Do Older Adults Aged 60–75 Years Benefit From Diabetes Behavioral Interventions?

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OBJECTIVE—In this secondary analysis, we examined whether older adults with diabetes (aged 60–75 years) could benefit from self-management interventions compared with younger adults. Seventy-one community-dwelling older adults and 151 younger adults were randomized to attend a structured behavioral group, an attention control group, or one-to-one education.

RESEARCH DESIGN AND METHODS—We measured A1C, self-care (3-day pedometer readings, blood glucose checks, and frequency of self-care), and psychosocial factors (quality of life, diabetes distress, frustration with self-care, depression, self-efficacy, and coping styles) at baseline and 3, 6, and 12 months postintervention.

RESULTS—Both older (age 67 ± 5 years, A1C 8.7 ± 0.8%, duration 20 ± 12 years, 30% type 1 diabetes, 83% white, 41% female) and younger (age 47 ± 9 years, A1C 9.2 ± 1.2%, 18 ± 12 years with diabetes, 59% type 1 diabetes, 82% white, 55% female) adults had improved A1C equally over time. Importantly, older and younger adults in the group conditions improved more and maintained improvements at 12 months (older structured behavioral group change in A1C −0.72 ± 1.4%, older control group −0.65 ± 0.9%, younger behavioral group −0.55 ± 1.2%, younger control group −0.43 ± 1.7%). Furthermore, frequency of self-care, glucose checks, depressive symptoms, quality of life, distress, frustration with self-care, self-efficacy, and emotional coping improved in older and younger participants at follow-up.

CONCLUSIONS—The findings suggest that, compared with younger adults, older adults receive equal glycemic benefit from participating in self-management interventions. Moreover, older adults showed the greatest glycemic improvement in the two group conditions. Clinicians can safely recommend group diabetes interventions to community-dwelling older adults with poor glycemic control.

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Diabetes self-management interventions are an integral component of diabetes care for all patients with diabetes. Meta-analyses of small diabetes education studies suggested that these interventions improve self-care and glycemic control, particularly when a behavioral intervention is incorporated (1–4), and supported that group-based education improves diabetes control in both the short and the long term (5). These findings have been confirmed in a recent randomized controlled trial (6). Although these studies have led to much emphasis on improving diabetes self-management and adherence to diabetes treatment prescriptions, minimal attention has been focused on the diabetes education needs of older adults.

Roughly 27% (∼11 million) of all adults aged ≥65 years have diabetes, the majority (90–95%) of whom have type 2 diabetes (7). Despite the large numbers of older adults with diabetes, how to best provide diabetes self-management support to this group remains unclear because of limited randomized controlled trial data. Older adults (aged ≥60 years) often are underrepresented in diabetes education interventions because of subtle changes in their functional, cognitive, and psychosocial statuses, which may affect diabetes self-care (8,9). Consequently, evidence-based guidelines for this age group are not well established (10). Although their physical and mental capacities may deteriorate over time, older adults’ ability to learn and manage diabetes may not diminish (11). Thus, thorough and systematic evaluation of diabetes education interventions for older adults is needed to provide evidence-based clinical care. In a secondary analysis of a randomized controlled trial (6), we examined whether community-dwelling older adults (aged 60–75 years) with type 1 or type 2 diabetes would benefit from self-management interventions similarly to younger and middle-aged adults. We also examined whether older adults would benefit from group versus individual self-management interventions.

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barriers to self-care. For example, each participant was required to check his or her glucose levels 6–8 times a day. During the classes, educators discussed glucose logs with the goal of helping participants to learn how food, medication, and exercise affected their glucose levels and possible actions they could take when levels were out of range. Additionally, each week, participants set broad goals (e.g., lose weight) and then more-specific goals (e.g., lose 1 lb this week). Participants wrote detailed steps for how they planned to accomplish each goal. At the next class, participants evaluated whether they performed the steps and whether the steps worked. If the steps did not work, participants reformulated their plans. The attention control arm consisted of a 5-session (over 6 weeks) manual-based, standard group diabetes education program. The attention control arm was matched to the structured experimental arm for 1) group classes, 2) diabetes education content (nutrition, exercise, medication, foot care, etc.), and 3) length of time and amount of contact with educators. The individual control arm comprised unlimited one-to-one sessions with diabetes educators for 6 months during which participants could discuss any aspect of their diabetes self-management.

All education was facilitated by separate teams of experienced certified diabetes educators (nurses and dietitians). The highly structured experimental arm was held in the behavioral research laboratory classroom, and the attention and individual control arms were held in the Joslin Clinic. All group sessions were separated by type of diabetes. Written curriculum, preapproved education materials, separate educator trainings, investigator observation of group education, and separate teams of trained, experienced diabetes educators prevented carryover of the education strategies and ensured integrity of the interventions. The Joslin Diabetes Center Committee on Human Subjects approved the protocol and all recruitment procedures and materials. All participants provided informed, written consent before participation.

Participants

Adults aged 18–75 years with type 1 or type 2 diabetes (A1C ≥7.5%) for at least 2 years, free of severe complications, and taking insulin or oral medications for 1 year were eligible for enrollment. Exclusion criteria were an inability to read and speak English; current or unplanned pregnancy; initiation of insulin treatment within 1 year; participation in diabetes education 6 months earlier; untreated proliferative retinopathy; severe complications of diabetes, including renal disease (albumin/creatinine >300 µg/mg); severe peripheral diabetic neuropathy, severe peripheral vascular disease, or severe arthritis that prevented brisk walking; symptomatic severe autonomic neuropathy; and a history of severe, unstable myocardial infarction, congestive heart failure, or other severe cardiac disease; or severe hypertension (systolic blood pressure ≥160/90 mmHg). Other exclusion criteria were dementia, mental retardation, organic mental disorder, bipolar disorder, schizophrenia, drug or alcohol abuse, and eating disorders. These exclusions were made to avoid confounding factors related to severe comorbidities, concurrent significant changes in mental status, and the effects of ongoing psychiatric treatment. Individuals with treated or stable major depression were eligible for participation. Inclusion and exclusion criteria were assessed through telephone screening, medical chart review, and a screening visit. Eligible participants were scheduled for a baseline and a randomization visit.

Randomization

Block randomization by type of diabetes was used to randomize participants to one of the three study groups. Educators and study physicians played no role in the randomization.

Measures

Data were collected at baseline and at 3, 6, and 12 months postintervention. The primary outcome was A1C measured by high-performance liquid chromatography ion capture method (Tosoh Medics, Inc., San Francisco, CA) (reference range 4.0–6.0%). We collected sociodemographic and health factors, including age, sex, race/ethnicity, education level, marital status, occupation, duration of diabetes, BMI, waist circumference, and blood pressure. We also collected mean 3-day pedometer readings (Accusplit Eagle; Accusplit, Inc., Livermore, CA) and mean daily blood glucose meter checks.

Participants completed the following validated psychosocial assessments:

- Self-Care Inventory-R (12): a 15-item scale measuring self-reported frequency of self-care behaviors on a 5-point Likert scale to which we added four questions about checking feet, eating heart-healthy foods, looking at blood glucose patterns, and knowing about blood pressure, A1C, and lipids.
- Diabetes Quality of Life Scale (13,14): a 46-item measure rated on a 5-point Likert scale where a high score indicates a higher diabetes-specific quality of life.
- Problem Areas In Diabetes (15,16): a 20-item scale that rates diabetes-related distress, including feelings related to living with diabetes and its treatment such as guilt, anger, frustration, depressed mood, worry, and fear, on a 5-point Likert scale.
- Problems with Diabetes Self-Management Scale (17): a 5-item measure of perceptions of the seriousness of self-care problems, including poor glucose control, meal planning, exercise, glucose monitoring, and medications.
- Brief Symptom Inventory (18): an 18-item measure that renders age- and gender-adjusted t scores of depressive and anxiety symptoms.
- Confidence in Diabetes Self-Care Scale (19): a 21-item measure rated on a 5-point Likert scale that assesses self-efficacy in diabetes, that is, the confidence individuals have in their ability to perform self-care tasks.
- Coping Styles (20,21): a 15-item measure assessing emotional coping (e.g., anger, impatience, anxiety) and self-controlled coping (e.g., stoicism, pragmatism) on a 4-point scale ranging from not at all like me to very much like me.

Statistical analysis

All analyses were performed with SAS version 9.2 statistical software (SAS Institute, Cary, NC). We examined descriptive statistics to ensure that data met statistical test assumptions. We compared baseline characteristics using χ², Wilcoxon two-sample, or Kruskal-Wallis tests to examine between-group differences. We generated 15 imputed datasets with the Markov chain Monte Carlo method (SAS Proc MI) (22) and analyzed the imputations with multivariate regression models. Finally, we combined the analysis results to derive a valid inference, thus accounting for missing data.

For this secondary data analysis, we used generalized linear models for longitudinal data to assess changes in A1C, self-care, and psychosocial outcomes over time. For testing the impact of the interventions
over time, we used generalized linear model repeated-measures ANOVA with contrasts and multiple comparison correction (Bonferroni). Included in the models were age, time, group effects, and their interactions. With interactions, we tested type of diabetes effects by intervention between older and younger adults. First, we compared mean changes in A1C from baseline to follow-up between the older (aged 60–75 years, n = 71) and the younger (aged 21–59, n = 151) groups. Next, we conducted an age-based analysis of the impact of the group versus individual self-management interventions on A1C at baseline and follow-up in the subset of older participants. Finally, we assessed changes in self-care and psychosocial outcomes at baseline and 3, 6, and 12 months for both older and younger participants.

**RESULTS**—Two hundred twenty-two adults with poorly controlled diabetes (age 53 ± 12 years, A1C 9.0 ± 1.1%, 18 ± 12 years with diabetes, 49% type 1) participated in the randomized controlled trial (6). Seventy-one older adults (age 67 ± 5 years, A1C 8.7 ± 0.8%, 19 ± 12 years with diabetes, 30% type 1 diabetes, 83% white, 41% female, 15 ± 3 years of education, 66% married, 37% retired) (Table 1) attended the structured behavioral group (n = 20), attention control group (n = 23), or individual control group (n = 28) interventions. At baseline, older participants in the three interventions did not differ by sociodemographic or health characteristics, frequency of self-care, or psychosocial factors; however, participants in the structured behavioral group had higher A1C levels than participants in both control groups (9.2 vs. 8.6 vs. 8.5%, P = 0.05). Similarly, 151 younger adults (age 47 ± 9 years, A1C 9.2 ± 1.2%, 18 ± 12 years with diabetes, 59% type 1 diabetes, 82% white, 55% female, 15 ± 2 years of education, 58% married, 15% retired) (Table 1) attended either the structured behavioral group (n = 54), attention control group (n = 52), or individual control group (n = 45) interventions. At baseline, the younger participants did not differ by sociodemographic or health characteristics, A1C levels, frequency of self-care, or psychosocial factors across interventions.

We first compared mean A1C changes over time in all three arms combined between older and younger participants. The linear mixed model showed no differences between older and younger participants in mean A1C levels at 3, 6, or 12 months postintervention (standardized beta [st b] = −0.002, SE 0.013, t statistic = −0.17, P = 0.87) (Fig. 1A and Table 2). Thus, in the total group, older and younger participants had improved A1C equally over time (Fig. 1A). Additionally, we observed no differences between older and younger participants for a given type of diabetes (P = 0.422 vs. 0.236 for type 1 and type 2, respectively).

We then compared mean A1C changes in older and younger participants by intervention through repeated-measures ANOVA with contrasts. Older and younger participants in the structured behavioral group improved equally over time (F = 0.22, P = 0.64) (Fig. 1B); however, older participants in the attention control group showed greater glycemic improvement than the younger participants (F = 14.19, P < 0.001) (Fig. 1C), whereas younger participants in the individual control group showed greater improvement than the older participants (F = 6.14, P = 0.01) (Fig. 1D). Importantly, both older and younger adults were able to maintain these A1C improvements similarly at 12 months in the group conditions.

**Table 1**—Baseline characteristics of older participants aged 60–75 years and younger participants aged <60 years randomly assigned to structured behavioral group, attention control group, or individual control group interventions

<table>
<thead>
<tr>
<th>Variable</th>
<th>All patients</th>
<th>Structured behavioral group</th>
<th>Attention control group</th>
<th>Individual control group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Older participants (n)</strong></td>
<td>71</td>
<td>20</td>
<td>23</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>A1C (%)</td>
<td>8.7 ± 0.8</td>
<td>9.2 ± 1.0</td>
<td>8.6 ± 0.6</td>
<td>8.5 ± 0.5</td>
<td>0.05</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>29.9 ± 6.2</td>
<td>29.0 ± 7.8</td>
<td>30.7 ± 5.6</td>
<td>29.8 ± 5.3</td>
<td>0.46</td>
</tr>
<tr>
<td>Age (years)</td>
<td>66.5 ± 4.5</td>
<td>66.6 ± 4.3</td>
<td>66.5 ± 4.4</td>
<td>66.6 ± 4.9</td>
<td>0.97</td>
</tr>
<tr>
<td>Diabetes duration (years)</td>
<td>19.6 ± 11.7</td>
<td>22.9 ± 16.6</td>
<td>17.6 ± 9.5</td>
<td>18.8 ± 8.8</td>
<td>0.73</td>
</tr>
<tr>
<td>Education (years)</td>
<td>14.7 ± 2.7</td>
<td>15.7 ± 2.1</td>
<td>15.0 ± 2.8</td>
<td>13.9 ± 2.7</td>
<td>0.07</td>
</tr>
<tr>
<td>Type 1 diabetes</td>
<td></td>
<td>29.6</td>
<td>30.0</td>
<td>26.1</td>
<td>0.89</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td>40.9</td>
<td>50.0</td>
<td>30.4</td>
<td>0.41</td>
</tr>
<tr>
<td>Non-Hispanic white</td>
<td></td>
<td>83.1</td>
<td>80.0</td>
<td>91.3</td>
<td>0.44</td>
</tr>
<tr>
<td>Married</td>
<td></td>
<td>66.2</td>
<td>50.0</td>
<td>69.6</td>
<td>0.14</td>
</tr>
<tr>
<td>Retired</td>
<td></td>
<td>36.6</td>
<td>30.0</td>
<td>30.4</td>
<td>0.19</td>
</tr>
<tr>
<td><strong>Younger participants (n)</strong></td>
<td>151</td>
<td>54</td>
<td>52</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>A1C (%)</td>
<td>9.2 ± 1.2</td>
<td>9.1 ± 1.1</td>
<td>9.3 ± 1.3</td>
<td>9.1 ± 1.2</td>
<td>0.75</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>30.0 ± 7.1</td>
<td>29.3 ± 6.0</td>
<td>31.0 ± 7.9</td>
<td>29.6 ± 7.5</td>
<td>0.62</td>
</tr>
<tr>
<td>Age (years)</td>
<td>46.8 ± 9.3</td>
<td>46.7 ± 8.8</td>
<td>47.0 ± 9.7</td>
<td>46.5 ± 9.5</td>
<td>0.92</td>
</tr>
<tr>
<td>Diabetes duration (years)</td>
<td>17.7 ± 11.7</td>
<td>16.0 ± 10.5</td>
<td>19.4 ± 12.6</td>
<td>17.7 ± 12.1</td>
<td>0.43</td>
</tr>
<tr>
<td>Education (years)</td>
<td>15.1 ± 2.2</td>
<td>15.2 ± 2.2</td>
<td>15.3 ± 2.2</td>
<td>14.8 ± 2.1</td>
<td>0.38</td>
</tr>
<tr>
<td>Type 1 diabetes</td>
<td>58.9</td>
<td>57.4</td>
<td>59.6</td>
<td>60.0</td>
<td>0.96</td>
</tr>
<tr>
<td>Female</td>
<td>55.0</td>
<td>44.4</td>
<td>55.8</td>
<td>66.7</td>
<td>0.09</td>
</tr>
<tr>
<td>Non-Hispanic white</td>
<td>81.5</td>
<td>79.6</td>
<td>82.7</td>
<td>82.2</td>
<td>0.91</td>
</tr>
<tr>
<td>Married</td>
<td>97.6</td>
<td>63.0</td>
<td>59.6</td>
<td>48.9</td>
<td>0.26</td>
</tr>
<tr>
<td>Retired</td>
<td>14.6</td>
<td>16.7</td>
<td>9.6</td>
<td>17.8</td>
<td>0.55</td>
</tr>
</tbody>
</table>

Data are mean ± SD or % unless otherwise indicated. P values are based on Wilcoxon two-sample or χ² test.
structured behavioral group change in A1C −0.72 ± 1.4%, older attention control group −0.65 ± 0.9%, younger structured behavioral group −0.55 ± 1.2%, younger attention control group −0.43 ± 1.7%).

Next, among the older participants only, we examined the impact of the two group interventions (structured behavioral and attention control) and the individual intervention on A1C at baseline and follow-up. Relative to baseline, the group interventions did not differ in mean A1C levels at 3 or 6 months, but they showed greater improvement in mean A1C levels at 12 months postintervention than did the individual intervention (P = 0.03 vs. 0.02, respectively) (Table 3). Older participants in the group interventions showed similar improvements in mean A1C levels at 12 months postintervention (P = 0.99). Of note, older adults with type 2 diabetes showed greater improvement in the group interventions than in the individual intervention over time, with Bonferroni correction used for multiple test comparison (P = 0.011). We observed no differences among older adults with type 1 diabetes by intervention (P = 0.428).

Finally, both older and younger participants showed improved frequency of self-reported self-care, daily blood glucose meter checks, depressive symptoms, diabetes-related quality of life, diabetes-related distress, frustration with self-care, diabetes-specific self-efficacy, and emotional coping postintervention (Supplementary Table 1). Frequency of self-reported self-care differed between older and younger participants at 3 (st b = 3.40, P = 0.02) and 6 months postintervention (st b = 4.91, P < 0.001), with younger participants showing greater improvement, but not at 12 months (st b = 1.50, P = 0.29). No other self-care or psychosocial variable differed by age group over time.

**CONCLUSIONS**—In a secondary analysis of a randomized controlled trial (6), we examined whether older adults with diabetes could benefit from self-management interventions compared with middle-aged and younger adults. We also examined whether older adults benefited from group versus individual self-management interventions. The data show that compared with the younger participants and attention control group served as the reference groups.

Table 2—Generalized linear model comparing mean change in A1C over time in younger versus older participants

<table>
<thead>
<tr>
<th>Estimate (SE)</th>
<th>t statistic</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>0.717 (0.126)</td>
<td>5.61</td>
</tr>
<tr>
<td>Structured behavioral group</td>
<td>−0.431 (0.174)</td>
<td>−2.48</td>
</tr>
<tr>
<td>Individual control group</td>
<td>−0.153 (0.182)</td>
<td>−0.84</td>
</tr>
<tr>
<td>Age</td>
<td>−0.859 (0.228)</td>
<td>−3.77</td>
</tr>
<tr>
<td>Time</td>
<td>−0.025 (0.008)</td>
<td>−3.19</td>
</tr>
<tr>
<td>Time × age</td>
<td>−0.002 (0.014)</td>
<td>−0.17</td>
</tr>
<tr>
<td>Structured behavioral group × age</td>
<td>0.970 (0.324)</td>
<td>3.00</td>
</tr>
<tr>
<td>Individual control group × age</td>
<td>0.315 (0.310)</td>
<td>1.02</td>
</tr>
</tbody>
</table>

The younger participants and attention control group served as the reference groups.
Table 3—Generalized linear model estimating mean change in A1C over time in older participants aged 60–75 years

<table>
<thead>
<tr>
<th></th>
<th>Estimate</th>
<th>SE</th>
<th>t</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>8.390</td>
<td>0.156</td>
<td>53.68</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Structured behavioral group</td>
<td>0.508</td>
<td>0.242</td>
<td>2.10</td>
<td>0.037</td>
</tr>
<tr>
<td>Attention control group</td>
<td>−0.017</td>
<td>0.233</td>
<td>−0.07</td>
<td>0.943</td>
</tr>
<tr>
<td>Month</td>
<td>−0.001</td>
<td>0.014</td>
<td>−0.08</td>
<td>0.935</td>
</tr>
<tr>
<td>Month × structured behavioral group</td>
<td>−0.040</td>
<td>0.021</td>
<td>−1.90</td>
<td>0.058</td>
</tr>
<tr>
<td>Month × attention control group</td>
<td>−0.045</td>
<td>0.020</td>
<td>−2.20</td>
<td>0.029</td>
</tr>
</tbody>
</table>

The individual control group served as the reference group.

adults in this study, the older adults received equal glycemic benefit from participating in self-management interventions, and this finding did not differ by type of diabetes. Moreover, older adults showed the greatest glycemic improvement in the two group interventions, with both groups achieving clinically significant improvements in A1C (≥0.5%). Of note, both older and younger adults in the group conditions maintained their A1C improvements similarly at 12 months postintervention. Finally, the diabetes self-management interventions had a positive impact on older and younger participants’ diabetes self-care and psychosocial outcomes. Improving diabetes self-management is important for improved health outcomes and reducing the economic burden of the disease (23). Diabetes self-management education improves self-care and glycemic outcomes (1–4), thus contributing to the reduction of diabetes-related morbidity and mortality and costs associated with diabetes care (24–26). Furthermore, the goals of diabetes education are the same for both younger and older adults, which are to 1) provide diabetes knowledge and skills training, 2) help to identify barriers to self-care, and 3) facilitate problem-solving and coping skills to improve self-care and achieve glycemic control (27). However, the majority of diabetes education programs are designed for younger patients or more recently diagnosed patients (28). As a result, only minimal progress has been made in the development of and evidence for successful interventions for older adults with diabetes, despite the emphasis on improving diabetes education interventions over the past 15–20 years.

In the present study, we showed that older adults (aged 60–75 years) compared with younger adults with diabetes received equal glycemic and psychosocial benefits from participating in self-management interventions. Furthermore, we demonstrated that these older adults were able to participate fully and improve glycemic control in both group and individual diabetes education. These findings are consistent with other diabetes education outcomes among older adults with diabetes (29,30). We also showed that older adults, particularly those with type 2 diabetes, received equal or more benefit from participating in group diabetes education classes compared with individual education. One possible explanation for this finding was the intensity of the group interventions. Participants randomized to group education received five 2-h sessions over 6 weeks that were devoted to nutrition, medication management, exercise, and blood glucose monitoring. Many interventions do not match the frequency and duration of education that we provided in this study (3,31,32).

Limitations to the study include the homogeneity of the study sample with regard to race/ethnicity (~18% minority), education, and participant self-selection. Finally, we did not recruit adults aged ≥76 years because these individuals may present with unique clinical (e.g., comorbidity, complications) and functional (e.g., impairment, disability) challenges that require special attention. For example, older diabetes patients are at greater risk for several geriatric syndromes, including depression, cognitive impairment, injurious falls, neuropathic pain, and urinary incontinence (33–35). These syndromes can have a deleterious effect on diabetes self-care (36–39), health status, and quality of life (40). Thus, the value of group versus individual diabetes education needs to be evaluated in the age ≥76 population. Importantly, future diabetes behavioral interventions need to address changes in older adult functional, cognitive, and psychosocial states and how best to assess and address these factors.

Diabetes self-management intervention is an important component of diabetes care for older adults. Importantly, the findings suggest that older adults up to age 75 receive equal or more benefit from participating in group versus individual interventions, and compared with younger adults, older adults receive equal glycemic benefit from participating in group diabetes education. Thus, clinicians can safely recommend group diabetes education classes for older patients with poor glycemic control. As the U.S. population ages and develops diabetes at a rapid rate, more high-quality research is needed to understand how normal aging processes influence how older adults learn about and take care of diabetes.

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The National Institute of Diabetes and Digestive and Kidney Diseases and these companies had no role in the conduct of the study or preparation of the manuscript.

E.A.B. assisted with analysis and interpretation of the data and wrote the manuscript. S.F. analyzed the quantitative data and reviewed and edited the manuscript. L.S., O.P.G., and A.E.C. acquired data, assisted with analysis and interpretation of the data, and reviewed and edited the manuscript. K.W. designed the study, acquired data, assisted with analysis and interpretation of the data, and reviewed and edited the manuscript. K.W. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Portions of this study were presented at the 72nd Scientific Sessions of the American
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