes biweekly 16 wk: home- delivered packages of vegetables weekly and whole grains biweekly adjusted for household size, monthly cooking classes, videos of recipes	-0.7 (-1.51, 0.11)	1.2 (-6.71, 9.11)	1.6 (–3.48, 6.68)	-0.2 (-0.84, 0.44)		
	Veldheer et al. [53] 2021	7 mo: \$1/ household member/d of vouchers for fresh F/V at a designated farmers' market, monthly 1-h diabetes self- management education sessions	-1.3 (-1.76, -0.84)	6.2 (1.61, 10.79)	1.7 (–1.25, 4.65)	-0.57 (-1.22, 0.08)		
	Wu et al. [41] 2022	12 wk: home- delivered food boxes to make 10 meals/wk for each participant's entire household, tailored recipe booklet, fortnightly phone appointments with dietitians trained in behavior change	-0.23 (-0.63, 0.18)	-2.94 (-7.17, 1.29)	-1.88 (-5.47, 1.70)	-0.67 (-1.06, -0.29)	-1.74 (-2.80, -0.68)	
	York et al. [54] 2020	support 12 wk: weekly packages of organic vegetables valued at \$31.33	0.3 Reported as not significant, but no CI or <i>P</i> value provided	No point estimate provided P < 0.05	No point estimate provided P < 0.05		0.8 Reported as not significant but no CI or <i>P</i> value provided	
Prospective cohort	Xie et al. [55] 2021	12 mo: \$40/mo of vouchers for fresh, frozen, or canned F/V or beans at a local grocery store chain	Adjusted coefficient for the effect of higher program use on HbA1c $\beta = -0.15$ (-0.61, 0.31)	Adjusted coefficient for the effect of higher program use on systolic BP $\beta = -1.09$ (-4.26, 2.08)		Adjusted coefficient for the effect of higher program use on BMI $\beta = 0.64$ (-1.35, 2.63)	<i>provide</i>	
Retrospective cohort	Young et al. [19] 2022	8 wk (January and February 2019): SNAP benefit with a household		(-7.20, 2.08)			(co	Adjusted difference in hypoglycemia rate compared to each week in a ntinued on next page

TABLE 2 (continued)

TABLE 2 (continued)

Author	Intervention	Clinical parame	ters				
	summary	Change in HbA1c (NGSP % units)	Change in systolic BP (mmHg)	Change in diastolic BP (mmHg)	Change in BMI (kg/m ²)	Change in body weight (kg)	Proportion experiencing hypoglycemia after intervention (%)
	average of \$200/ mo. The government shutdown in 2019 led to an early SNAP disbursement in week 4 of January instead of week 1 of February.						month with regularly timed SNAP disbursement. Only results from week 4 of January 2019 onwards are presented here: January 2019 Week 4 (week of early SNAP disbursement): 0.0001 (-0.005, 0.0007) February 2019 Week 1: 0.0003 (-0.0005, 0.0011) Week 2: -0.0001 (-0.0007, 0.0005) Week 3: -0.0006 (-0.0012, 0.0000) Week 4: 0.0005 (-0.0003, 0.0013)

HbA1c, glycosylated hemoglobin; APFHL, a prescription for healthy living; BP, blood pressure; Ctrl, control group; F/V: fruits and vegetables; Int: intervention group; NGSP: national glycohemoglobin standardization program; RCT, randomized controlled trial; SNAP, Supplemental Nutrition Assistance Program.

Bold text signifies P < 0.05 for an outcome. An unshaded box signifies a nonsignificant change. A blank box signifies that an outcome was not reported in the study. Risk of bias was moderate for Hager et al. and high for all other studies.

¹ Results are the value of each outcome at the end of the on-meals (intervention) or off-meals (control) periods.

at 7 mo follow-up. Wu et al. [41] found significant decreases in BMI and body weight and no change in blood pressure at 12 wk follow-up. The retrospective cohort study by Young et al. [19] reported a significant decrease in hypoglycemia encounters in the third week of February 2019 after the early disbursement of SNAP benefits, compared to the third week of a month with the typical timing of benefit disbursement. One controlled prepost study [45], 5 uncontrolled prepost studies [15,48,50–52], and 1 prospective cohort study [55] reported no significant changes in other clinical parameters, including blood pressure, BMI, body weight, and hypoglycemia.

The GRADE certainty of evidence for no changes in systolic and diastolic blood pressure, BMI, body weight, and hypoglycemia was rated as very low due to high risk of bias and inconsistency, indirectness, and imprecision of results (Table 3).

Daily intake of fruits and vegetables

One RCT [18] and 3 uncontrolled prepost studies [22,50,53] reported daily intake of fruits and vegetables (Table 4). The RCT by Seligman et al. [18] found a statistically significant higher adjusted mean daily intake of fruits and vegetables at 6 mo follow-up in the

intervention group compared to the control group [18]. The uncontrolled prepost study by Seligman et al. [50] found a significant improvement in the adjusted change in daily intake of fruits and vegetables at 6 mo follow-up. The uncontrolled prepost studies by Freedman et al. [22] and Veldheer et al. [53] found no statistically significant changes in daily intake of fruits and vegetables at 11 wk and 22 wk follow-ups or at 7 mo follow-up.

The GRADE certainty of evidence for improvement in daily intake of fruits and vegetables was rated as very low due to high risk of bias and inconsistency, indirectness, and imprecision of results (Table 3).

Daily whole grain intake

Two uncontrolled prepost studies reported daily intake of whole grains (Table 4) [41,51]. Sharma et al. [51] reported no significant change in self-reported whole grain servings per day in adjusted results at 9 mo. Wu et al. [41] reported no significant change in whole grain intake, measured in grams per day, at 12 wk. The GRADE certainty of evidence for no change in daily intake of whole grains was rated as very low due to high risk of bias, indirectness, and imprecision of results (Table 3).

Summary of findings from randomized controlled trials and nonrandomized studies of the impacts of providing material benefits to improve access to food in people with diabetes

Outcome	Number of RCTs reporting significant improvement	Number of RCTs reporting no change	Number of nonrandomized studies reporting significant improvement	Number of nonrandomized studies reporting significant worsening	Number of nonrandomized studies reporting no change	Certainty of evidence (GRADE)
No change in HbA1c No change in the proportion of participants below a specified glycemic threshold	1 0	5 2	4 1	0 0	8 1	Very low Very low
No change in systolic blood pressure	0	3	1	1	6	Very low
No change in diastolic blood pressure	0	3	1	0	6	Very low
No change in BMI	0	5	2	0	6	Very low
No change in body weight	0	0	1	0	2	Very low
No change in hypoglycemia	1	1	1	0	1	Very low
Improvement in fruit and vegetable intake	1	0	1	0	2	Very low
No change in whole grain intake	0	0	0	0	2	Very low
Improvement in overall diet quality	2	0	1	0	0	Low
Improvement in household food insecurity	2	1	0	0	0	Very low

A breakdown of the ratings by GRADE for each outcome are in Supplementary Table 6.

HbA1c, glycosylated hemoglobin; GRADE, grading of recommendations assessment, development, and evaluation; RCT, randomized controlled trial.

Overall diet quality

Two RCTs [17,42] and 1 uncontrolled prepost study [41] reported overall diet quality (Table 3). The RCT by Ferrer et al. [42] reported overall diet quality using Starting the Conversation – Diet score and found a significantly greater improvement between baseline and 6 mo follow-up in the intervention group compared to the control group [58]. In the crossover RCT, Berkowitz et al. [17] measured overall diet quality using the Healthy Eating Index-2010 [32,59]. Participants had a significantly higher score at the end of the 12 wk intervention period compared to the 12 wk control period. The uncontrolled prepost study by Wu et al. [41] reported significant improvements in both Alternate Healthy Eating Index and Australian Recommended Food scores at 12 wk [60,61].

The GRADE certainty of evidence for improvement in overall diet quality was rated as low (Table 3). The rating was downgraded due to high risk of bias and indirectness of results. The rating was upgraded to 1 level due to large effect sizes.

Household food insecurity

Three RCTs [17,18,43] and 2 uncontrolled prepost studies [41,54] reported household food insecurity (Table 4). The RCT by Kempainen et al. [43] reported no significant difference between intervention and control groups in the change in household food insecurity between baseline and 6 mo follow-up. The RCT by Seligman et al. found a significantly lower relative risk of experiencing household food insecurity at 6 mo follow-up in the intervention compared to the control group [18]. The crossover RCT by Berkowitz et al.

[17] reported a significantly lower percentage of participants reporting household food insecurity at the end of the intervention period compared to the control period. Both uncontrolled prepost studies by York et al. [54] and Wu et al. [41] found that food insecurity improved in study participants; however, neither study tested the statistical significance of these findings. The GRADE certainty of evidence for improvement in household food insecurity was rated as very low due to high risk of bias, indirectness, and inconsistency of results (Table 3).

Adverse effects

One RCT [17] and 1 uncontrolled prepost study [41] reported adverse effects. Berkowitz et al. [17] reported that 1 individual withdrew from the study due to experiencing gastrointestinal symptoms after 1 wk of receiving medically tailored meals. Wu et al. [41] reported that no participants experienced adverse events due to the intervention.

Discussion

This systematic review synthesized evidence from 6 RCTs [16–18,42–44], 1 controlled prepost study [45], 12 uncontrolled prepost studies [15,18,22,41,46–49,51–54], 1 prospective cohort study [55], and 1 retrospective cohort study [19] on the impacts of providing material benefits to improve food access on clinical parameters, dietary intake, and household food insecurity in adults with diabetes. Ten interventions provided food packages to individuals on a daily to monthly basis over the span

Dietary intake and food insecurity results from included studies with point estimates and 95% CIs

		Dietary intake			FI
Author	Intervention summary	Change in F/V intake (servings/day)	Change in whole grain intake (servings/day)	Change in overall diet quality	Proportion experiencing household FI after intervention (%)
Ferrer et al. [42] 2019	6 mo: 10 lb F/V and 10 lb canned food biweekly, dietitian teaching, health promotor home visits			STC-diet Int: 2.5 (1.4, 3.5) Ctrl: 0.1 (–1.0, 0.9)	
Kempainen et al. [43] 2023	24 wk: home-delivered boxes with 30–33 lb of shelf-stable foods tailored to 3 cultural preferences (American, Somali, or Hispanic)				Int: 78 Ctrl: 87
Seligman	6 mo: twice monthly packages	Int: -1.6			Int: 60
	of 22 meals of diabetes-	Ctrl: -1.8 (no CIs			Ctrl: 69
2018 Seligman et al. [39] 2022	appropriate foods, primary care referral, diabetes self- management classes, diabetes educator check-ins	provided) Adjusted risk difference in F/V intake after intervention = 0.34 (0.18, 0.50)			RR = 0.85 (0.73 0.98)
Berkowitz et al. [17] 2019	12 wk: 5 lunches and 5 dinners/wk of home-delivered complimentary medically tailored meals			HEI-2010 ¹ Int: 71 (69, 74) ¹ Ctrl: 40 (38, 42)	Int: 42 Ctrl: 62
Freedman et al. [22] 2013 Friedman et al. [38] 2014	22 wk: 2 \$25 vouchers for F/V at a farmer's market	11 wk: 1.6 (-0.1, 3.3) 22 wk: 0.5 (-1.1, 2.2)			
Seligman et al. [50] 2015	6 mo: monthly or biweekly prepacked boxes of diabetes- appropriate foods designed to last 1–2 wk, individual and small group education (type of education not specified)	0.2 (0.1, 0.4)			
Sharma et al. [51] 2021	APFHL subgroup: 9 mo: 30 lb healthy food boxes biweekly with 5 2-h sessions on culinary medicine education		APFHL subgroup: adjusted change in whole grain servings/day $\beta = 0.36$ (-0.2, 0.91)		
Veldheer et al. [53] 2021	7 mo: \$1/household member/ d of vouchers for fresh F/V at a designated farmers' market, monthly 1-h diabetes self- management education sessions	0.49 (-0.23, 1.21)			
Wu et al. [41] 2022	12 wk: home-delivered food boxes to make 10 meals/wk for each participant's entire household, tailored recipe booklet, fortnightly phone appointments with dietitians trained in behavior change support		Whole grain grams/day 10 (–1, 21)	Alternative HEI 12.9 (8.7, 17.1) Australian Recommended Food Score 8.3 (5.9, 11)	Baseline 82 Week 6: 2 Week 12: 0 No <i>P</i> value reported
York et al. [54] 2020					Improved in 12/ 21 (57%)
	Ferrer et al. [42] 2019 Kempainen et al. [43] 2023 Seligman et al. [18] 2018 Seligman et al. [39] 2022 Berkowitz et al. [17] 2019 Freedman et al. [22] 2013 Friedman et al. [22] 2013 Friedman et al. [38] 2014 Seligman et al. [50] 2015 Sharma et al. [51] 2021	Ferrer et al. [42] 20196 mo: 10 lb F/V and 10 lb canned food biweekly, dietitian teaching, health promotor home visitsKempainen et al. [43]24 wk: home-delivered boxes with 30–33 lb of shelf-stable foods tailored to 3 cultural preferences (American, Somali, or Hispanic)Seligman et al. [18]6 mo: twice monthly packages of 22 meals of diabetes- appropriate foods, primary Seligman et al. [39]Berkowitz et al. [17]12 wk: 5 lunches and 5 dinners/wk of home-delivered complimentary medically tailored mealsBerkowitz et al. [22] 201312 wk: 5 lunches and 5 dinners/wk of home-delivered complimentary medically tailored mealsFreedman et al. [22] 20136 mo: monthly or biweekly prepacked boxes of diabetes- appropriate foods designed to last 1–2 wk, individual and small group education (type of education not specified)Sharma et al.7 mo: \$1/household member/ d of vouchers for fresh F/V at a designated farmers' market, monthly 1-h diabetes self- management educationVeldheer et al. [53] 20217 mo: \$1/household member/ dof vouchers for fresh F/V at a designated farmers' market, monthly 1-h diabetes self- management education sessionsWu et al. [41] 202212 wk: home-delivered food boxes to make 10 meals/wk for each participant's entire household, tailored recipe booklet, fortnightly phone appointments with dietitians trained in behavior change support	Yerrer et al. [42] 20196 mo: 10 lb F/V and 10 lb canned food biweekly, dicitian teaching, health promotor home visitsInt: -1.6Kempainen et al. [43]24 wk: home-delivered boxes with 30-33 lb of shelf-stable 2023Int: -1.6Seligman et al. [18]6 mo: twice monthly packages of 22 meals of diabetes- appropriate foods, primary care referral, diabetes self- management classes, diabetes educator check-insInt: -1.6Ctrl: -1.8 (no Cls provided)Adjusted risk difference in F/V intake after intervention = 0.34 (0.18, 0.50)Int: -1.6Berkowitz et al. [17]12 wk: 5 lunches and 5 et al. [17] dinners/wk of home-delivered complimentary medically tailored meals11 wk: 1.6 (-0.1, 3.3) 22 wk: 2 \$25 vouchers for F/V at a farmer's market 2013 Friedman et al. [36] 20140.2 (0.1, 0.4)Seligman et al. [36] 20146 mo: monthly or biweekly education not specified) Aprepriate foods designed to last 1-2 wk, individual and small group education (stat 1-2 wk, individual and small scale, forthighty phone appropriate foods designed to last 1-2 wk. individual and small scale (stat 1-12 wk individual and scale0.49 (-0	Ferrer et al. [42] 20196 mo: 10 lb F/V and 10 lb canned food biweekly, dicitian teaching, health promotor home visits(servings/day)Kempainen 24 wik home-delivered boxes et al. [43]24 wik home-delivered boxes foods tailored to 3 cultural preferences (American, Somali, or Hispanic)Int: -1.6 Ctri1.8 (no Cls provided)Seligman et al. [19] 20226 mo: twice monthly packages educator check-insInt: -1.6 Ctri1.8 (no Cls provided)Zu226 mo: twice monthly packages educator check-insInt: -1.6 Ctri1.8 (no Cls provided)Berkowitz et al. [17] climentary medically 	(servings/day)whole grain intake (servings/day)diet quality intake (servings/day)Ferrer et al. [4:2] 20136 mo: 10 lb F/V and 10 lb canned food biweekly, dietitian teaching, health promotor howe wistsSTC-diet Int: 2.5 (1.4, 3.5) Ctri: 0.1 (-1.0, 0.9)Kempainen 202324 wk: home-delivered boxes with 30-33 tb of shelf-stable food stallored to 3 cultural preferences (Lamerican, Somali, or Hispanic)Int: -1.6 Ctri: -1.8 (no Cls provided) Adjusted riskSTC-diet Int: 2.5 (1.4, 3.5) Ctri: 0.1 (-1.0, 0.9)Seligman et al. [13]of 22 meals of diabetes- of 22 meals of diabetes- care referral, (labbetes seli- management classes, diabetes care referral, (labbetes seli- minake drefer intake after intake after int

TABLE 4 (continued)

	Dietary intake	FI
12 wk: weekly packages of		participants
organic vegetables valued at		No P value
\$31.33		reported

APFHL, a prescription for healthy living; CI, confidence interval; Ctrl, control; F/V, fruits and vegetables; FI, food insecurity; HEI-2010, Healthy Eating Index-2010; Int, intervention group; NGSP, National Glycohemoglobin Standardization Program; RCT, randomized controlled trial; RR, relative risk; SNAP, Supplemental Nutrition Assistance Program; STC-Diet, Starting the Conversation-Diet

A grey-shaded box signifies P < 0.05 for an outcome. An unshaded box signifies a nonsignificant change. A blank box signifies that an outcome was not reported in the study. Risk of bias was high for all studies.

¹ Results are the value of each outcome at the end of the on-meals (intervention) or off-meals (control) periods.

of 12–40 wk [17,18,41–43,49–52,54], and 10 interventions provided individuals with fruit and vegetable vouchers on a biweekly to monthly basis over 13–52 wk [15,16,22,44–48,53, 55]. One study compared the effect of early SNAP disbursement on hypoglycemia [19]. Twenty studies were at a high overall risk of bias [15–19,22,41–55], most commonly because of high attrition, unblinded outcome assessment, and inadequate control for confounding. One controlled prepost study was at moderate risk of bias [45]. The certainty of evidence was very low for no change in all clinical parameters, very low for no change in whole grain intake, very low for improvement in fruit and vegetable intake, low for improvement in overall diet quality, and very low for improvement in household food insecurity.

There is very low certainty of evidence for no change in HbA1c, with 1/6 RCTs and 4/12 nonrandomized studies finding significant improvements and the remaining studies finding no change. There is also very low certainty of evidence for no change in the proportion of participants under a specific glycemic threshold, with 2/2 RCTs [18,43] and 1/2 uncontrolled prepost studies [49] reporting no change, and 1/2 uncontrolled prepost study reporting significant improvement [47]. The inconsistency in HbA1c results is likely due to heterogeneity in study design, amount of material benefit, and participant characteristics. Berkowitz et al. [17] included HbA1c as an exploratory outcome and found no significant improvement; however, the study was underpowered and too short in duration to detect effects on HbA1c. The 1 RCT that reported a significant impact on HbA1c was by Ferrer et al. [42], which provided a relatively large material benefit of 10 pounds (lb) of fresh fruits and vegetables and 10 pounds (lb) of canned foods biweekly for 6 mo. The study also included adults with a very high mean baseline HbA1c (11.0%, 97 mmol/mol), which has been associated with greater reductions in HbA1c in other studies [46,50]. The RCTs that did not report a significant improvement in HbA1c either had participants with much lower baseline HbA1c [18,43] or provided less material benefits that were likely insufficient to meaningfully affect HbA1c (1 voucher of \$6) [44]. The inconsistency in HbA1c results in nonrandomized prepost studies was likely due to inadequate control for confounding, as most studies either did not adjust for potential confounders or only adjusted for a few of them. Similar issues with heterogeneity and inconsistent results have also been reported in other systematic reviews reporting the impact of material benefits on HbA1c in the general population of adults, with 1 review finding significant improvement in HbA1c [23] and 2 finding no significant change [24,25].

There is very low certainty of evidence for no change in other clinical parameters. Significant improvements were reported in the following proportion of RCTs and nonrandomized studies, respectively: systolic blood pressure: 0/3 and 1/8 with 1 study showing worsening, diastolic blood pressure: 0/3 and 1/7, BMI: 0/5 and 2/8, body weight: 0/0 and 1/3, hypoglycemia: 1/2 and 1/2. Evidence of significant improvements in blood pressure and BMI were all from uncontrolled prepost studies that did not adjust for any potential confounders [41,49,54]. An improvement in hypoglycemia was seen in 1 RCT [17], and 1 retrospective cohort study [19], and null results were reported in 1 RCT [18] and 1 uncontrolled prepost study [50]. There is no clear explanation for the difference in hypoglycemia results between the 2 RCTs, so further studies investigating the effect on hypoglycemia of providing material benefits to improve access to food in patients with diabetes are warranted. Other systematic reviews of material benefit interventions to improve food access in adults with or without diabetes found either significant [24, 25] or nonsignificant changes in BMI [23] and nonsignificant changes in blood pressure [23,24]. Impacts on body weight and hypoglycemia were not investigated in other relevant systematic reviews.

There is very low certainty evidence of small improvements in fruit and vegetable intake, with 1/1 RCT and 1/3 uncontrolled prepost studies reporting significant improvements and the other studies reporting no change. The RCT and uncontrolled prepost study that found significant improvements in fruit and vegetable intake reported a relatively small increase (~ 0.2 servings/d), which is unlikely to be clinically meaningful [62,63]. Two uncontrolled prepost studies [22,53] with small sample sizes (n <100) reported no change in fruit and vegetable intake, which was potentially because the studies were underpowered to detect small changes in fruit and vegetable intake. Meta-analyses of the effectiveness of food prescription programs provided to broader patient populations have found more substantial increases in fruit and vegetable intake of ~0.8 servings/d [23,24]. However, in both analyses, the statistical heterogeneity was high (I² between 97–100%), and multiple studies were at high risk of bias.

There is very low certainty evidence of no change in intake of whole grains, with 2/2 uncontrolled prepost studies reporting no change. One of these studies [51] quantified self-reported intake of whole grains in servings per day, and the other study [41] quantified self-reported intake of whole grains in grams per day. Neither study provided a clear definition of whole grains [64]. No RCTs reported intake of whole grains as an outcome. Whole grain intake is an important outcome to include in studies on dietary interventions in diabetes, as increased intake of whole grains is associated with reduced HbA1c [65] and lower risk of CVD and other chronic diseases [66]. However, there are many ways of defining whole grains, and the different definitions affect estimated intakes [67]. Therefore, future interventions in adults

with diabetes should be careful to indicate how they defined whole grains. Notably, our systematic review is the first to examine the impact of providing material benefits on intake of whole grains among people with diabetes.

There is low certainty of evidence of improvements in overall diet quality, with 2/2 RCTs and 1/1 uncontrolled prepost studies reporting significant improvement. In a crossover RCT by Berkowitz et al. [17], mean Healthy Eating Index-2010 scores at the end of the control and intervention phases were 40 and 71 on a 100-point scale, which correspond to the ~10th and ~95th percentiles of Healthy Eating Index-2010 scores in the United States population [32]. This large increase is likely due to the low-barrier and high-intensity nature of the medically tailored meals intervention, as meals were delivered to participants' homes and comprised ~50% of their weekly dietary intake. The RCT by Ferrer et al. [42] found a significant but smaller improvement in the intervention group of 2.5 points on a 21-point scale. The smaller effect size in Ferrer et al. was likely due to a smaller material benefit of 10 pounds (lb) of fruits and vegetables and 10 pounds (lb) of canned foods biweekly that participants had to pick up from a clinical site.

There is very low certainty of evidence for improvement in household food insecurity, with 2/3 of RCTs finding significant improvement. The certainty of evidence for food insecurity was limited by high risk of bias in the included studies, inconsistency, and indirectness of evidence. A recent systematic review of food insecurity interventions in adults similarly found that offering food or providing monetary assistance reduced household food insecurity [25]. Reduction in food insecurity is both an important outcome and is linked to numerous other benefits among adults with diabetes, such as improved capacity for diabetes self-management, medication adherence, and overall mental well-being [14,21,25,68,69].

Economic evidence

Two studies were eligible for the economic analysis [70,71]. Nicholas [70] conducted a cross-sectional analysis of 1825 older adults (>65 y) with diabetes that compared Medicare spending between SNAP participants and SNAP-eligible nonparticipants between 1992 and 2006. Medicare administrative claims data were used to estimate spending. Data from the Health and Retirement Study [72] were used to determine SNAP eligibility and SNAP participation and to adjust for the following potential confounders: physical activity level, smoking status, completion of biannual HbA1c and annual cholesterol assessments, and presence of retinopathy. There were no associations between SNAP participation and Medicare spending in adjusted or unadjusted models. These results are limited by the fact that there are several variables that may confound the relationship between SNAP participation and Medicare spending that were not considered, including sociodemographic variables or indicators of health status, such as clinical biomarkers or the presence of other medical comorbidities.

Hager et al. [71] conducted a simulated prospective cohort study to estimate changes in healthcare expenditures over 10-y from providing medically tailored meals to medically insured adults in the United States with ≥ 1 diet-sensitive condition (including diabetes) and 1 limitation in instrumental activities of daily living. The effects of medically tailored meals on healthcare costs were meta-analyzed from 5 studies that investigated the effect of medically tailored meals on annual healthcare usage in United States adults. In a subgroup analysis of people with diabetes, the study showed that medically tailored meals were projected to have annual per-capita cost-savings of \$6838 in healthcare expenditures and \$3870 from the policy overall when including costs of implementing the intervention.

We did not locate any studies that investigated the costeffectiveness, return on investment, or cost-benefit of providing material benefits to improve food access in patients with diabetes. Economic evidence, particularly costeffectiveness analyses, will be important additions to future clinical trials of material benefit interventions to improve access to food in patients with diabetes.

Strengths and limitations

This is the first systematic review to examine the impact of providing material benefits to improve access to food on clinical parameters, dietary intake, and food insecurity in patients with diabetes. We synthesized evidence from multiple types of interventions that may act through similar mechanisms to improve food access, such as food prescription programs, food vouchers, and medically tailored meals. Our specific focus on diabetes allowed us to explore aspects of these interventions that may provide unique benefits for people with diabetes, such as assisting them in adhering to a healthful dietary pattern [2], to self-manage their diabetes [73], and supporting the high cost of diabetes medications [9,13,14]. Our review used rigorous methods [37,74], including duplicate full-text reviews, data extraction, risk of bias, and GRADE assessments. We also used Cochrane-recommended risk of bias assessment tools [37,75]. Databases were also searched from inception, and all relevant reviews were hand searched to ensure a comprehensive search.

There are also limitations to this review. Our reviews pertained to all adults with diabetes; however, many studies included only adults with food insecurity or low incomes. As a result, we downgraded the certainty of evidence for these studies because of the indirectness of the study population. This downgrading had minimal impact on GRADE ratings, as the certainty of evidence was already very low for all outcomes except overall diet quality. There is diversity in the types of interventions that provide material benefits to improve food access, and therefore it is possible that some relevant search terms were not included in our literature searches. However, hand-searching prior systematic reviews minimizes risk that potentially eligible studies were not included. Risk of bias assessments was completed at a study level instead of for each individual outcome in each study to improve interpretability of results. A narrative synthesis was used because of high study heterogeneity; however, this synthesis method did not allow us to derive a single effect size for each outcome.

There are important limitations in the evidence. Only 6 RCTs met the inclusion criteria, all of which were at high risk of bias. The included studies often had high attrition, and those that assessed dietary intake relied on self-reported data. Inadequate or no adjustment for confounding was also a common limitation of nonrandomized studies. The inconsistency of results between

studies, particularly for clinical parameters, limited the ability to draw firm conclusions. Based on the evidence, we recommend that future studies focus on minimizing loss to follow-up and use objective measures to accompany dietary intake assessment, such as nutritional biomarkers [76–78].

In conclusion, this systematic review finds that providing material benefits to improve food access for adults with diabetes may improve household food insecurity (very low certainty), fruit and vegetable intake (very low certainty), and overall diet quality (low certainty). However, these interventions are less likely to lead to a significant change in HbA1c (very low certainty), other clinical parameters (very low certainty), and whole grain intake (very low certainty). The economic search identifies 1 cross-sectional study showing no association between SNAP participation and Medicare costs in adults with diabetes, and 1 simulation study finds that providing medically tailored meals to adults with diabetes and limited instrumental activities of daily living can be cost-saving in the United States. This review presents a novel synthesis of evidence that supports using material benefits to improve food access as an intervention to improve household food insecurity, fruit and vegetable intake, and overall diet quality in people with diabetes. However, highquality RCTs and objective measurements of dietary intake are needed to understand the effects of these interventions better.

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Author contributions

The authors' responsibilities were as follows– KJDS, DLO, RB, DJTC, and ES: designed the research; KJDS, SC-R, SMA, and ES: conducted the search, data extraction, and risk of bias assessment; KJDS and ES: analyzed the data; KJDS, DLO, and ES: wrote the manuscript; KJDS and ES: had primary responsibility for final content, and all authors: read and approved the final manuscript.

Data availability

There was no analytic code used. The review protocol can be accessed via the PROSPERO registration number CRD42021212951. Data described in the manuscript, code book, and analytic code will be made available upon request pending (e.g., application and approval, payment, other).

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https ://doi.org/10.1016/j.advnut.2023.05.012.

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