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Testing the Feasibility and Dietary Impact of a "Produce Prescription" Program for Adults with Undermanaged Type 2 Diabetes and Food Insecurity in Australia

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ABSTRACT

Background: There is growing interest in *Food is Medicine* programs that incorporate food-based interventions into health care for patients with diet-related conditions.

Objectives: We aimed to test the feasibility of a "produce prescription" program and its impact on diet quality for people with type 2 diabetes (T2D) experiencing food insecurity in Australia.

Methods: We conducted a pre–post intervention study in $n = 50$ adults experiencing food insecurity with T2D and glycated hemoglobin (HbA1c) ≥8%. Once enrolled, participants received healthy food boxes weekly free of charge, with the contents sufficient to create 2 meals/d, 5 d/wk for the entire household, over 12 wk. Participants were also provided with tailored recipes and behavioral change support. The primary outcome was change in diet quality assessed by 24-h diet recalls. Secondary outcomes included differences in cardiovascular disease risk factors; blood micronutrients; and feasibility indicators. Differences in the baseline and 12-wk mean primary and secondary outcomes were assessed by paired *t* tests.

Results: Participants were older adults with mean ± SD age 63 ± 9 y (range: 40–87 y), HbA1c 9.8% ± 1.5%, and 46% were female. Overall, 92% completed the final study follow-up for the primary outcome. Compared with baseline, diet quality improved at week 12, with an increase in the mean overall diet quality (Alternate Healthy Eating Index score) of 12.9 (95% CI: 8.7, 17.1; $P < 0.001$), driven by significant improvements in vegetables, fruits, whole grains, red/processed meat, *trans* fat, sodium, and alcohol consumption. Blood lipids also improved (total:HDL cholesterol: −0.48; 95% CI: −0.72, −0.24; $P < 0.001$), and there was significant weight loss (−1.74 kg; 95% CI: −2.80, −0.68 kg, $P = 0.002$), but no changes in other clinical outcomes. Participants reported high levels of satisfaction with the program.

Conclusions: These findings provide strong support for an adequately powered randomized trial to assess effects of produce prescription as an innovative approach to improve clinical management among individuals with T2D experiencing food insecurity. This trial was registered at https://anzctr.org.au/ as ACTRN12621000404820. *J Nutr* 2022;152:2409–2418.

Keywords: food is medicine, food insecurity, produce prescription, cardiometabolic, type 2 diabetes

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Introduction

"Food is medicine" programs incorporate the provision of healthy foods or meals into the health care system as a therapy to prevent, or improve the management of, nutrition-sensitive conditions, in particular type 2 diabetes (T2D) and other diet-related noncommunicable diseases (NCDs) (1). Produce prescription is one such approach, which allows health professionals to prescribe nonprepared healthy foods for patients with lower income, food insecurity, and/or diet-sensitive conditions but able to cook and prepare food at home (1). Initial evidence on produce prescription is promising, suggesting improvements in diet behavior and clinical risk factors in patients (2). When connected with local food producers, produce prescription has the cobenefit of supporting the local economy. However, most evidence related to produce prescription is from the United States, and the feasibility and acceptability of produce prescription programs in other countries are unclear.

The burden of NCDs in Australia has risen over the past few decades and is projected to rise further owing mainly to unhealthy behaviors. In particular, poor dietary quality is driving an epidemic of obesity and metabolic diseases (3). T2D is a case in point, with rising prevalence and tremendous health, social, and economic costs (4–6). Only 1 in 20 Australian adults consume the recommended amounts of fruits and vegetables (7) and ultra-processed foods contribute on average nearly 40% of daily caloric intake (8). The ability to eat a healthy diet and manage T2D is further undermined in those experiencing food insecurity, estimated at ∼1 in 20 Australian households nationally (9) and substantially higher among those who are currently experiencing financial constraints (9). The prevalence of food insecurity has also likely risen owing to the COVID-19 pandemic–induced economic restrictions (10).

The current study was a small-scale feasibility study testing produce prescription for older adults with undermanaged T2D experiencing food insecurity in Australia.

Methods

Study design

This was a pre–post intervention study with a targeted sample size of 50 participants. Recruitment was between November 2020 and July 2021, with follow-up completed in October 2021. The study was approved by the Sydney Local Health District Ethics Review Committee (Project Number: X20-0387 and 2020/ETH02247) and all participants provided informed written consent. The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12621000404820).

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Supplemental Tables 1–4 and Supplemental Figure 1 are available from the "Supplementary data" link in the online posting of the article and from the same link in the online table of contents at https://academic.oup.com/jn/.

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Abbreviations used: AHEI, Alternate Healthy Eating Index; ARFS, Australian Recommended Food Score; BP, blood pressure; HbA1c, glycated hemoglobin; NCD, noncommunicable disease; RCT, randomized controlled trial; T2D, type 2 diabetes.

Study participants

We recruited adults ≥18 y of age living within the Sydney metropolitan area with clinically diagnosed T2D of ≥6 mo duration, with consistently high blood glucose [defined as measured blood glycated hemoglobin (HbA1c) ≥8% at their most recent clinical assessment]. Participants also had to be experiencing food insecurity as ascertained by a 2-item questionnaire derived from the USDA's Core Food Security Module (11). The 2-item questionnaire was chosen to minimize administrative burden during recruitment screening, and prior research suggests using these 2 items provides adequate sensitivity (>97%) and specificity (>70%) compared with the USDA's 18-item Core Food Security Module for assessing food insecurity and is suitable for clinical use. Exclusion criteria were as follows: unable or unwilling to provide informed consent; not planning to stay within their home for the next 4 mo; currently pregnant; living in a hospice or receiving palliative care; living in a facility that provides meals; not having a refrigerator at home for storing study foods; existing medical conditions that may preclude completion of data collection, or limited food consumption, including active cancer, need for dialysis, or celiac disease; participating in any other lifestyle modification research projects; or having another household member already participating in the study.

Recruitment.

Study participants were recruited from the Diabetes Centre at the Royal Prince Alfred Hospital, a major public hospital in Sydney, Australia. Clinical staff identified potentially eligible participants based on T2D diagnosis date and last recorded HbA1c level and briefly described the study at routine clinic or telehealth appointments. Patients expressing interest were referred to the study team who scheduled a telephone appointment to describe the study and seek consent for participation.

Baseline data collection and follow-up

Once consent was obtained and eligibility was confirmed (**Supplemental Table 1**), an interviewer-administered baseline questionnaire was completed to document medical history and demographics, and food insecurity was assessed using the USDA's Core Food Security Module 6-item questionnaire (9). Level of physical activity was assessed using the International Physical Activity Questionnaire (12). A blood specimen was collected by an accredited pathology service provider to assess clinical biomarkers; and blood pressure (BP), weight, and height either were measured in person by the research staff or participants were provided standardized instructions for self-measurement at home. Weighing scales (Bodisure BWS100) and BP monitors (Omron HEM-7121-BP) were provided for participants who chose self-measurement at home. At baseline, study personnel ascertained the participants' dietary behavior using 2 phone-based approaches: *1*) the multiple-pass 24-h diet recall (13), which was conducted by Accredited Practicing Dietitians and taken twice (once on a weekday and once on a weekend day), then used to assess the primary outcome of Alternate Healthy Eating Index (AHEI) score (see "Study outcomes"). The multiple-pass 24-h diet recall probes for complete food descriptions, detailed food preparation methods, and portion size descriptions. To assist with reporting of portion sizes of food intake, participants were asked to describe portions in terms of metric cup and spoon sizes and to use visual hand guides, e.g., clenched fist size (∼1 cup). *2*) A semiquantitative 120-item FFQ (the Australian Eating Survey) (14), which was also used to assess the participants' habitual dietary pattern over the past 3 mo as a complement to the 24-h diet recall approach. The Australian Eating Survey has good reproducibility and comparative validity as measured against 3-d weighted food records in Australian adults (15). All outcome measures were assessed again at weeks 6 and 12 except for the clinical biomarkers, which were only recorded at week 12. In addition, at weeks 6 and 12, participants were asked to report any adverse events, as well as complete a self-administered process outcome evaluation questionnaire related to the feasibility and acceptability of the intervention over the prior 6 wk. Throughout the study, participants were advised to continue their usual medications and could make changes to medication requirements at the discretion of their treating clinicians.

TABLE 1 A representative example of the content and amounts in a healthy food box provided to the study participants[1]

Food groups	Examples of foods[2]	Servings per day recommended by the Australian Dietary Guidelines,[3] *n*	Servings per day provided per person, to allow for 2 meals/d, *n*	Servings per week provided for a household of 3 or 4 (including the participant), to allow for 2 meals/d, 5 d/wk,[4] *n*
Fruits	Apples, bananas, strawberries, kiwi fruit, oranges, and pears	2	2	40
Vegetables	Cauliflower, broccolini, asparagus, zucchinis, baby spinach leaves, mushrooms, onions, carrots, broccoli, tomatoes, canned beans, canned beetroot, canned brown lentils	6	4	80
Whole grains	Rolled oats, quinoa, freekeh, wholegrain bread. Only products with carbohydrate to fiber ratio of <10:1 included[5]	6	4	80
Lean meats and plant-based alternatives	Chicken breasts, eggs, canned tuna in water, walnut kernels, and smooth peanut butter with no added sugar and salt[6]	3	2	40
No-added-sugar milk, cheese, and yogurt, and alternatives	Reduced-fat milk, soy milk, cheddar cheese, and unsweetened yogurt[7]	2.5	1.5	30

[1] In addition to receiving weekly healthy food boxes, all participants were provided with a one-off supply at the beginning of the study consisting of 3 L of extra-virgin olive oil and a "spice kit" (containing herbs and spices) to facilitate meal preparation.
[2] Fruits and vegetables provided were occasionally modified throughout the study to choose the most seasonal produce available and which met cost constraints.
[3] Based on number of recommended servings per day for adults aged 19–50 y (16).
[4] The amount of foods provided was adjusted for household size with 3 box sizes available, i.e., a household with 1–2 members received boxes that had half the weekly amount listed in the table, whereas those with ≥5 members received boxes with 1.5 times the weekly amount listed in the table.
[5] Carbohydrate to fiber ratio of <10:1 identifies the healthiest whole-grain products based on prior research.
[6] Only poultry, fish, and plant-based alternatives were provided in this core food group; no red or processed meats (lean or otherwise, including pork, beef, or lamb) were provided. All nuts provided were unsalted, and all nut butters did not contain added sugar and salt.
[7] Only plain milk was provided, and all yogurt products provided were unsweetened.

Intervention

Once enrolled and after completing their baseline data collection, participants received a "healthy food box prescription program," with food boxes delivered to their home weekly, free of charge, by the study food supplier (Harris Farm Markets, a family-owned grocery chain that operates in the states of New South Wales and Queensland in Australia; https://www.harrisfarm.com.au/). We note that there is no consensus regarding nomenclature that should be applied to describe interventions similar to our program, with a variety of terms such as produce prescription, food farmacy, and medically tailored groceries having being proposed or used. For simplicity and consistency with the literature, our intervention will be referred to as "produce prescription" hereafter.

Box contents were designed by the study investigators and included different categories of healthy foods in amounts recommended by the Australian Dietary Guidelines (**Table 1**) (16). Contents were designed to support management of T2D by emphasizing overall diet quality and mostly minimally processed, plant-based foods, rather than to meet a specific macronutrient composition (17). The boxes included fruits; vegetables; legumes/beans; whole grains (selected based on evidence-based ratio of carbohydrate to fiber criteria to identify the healthiest whole-grain products) (18), plain, unflavored milk, cheese, and yoghurt and/or soy milk; healthy plant-based fats (extra-virgin olive oil); nuts; poultry; and fish. Boxes were tailored to provide gluten-free (e.g., gluten-free bread) and lactose-free foods (e.g., soy milk) for participants as needed. Amounts were designed to create 2 meals/d, 5 d/wk, for the participants' entire household because we hypothesized this approach would enable a supportive healthy-eating home environment.

Participants also received a tailored recipe booklet containing suggestions for healthy breakfast, lunch, and dinner meals to be prepared using the contents of the boxes; and were encouraged but not required to access fortnightly 30-min phone appointments with Accredited Practicing Dietitians trained in providing behavior change support, including motivational interviewing and the setting of action plans. Dietitians used motivational interviewing techniques during the consultations to strengthen intrinsic motivation and behavior change. Although the consultations differed according to the goals of the participant, they generally covered the following aspects: description of the diet–disease relation between healthy eating and T2D, advice around how to store and cook the foods provided, personalized dietary advice to improve overall diet and glycemic control, identifying barriers and facilitators to healthy eating and exploring ways to overcome these barriers, and goal setting and action planning to encourage participants to focus on specific goals in between consultations. A lesson plan was created by dietitians to support the consultations and the dietitians also logged the number of dietary consultations the participants took part in. Although the contents of the foods provided remained similar over the course of the study, minor variations were made to provide seasonal fruits and vegetables. Participants were also asked to provide feedback on the content of the healthy food boxes during their consultations with the dietitians over the course of the study, and their suggestions were incorporated based on considerations of healthiness, cost, and availability as part of regular review of box contents.

Study outcomes

The primary outcome was the change in the mean usual diet quality of the participants, based on the average of the two 24-h diet recalls and assessed by the AHEI, a measure of diet quality. Higher diet quality as indicated by the AHEI is related to better cardiometabolic outcomes in individuals with T2D, including lower risk of cardiovascular mortality (19, 20). The 24-h recall data were analyzed using FoodWorks software (Xyris Pty Ltd), which uses the AUSNUT 2011–13 nutrient database to estimate nutrient intake. AUSNUT 2011–13 contains nutrient values for $n = 5740$ foods and beverages and was developed for the 2011–13 Australian Health Survey. The AHEI was calculated based on a scoring algorithm assigning continuous scores (out of 10) for intakes of vegetables, fruits, whole grains, nuts and legume protein, total intake of long-chain omega-3 fatty acids, percentage of total energy from polyunsaturated fat, sugar-sweetened beverages, red and processed meat, percentage of total energy from *trans* fat, sodium, and alcohol, with a higher AHEI score reflecting better diet quality (19, 20).

Secondary outcomes involved additional evaluation of dietary intake in order to characterize the change in the participants' dietary pattern, and included *1*) each individual component of the AHEI score, *2*) ultra-processed food intake according to the NOVA classification system (21), and *3*) the "Australian Recommended Food Score" (ARFS), which is a composite diet quality score reflecting alignment with the Australian Dietary Guidelines (14). Based on literature review, very few studies have assessed impact of produce prescription programs on cardiometabolic outcomes, and hence we also included the following secondary outcomes (all blood biomarkers were assessed by Douglass Hanly Moir Laboratories, an accredited pathology service provider): whole blood HbA1c (Biorad D-100 analyzer); serum lipid concentrations and levels including total cholesterol, LDL cholesterol, HDL cholesterol, total to HDL cholesterol ratio, and triglycerides (Abbott CI6000 analyzer); micronutrient status including plasma vitamin C (HPLC with UV detection), serum zinc (Varian AA analyzer using atomic absorption spectroscopy), and serum magnesium (Abbott CI6000 analyzer, isocitrate dehydrogenase method); BP; body weight; and BMI. Vitamin C is a well-established biomarker of fruit and vegetable intake, and individuals experiencing food insecurity have higher estimated prevalence of magnesium and zinc deficiency (22)—circulating concentrations of magnesium are also inversely associated with CVD risk (23). Other secondary outcomes were feasibility and acceptability indicators including attrition rates from the study; delivery of healthy food boxes; food quality, type, quantity, storage, and preparation; the diet consultations (including participation rates); and satisfaction with the recipes provided as measured by the process outcome evaluation questionnaire.

Sample size

A sample size of 50 individuals was calculated to provide >90% power with 2-sided α of 0.05 to detect a mean difference of 4 units in AHEI score comparing the baseline with the follow-up measures assuming an SD of 7.4 units and allowing for 10% dropout. The distribution assumptions were based on previously observed AHEI scores in a clinical study in people with T2D in Australia (24). We assumed a within-subject AHEI correlation of 0.5, and had >80% power if the within-person correlation was as low as 0.2.

Statistical analysis

Baseline demographics were summarized as mean ± SD for continuous variables and *n* (%) for categoric variables. Self-reported dietary intakes of major food groups and macronutrients at baseline and end of trial were summarized as servings per day or percentage of total energy. Statistical significance of the differences in the baseline and 12-wk mean primary outcome measure (AHEI score) and the secondary outcome measures (HbA1c, blood lipids, micronutrient status, BP, body weight, and BMI) was assessed by paired *t* tests. For participants with missing end-of-study (week 12) data, their week 6 data were used when available. All analyses were done in Rstudio version 1.4.1106 and R version 4.1.0 (both RStudio PBC).

Results

There were 139 individuals referred as potential participants (**Supplemental Figure 1**) but 53 were not interested in taking part; of the 86 that were assessed, 50 (58%) met the inclusion criteria and agreed to participate. The numbers of participants who completed the 6-wk and 12-wk follow-up assessments for the primary endpoint of dietary outcome assessment were 49 (98%) and 46 (92%), respectively.

Baseline characteristics

Participants were middle-aged to older adults (age range: 40–87 y) and approximately half were female (**Table 2**). The participants were from diverse ethnic backgrounds including Oceanians, Europeans, Asians, and others. Most participants were from single- or 2-person households, did not have children, and were the main person who prepared food in their

TABLE 2 Demographic characteristics of individuals with type 2 diabetes experiencing food insecurity who took part in the study at baseline[1]

Characteristics	$n = 50$
Age, y	63 ± 9
Sex, female	23 (46)
Ethnicity[2]	
African and Middle Eastern	1 (2.0)
Asian	6 (12)
European	17 (34)
Oceanian	21 (42)
Peoples of the Americas	5 (10)
Total household size, *n*	
1	21 (42)
2	15 (30)
3	7 (14)
4	5 (10)
5	2 (4.0)
Adults (≥18 y old) in the household, *n*	
1	23 (46)
2	18 (36)
3	7 (14)
4	2 (4.0)
Children and toddlers (<18 y old) in the household, *n*	
0	41 (82)
1	4 (8.0)
2	5 (10)
Is the main person who prepares or cooks food in the household	43 (86)
Highest level of education and training completed	
Primary school	15 (30)
High school	20 (40)
TAFE or Trade Certificate or Diploma	7 (14)
University, or some other tertiary institute degree	8 (16)
Total annual household income, $	
<25,948	30 (60)
25,948–51,948	19 (38)
>51,948	1 (2.0)
Current work status	
Unemployed	20 (40)
Employed	11 (22)
Retired	19 (38)
Most recent HbA1c,[3] %	9.8 ± 1.5
Most recent HbA1c, mmol/mol	85 ± 17
Level of physical activity[4]	
Low	28 (56)
Moderate	17 (34)
High	5 (10)
Prevalent medical conditions	
High blood pressure	26 (52)
Heart disease	12 (24)
Stroke	5 (10)
Taking antihyperglycemic medication	41 (82)

[1]Values are mean ± SD or *n* (%). HbA1c, glycated hemoglobin; TAFE, Technical and Further Education.
[2]Ethnicity defined using the Australian Bureau of Statistics Standard Classification of Cultural and Ethnic Groups classification system.
[3]Range: 8%–14%.
[4]Level of physical activities was calculated according to the IPAQ (International Physical Activity Questionnaire) short form scoring protocol (12).

TABLE 3 Change in mean Alternate Healthy Eating Index diet quality score and food intake among people with type 2 diabetes experiencing food insecurity over 12 wk[1]

Diet quality and components of dietary intake	Baseline, mean ± SD	End of study, mean ± SD	Mean difference (95% CI)
Overall diet quality score (range: 0–110)[2]	52.3 ± 13.7	65.2 ± 12.9	12.9 (8.7, 17.1)
Components of diet quality score (range: 0–10 for each)			
1. Vegetable score	3.97 ± 2.99	5.30 ± 2.63	1.33 (0.29, 2.36)*
2. Fruit score	2.97 ± 2.47	5.53 ± 2.73	2.56 (1.69, 3.43)*
3. Whole grains score	3.59 ± 3.35	4.73 ± 2.81	1.13 (0.35, 1.92)*
4. Nuts and legumes score	2.19 ± 3.57	3.54 ± 4.05	1.35 (−0.06, 2.76)
5. Long-chain omega-3 fats score	5.44 ± 3.52	6.00 ± 3.58	0.56 (−0.69, 1.81)
6. Polyunsaturated fats score	6.18 ± 2.37	6.45 ± 2.27	0.27 (−0.61, 1.15)
7. Sugar-sweetened beverages and fruit juice score	7.27 ± 4.04	8.46 ± 3.06	1.20 (−0.01, 2.40)
8. Red/processed meat score	4.17 ± 4.14	5.65 ± 4.15	1.47 (0.03, 2.91)*
9. *Trans* fat score	9.50 ± 0.63	9.89 ± 0.26	0.39 (0.19, 0.59)*
10. Sodium score	4.59 ± 2.67	6.55 ± 2.35	1.96 (1.07, 2.85)*
11. Alcohol score	2.43 ± 0.55	3.11 ± 2.07	0.69 (0.00, 1.37)*
Absolute intake			
1. Vegetables,[3] servings/d	2.15 ± 1.90	2.72 ± 1.47	0.57 (−0.06, 1.21)
2. Fruit,[4] servings/d	1.19 ± 1.00	2.35 ± 1.48	1.16 (0.77, 1.55)*
3. Whole grains, g/d	35 ± 41	45 ± 37	10 (−1, 21)
4. Nuts and legumes,[5] servings/d	0.31 ± 0.68	0.53 ± 0.80	0.22 (−0.06, 0.51)
5. Long-chain omega-3 fats, mg/d	446 ± 730	287 ± 406	− 159 (−364, 46)
6. Polyunsaturated fats, % of energy	6.41 ± 2.75	6.83 ± 3.06	0.43 (−0.69, 1.54)
7. Sugar-sweetened beverages and fruit juice,[6] servings/d	0.43 ± 0.82	0.19 ± 0.48	− 0.24 (−0.45, −0.03)*
8. Red/processed meat,[7] servings/d	1.38 ± 1.36	0.81 ± 1.00	− 0.56 (−1.01, −0.12)*
9. *Trans* fat, % of energy	0.61 ± 0.29	0.41 ± 0.18	− 0.20 (−0.30, −0.10)*
10. Sodium, mg/d	2800 ± 1430	1950 ± 833	− 852 (−1280, −423)*
11. Alcohol,[8] drinks/d	0.23 ± 0.92	0.11 ± 0.38	− 0.12 (−0.29, 0.05)
Total energy, kJ/d	9990 ± 3370	7850 ± 3240	− 2130 (−3080, −1190)*

[1] Analyses were based on data for $n = 49$ participants: $n = 46$ with complete data at baseline and week 12, $n = 3$ with baseline and week 6 data because week 12 data collection was not completed. Findings were minimally affected when analyses were restricted to the 46 participants who completed outcome data assessment at baseline and at the end of the 12-wk study (data not shown). Dietary intake was assessed by 2 × 24-h diet recalls administered by accredited dietitians (1 weekday and 1 weekend day) at baseline, week 6, and week 12 of the study. One participant at baseline and 2 participants at the end of study had data from only one 24-h diet recall available; exclusion of these participants from analyses did not appreciably affect the findings (not shown).
[2] Overall dietary score was calculated according to Chiuve et al. (20), and is a composite score accounting for 11 dietary components. Higher scores indicate healthier consumption. For components 1–6, a higher score represents higher intake; for components 7–11, a higher score indicates lower consumption.
[3] One serving is 0.5 cups of vegetables or 1 cup of green leafy vegetables (1 cup = 237 g).
[4] One serving is 1 medium piece of fruit (150 g) or 0.5 cups of berries (1 cup = 237 g).
[5] One serving is 1 oz (1 oz = 28.4 g) of nuts or 1 tablespoon (15 mL/15 g) of peanut butter.
[6] One serving is 8 oz (1 oz = 28.4 g).
[7] One serving is 4 oz of unprocessed meat or 1.5 oz of processed meat (1 oz = 28.4 g).
[8] One standard drink consists of 10 g ethanol.
* $P < 0.05$ assessed by paired *t* tests.

household. Participants generally had less than high school education, often had low household income, and were often unemployed or retired (78%). As per study entry criteria, the participants had high average baseline HbA1c; about half of participants also had high BP and about one-third had a self-reported history of heart disease or stroke.

Association of intervention with diet quality assessed by 24-h diet recall

Comparing post- with pre-intervention, significant improvements in participants' mean usual diet quality (as assessed by the AHEI score) were documented (**Table 3**). Seven components of the AHEI score also improved significantly from baseline to 12 wk including scores for intakes of vegetables, fruits, whole grains, red/processed meat, *trans* fat, sodium, and alcohol ($P < 0.05$ for each).

The corresponding changes in the mean absolute intakes per day of each dietary component (Table 3) showed increase in mean fruit intake and decrease in mean sugar-sweetened beverages and fruit juice, red/processed meat, *trans* fat, and sodium intakes. Mean total energy intake also decreased from baseline. In addition, it was observed that, over 12 wk, the mean intake of ultra-processed foods also declined by −1860 kJ/d (95% CI: −2550, −1170 kJ/d; $P < 0.001$), representing a decline from ∼41% of daily caloric intake at study baseline to ∼30% by the end of the trial.

Diet quality score did not differ at 6 and 12 wk of the intervention (**Supplemental Table 2**).

Association of intervention with diet quality assessed by FFQ

Consistent with analyses based on the 24-h diet recalls, there were significant improvements in the overall dietary quality as assessed by the FFQ (the ARFS) (**Supplemental Table 3**). This was due to significant increases in intakes of fruits, vegetables, and meat alternatives; and reductions in unhealthy foods such as sweetened drinks, packaged snacks, and confectionery.

Association of intervention with food insecurity

At study baseline, participants' responses to the USDA 6-item Core Food Security Module indicated that 82% were living in a household experiencing food insecurity without hunger and

TABLE 4 Food insecurity assessment based on the USDA's Core Food Security Module 6-item questionnaire[1]

Level of food security[2]	Baseline ($n = 50$)	Week 6 ($n = 49$)	Week 12 ($n = 44$)
Food secure[3]	9 (18)	48 (98)	44 (100)
Food insecure without hunger[4]	23 (46)	1 (2.0)	0 (0)
Food insecure with hunger[5]	18 (36)	0 (0)	0 (0)

[1]Values are *n* (%). For the baseline assessment participants were asked about their experience for the past 12 months, whereas at week 6 they were asked about the prior 6 weeks, and at week 12 the past 12 weeks, i.e. while they were participating in the produce prescription program.
[2]Each question of the 6-item questionnaire was scored as affirmative or negative according to the "Guide to Measuring Household Food Security" (5).
[3]0–1 affirmative responses across the 6 items.
[4]2–4 affirmative responses across the 6 items.
[5]5–6 affirmative responses across the 6 items.

with hunger (Table 4). In contrast, responses at the end of the study indicated all participants had not been experiencing food insecurity over the past 12 wk.

Association of intervention with clinical biomarkers, anthropometric parameters, and BP

Participants' average HbA1c (95% CI) did not significantly change over the study (Table 5). There were, however, improvements in mean total cholesterol, LDL cholesterol, HDL cholesterol, and total:HDL cholesterol ratio. Adiposity also significantly improved, with reductions in both body weight and BMI. BP levels did not vary from baseline to week 12, and similarly, there were no differences in the concentrations of 3 micronutrient biomarkers (vitamin C, zinc, magnesium) comparing week 12 with baseline.

Safety

No adverse events were reported throughout the duration of the study.

Participants' perception of the produce prescription intervention

Almost all participants found the program "helpful" or "extremely helpful" in improving their diet and that the food delivery model was suitable for their needs (Table 6). Nearly all felt that the foods provided were of "good" or "excellent" quality, and all liked or strongly liked the type of foods provided. Nearly all were satisfied with the amount of food provided and had the facilities to store the foods appropriately. All reported consuming at least "three quarters" to "all" of the foods provided. During the period of the trial, nearly all participants reported they were able to have regular meals including breakfasts. A majority found the recipes provided to be useful to extremely useful, and nearly all reported preparation of meals

TABLE 5 Changes in clinical measurements among people with type 2 diabetes experiencing food insecurity over 12 wk[1]

	n	Baseline, mean ± SD	End of study, mean ± SD	Change over the study, mean difference (95% CI)
Whole blood HbA1c,[2] %	35	8.47 ± 1.84	8.24 ± 1.47	− 0.23 (−0.63, 0.18)
Lipid risk factors for cardiovascular disease[2]				
Total serum cholesterol, mmol/L	36	4.21 ± 1.29	3.93 ± 1.17	− 0.28 (−0.52, −0.03)*
Serum LDL cholesterol, mmol/L	30	2.05 ± 0.99	1.82 ± 0.96	− 0.23 (−0.45, −0.01)*
Serum HDL cholesterol, mmol/L	36	1.08 ± 0.27	1.15 ± 0.30	0.06 (0.003, 0.12)*
Serum triglycerides, mmol/L	36	2.63 ± 2.15	2.39 ± 2.47	− 0.25 (−0.65, 0.16)
Total serum cholesterol to serum HDL cholesterol ratio	36	4.11 ± 1.59	3.63 ± 1.33	− 0.48 (−0.72, −0.24)*
BP[3]				
Systolic BP, mm Hg	40	130 ± 14.0	127 ± 10.2	− 2.94 (−7.17, 1.29)
Diastolic BP, mm Hg	40	80.5 ± 11.5	78.6 ± 9.78	− 1.88 (−5.47, 1.70)
Anthropometry[3]				
Body weight, kg	45	95.9 ± 25.5	94.1 ± 25.2	− 1.74 (−2.80, −0.68)*
BMI, kg/m^2	41	33.8 ± 7.54	33.2 ± 7.46	− 0.67 (−1.06, −0.29)*
Micronutrient status biomarkers[2]				
Plasma vitamin C, μmol/L	31	38.6 ± 27.0	41.3 ± 27.9	2.71 (−5.85, 11.27)
Serum zinc, μmol/L	33	13.3 ± 2.57	13.5 ± 2.40	0.14 (−0.64, 0.92)
Serum magnesium, mmol/L	33	0.78 ± 0.08	0.79 ± 0.07	0.01 (−0.01, 0.03)

[1]BP, blood pressure; HbA1c, glycated hemoglobin.
[2]Values and analyses were based on participants with complete biomarker measurements at baseline and week 12, i.e., $n = 30$–36 (60%–72%) of the study participants. Several participants declined to visit pathology testing centers for data collection owing to the COVID pandemic and prevalent public health advice.
[3]Values and analyses were based on participants with complete anthropometry and BP at baseline and week 6 or week 12, i.e., $n = 40$–45 (80%–90%) of the study participants. Measurements for these secondary outcomes were available at week 12 for $n = 36$–41 of the participants; for $n = 4$ participants who did not complete week 12 measurements, their week 6 measurements were used. Results were not appreciably altered by restricting the analysis to only participants who completed the 12-wk outcome assessment. At study baseline, each of these secondary outcomes was collected by trained research staff at a central location. Owing to the COVID pandemic and prevalent public health advice, many participants (~50%) opted to conduct home measurements for these outcomes during follow-up and therefore they were sent scales and BP monitors (valid for clinical use) and instructions for measuring their weight and BP, following established standardized methods.
*$P < 0.05$ assessed by paired *t* tests.

TABLE 6 Process-related outcomes reported by study participants based on a questionnaire conducted at 12 wk[1]

Characteristics	Week 12 ($n = 44$)
1. Has the "Produce Prescription" program been helpful in improving you and your family's diet?	
Extremely helpful	22 (50.0)
Helpful	20 (45.5)
Somewhat helpful	1 (2.3)
A little helpful	1 (2.3)
2. Were the delivery/pick-up arrangements (e.g., time and frequency) suitable for you?	
Yes, the delivery/pick-up arrangements were suitable	44 (100.0)
3. How was the quality of foods in the healthy food boxes?	
Excellent	16 (36.4)
Good	25 (56.8)
Moderate	3 (6.8)
4. How was the type of food included in the healthy food boxes?	
Strongly like	9 (20.5)
Like	35 (79.5)
Neutral	0 (0.0)
5. On average, was the amount of food provided enough for 2 meals per day, 5 days per week for the household?	
Too much or far too much	5 (11.4)
Right amount	38 (86.4)
Far too little or too little	1 (2.3)
6. Was food storage a problem each week?	
A lot of food was spoiled—I don't have the right storage facilities and I would like more advice about food storage	1 (2.3)
No foods were spoiled—I have the right storage facilities and understand how to store foods properly	43 (97.7)
7. How did you find preparing and cooking meals using foods from the healthy food box?	
Meal preparation and cooking was easy AND did not take much time	42 (95.5)
Meal preparation and cooking was easy BUT took too much time	0 (0.0)
Meal preparation and cooking was difficult BUT did not take much time	0 (0.0)
Meal preparation and cooking was difficult AND took too much time	2 (4.5)
8. On average, how much of the weekly healthy food boxes was used or eaten?	
All	11 (25.0)
Three quarters	33 (75.0)
Half	0 (0.0)
9. How confident do you feel that you can eat your meals regularly every day, including breakfast every day?	97 (94.0, 100)
10. How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?	
Completely confident	35 (79.5)
Confident	8 (18.2)
Somewhat confident	1 (2.3)
11. How useful were the dietary consultations?	
Extremely useful	25 (56.8)
Useful	15 (34.1)
Somewhat useful	3 (6.8)
A little useful	1 (2.3)
12. How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)?	
Completely confident	30 (68.2)
Confident	14 (31.8)
Somewhat confident	0 (0.0)
13. How useful were the recipes provided?	
Useful or extremely useful	12 (27.3)
Somewhat useful	19 (43.2)
Not at all useful or a little useful	13 (29.5)

[1] $n = 44$ participants completed the exit questionnaire. Values are n (%) except question 9, for which the participants responded on a continous scale from 0 to 100%, and the values presented are the median (25th percentile, 75th percentile).

with the foods provided to be easy and not take too much time. All participated in ≥1 dietitian consultation, and three-quarters (74%) participated in all 5 dietitian consultations available over the 12 wk, with a median attendance of 5 (IQR: 25th percentile: 4, 75th percentile: 5). Nearly all participants found the dietary consultations to be useful or extremely useful. Nearly all of the participants reported that they would be willing to pay at least between $51 and $100 AUD/wk for the produce prescription program, with larger-sized households willing to pay more for the program (**Supplemental Table 4**).

Discussion

In this feasibility study in ethnically diverse older adults with T2D with high blood glucose who were experiencing food insecurity, participation in a healthy produce prescription program over 12 wk was associated with substantial improvements in diet quality, significant weight loss, and improvements in blood lipid profile. In addition to these clinically relevant outcomes, the program led to reduced likelihood of study participants experiencing food insecurity. Participants reported very high levels of satisfaction with the components of the program including the quality and quantity of healthy foods provided, and the support received to change dietary behaviors; and that they extensively engaged with and utilized the program.

Overall diet quality as assessed by the AHEI score improved by ∼13 points. AHEI is related to better cardiometabolic outcomes in people with T2D in observational studies, including better long-term vascular health and lower risk of cardiovascular mortality (19, 24). Specifically, a 13-unit difference of

AHEI score was associated with an HR of 0.86 (95% CI: 0.83, 0.90) for all-cause mortality and 0.88 (95% CI: 0.82, 0.95) for cardiovascular deaths among people with T2D in the United States (19). Interpreted in this context, the improvement in AHEI score observed in our feasibility study could lead to meaningful reductions in clinical risk in people with T2D if the program was sustained over time.

Our findings also highlight the potential of the produce prescription program to reduce health inequity. Our study involved culturally and linguistically diverse individuals with lower education, lower income, and high rates of unemployment or retirement—groups known to more frequently experience poor diet quality, food insecurity, and diet-related NCDs (25–27). As such, the produce prescription program is an example of a clinical and public health initiative focused on prioritizing interventions that address health inequity, by supporting groups that experience poorer health outcomes to have greater improvements in health than the rest of the population (28).

Consistent with the significant improvements in diet quality, cardiometabolic risk factors including blood lipids, body weight, and BMI each meaningfully improved. Changes in HbA1c and BP were not statistically significant, although central estimates were promising and can aid in the design of a larger, longer-duration trial to assess these endpoints. Of note, reductions in adiposity occurred even though the intervention was not designed as a weight loss or caloric restriction program. Rather, the provided healthy food and dietary consultations focused on diet quality and how to prepare, cook, and consume healthful meals. The intervention was associated with a significant reduction in energy intake compared with habitual dietary intake at study baseline. To explain this finding, we conducted additional analyses which found a reduction in the amount of ultra-processed foods consumed. In a prior crossover randomized controlled trial (RCT) of inpatient adults in a metabolic ward, ad libitum daily energy intake was ∼2100 kJ (∼500 kcal) lower for a diet rich in unprocessed foods than for one rich in ultra-processed foods (with both diets matched for available calories, protein, carbohydrate, fat, sugar, sodium, and palatability) over 14 d of each diet; and this resulted in 0.9 kg weight loss (29). Although exact mechanisms remain to be elucidated, factors such as slower meal eating rates, improvements in gut microbiota composition and function, and changes in appetite regulatory hormones may contribute to the lower energy intake when switching from ultra-processed to unprocessed foods (29). Together with prior literature, our current results suggest that a produce prescription program may meaningfully improve diet quality, blood lipid risk factors, and adiposity in people with T2D and food insecurity.

The very high (92%) follow-up rate, together with very high patient-reported levels of satisfaction, both support the feasibility of conducting a long-term and large-scale RCT of the produce prescription intervention. The positive feedback from the participants across multiple aspects of the intervention compares favorably against other well-established medical interventions for T2D, such as insulin and glucagon-like peptide-1 receptor agonists (GLP1-AR) which have been reported to induce stress and are perceived as highly burdensome owing to the injection regimen needed for their administration (30–32).

There is increasing interest among governments, public health advocates, and health care providers and payers in the integration and reimbursement of nutrition interventions in health care systems (33). In Australia, despite tremendous diet-related NCD burdens, very few effective and reimbursed nutritional approaches are available to support improved diet for the management of NCDs, beyond government-supported access of ≤5 dietitian consultations per year. The novel findings of this study support the promise of healthy food prescriptions in Australia and indicate the need for appropriately designed and powered RCTs. Studies should also formally evaluate cost-effectiveness compared with other T2D interventions and if produce prescription is considered value for money to health care payers. The household weighted average cost of the healthy food boxes for the study was ∼$150 AUD/wk, and the average cost per person in participating households was ∼$7.50 AUD/meal. Although such cost is higher than for some commonly prescribed antihyperglycemic medications, it compares favorably with frozen healthy home meal delivery services (which typically cost between $10 and $16 per meal per person, unpublished observation) that are already subsidized for individuals with qualified disability under the Australian National Disability Insurance Scheme (NDIS). This suggests that the costs of the program may be within an acceptable range to health care payers. In addition, our finding of willingness of the participants to pay $50–$100 AUD/wk for the program also suggests a potential for various copayment models, based on ability to pay, to distribute the costs of the healthy foods between patients and health care systems.

A recently published systematic review identified only 13 mostly small, quasi-experimental investigations that have evaluated effects of produce prescription programs on dietary intakes and cardiometabolic risk factors. A meta-analysis of this limited body of evidence found increased intake of fruits and vegetables by 0.8 servings/d (95% CI: 0.2, 1.4 servings/d); reduction in BMI (in kg/m^2) by −0.6 (95% CI: −0.2, −1.1) and HbA1c by −0.8% (95% CI: −0.1%, −1.6%); and no significant effect on other risk factors including BP and blood lipids (2). Our study builds upon and extends these prior findings by assessing overall dietary quality using both repeated 24-h recalls and FFQs and by evaluating patients in Australia, informing the acceptability and potential benefits of a healthy food prescription program in Australia's health care systems. Our feasibility study suggests that programs like ours may be part of a suite of programs that health care systems and antipoverty policies can implement to support food-insecure individuals to achieve improved health outcomes.

Our study has important strengths. Whereas nearly all prior healthy food prescription programs provided only fruits and vegetables (2), we incorporated a wider range of healthy foods, including for example nuts and whole grains, potentially augmenting cardiometabolic benefits (34). This approach also enabled study participants to more readily prepare meals based on the foods provided. We demonstrated the acceptability and feasibility of using a home delivery service for the groceries, which may reduce participant burden and increase compliance—particularly because many individuals with food insecurity struggle with transportation or other access to stores selling healthy food (35–37). We used repeated 24-h diet recalls and the AHEI score to assess impact on dietary quality (38), which allowed detailed characterization of diet quality and food intake patterns. Having 2 separate measures of dietary change, using both repeated 24-h recalls and an FFQ, and using 2 different diet quality scores, are additional strengths of the study. Whereas 24-h diet recalls provide accurate estimates of group average intake based on details about an individual's entire dietary intake for single days, the FFQ has the strength of obtaining data on usual intake over the longer term. Only a few participants withdrew from the study, reducing the potential for bias due to loss to follow-up.

Potential limitations should be considered. Our pre–post design precludes confirmation of causality. It is also frequently the case that pre–post study designs overestimate the real effects of an intervention compared with evaluations based on RCTs, because individuals may change their reporting of intake in response to the intervention itself (39, 40). We were also unable to differentiate the impact of fortnightly dietetic support and the provision of the food boxes, and would see this as an integrated intervention where the sum is greater than the parts. Two 24-h diet recalls do not capture an individual's usual diet; however, such measures are valid for capturing comparisons of changes in means as analyzed in our study. Owing to the COVID-19 pandemic, assessment of some of the secondary outcomes relied on a combination of clinical measurements conducted by trained staff and home measurement by participants, resulting in increased measurement error. The completion rates of some secondary outcomes were also lower than for the primary outcome, reducing statistical power. Although circulating concentrations of magnesium and zinc are responsive to supplementation and long-term dietary changes, they are not strong biomarkers of diet intake (23, 41). We did not assess change in diabetes medication; nor whether participants accessed other food assistance programs externally.

In conclusion, participation in a healthy produce prescription intervention for 12 wk was associated with improved diet quality, blood lipid concentrations and levels, adiposity, and food insecurity in a diverse population of older Australians with T2D experiencing food insecurity. The magnitudes of observed benefits are of potential clinical significance, and these findings support the need to evaluate this intervention in additional, appropriately powered RCTs.

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Data Availability

Data described in the article, code book, and analytic code will be made available to editors upon request either before or after publication.

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