Medical school-based teaching kitchen improves HbA1c, blood pressure, and cholesterol for patients with type 2 diabetes: Results from a novel randomized controlled trial

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A B S T R A C T

Aims: A medical school-based teaching kitchen sought to establish proof-of-principle for its hands-on Mediterranean diet (MD)-based cooking and nutrition curriculum for patients with type 2 diabetes (T2D).

Methods: This pilot randomized controlled trial (RCT) allocated 27 patients with T2D between the control and GCCM arms. Mixed effects linear regression with repeated measures was used to investigate differences from baseline to 6 months. The primary and secondary endpoints were HbA1c (−0.3% [−27 mmol/mol]) and diastolic blood pressure (DBP) (−10 mmHg) and a 25% improved responses in dietary habits and attitudes and competencies in healthy nutrition.

Results: Compared to the control group, the GCCM group had superior HbA1c reduction (−0.4% vs. −0.3%, p = 0.575) that was not statistically significant. There were significantly greater reductions in the GCCM vs. control group for DBP (−4 vs. 7 mmHg, p = 0.037) and total cholesterol (−14 vs. 17 mg/dL, p = 0.044). There was a greater proportion increase though not significant of GCCM subjects compared to controls who mostly believed they could eat correct portions (18% vs. −11%, p = 0.124), and who used nutrition panels to make food choices (34% vs. 0%, p = 0.745).

Conclusion: This is the first known RCT demonstrating improved biometrics using a novel MD-based hands on cooking and nutrition curriculum for patients with T2D. These results suggest subsequent clinical trials are warranted on the grounds of documented feasibility and clinical efficacy.

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1. Introduction

Despite the critical link between obesity and the global diabetes epidemic amid widening health disparities, medical professionals are inadequately prepared to respond with financially and clinically effective nutrition lifestyle counseling for patients [1–3]. These hurdles have significant human and financial costs as diabetes is the seventh leading cause of mortality in the United States [4], resulting in $245 billion annually or 1 of every 5 health care dollars [5]. This epidemic is worsened by the negative impact of reduced access to healthy foods and underlying health disparities in the lower income minority food deserts, as noted by the American Diabetes Association’s 2013 Scientific Statement [6]. Delays in eliminating such racial and ethnic health inequities results in an additional $308 billion annual costs [7]. Improved diet is a promising approach that has been shown to result in significant reductions in disease incidence and burden, chiefly with the Mediterranean diet (MD) [8–11]. Currently, first line therapy for 90% of diabetes cases [12,13] features diet modification aimed at reducing patients’ serum glucose to optimal levels [14]. The standard for nutrition education for patients with documented patient diet improvements is registered dietitian (RD)-led medical nutrition therapy (MNT); [15,16] however, MNT programs have several key challenges including attrition rates up to 79%, for the sub-set of patients who follow their primary care physicians’ referral for RD counseling [17].

An alternative approach is pioneered by the Goldring Center for Culinary Medicine (GCCM) at Tulane University School of Medicine, to our knowledge the world’s first medical school-based research-oriented teaching kitchen. GCCM concurrently educates patients and physicians and trainees in nutrition for immediate and long-term social capital development by hands-on cooking and nutrition education [18–21]. Such operationalization of the MD as a scalable education model for medical schools nationally is needed as this diet has been extensively proven for health improvements in multiple chronic diseases [22,23]. Yet little evidence exists for interventions that equip people with the dietary habits, attitudes, and competencies needed to have sustainable health improvements even after the study period.

This pilot study, Cooking for Health Optimization with Patients (CHOP)-Diabetes Randomized Controlled Trial investigated feasibility and clinical activity of a novel, scalable MD-education model for patients with type 2 diabetes (T2D) including those from food desert areas affected by health inequities. This phase 1 trial sought to provide proof-of-principle for later phases of a multi-center RCT and comparative effectiveness trial. This current study is thus necessary for eventual testing of the null hypothesis that GCCM hands-on cooking and nutrition curriculum led by chefs, physicians, and medical students is equivalent to RD-led MNT for T2D nutrition management as a model replicable at medical schools nationally.

2. Subjects

Inclusion criterion was patients with diagnosed T2D. Exclusion criterion was pre-existing enrollment in another study involving interventions for diabetes. Institutional Review Board approval was granted through Tulane University for this study, and informed patient consent was collected.

3. Materials and methods

3.1. Design

This study uses a RCT design to compare RD-led MNT with chef, physician, and medical student-led hands-on cooking and nutrition classes. The six-module cooking and nutrition curriculum translates the MD for culture-specific kitchens across different socioeconomic levels. The control group received the standard of nutrition education, RD-led MNT, consisting of a one-time RD counseling visit with a referral opportunity to an American Diabetes Association-certified diabetes education class. The treatment group participated in the GCCM modules over 1.5 months as part of an evidence-based GCCM curriculum [18]. Each two-hour cooking class consisted of 30 min of didactic lessons and 90 min of cooking time. This pilot study and analysis was designed after a recent RCT provided evidence of MD improving HbA1c for patients with T2D [24].

3.2. Data

Biometric data were collected through chart reviews from baseline to 6 months after participation in the intervention or control groups according to regularly scheduled primary care clinic visits. Reviewers had to have knowledge of subjects’ study groups in order to collect biometric data at the correct 6 month time point following their completion of the last cooking class or their MNT session. Biometric data points included: HbA1c, systolic and diastolic blood pressures (SBP and DBP), total cholesterol, triglycerides, low density lipoproteins (LDL), high density lipoproteins (HDL), heart rate (HR), body mass index (BMI), and hypoglycemic agents and insulin. Psychometric data were collected through a survey developed from validated tools [1,2,20] at baseline and again at 1.5 months following the MNT session for control patients or the last GCCM class for intervention patients. These data points included: dietary habits, attitudes, and competencies (DAGs) for healthy shopping, meal-preparation, eating, and storage.

Food desert residence was defined by the United States Food and Drug Administration (USDA) as a subject claiming a permanent home address in a low-income census track where a significant number or share of residents are more than 1 mile (urban) or 10 miles (rural) from the nearest supermarket [25].

Survey responses used a multi-point Likert scale for dietary habits with different foods (9 point scale ranging from never per month to over 3 times daily), attitudes (5 points ranging from very unconfident to very confident), and competencies as frequencies of healthy eating actions (5 points ranging from never to always). Survey responses were dichotomized to aid in interpretation into: most times for dietary habits (over 4 times weekly versus less), mostly confident for attitudes (confident and very confident versus neither), and competencies (most of the times or always versus neither).
3.3. Endpoints

A permuted block design randomization scheme was used. The primary endpoint over six months of follow-up was HbA1c reduction of \(-0.3\% (-27\text{ mmol/mol})\) from baseline to follow-up within each group, with secondary endpoints including DBP reduction of 10 points and a 25% improved responses in the DAC sections from baseline to follow-up, based on the existing literature for such nutrition education interventions for this patient population [15,16,22,23,27].

3.4. Statistical analysis

This intention-to-treat statistical analysis used the mean biometric values with 95% confidence intervals, which were calculated after verifying normal distribution with the Shapiro–Wilk, Shapiro–Francia, and skewness and kurtosis tests for normality. Mixed effects linear regression with repeated time measures were used to investigate differences from baseline to 6 months for the GCCM compared to control groups [26]. An increase in a metric over the study period was represented as a positive value, and a decrease was represented as a negative value. This regression was used in place of ANOVA with repeated measures due this method producing correct standard errors for each effect automatically while handling unequal observations within subjects. This irregularity was contributed to by the sample including lower socioeconomic patients with less reliable transportation and communication capacities, with their subsequent irregular attendance at scheduled clinic visits or response to study staff attempts to contact them. Analyses were conducted using STATA 12.0 (StataCorp LP, College Station, TX, USA). A p-value <0.05 was considered statistically significant.

4. Results

4.1. Biometric results

In this study, 18 (67%) participated in the GCCM intervention with an average age of 62 years, 75% being African American, 67% female, and 46% residing in a USDA-defined food desert, all comparable to the control group. In contrast to the control group, the GCCM group had superior mean HbA1c reduction from baseline to 6 months, \(-0.4\% (-28\text{ mmol/mol})\) vs. \(-0.3\% (-27\text{ mmol/mol}) p = 0.575\), that was not statistically significant (Table 1). There were significantly greater reductions in the GCCM vs. control group for DBP (\(-4\% vs. 7\text{ mmHg}, p = 0.037\)) and total cholesterol (\(-14\% vs. 17\text{ mg/dL}, p = 0.044\)). The control group had a transient negative HbA1c improvement one month after the intervention; whereas, the improvement was sustained at 6 months for the GCCM group after the intervention lasted 1.5 months. GCCM subjects either had greater reductions or a slower rise in all negative risk factor biometrics compared to the control group, which instead worsened in these biometrics (SBP, DBP, total cholesterol, and LDL) with the exception of triglycerides and HR (Fig. 1). Both the GCCM and controls groups had similar pre-post BMI measurements.

The largest biometric difference for both groups was total cholesterol as the GCCM group decreased by 14 mg/dL (\(-0.4\text{ mmol/L}\)), compared to the control group increasing by 17 mg/dL (0.4 mmol/L). This inverse relationship is similar for LDL, as the GCCM group decreased by 6 mg/dL (\(-0.2\text{ mmol/L}\)) while the control group increased by 13 mg/dL (0.3 mmol/L). The control group did have a \(-20\text{ mg/dL} (-0.2\text{ mmol/L})\) greater drop in triglycerides than the GCCM group and 15 mg/dL (0.4 mmol/L) greater increase in HDL. Lipid lowering medications and insulin were similar for both groups at baseline, though there were two GCCM patients who ceased use of hypoglycemic agents, compared to no control patients coming off their medications during the study period. Metformin 1000 mg and Lantus (15–50 units) respectively were the most common hypoglycemic agent and insulin used for both groups.

4.2. Psychometric results

GCCM patients’ psychometrics improved but without statistical significance compared to the control group in their attitudes and competencies in healthy food shopping and eating (Fig. 2). The two largest differences in DAC changes between the groups were in competencies. There was a greater proportion increase of GCCM subjects compared to controls who mostly believed they could eat correct portions (18% vs. \(-11\%, p = 0.124\)), and who used nutrition panels to make food choices (34% vs. 0%, p = 0.745) (Table 1). The GCCM group lagged behind the control group in the proportion increasing their vegetable consumption (16% vs. 23%, p = 0.736) and fruits (0% vs. 22%, p = 0.255). Though both the GCCM and control subjects met the primary endpoint for HbA1c and missed the secondary endpoint for DBP, only the GCCM group met the 25% endpoint for DAC improvement, specifically in competencies for using nutrition panels in food choices.

5. Discussion

5.1. Contribution

This is the first randomized controlled trial to our knowledge that demonstrates improved blood pressure and lipid panels using a novel Mediterranean diet (MD)-based hands on cooking and nutrition curriculum for patients with T2D, including subjects from lower income food deserts. We also demonstrate non-significant HbA1c and healthy eating competency improvements for the cooking vs. control subjects. This intervention may thus provide evidence for a novel clinical education model able to operationalize the validated MD into a scalable competency and attitude modification model, particularly for patients burdened by healthy food disparities. These results suggest that subsequent clinical trial phases are warranted on the grounds of documented feasibility and clinical efficacy to confirm these findings. Global health system implications for this model include a potentially rapid diffusion of this education innovation through medical schools and hospitals to improve patients’ health in the short-term as 13 medical schools in the past two years have partnered with GCCM to provide this curriculum for their communities. The long-term implication is building workforce capacity of medical students and physicians better trained in nutrition counseling as they teach these classes for...
<table>
<thead>
<tr>
<th>Biometric</th>
<th>Control mean, 95% CI n = 9, 33%</th>
<th>Baseline to 6 months</th>
<th>GCCM mean, 95% CI n = 18, 67%</th>
<th>Baseline to 6 months</th>
<th>GCCM vs. control changes P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c % (mmol/mol)</td>
<td>8.1 (65), 6.8–9.4 (51–79)</td>
<td>−0.3 (−27)</td>
<td>7.6 (60), 7.1–8.1 (54–65)</td>
<td>−0.4 (−28)</td>
<td>0.575</td>
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<tr>
<td>Total chol</td>
<td>128 (1.5), 119–137 (1.3–1.5)</td>
<td>17 (0.4)</td>
<td>185 (2.1), 150–220 (1.7–2.5)</td>
<td>171 (1.9), 134–208 (1.5–2.4)</td>
<td>0.044</td>
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<tr>
<td>Trig</td>
<td>188 (2.1), 47–330 (0.5–3.7)</td>
<td>−58 (−0.7)</td>
<td>170 (1.9), 105–234 (1.2–2.6)</td>
<td>132 (1.5), 79–184 (0.9–2.1)</td>
<td>0.789</td>
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<tr>
<td>LDL</td>
<td>66 (0.7), 60–72 (0.7–0.8)</td>
<td>13 (0.3)</td>
<td>110 (1.2), 83–136 (0.9–1.6)</td>
<td>104 (1.2), 78–130 (0.9–1.5)</td>
<td>0.149</td>
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<tr>
<td>HDL</td>
<td>36 (0.4), 21–51 (0.2–0.6)</td>
<td>20 (0.5)</td>
<td>49 (0.6), 43–55 (0.5–0.6)</td>
<td>54 (0.6), 44–64 (0.5–0.7)</td>
<td>0.043</td>
</tr>
<tr>
<td>HR bpm</td>
<td>36, 66–80</td>
<td>34, 29–40</td>
<td>37, 32–41</td>
<td>37, 31–42</td>
<td>0.184</td>
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<tr>
<td>Mostlty believe can eat</td>
<td></td>
<td></td>
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<tr>
<td>correct portions</td>
<td>44%, 8–81</td>
<td>33%, −1–68</td>
<td>−11%</td>
<td>63%, 37–88</td>
<td>81%, 61–102</td>
</tr>
<tr>
<td>Eat vegetables most</td>
<td>33%, −1–68</td>
<td>56%, 19–92</td>
<td>23%</td>
<td>31%, 7–56</td>
<td>47%, 19–74</td>
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<tr>
<td>nights per week</td>
<td></td>
<td></td>
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<tr>
<td>Eat fruits most nights</td>
<td>11%, −12–34</td>
<td>33%, −1–68</td>
<td>22%</td>
<td>47%, 21–73</td>
<td>47%, 19–74</td>
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<tr>
<td>per week</td>
<td></td>
<td></td>
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<tr>
<td>Mostly use nutrition</td>
<td>22%, −8–53</td>
<td>22%, −8–53</td>
<td>0%</td>
<td>35%, 11–60</td>
<td>69%, 44–94</td>
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<tr>
<td>panel for food choices</td>
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Fig. 1 – Biometric changes for GCCM vs. control subjects from baseline to 6 months.

Fig. 2 – Psychometric changes in GCCM vs. control subject proportions from baseline to 6 months.
health disparity reduction and improved population health management.

The results should be considered against the study limitations. First, this is a smaller single-site pilot study investigating feasibility and early signs of clinical efficacy. Second, though rigorous 1:1 randomization was utilized with follow-up communication connecting subjects to their respective treatment or control exposures, there were a lower number of control subjects compared to treatment who completed their study exposure. The potential greater appeal of cooking classes or recruiter bias may have contributed to this, though control subjects were informed they could participate in the cooking classes six months after their MNT session. Medication changes by treating physicians may have also contributed to biometric changes, though this treatment bias was addressed by randomization, blinding of treating physicians to study group assignment, and medication comparison showing no notable differences between treatment and control groups.

The only systematic review and meta-analysis of different dietary interventions on T2D glycemic levels, lipids, and weight representing 20 RCTs (n = 3073 subjects) failed to show any other RCT achieving improved health metrics with hands-on cooking and nutrition education [27]. Rather than simply mirroring previous trials included in this large meta-analysis assessing the impact of MD foods on patients’ biometric health, this trial actually taught patients with T2D what to do with the foods they enjoy. Further, this study demonstrated superior HbA1c reduction with its MD-based intervention group compared to the MD groups in the meta-analysis, −0.4% (−28 mmol/mol) vs. −0.1% (−25 mmol/mol) that was sustained even after the intervention, including blood pressure and cholesterol improvements. Larger randomized controlled trials are needed to determine if the HbA1c impact is statistically significant. Yet this current study still suggests that subjects can improve their competencies in healthy eating with the MD even without ongoing education or provision of healthy MD foods. Superiority testing compared to the standard of care is proper to later clinical trial phases, but it is noteworthy that the GCCM treatment effect superiority may be an underestimate in diet-based supplemental management for diabetes, considering the majority of primary care physicians fail to provide any substantive nutrition counseling to their patients, let alone an RD referral [28, 29]. As the GCCM curriculum targets not only patients but also their current and future physicians, this intervention provides evidence for a capacity-building, clinically effective intervention that is implementable at medical schools and health centers nationally. Future research is needed to test the optimal dose and timing of GCCM education for diabetes and other nutrition-related chronic diseases, in addition to the optimal diffusion of this GCCM innovation through patients’ social networks to determine if such networks can help sustain the health improvements.

5.2. Conclusion

The results demonstrate the feasibility and signals of treatment efficacy needed to launch Phase II. This subsequent stage will include similar inclusion and exclusion criteria as Phase I, but will include: a third arm for no dietary change, cost analysis, an extended study period of 12 months, social network analysis to determine if health improvements from GCCM subjects extend to their friends and families in superior magnitude compared to the control group, and tertiary endpoint of 30% subjects from food desert areas. Thirteen medical schools and universities are currently participating in the multi-site study for assessing the GCCM curriculum among a 10,000+ medical student sample. Expansion of this dietary study at those sites thus should allow a larger Phase II multi-site trial, in addition to one novel enough to bridge the gap between meaningful lifestyle modifications in chronic management of T2D and improved patient outcomes in a sustainable and scalable manner. Conflict of interest statement

The authors declare that they have no conflict of interest.

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