Exercise Training and Quality of Life in Individuals With Type 2 Diabetes

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OBJECTIVE—To establish whether exercise improves quality of life (QOL) in individuals with type 2 diabetes and which exercise modalities are involved.

RESEARCH DESIGN AND METHODS—Health Benefits of Aerobic and Resistance Training in individuals with type 2 Diabetes (HART-D; n = 262) was a 9-month exercise study comparing the effects of aerobic training, resistance training, or a combination of resistance and aerobic training versus a nonexercise control group on hemoglobin A1c (HbA1c) in sedentary individuals with type 2 diabetes. This study is an ancillary analysis that examined changes in QOL after exercise training using the Short Form-36 Health Survey questionnaire compared across treatment groups and with U.S. national norms.

RESULTS—The ancillary sample (n = 173) had high baseline QOL compared with U.S. national norms. The QOL physical component subscale (PCS) and the general health (GH) subscale were improved by all three exercise training conditions compared with the control group condition (resistance: PCS, \(P = 0.003\); GH, \(P = 0.003\); aerobic: PCS, \(P = 0.001\); GH, \(P = 0.024\); combined: PCS, \(P = 0.015\); GH, \(P = 0.024\)). The resistance training group had the most beneficial changes in bodily pain (\(P = 0.026\)), whereas physical functioning was most improved in the aerobic and combined condition groups (\(P = 0.025\) and \(P = 0.03\), respectively). The changes in the mental component score did not differ between the control group and any of the exercise groups (all \(P > 0.05\)). The combined training condition group had greater gains than the aerobic training condition group in the mental component score (\(P = 0.004\)), vitality (\(P = 0.031\)), and mental health (\(P = 0.008\)) and greater gains in vitality compared with the control group (\(P = 0.021\)).

CONCLUSIONS—Exercise improves QOL in individuals with type 2 diabetes. Combined aerobic/resistance exercise produces greater benefit in some QOL domains.

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Thus, past studies have provided evidence for a beneficial effect of exercise training interventions on QOL in nonmedically ill and in chronically ill populations; however, the largest trials to date conflict on whether exercise benefits mental health QOL in individuals with type 2 diabetes (14,15). The current study is an ancillary analysis from the Health Benefits of Aerobic and Resistance Training in individuals with type 2 diabetes (HART-D) trial (16). In this study, we attempted to further elucidate QOL outcomes by assessing changes in all QOL subscales measured on the Short-Form 36 Health Survey (SF-36) and compared SF-36 scores to U.S. national norms. Changes in QOL from preintervention to postintervention were compared across the four exercise conditions (aerobic only, resistance only, combined aerobic and resistance, and no-exercise control). We hypothesized that the resistance training group would demonstrate the greatest improvements in physical functioning QOL subscales, and that there would be no beneficial effects of exercise interventions on mental health QOL subscales.

RESEARCH DESIGN AND METHODS—HART-D was a 9-month exercise study comparing the effects of aerobic, resistance, or a combination of both on HbA1c measures in sedentary individuals with type 2 diabetes. The methods and main outcomes for HART-D have been previously published (16). A total of 262 sedentary adults with HbA1c levels of 6.5–11.0% were randomized (see Supplementary Fig. 1). Diabetes diagnosis was confirmed by a medical history review. Sedentary status was defined as not participating in exercise training sessions >20 min/day on ≥3 days/week and not participating in resistance training. Exclusion criteria included a BMI >48 kg/m², younger than 30 years old or older than 75 years old, blood pressure ≥160/100 mmHg, fasting triglycerides ≥500 mg/dL, use of an insulin pump, urine protein >100 mg/dL, history of stroke, advanced neuropathy, or retinopathy, or any serious medical condition that prevented participant adherence to the study protocol or ability to exercise safely. The protocol was approved by the Institutional Review Board at Pennington Biomedical Research Center, and all participants provided written informed consent.

Study design
Participants were randomized to one of four groups: aerobic training only; resistance training only; a combination of resistance and aerobic training (combination); or a nonexercise control group. The nonexercise control group participants were offered a weekly stretching and relaxation class and were asked to maintain their current level of activity during the 9-month study period. The primary outcome of this secondary analysis is the change in QOL measures (evaluated via the SF-36) after exercise training.

Weight and height
Weight was measured on a GSE 450 electronic scale (GSE Scale Systems; NOVI), and height was measured using a standard stadiometer. BMI was calculated as weight in kilograms divided by height in meters squared.

Quality of life
Change in QOL was evaluated using the SF-36 questionnaire (17,18). The SF-36 is a validated, self-administered questionnaire that measures QOL through the evaluation of physical functioning, role limitations attributable to physical health problems, bodily pain, general health, vitality, social functioning, emotional health, and mental health (17). QOL measures were administered at baseline and at the 9-month follow-up. Norm-based scores were used rather than raw scores, per the recommendation of the SF-36 user manual (18).

Exercise training
The exercise intervention was designed to have similar time requirements among the three exercise groups. The exercise prescription for each participant was standardized to body weight, and it was estimated that ~10–12 kcal/kg of body weight is equivalent to 150 min of moderate intensity exercise per week. The derivation of these calculations was based on the consensus physical activity recommendations (19). The exercise intensity for the aerobic exercise training was 50–80% of maximal oxygen consumption. The selected dose of exercise for the aerobic group was 12 kcal/kg per week and 10 kcal/kg for the combination exercise group. American College of Sports Medicine equations were used to estimate caloric expenditure rate and time required for each session (20). Participants were weighed weekly to calculate their personalized energy expenditure target. During weeks 12 and 24 only, the exercise dose was reduced by one-third to provide a recuperation week. Each session had 5-min warm-up and cool-down periods.

Participants in the resistance training group exercised 3 days/week, with each session consisting of two sets of four upper body exercises (bench press, seated row, shoulder press, and lateral pull-down), three sets of three leg exercises (leg press, extension, and flexion), and two sets of each abdominal crunches and back extensions. The combination exercise group had two resistance sessions per week, with each session consisting of one set of each of the aforementioned nine exercises. For the combination and resistance training groups, each session consisted of 10 to 12 repetitions. Once the participant was able to complete 12 repetitions for each set of exercises during two consecutive exercise sessions, the prescribed resistance (weight) was increased.

All exercise interventions were conducted at our on-site fitness center under the supervision of trained exercise interventionists. Instruction was provided on a one-on-one basis; however, participants often exercised with other study participants present because of the open environment of the fitness center. Resistance training was based on a circuit protocol, and aerobic exercise was performed primarily using the treadmill.

The stretching and relaxation condition was developed specifically for this trial (e.g., control group) and has not been validated. It included 45 min weekly sessions focused on increasing flexibility and reducing stress. The control group intervention was optional and was designed to be light-intensity stretching and relaxation exercises. The program was not intended to produce physiological or psychological benefits that may be observed in higher-intensity yoga exercise specifically designed to improve overall well-being. Rather, the intent of the nonexercise control condition was to provide a comparison control group that also provided a structured participation experience, thus promoting participant retention, and reduced the potential of any exposure bias between conditions (e.g., amount of time spent with study staff). Participants were engaged in the exercise interventions was a critical component of the study design (i.e., exercise prescriptions were designed to have similar time requirements standardized to body weight); therefore, the addition of an optional stretching and relaxation class to the three exercise condition groups could have introduced study bias. Participants in the stretching and relaxation
condition group were encouraged to maintain their prerandomization level of physical activity; participants who chose to engage in an exercise program outside of the study were neither encouraged nor discouraged to continue with those efforts.

**Blinding**
Separate intervention and assessment teams were used, and all assessment staff members were blinded to randomized assignment of participants to intervention groups. The clinical testing and exercise training laboratories were in separate buildings, and participants were reminded frequently to not disclose their group assignment to assessment staff.

**Statistical analysis**
All data were analyzed using SAS 9.2 (SAS Institute, Cary, NC). Because HART-D was designed as an efficacy study, “per-protocol” analyses limited to a subgroup of participants composed of all control participants and only the exercise group participants who met the criteria of at least 70% adherence to their exercise prescription for at least 6 months were performed. The current study modeled this “per-protocol” study approach and, as such, chose to only include those participants who met a minimum criteria of 70% attendance to their exercise prescription for at least 6 months and had SF-36 data at baseline and follow-up (n = 173). Simple linear regression was implemented to test for trend across sample characteristics at baseline. Bonferroni correction was applied when testing multiple comparisons. A linear mixed-effects model for repeated measures over time was used to determine the effect of the

| Characteristics of participants |
|---------------------------------|
| **Demographics**                |
| Age, years, mean (SD)           | 57.1 (8.2)  | 58.1 (8.3)  | 58.3 (8.9)  | 55.1 (7.5)  | 56.9 (7.9)  |
| Women, n (%)                    | 103 (59.5)  | 19 (67.9)   | 29 (55.8)   | 27 (61.4)   | 28 (57.1)   |
| Race/ethnicity, n (%)           | 101 (58.4)  | 15 (53.6)   | 31 (59.6)   | 25 (56.8)   | 30 (61.2)   |
| White                            | 66 (38.2)   | 12 (42.9)   | 21 (40.4)   | 19 (43.2)   | 14 (28.6)   |
| African American                 | 6 (3.5)     | 1 (3.6)     | 0 (0.0)     | 0 (0.0)     | 5 (10.2)    |
| Other                            | 112 (64.7)  | 14 (50.0)   | 38 (73.1)   | 29 (65.9)   | 31 (63.3)   |
| Married, n (%)                   | 8 (4.6)     | 1 (3.6)     | 3 (5.8)     | 1 (2.3)     | 3 (6.1)     |
| Smoking history, n (%)           | 50 (28.9)   | 9 (32.1)    | 15 (28.9)   | 12 (27.3)   | 14 (28.6)   |
| Current                          | 36 (20.8)   | 3 (10.7)    | 13 (25.0)   | 11 (25.0)   | 9 (18.4)    |
| Former                           | 21 (12.1)   | 2 (7.1)     | 6 (11.5)    | 5 (11.4)    | 8 (16.3)    |
| History of depression, n (%)     | 32 (18.5)   | 6 (21.4)    | 11 (21.2)   | 7 (15.9)    | 8 (16.3)    |
| History of anxiety, n (%)        | 53.6 (6.3)  | 53.2 (7.3)  | 53.5 (6.3)  | 53.8 (5.3)  | 53.6 (6.9)  |
| Antidepressant medication use, n (%) | 54.7 (7.3)  | 55.8 (6.7)  | 52.9 (7.9)  | 55.6 (5.7)  | 55.1 (8.1)  |
| QOL (SF-36 score)                | 50.2 (7.7)  | 51.2 (6.3)  | 49.7 (8.3)  | 49.8 (7.7)  | 50.6 (7.9)  |
| Component score                  | 51.8 (5.8)  | 51.2 (5.9)  | 50.9 (5.9)  | 52.0 (5.0)  | 52.7 (6.3)  |
| Physical                         | 51.6 (6.0)  | 51.1 (5.7)  | 51.4 (6.1)  | 51.5 (6.5)  | 52.1 (5.7)  |
| Role limitations                 | 53.6 (6.3)  | 53.2 (7.3)  | 53.5 (6.3)  | 53.8 (5.3)  | 53.6 (6.9)  |
| Bodily pain                      | 54.7 (7.3)  | 55.8 (6.7)  | 52.9 (7.9)  | 55.6 (5.7)  | 55.1 (8.1)  |
| General health                   | 50.2 (7.7)  | 51.2 (6.3)  | 49.7 (8.3)  | 49.8 (7.7)  | 50.6 (7.9)  |
| Component score                  | 51.8 (5.8)  | 51.2 (5.9)  | 50.9 (5.9)  | 52.0 (5.0)  | 52.7 (6.3)  |
| Mental                           | 54.3 (6.0)  | 54.2 (5.6)  | 54.9 (4.3)  | 54.4 (5.7)  | 53.6 (7.9)  |
| Social functioning               | 53.1 (5.9)  | 54.6 (2.8)  | 52.9 (7.1)  | 53.4 (4.1)  | 52.1 (6.9)  |
| Role limitations                 | 52.9 (8.5)  | 53.7 (8.0)  | 52.6 (8.7)  | 54.3 (8.9)  | 51.5 (8.4)  |
| Vitality                         | 55.3 (6.3)  | 57.6 (4.2)  | 55.6 (5.7)  | 55.0 (6.9)  | 53.7 (7.0)  |
| Mental health                    | 54.5 (6.4)  | 56.5 (4.5)  | 54.9 (6.2)  | 54.8 (5.9)  | 52.6 (7.5)  |
| Component score                  | 54.7 (6.0)  | 34.5 (6.3)  | 34.8 (5.6)  | 33.7 (5.8)  | 35.6 (6.5)  |
| Biometric data                   | 7.6 (1.0)   | 8.0 (1.5)   | 7.6 (0.9)   | 7.4 (0.9)   | 7.5 (0.9)   |
| HbA1c, %                         | 150.6 (36.6) | 163.0 (45.5) | 154.3 (38.8) | 142.1 (29.3) | 148.9 (34.5) |
| Fasting glucose, mg/dL           | 98.3 (19.3) | 96.9 (20.4) | 99.0 (16.8) | 95.7 (18.7) | 100.5 (21.8) |
| Weight, kg                       | 34.7 (6.0)  | 34.5 (6.3)  | 34.8 (5.6)  | 33.7 (5.8)  | 35.6 (6.5)  |
| Waist circumference, cm          | 116.2 (14.8) | 115.3 (16.9) | 114.3 (13.0) | 115.4 (14.9) | 119.4 (15.7) |

Data presented as mean (SD) unless otherwise stated. BMI was calculated as weight in kilograms divided by height in meters squared. To convert fasting glucose to mmol/L, multiply by 0.0555. No significant differences in demographic characteristics at baseline were revealed across the different treatment conditions.
intervention on QOL. Covariates included in the model were for age, weight, ethnicity, antidepressant use, and marital status. Results are presented as adjusted least squares means with 95% CIs. In addition, we used z-scores to compare QOL measures in our study sample to U.S. normative SF-36 data in individuals with type 2 diabetes (21). Statistical significance was set at $P \leq 0.05$ (two-tailed) throughout.

**RESULTS**

**Participant characteristics**

A total of 2,421 adults were screened for possible participation in the study and 262 participants were randomized. The main trial was completed by 243 participants. The QOL assessment materials were added to the protocol soon after the study was initiated because of a delay in obtaining copyright permissions, thus resulting in QOL data for 173 participants.

Baseline characteristics of the analytic sample are presented in Table 1. The mean age of participants was 57.1 (SD 8.2) years. The majority of participants were female (59.5%), white (58.4%), and married (64.7%). Few current smokers participated in the trial (4.6%). Antidepressant medication was used by 18.5% of the participants, and a history of depression and anxiety was reported by 20.8% and 12.1% of participants, respectively. Mean BMI at study entry was 34.7 (SD 6.0) kg/m² and the mean HbA₁c was 7.6% (SD 1.0%). These characteristics were similar to those of the main study cohort, and no significant differences in demographic characteristics at baseline were revealed across the different treatment conditions.

United States population norms for individuals with type 2 diabetes and baseline means for the current study sample are presented in Table 1. The United States population norms for individuals with type 2 diabetes and baseline means for the current study sample had higher mean SF-36 QOL scores compared to the control condition group ($P \leq 0.05$). However, greater improvements in the mental component summary score did not differ between the control group and any of the exercise groups (all $P > 0.05$). In addition to all three exercise condition groups having greater improvements than the control group ($P = 0.001, 0.004, 0.005, 0.004$), respectively. The mental health subscale also improved more for all three exercise conditions compared with the control condition ($P = 0.003, 0.004, 0.004$). On the physical functioning subscale, the aerobic training condition group and the combined training condition group had greater improvements than the control condition group ($P = 0.025$ and $P = 0.03$, respectively). The bodily pain subscale was higher postintervention in all condition groups; however, the resistance training group reported a smaller increase in bodily pain compared with the control condition group ($P = 0.026$).

### Table 2—Quality of life by subgroup

| Ethnicity category | N  | Physical component score, mean (SD) | Mental component score, mean (SD) |
|-------------------|----|-------------------------------------|----------------------------------|
| White             | 101| 52.0 (5.9)                          | 53.7 (6.8)                       |
| African American  | 66 | 51.0 (5.8)                          | 55.5 (5.8)                       |
| Other             | 6  | 55.4 (1.7)                          | 55.6 (4.6)                       |
| Age, years        |    |                                     |                                  |
| 35–54             | 63 | 51.6 (5.7)                          | 54.0 (5.9)                       |
| 55–64             | 80 | 52.2 (5.9)                          | 54.5 (6.5)                       |
| 65+               | 30 | 51.1 (5.9)                          | 55.5 (7.1)                       |
| BMI range         |    |                                     |                                  |
| 18.5 to <25       | 9  | 54.6 (5.5)                          | 55.0 (6.0)                       |
| 25 to <30         | 31 | 53.2 (4.7)                          | 53.5 (6.2)                       |
| 30 to <35         | 50 | 52.8 (5.4)                          | 55.1 (6.1)                       |
| 35 to <40         | 45 | 51.2 (5.0)                          | 54.5 (6.1)                       |
| 40 or more        | 38 | 49.3 (7.1)                          | 54.2 (7.6)                       |
| Smoking status    |    |                                     |                                  |
| Never             | 115| 51.3 (6.3)                          | 54.4 (6.4)                       |
| Former            | 50 | 52.9 (4.6)                          | 54.4 (6.9)                       |
| Current           | 8  | 52.1 (3.8)                          | 55.7 (3.9)                       |
| Marital status    |    |                                     |                                  |
| Not married       | 52 | 51.7 (6.3)                          | 52.8 (7.7)$^*$                   |
| Married           | 112| 51.9 (5.4)                          | 55.2 (5.6)                       |
| Antidepressant use|    |                                     |                                  |
| No                | 141| 52.2 (5.5)                          | 55.5 (5.0)$^+$                   |
| Yes               | 32 | 50.0 (6.7)                          | 49.9 (9.5)                       |
| HbA₁c, % category |    |                                     |                                  |
| <7.0              | 58 | 51.3 (6.3)                          | 52.7 (7.9)$^+$                   |
| ≥7.0              | 113| 52.0 (5.5)                          | 55.5 (3.3)                       |

*Individuals who were not married had lower mental component summary scores than those who were married ($P < 0.05$). ‡Individuals using antidepressants had lower mental component summary scores than those not using antidepressants ($P < 0.05$). †Individuals with HbA₁c < 7.0% had a significantly lower mental component score than those with HbA₁c ≥ 7.0% ($P < 0.05$). ‡Individuals with BMI ≥ 40 kg/m² had a lower physical component score than those with BMI between 25 and 35 kg/m² ($P < 0.05$).
Quality of life in diabetes

The combined training also was associated with gains relative to the aerobic training on the vitality (P = 0.031) and mental health (P = 0.008) subscales. The only mental health QOL subscale for which an exercise group benefited relative to the control group was the vitality subscale. Specifically, the combined training group had greater gains in vitality than the control group (P = 0.021).

CONCLUSIONS—The primary finding of the current study is that exercise training interventions improved physical health QOL in individuals with type 2 diabetes mellitus regardless of training modality (aerobic, resistance, or combined). In addition, although the effects of the exercise training on mental health QOL were limited, the improvements in mental QOL often favored combined aerobic and resistance training. Overall, our data suggest that exercise training has a beneficial effect on QOL in individuals with type 2 diabetes, who generally report reduced QOL compared with individuals without diabetes.

In the current study, all exercise groups reported greater improvements in overall physical health QOL (i.e., physical component summary) compared with the control group. These results can be contrasted to the DARE trial (14) and IDES study (15), which previously have investigated the effect of different exercise training modalities in a randomized control trial of comparable size and design as HART-D (16). In the DARE trial, Reid et al. (14) found improvements in physical QOL with resistance training but not with aerobic or combined aerobic and resistance training. Differences in study design between these two studies may have contributed to the discrepancy. For example, the training intervention used by Reid et al. lasted five and one-half months, compared with 9 months for the current study, suggesting that it may require a greater amount of time of exercise training before improvements in QOL become apparent. This hypothesis is supported by the IDES study (15), which found a beneficial effect on physical QOL during a 12-month intervention. Additionally, in the study by Reid et al., the combined exercise intervention group spent twice as long exercising per week as the aerobic or resistance intervention condition group, whereas in the current study the amount of time exercising was held constant across condition groups. In the IDES study (15), the authors noted that significant improvement in physical QOL occurred only when exercise volume increased >17.5 metabolic equivalents \( \cdot h^{-1} \cdot \text{week}^{-1} \). We did not measure dose response for our intervention but similarly found benefits in physical QOL regardless of treatment modality. The findings of the current study are supported by data from large randomized trials of individuals without diabetes (2–5) and trials of individuals with type 2 diabetes showing improvements in QOL after an exercise training intervention (6,10–13,15,22).

There are other notable results regarding physical health QOL from the current study. Reported bodily pain was higher postintervention compared with preintervention in all condition groups, including the control condition group. It is possible that increases in bodily pain in the exercise condition groups were related to muscle soreness caused by the exercise training. Of note, resistance training, but not aerobic or combined training, appeared to mitigate the increase in pain that participants experienced over the course of the study. In contrast, aerobic and combined training showed improvements in QOL after an exercise training intervention (6,10–13,15,22).

No differences were found in the mental health QOL summary score for...
any of the exercise groups compared with the control group. These results are different from those found by Reid et al. (14), who unexpectedly found that mental QOL improved most in the nonexercise control group compared to the three exercise intervention groups. These results also differ from those of Nicolucci et al. (15), who found benefits in mental health QOL with exercise. In the current study, vitality was the only mental health QOL subscale for which any exercise group showed improvements relative to the control condition group, with the combined aerobic and resistance training condition resulting in increased vitality ratings compared with the control condition. The lack of improvements in mental QOL for the exercise groups compared with the control group on all subscales except vitality is notable and contrasts with studies of nondiabetic populations showing more widespread mental QOL gains with exercise. It is possible that the baseline level of mental QOL impacted our results. The mental health QOL for our study sample was higher than average on initiation of the program, and it is possible that individuals with lower baseline mental QOL receive more benefit from exercise. Additionally, it may be that longer exercise programs are necessary to improve mental QOL. It is notable that of the two comparable studies discussed (14,15), the shorter study, which was 5.5 months (14), found mental QOL decreases with exercise whereas the longer study, which was 12 months (15) reported mental health QOL gains. Our study, of intermediate length (9 months), found minimal mental health QOL changes.

These results have significant clinical implications. For a number of QOL measures, the combined exercise training condition appeared to have more beneficial effects on mental QOL compared with the aerobic condition. For example, the combined group had greater increases in the mental component summary and the mental health subscale compared with the aerobic group. Given that the combined exercise condition was the only condition to significantly improve HbA1c in the main outcomes study (16), and given that all conditions were similarly effective in improving physical health QOL, these disparate effects of exercise modality on mental health QOL support recommendations for individuals with type 2 diabetes to adopt exercise programs with combined aerobic and resistance training. At the same time, these results demonstrate that regardless of the exercise modality, a moderately intensive exercise program consistent with public health recommendations in sedentary individuals with diabetes is likely to result in improved QOL, and that exercise interventions should be further integrated into standard care for individuals with diabetes.

This study has certain limitations. The participants in the current study had higher baseline QOL compared with normative U.S. samples of individuals with diabetes. In general, the diabetes in HART-D participants was relatively well controlled, with average HbA1c levels of 7.6%. Therefore, it is possible that an exercise intervention could have a more substantial impact on QOL in individuals with lower baseline QOL and more poorly controlled diabetes.

A potential concern is that the control condition (e.g., stretching and relaxation group) could have biased the outcomes by providing a therapeutic effect on QOL. The control condition was designed to be light in intensity, thus not reaching any therapeutic level to trigger improvements in physiological or emotional health outcomes. Because of low attendance in the stretching and relaxation class (22.7%), it is reasonable to assume that this condition...
Quality of life in diabetes
did not have any significant effect on QOL as a group.
This study also has notable strengths. We studied a large sample that included substantial African American representation, and we used a carefully controlled, randomized study design. In addition, the exercise intervention was controlled for exercise dose, and all exercise groups participated in a similar amount of training.

In conclusion, the current study provides evidence that adults with type 2 diabetes mellitus are likely to benefit from adopting an exercise training regimen regardless of exercise training modality (aerobic, resistance, or a combination of both). Given the overall beneficial effects of combined training on many aspects of QOL and the previously reported benefits of combined training on glycemic control, a combined aerobic and resistance approach is particularly worthy of further study.

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V.H.M. contributed to the study concept and design, acquisition of data, critical revisions of the manuscript for important intellectual content, and administrative, technical, and material support; analyzed and interpreted the data; drafted the manuscript; and conducted statistical analyses. M.A.M. contributed to the study concept and design, critical revisions of the manuscript for important intellectual content, and analyzed and interpreted the data; drafted the manuscript; and conducted statistical analyses. M.M.B. contributed to study concept and design, and material support; analyzed and interpreted the data; obtained funding, drafted the manuscript, and conducted statistical analyses. V.H.M. had full access to all of the data and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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