Objective: To develop and test a family-centered behavioral weight loss intervention for African American adults with type 2 diabetes.

Methods: In this randomized trial, dyads consisting of an African American adult with overweight or obesity and type 2 diabetes (index participant) paired with a family partner with overweight or obesity but not diagnosed with diabetes were assigned in a 2:1 ratio to a 20-week special intervention (SI) or delayed intervention (DI) control group. The primary outcome was weight loss among index participants at the 20-week follow-up.

Results: One hundred eight participants (54 dyads—36 (SI) and 18 (DI) dyads) were enrolled: 81% females; mean age, 51 years; mean weight, 103 kg; and mean BMI, 37 kg/m². At post-intervention, 96 participants (89%) returned for follow-up measures. Among index participants, mean difference in weight loss between groups was 2.5.0 kg, P < 0.0001 (2.3.6 kg loss among SI; 1.4 kg gain in DI). SI index participants showed significantly greater improvements in hemoglobin A1c, depressive symptoms, family interactions, and dietary, physical activity, and diabetes self-care behaviors. SI family partners also had significant weight loss (2.3.9 kg (SI) vs. 2.1.0 kg (DI), P = 0.02).

Conclusions: A family-centered, behavioral weight loss intervention led to clinically significant short-term weight loss among family dyads.

Introduction

Obesity is estimated to account for 64% to 74% of new type 2 diabetes cases in the United States (1). There is solid evidence from the Diabetes Prevention Program (DPP) (2) trial that modest weight loss (about 7% of body weight) can reduce the onset of diabetes by about half among persons with overweight and obesity who are at high risk for diabetes. Further, modest weight loss among those with diabetes, achieved through lifestyle behavior changes, provides cardiometabolic and other health benefits (3). In the Look AHEAD trial, 1-year weight losses of 5% to <10% of initial body weight were significantly associated with clinically meaningful improvements in glycemia, blood pressure, triglycerides, and HDL cholesterol (3). Thus, weight loss among those with and at risk for diabetes would lessen the burden of diabetes and reduce its social and economic costs.

The higher than average burden of type 2 diabetes and its complications among African Americans is well documented (4) and is linked to the above-average rates of overweight and obesity in this population (5-7). Although black participants in the DPP lost...
statistically and clinically significant amounts of weight, the DPP and other randomized controlled trials (RCTs) of intensive behavioral weight loss interventions have reported less weight loss among African Americans, especially women, compared with white participants (8-11). These differential outcomes suggest the need for adaptations of current evidence-based interventions to improve their effectiveness among African Americans. This need, which also applies to diabetes self-management behaviors, may be met in part by interventions adapted to the social, family, and community contexts of African Americans (12,13). Family-centered weight loss interventions for those with diagnosed diabetes may also help to prevent diabetes onset in participating family members whose body weight puts them at risk of developing diabetes. Family characteristics such as low family cohesion, high family conflict, low levels of family organization, poor communication, low spouse involvement, too rigid or too permeable family boundaries, and high levels of criticism and hostility have been associated with poor diabetes outcomes (14). In African Americans, family conflict and togetherness are two factors that emerge as significant influences on diabetes management (14,15). Limited data also suggest that family cohesion (or family closeness and togetherness) and family support may also be important to weight loss success among African Americans (16,17).

Despite the potential promise of family-centered approaches to weight loss among African Americans with diabetes, to date we have not identified published reports of any such interventions. A systematic review of family-centered self-management interventions among adults with diabetes identified 10 studies, but none included African Americans (18). Similarly, a previous review of family involvement in weight control interventions (19) reported no studies with African Americans, and only one included an overweight adult family member (20). To fill this research gap, we developed and tested a family-centered behavioral weight loss intervention for African American adults with overweight/obesity and type 2 diabetes and a family partner with overweight/obesity but not diagnosed with diabetes. We hypothesized that a family-centered intervention would lead to better weight loss outcomes among African American adults with type 2 diabetes, compared with delayed intervention (DI) controls. This report includes primary and secondary study outcomes for weight, lifestyle and diabetes self-care behaviors, family interactions, and psychosocial outcomes.

Methods

Study design

The Family PArtners in Lifestyle Support (PALS) study was a RCT designed to test a primary outcome of weight change in African American adults with type 2 diabetes (index participants), while also evaluating secondary outcomes of: weight change among family partners; hemoglobin A1c changes among index participants; and changes among both index and family partners in lifestyle behaviors (diet and physical activity (PA)), blood pressure, and selected family and psychosocial factors.

Study participants

Study participants represented a mix of community and clinical samples recruited via TV ads, email messages, flyers, and a clinical diabetes registry with referrals from diabetes care providers. Inclusion criteria for index participants were: self-described African American aged 21 to 75 years; self-reported diagnosis of type 2 diabetes; BMI between 25 and 47 kg/m², inclusive; hemoglobin A1c value ≤11%; currently under the care of a health care provider; able to participate in moderate-intensity PA; and willing to participate with a family partner not diagnosed with diabetes. Family members were eligible to be partners if they did not have a diagnosis of diabetes and lived with or were married (for at least 1 year) to the index person, or were self-described blood relatives who had regular, ongoing contact with the index participant, whether or not they lived with the index person (14). Family partners had the same age, BMI, and PA inclusion criteria as index participants but did not have to be African American (see Supporting Information for exclusion criteria).

The Physical Activity Readiness Questionnaire (21) was used to screen participants for the ability to safely engage in moderate-intensity PA. Participants with a positive Physical Activity Readiness Questionnaire were required to obtain written clearance from their clinician before participating in the PA component of the study intervention. The study was conducted at both the University of North Carolina at Chapel Hill and Duke University and the Institutional Review Boards at both institutions approved and monitored the study. All participants provided written informed consent.

The flow of recruitment and randomization is depicted in Figure 1. Trained research staff prescreened prospective participants by phone for study eligibility and motivation to participate. Since randomization to the study required paired participants, during the prescreening call the index person was asked to identify the family partner of choice. After completing baseline data collection, eligible participant dyads (index participant + family partner) were randomly assigned in a 2:1 ratio to either the family-based special intervention (SI) or the DI control group. Permutated block randomization with block sizes of 3, 6, and 9 was used to ensure balance between study groups. Enrollment began in January 2011 and follow-up data collection was completed in September 2012.

Intervention

The weight loss component of Family PALS was informed by several evidence-based behavioral weight loss interventions (2,22-24), and we conducted formative research (both qualitative and quantitative) to guide our cultural adaptations of the intervention’s family component. Constructs from social interdependence (25) and social support (26) theories provided additional theoretical support for the family-centered adaptations. According to social interdependence theory, when the accomplishment of an individual’s goals is affected by the actions of others there is “social interdependence,” which can be positive (cooperative) or negative (competitive). This positive interdependence leads individuals to encourage and facilitate each other’s efforts to achieve goals and thus mutually supports goal achievement (25). Elements of social support (mutual help and exchange of resources) effective communication, and constructive management of conflict are key components of these positive interactions (25). In Family PALS, this social interdependence (cooperative) was hypothesized to positively influence weight loss and diabetes self-management both within dyads and among the group of dyads attending intervention sessions.

Family dyads were encouraged to attend 20 weekly group-based sessions together. Each session was offered at least twice weekly.
for groups of no more than 10 dyads. Sessions were facilitated by trained staff (registered dietitians) and planned to last 120 min with the following components: participant weigh-in; group sharing and problem solving; discussion of a weight control topic (nutrition, PA, or behavior change); opportunity to try a different PA and/or taste-test a new food or recipe; and goal setting. The study weight loss goal was set at $10$ lb (4.5 kg) (minimum rate of $0.5$ lb ($0.2$ kg) weekly). Caloric intake to promote modest weight loss was individualized; the dietary pattern promoted high-quality carbohydrates (fruits, vegetables, whole grains, and beans) and fats (vegetable oil and nuts) (27). For PA, we recommended at least 180 up to a maximum of 300 min/week of moderate-intensity PA (5). Participant incentives were also included; points were earned for reaching weekly behavioral goals (self-monitoring, fruit and vegetables servings, calories, PA). At sessions #8 and #19, earned points could be redeemed for items such as exercise DVDs, handheld weights, small kitchen appliances, and bathroom scales. For the DI participants, no educational materials about weight loss were provided during the study period; participants received one newsletter with Family PALS program updates. After post-intervention data collection, DI participants were offered a 6-week program based on Family PALS.
Family-Based Weight Loss in Diabetes  
Samuel-Hodge et al.

A “Family Time” component (Table 1) was included in every other group session. This was a 20-min segment focused on improving family interactions (cognitive and behavioral skills), rather than diabetes education for family members, which is consistent with evidence that this focus leads to greater effectiveness in family-centered interventions for chronic disease management (28,29). Our adaptations were also guided by formative research conducted specifically to inform the Family PALS intervention (30) and consultations with a clinical psychologist. Formative data (from focus groups and validated family surveys administered to African Americans with diabetes) suggested addressing family issues of: unresolved diabetes conflict, communication, togetherness (cohesion), support, and problem solving.

Data collection
We collected baseline and follow-up data during in-person visits and by telephone. Except for A1c and diabetes-specific surveys which were administered only to index participants, all other study measures were collected from all participants. At baseline, weight and height were measured without shoes using an electronic scale; blood pressure was measured with an automated monitor and A1c with a standard point-of-care A1c test kit (see Supporting Information for measurement details).

In-person data collection included validated questionnaires to assess PA readiness (baseline only), PA behaviors, dietary intake, diabetes self-management, and health-related quality of life. Phone-administered surveys assessed depressive symptoms, family interactions, and diabetes-related perceptions of control and family conflict (see Supporting Information for survey details). Staff not masked to participants’ group assignment recorded a single weight measure at each intervention group session. At 20 weeks post-baseline, follow-up weight (two measures) and in-person and telephone interviews were administered by trained staff masked to participants’ randomization assignment. Participants received $15 cash for each office visit and a $10 check for each data collection phone call.

| Session number | Topic | Behavioral target area(s) |
|----------------|-------|---------------------------|
| 1              | Introduction to family goals (connect, communicate, cope) | ● Strengthening family ties by encouraging family members to set goals for connecting and communicating well with each other and using good coping strategies to deal with family stress. |
| 3              | Family goals and PAL wishes | ● Share views on family interactions (cohesion, conflict, communication, etc.) from general and diabetes perspectives. ● Discuss family goals and PAL wishes for better family connection, communication, and coping. |
| 5              | Family conversations | ● Share feelings and challenges related to favorite foods. Focus on how family influences feelings about food and sometimes create food-related challenges. ● Discuss solutions for challenging food-related issues. ● Target: communication; problem solving. |
| 7              | Family portrait | ● Describe family support for diabetes and weight loss. ● Share what’s good and what could be improved to support better health in families. ● Target: family communication; family support. |
| 9              | Personal views about diabetes and weight | ● Recognizing old patterns that don’t work and trying a new way of doing things. ● Discuss how beliefs and feelings might be influencing behaviors related to weight loss and diabetes. ● Target: problem solving. |
| 11             | Family conflict–Part 1 (conflict resolution) | ● Introduce strategies for conflict resolution in families. ● Discuss emotional hot button issues that lead to conflict in families and then problem-solve to generate a list of possible solutions or coping strategies. |
| 13             | Family conflict–Part 2 (emotional management) | ● Discuss how family communications can influence mood, thoughts, and behaviors. This segment addresses emotional management (e.g., in the context of food policing by family members). |
| 15             | Listening and I-statements | ● Practice skills in better family communication (general and/or diabetes specific). ● Practice using active listening and I-statements. ● Generate key strategies for improving family communication. |
| 17             | Family collage | ● Practice skills in better family communication (general and/or diabetes specific) using a family collage to facilitate discussion. |
| 19             | My family now | ● Share progress in reaching family goals made at the first session. ● Share successes, challenges, and plans for the future. |

This 20-min intervention component was incorporated into every other session of the 20-week intervention. Participants were provided with a worksheet 1 week prior and encouraged to reflect on the topic to be discussed. A family trivia question was also included in each segment as an icebreaker.

A “Family Time” component was included in every other group session. This was a 20-min segment focused on improving family interactions (cognitive and behavioral skills), rather than diabetes education for family members, which is consistent with evidence that this focus leads to greater effectiveness in family-centered interventions for chronic disease management (28,29). Our adaptations were also guided by formative research conducted specifically to inform the Family PALS intervention (30) and consultations with a clinical psychologist. Formative data (from focus groups and validated family surveys administered to African Americans with diabetes) suggested addressing family issues of: unresolved diabetes conflict, communication, togetherness (cohesion), support, and problem solving.

Data collection
We collected baseline and follow-up data during in-person visits and by telephone. Except for A1c and diabetes-specific surveys which were administered only to index participants, all other study measures were collected from all participants. At baseline, weight and height were measured without shoes using an electronic scale; blood pressure was measured with an automated monitor and A1c with a standard point-of-care A1c test kit (see Supporting Information for measurement details).

In-person data collection included validated questionnaires to assess PA readiness (baseline only), PA behaviors, dietary intake, diabetes self-management, and health-related quality of life. Phone-administered surveys assessed depressive symptoms, family interactions, and diabetes-related perceptions of control and family conflict (see Supporting Information for survey details). Staff not masked to participants’ group assignment recorded a single weight measure at each intervention group session. At 20 weeks post-baseline, follow-up weight (two measures) and in-person and telephone interviews were administered by trained staff masked to participants’ randomization assignment. Participants received $15 cash for each office visit and a $10 check for each data collection phone call.
Sample size and statistical methods

Sample size for the primary study outcome (comparison of index participants’ weight change in the SI and DI groups at 20 weeks) was based on the following assumptions: a two-sided test of significance at \( \alpha = 0.05 \), random allocation ratio of 2:1, 4 kg standard deviation (SD) of weight change (10,31), and 15% anticipated attrition rate. We estimated enrolling 75 index participants (50 in intervention arm and 25 in DI arm), which provides 80% power to detect a difference of 2.8 kg in mean weight change between groups.

Baseline study sample characteristics were summarized using descriptive statistics and compared between study groups using \( \chi^2 \) and t-tests. For the analysis of the primary outcome, we used a simple \( \chi^2 \)-test under the intention-to-treat (ITT) principle, with last observations carried forward for missing values at follow-up. Additional analyses were conducted using linear regression models adjusting for baseline weight and baseline variables that were considered predictors of weight loss or substantially different between study groups. Analyses for secondary outcomes and weight loss among dyads were similarly performed using t-tests and linear regression models with data from those who completed the study. SAS software (Version 9.3, SAS Institute, Cary, NC) was used for all analyses.

Results

Participant characteristics

As depicted in Figure 1, 108 (54 dyads) completed baseline measures and made up the study sample. Table 2 shows baseline characteristics of study participants. Overall, 81% of participants were females, with a mean age of 51 years and educational attainment of 15 years, and nearly half had annual household incomes between $30,000 and $70,000. Among the dyads, only 37% had family partners in the same household as the index participant. Slightly over half lived in households with a spouse or someone like a spouse (data not shown), but only 29% of dyads included a spouse. On average, participants weighed 103 kg with a mean BMI of 37 kg/m². Among index participants, 24% were treated with insulin and 78% diagnosed with hypertension. Baseline values for health-related quality of life were slightly higher than the established norms for persons with diabetes (for both mental and physical scores) (32). Index and family partners scored similarly for family interactions and psychosocial factors.

Outcomes

After the intervention, we obtained weight data from 89% (96 of 108) of participants overall (90% (65 of 72) among SI and 86% (31 of 36) in the DI group). Participants lost to follow-up were significantly younger than those assessed (43 vs. 52 years; \( P < 0.01 \)). We also assessed serious adverse events (events considered life-threatening or requiring an emergency room visit or an overnight hospital stay). Only two events were reported (a heart attack and hospital stay for chest pains related to blood clots); neither was study-related.

Index participants

For the primary outcome of weight change comparison between index participants by study group (ITT), the unadjusted mean difference in weight loss between groups was \(-5.0 \text{ kg}, P < 0.0001\), with a mean weight loss of \(-3.6 \text{ kg}\) among SI and a \(1.4 \text{ kg}\) gain in DI index participants. Adjusting for baseline weight, diastolic blood pressure, and frequency of eating breakfast, the mean weight loss difference between groups (ITT) was \(-4.9 \text{ kg}, P = 0.0001\). In the analysis of weight change among completers (Table 3 and Figure 2), the adjusted mean difference in weight between groups was \(-5.7 \text{ kg}, P < 0.0001\) (4.3 kg loss (SI) vs. 1.4 kg gain (DI)). Among SI index participants, 42% (14 of 33) lost at least 5% of initial weight, compared with none in DI.

Group session attendance among SI index participants averaged 75% (15 of 20 sessions). Figure 3 shows the pattern of weight loss by attendance (for completers only) at the weekly intervention sessions. For completers, 17 sessions was the median number attended. Weight loss was greater with more sessions attended (\(-7.1 \text{ kg}\) among those attending all 20 session, \(-5.9 \text{ kg}\) for those attending 17 or more sessions, and \(-1.1 \text{ kg}\) with fewer than 17 sessions attended). Moreover, index participants who attended more sessions and lost more weight on average started at a higher baseline weight.

For secondary outcomes in index participants (Table 3), adjusted analyses showed significantly greater improvements in SI for A1c, dietary and PA behaviors, depressive symptoms, diabetes control perceptions, and self-care behaviors. For blood pressure, the mean difference between groups (\(-7.9 \text{ mm Hg}\) systolic and \(-5.3 \text{ mm Hg}\) diastolic) did not retain statistical significance after full model adjustments.

Family partners

Table 4 shows secondary outcomes for family partners. Like index participants, family partners (SI) also showed positive changes in weight, although smaller on average. Among family partners, the unadjusted mean change from baseline was \(-3.9 \text{ kg}\) (SI) and \(-1.0 \text{ kg}\) (DI), for a mean difference of \(-2.9 \text{ kg}, P = 0.02\). The adjusted mean difference between groups was \(-3.7 \text{ kg}, P = 0.006\) (\(-4.1 \text{ kg}\) (SI) and \(-0.5 \text{ kg}\) (DI)). Among SI family partners, 38% (12 of 32) lost at least 5% of initial body weight. Overall, among both SI family partners and index participants, 28% of completers (18 of 65) lost at least 5% of initial body weight, and 40% (26 of 65) lost at least 5% (range 5.3–15.4%).

In Figure 3, weight change among family partners (completers only) is also depicted by attendance. Family partners attended slightly fewer sessions on average than their index partners (12 vs. 15 sessions, respectively). Weight change was \(-5.5 \text{ kg}\) among those attending all 20 sessions, \(-4.3 \text{ kg}\) for those attending 14 or more sessions, and \(-1.1 \text{ kg}\) with fewer than 14 sessions attended. In contrast to index participants, family partners who lost more weight and attended more sessions on average had a lower initial weight. Other outcomes among family partners (Table 4) were generally not significantly different when comparing SI and DI. Improvement in physical well-being among SI family members was the only outcome where the adjusted difference remained statistically significant (\(P = 0.05\)).

Family and dyadic outcomes

Tables 3 and 4 also show changes in selected family interaction scores. Among index participants, adjusted differences in family cohesion and support of diet and PA were all significant, with greater improvements among SI compared with DI. Similarly,
### TABLE 2 Participant characteristics

| Demographic | Index participants (n = 54) | Family partners (n = 54) | Special intervention | Index (n = 36) | Family (n = 36) | Delayed intervention | Index (n = 18) | Family (n = 18) |
|-------------|-----------------------------|--------------------------|----------------------|---------------|----------------|----------------------|---------------|----------------|
| Age (yr)    | 54                          | 48                        | 55                   | 46            | 53             | 50                   |               |                |
| Female, n (%) | 40 (74)                    | 47 (87)                   | 27 (75)              | 34 (94)       | 13 (72)        | 13 (72)              |               |                |
| Educational achievement (yr) | 14.8 (5)       | 15.3 (6)                  | 15.0 (5)             | 15.7 (6)      | 14.5 (5)       | 14.9 (6)             |               |                |
| Annual family income, n (%) |
| < $30,000     | 9 (17)                     | 7 (13)                    | 15 (42)              | 13 (36)       | 5 (28)         | 5 (28)               |               |                |
| $30,000–< $70,000 | 22 (41)                  | 19 (35)                   | 17 (47)              | 14 (39)       | 11 (61)        | 10 (56)              |               |                |
| ≥ $70,000     | 17 (31)                    | 16 (30)                   | 4 (11)               | 9 (25)        | 2 (11)         | 3 (17)               |               |                |
| Spouse or spouse-like person in household, n (%) | 26 (48)            | 35 (65)                   | 14 (39)              | 23 (64)       | 12 (67)        | 12 (67)              |               |                |
| Employed full time, n (%) | 34 (63)            | 37 (68)                   | 23 (64)              | 24 (67)       | 11 (61)        | 13 (72)              |               |                |
| Family relationships |                      |                          |                      |               |                |                      |               |                |
| Family partner in household with index participant, n (%) | 20 (37)          | -                         | 10 (28)              | 10 (56)       |               | -                    |               |                |
| Family partner as spouse-like spouse, n (%) | 16 (29)             | -                         | 8 (22)               | -             | 8 (44)         | -                    |               |                |
| Physiologic and diabetes treatment |                  |                          |                      |               |                |                      |               |                |
| Weight (kg)  | 106.0                      | 99.2                      | 105.4                | 101.0         | 107.1          | 95.3                 |               |                |
| BMI (kg/m²)  | 37.8                       | 36.4                      | 38.1                 | 36.6          | 37.1           | 36.1                 |               |                |
| A1c (%)      | 7.5                        | 6.0                       | 7.5                  | 6.1           | 7.6            | 5.9                  |               |                |
| Systolic blood pressure (mm Hg) | 127                      | 126                       | 130                  | 128           | 121            | 124                  |               |                |
| Diastolic blood pressure (mm Hg) | 77                       | 80                        | 78                   | 81            | 75             | 76                   |               |                |
| Years diagnosed with diabetes | 6.6                        | -                         | 7.3                  | -             | 5.4            | -                    |               |                |
| Diabetes treated with insulin, n (%) | 13 (24)            | -                         | 7 (19)               | -             | 6 (33)         | -                    |               |                |
| Diagnosed hypertension, n (%) | 42 (78)             | 28 (52)                   | 30 (63)              | 18 (50)       | 12 (67)        | 10 (56)              |               |                |
| Lifestyle, diabetes self-care, family interactions |                  |                          |                      |               |                |                      |               |                |
| Moderate-intensity PA (min/wk) | 95.1                      | 91.2                      | 103.8                | 107.2         | 77.8           | 59.2                 |               |                |
| Vigorous-intensity PA (min/wk) | 12.6                      | 21.1                      | 14.3                 | 25.8          | 9.2            | 11.7                 |               |                |
| Fruit, vegetables (servings/d) | 3.4                        | 3.5                       | 3.5                  | 3.4           | 3.2            | 3.6                  |               |                |
| Fruits, vegetables, beans score | 15.7                      | 15.2                      | 16.1                 | 15.1          | 14.8           | 15.5                 |               |                |
| Diabetes self-care composite score, five behaviors^d | 19.3                      | -                         | 20.3                 | -             | 17.2           | -                    |               |                |
| Health-related quality of life, mental composite score^e | 52.6                      | 52.7                      | 53.4                 | 52.4          | 51.0           | 53.4                 |               |                |
| Health-related quality of life, physical composite score^e | 46.3                      | 49.3                      | 46.2                 | 48.5          | 46.6           | 51.1                 |               |                |
| Depressive symptoms (PHQ8), sum score^f | 3.6                        | 3.1                       | 3.5                  | 3.8           | 3.8            | 1.8                  |               |                |
| Perceived diabetes negative control, mean score^g | 1.9                        | -                         | 1.9                  | -             | 1.9            | -                    |               |                |
| Family support for diet score^h | 2.9                        | 2.5                       | 2.8                  | 2.5           | 3.1            | 2.6                  |               |                |
| Family support for PA score^h | 2.7                        | 2.3                       | 2.5                  | 2.3           | 3.0            | 2.3                  |               |                |
| Family cohesion, sum score | 36.7                      | 38.3                      | 36.9                 | 38.3          | 36.2           | 38.3                 |               |                |
| Family problem-solving communication score, total | 21.5                      | 22.3                      | 21.6                 | 21.3          | 21.2           | 24.2                 |               |                |
| Affirming communication | 11.3                      | 11.9                      | 11.3                 | 11.6          | 11.4           | 12.7                 |               |                |
| Incendiary communication | 4.9                        | 4.7                       | 4.7                  | 5.3           | 5.2            | 3.5                  |               |                |
| Unresolved diabetes conflict, mean score^g | 1.7                        | -                         | 1.7                  | -             | 1.8            | -                    |               |                |

^aData are expressed as means (SD) unless otherwise indicated.
^bIndex (n = 6) and family partners (n = 12) chose not to provide income information.
^cDiastolic blood pressure was the only variable significantly different (P < 0.05) between SI and DI.
^dComposite score for self-monitoring blood glucose, PA, dietary and medication adherence, and foot self-checks.
^eSF-12 (32), norm-based mean composite score for mental and physical well-being; norms for persons with diabetes: mental composite score mean (SD) = 47.3 (10.7); physical composite score mean (SD) = 41.5 (11.1).
^fA score of 10 or greater is considered major depression.
^gLower score is a better score; max mean score = 4.
^hHigher score is a better score; max mean score = 5.
PA, physical activity.
| Index participants | Study group | No. assessed | Change in mean (SE) | Difference between groups (SE) | P | Adjusted change from baseline (SE) | Adjusted difference between groups (SE) | Adjusted P |
|---------------------|-------------|--------------|---------------------|-------------------------------|---|-------------------------------|-------------------------------------|-----------|
| Weight (kg)         | Intervention | 33 | -4.4 (0.75) | -5.9 (1.1) | <0.0001 | -4.3 (0.74) | -5.7 (1.1) | <0.0001 |
|                     | Control     | 16 | 1.6 (0.92)  | -0.51 (0.31) | 1.6 (0.25) | 0.44 (0.30) | -2.0 (0.38) | <0.0001 |
| BMI (kg/m²)         | Intervention | 33 | -1.6 (0.27) | -2.1 (0.40) | <0.0001 | -1.6 (0.25) | -2.0 (0.38) | <0.0001 |
|                     | Control     | 16 | 0.51 (0.31) | 0.04 (0.38) | 0.51 (0.15) | 0.38 (0.38) | 0.89 (0.43) | 0.04      |
| A1c (%)             | Intervention | 33 | -0.45 (0.19) | -0.71 (0.38) | 0.07 | -0.51 (0.15) | -0.89 (0.43) | 0.13      |
|                     | Control     | 16 | 0.26 (0.34) | 0.04 (0.38) | 0.13 (0.19) | 0.13 (0.33) | 0.58      |
| Systolic blood pressure (mm Hg) | Intervention | 33 | -9.0 (2.7) | -7.9 (3.9) | 0.05 | -7.1 (2.3) | -1.9 (3.4) | 0.58      |
|                     | Control     | 16 | -1.2 (2.9)  | -5.2 (2.9)  | 0.05 | -5.2 (2.3) | -1.9 (3.4) | 0.58      |
| Diastolic blood pressure (mm Hg) | Intervention | 33 | -6.7 (1.7) | -5.3 (2.5) | 0.05 | -6.3 (1.6) | -4.2 (2.7) | 0.13      |
|                     | Control     | 16 | -1.3 (2.0)  | -2.1 (1.9)  | 0.05 | -2.1 (1.9) | -4.2 (2.7) | 0.13      |
| Fruit and vegetable servings per day | Intervention | 33 | 0.47 (0.29) | 0.75 (0.37) | <0.05 | 0.58 (0.26) | 1.1 (0.33) | 0.002     |
|                     | Control     | 16 | -0.28 (0.23) | -0.51 (0.21) | <0.05 | 0.58 (0.26) | 1.1 (0.33) | 0.002     |
| Recreational walk time (self-report) (min/wk) | Intervention | 33 | 74.7 (22.2) | 73.5 (25.8) | 0.007 | 77.4 (23.7) | 81.6 (32.5) | 0.02      |
|                     | Control     | 16 | 1.3 (14.2)  | 0.27 (12.5) | 0.007 | 77.4 (23.7) | 81.6 (32.5) | 0.02      |
| Vigorous-intensity PA (self-report) (min/wk) | Intervention | 33 | 38.8 (12.3) | 45.3 (14.9) | 0.004 | 38.0 (12.2) | 43.0 (5.9) | 0.001     |
|                     | Control     | 16 | -6.6 (9.0)  | -5.0 (5.9)  | 0.004 | 38.0 (12.2) | 43.0 (5.9) | 0.001     |
| Depressive symptoms score (PHQ8) | Intervention | 34 | -2.1 (0.60) | -2.1 (1.00) | 0.04 | -2.2 (0.24) | -2.4 (0.91) | 0.01      |
|                     | Control     | 16 | 0.00 (0.83) | 0.16 (0.82) | 0.04 | 0.16 (0.82) | 0.01      |
| Mental composite score (SF-12) | Intervention | 33 | 0.06 (0.90) | 1.0 (1.6) | 0.52 | 0.84 (0.69) | 1.4 (1.3) | 0.31      |
|                     | Control     | 16 | 1.1 (1.3)   | 0.54 (1.1)  | 0.52 | 0.54 (1.1) | 0.31      |
| Physical composite score (SF-12) | Intervention | 33 | 3.9 (1.7) | 2.2 (2.0) | 0.28 | 3.7 (1.1) | 1.5 (1.2) | 0.23      |
|                     | Control     | 16 | 1.8 (1.1)   | 2.2 (0.8)   | 0.28 | 2.2 (1.1) | 2.2 (0.8) | 0.23      |
| Perceived diabetes negative control, mean score | Intervention | 34 | -0.38 (0.12) | -0.36 (0.15) | 0.03 | -0.39 (0.09) | -0.38 (0.16) | 0.02      |
|                     | Control     | 16 | -0.02 (0.11) | -0.02 (0.11) | 0.03 | -0.39 (0.09) | -0.38 (0.16) | 0.02      |
| Diabetes self-care composite 7-day score | Intervention | 33 | 3.9 (0.69) | 2.3 (1.8) | 0.20 | 4.3 (0.74) | 3.4 (1.6) | 0.03      |
|                     | Control     | 16 | 1.6 (1.6)   | 0.83 (1.4)  | 0.20 | 4.3 (0.74) | 3.4 (1.6) | 0.03      |
| Family support for diet | Intervention | 31 | 0.62 (0.12) | 0.78 (0.24) | 0.002 | 0.67 (0.22) | 0.74 (0.22) | 0.002     |
|                     | Control     | 14 | -0.15 (0.22) | -0.13 (0.17) | 0.002 | 0.67 (0.22) | 0.74 (0.22) | 0.002     |
| Family support for PA | Intervention | 32 | 0.62 (0.17) | 0.91 (0.23) | 0.003 | 0.55 (0.16) | 0.69 (0.21) | 0.002     |
|                     | Control     | 15 | -0.29 (0.17) | -0.15 (0.14) | 0.003 | 0.55 (0.16) | 0.69 (0.21) | 0.002     |
| Family cohesion | Intervention | 34 | 1.5 (0.89) | 2.2 (1.3) | 0.10 | 1.9 (0.78) | 3.6 (1.0) | 0.001     |
|                     | Control     | 16 | -0.67 (0.90) | -1.6 (0.73) | 0.10 | 1.9 (0.78) | 3.6 (1.0) | 0.001     |
significant improvements were seen in family cohesion and support among SI compared with DI family members; the adjusted difference in family support for PA, however, was marginally statistically significant ($P < .05$). Overall, improvements in family problem-solving communication and unresolved conflict were significantly improved in SI index participants, but compared with DI the adjusted differences were mostly marginally significant. In contrast, among family members the only significant adjusted difference between SI versus DI was in affirming communication (where DI showed greater improvements).

We also explored a number of outcomes based on the behaviors of the dyads or pairs. For example, we looked at how attending sessions together affected weight loss outcomes and how weight loss in the family partner related to weight loss in the index participant. Pairs attending more than 10 sessions (median) together lost 2.4 kg more than those attending 10 or fewer together ($-2.4$ vs. $-3.3$ kg, respectively; $P = .11$). Furthermore, index participants lost more weight when paired family members lost at least 5% of initial weight ($r = 0.24$, $P = 0.46$) or 7% ($r = 0.47$, $P = 0.24$). As expected, with the small sample sizes these findings are not statistically significant.

**Discussion**

Our results demonstrate that a culturally-adapted, family-centered behavioral weight loss intervention for African American adults with diabetes (Family PALS) leads to clinically meaningful weight loss in both index and family partners. We also observed...
improvements among index participants in A1c, self-reported lifestyle and diabetes self-management behaviors, depressive symptoms, quality of life, and perceptions of diabetes control. Moreover, family interactions (cohesion and social support) improved significantly in both index and family partners. Thus, our study adds meaningfully to the very limited research literature on family-centered interventions for adults with diabetes. More importantly, to our knowledge, it is the first family-centered weight loss intervention study conducted among African American adults with diabetes.

For patients with type 2 diabetes it is challenging to lose weight because of a host of metabolic and psychological factors, including the fact that many conventional glucose-lowering agents (like insulin) commonly result in weight gain (33). Because of this, we are particularly encouraged by our weight loss findings. In a recent review (11) for example, among DPP translations including African Americans with diabetes, two studies with over 82% African Americans reported weight loss outcomes of $\pm 2.2$ and $\pm 2.5$ kg (at 1 year and 9 months, respectively), while a third reported $\pm 3.0$ kg weight loss (at 6 months) among African Americans (39% of sample). Family PALS weight loss of $\pm 3.6$ kg exceeds these outcomes, despite a shorter weight loss period of 5 months. Furthermore, Family PALS had 42% of SI index participants lose at least 5% of their initial weight which exceeds the 36% observed after 1 year of weight loss treatment among African Americans in the Look AHEAD trial (3). With a family-centered adaptation of evidence-based interventions, we have demonstrated the potential to greatly improve weight loss outcomes among African Americans with diabetes.

For family partners, weight loss outcomes are equally encouraging. Among PALS family partners, weight loss was slightly higher than that among high-support family partners in SHARE (17) ($\pm 3.4$ kg vs. $\pm 2.8$ kg, respectively, using adjusted ITT values). Even more interesting are the descriptive findings suggesting that weight loss was much higher for the index participant when pairs attended more sessions together, and when the family member lost more weight. These observations are similar to those in the SHARE study (17) where greater participation by family/friend partners was associated with greater weight loss. In Family PALS, like other weight loss interventions, attendance was significantly correlated with weight loss ($r = 0.48$, $P = 0.005$). Family PALS’ overall attendance (67%), however, was not higher than that of several studies (68% to 75%) in a recent review of behavioral weight loss interventions among African Americans (9). These findings suggest the importance of pairs attending sessions together.

There are a number of strengths in the development, implementation, and testing of Family PALS. To address the concern that many family-centered chronic disease management interventions have not included input from professionals in the field of psychology or family therapy (34), we sought guidance (during intervention development) from a clinical psychologist with expertise in this field. Consistent with the recommendations from recent reviews of family-centered interventions among adult with diabetes (18,35) and family interventions for weight control (19), we started with a theory-informed intervention, measured family behaviors and interactions as well as a number of psychosocial outcomes, and evaluated outcomes among family members. Other strengths include good retention (89%) and overall intervention uptake (67%), which exceed rates reported in most single-site weight loss studies among African Americans (9,11).

Study limitations include a short study duration, self-reported PA measurement, point-of-care A1c measurement, and a DI control group. The comparison of the study intervention with a control group receiving no treatment during the RCT period, limits what Family PALS tells us about the added benefit of actively including family members in weight loss among African American patients with diabetes. For example, we do not know what the difference in weight loss would be if Family PALS was compared with a similar intervention without active participation of family partners and the
### TABLE 4 Secondary study outcomes: family partners’ changes from baseline to 20 weeks and mean differences between groups (completers)\(^a\)

| Family partners | Study group | No. assessed | Change in mean (SE) | Difference between groups (SE) | \(P\) | Adjusted change from baseline (SE) | Adjusted difference between groups (SE) | \(P\) |
|-----------------|-------------|-------------|---------------------|--------------------------------|--------|-----------------------------------|------------------------------------------|--------|
| Weight (kg)     | Intervention | 32          | −3.9 (0.97)         | −2.9 (1.2)                     | 0.02   | −4.1 (0.76)                       | −3.7 (1.3)                              | 0.006  |
|                 | Control     | 14          | −1.0 (0.79)         |                                |        | −0.5 (0.98)                       |                                          |        |
| BMI (kg/m\(^2\))| Intervention | 32          | −1.4 (0.34)         | −0.98 (0.44)                   | 0.03   | −1.5 (0.27)                       | −1.3 (0.44)                              | 0.006  |
|                 | Control     | 14          | −0.40 (0.29)        |                                |        | −0.2 (0.34)                       |                                          |        |
| Systolic blood pressure (mm Hg) | Intervention | 32          | −6.3 (2.6)          | 0.09 (4.6)                     | 0.99   | −5.7 (2.3)                       | 1.9 (3.5)                               | 0.59   |
|                 | Control     | 15          | −6.4 (4.0)          |                                |        | −7.6 (2.7)                       |                                          |        |
| Diastolic blood pressure (mm Hg) | Intervention | 32          | −2.8 (1.7)          | 1.7 (2.5)                      | 0.51   | −2.6 (1.4)                       | 2.4 (2.5)                               | 0.35   |
|                 | Control     | 15          | −4.5 (1.9)          |                                |        | −5.0 (2.1)                       |                                          |        |
| Fruit and vegetable servings per day | Intervention | 32          | 0.51 (0.22)         | 0.56 (0.38)                    | 0.15   | 0.50 (0.17)                       | 0.53 (0.39)                              | 0.19   |
|                 | Control     | 15          | −0.06 (0.32)        |                                |        | 0.03 (0.34)                       |                                          |        |
| Recreational walk time (self-report) (min/wk) | Intervention | 32          | 60.0 (26.9)         | 11.0 (37.9)                    | 0.79   | 64.2 (25.9)                       | 3.1 (44.6)                               | 0.95   |
|                 | Control     | 15          | 70.0 (26.9)         |                                |        | 61.1 (33.16)                      |                                          |        |
| Vigorous-intensity PA (self-report) (min/wk) | Intervention | 32          | 13.8 (14.5)         | 11.8 (17.4)                    | 0.50   | 15.4 (13.9)                       | 16.6 (22.9)                              | 0.47   |
|                 | Control     | 15          | 2.0 (10.3)          |                                |        | 1.2 (14.8)                       |                                          |        |
| Depressive symptoms score (PHQ8) | Intervention | 34          | −1.0 (0.48)         | −1.6 (0.65)                    | 0.02   | −0.71 (0.34)                      | −0.59 (0.66)                             | 0.38   |
|                 | Control     | 17          | 0.53 (0.46)         |                                |        | −0.12 (0.58)                      |                                          |        |
| Mental composite score (SF-12) | Intervention | 32          | −2.2 (1.0)          | −0.54 (1.4)                    | 0.70   | −2.1 (0.84)                       | −0.34 (1.5)                              | 0.83   |
|                 | Control     | 15          | −1.7 (1.0)          |                                |        | −1.8 (1.2)                       |                                          |        |
| Physical composite score (SF-12) | Intervention | 32          | 3.5 (1.4)           | 3.2 (1.6)                      | <0.05  | 3.5 (1.1)                        | 3.30 (1.7)                               | 0.05   |
|                 | Control     | 15          | 0.30 (0.85)         |                                |        | 0.23 (1.2)                       |                                          |        |
| Family support for diet | Intervention | 33          | 0.50 (0.11)         | 0.62 (0.33)                    | 0.06   | 0.51 (0.11)                       | 0.65 (0.21)                              | 0.003  |
|                 | Control     | 16          | −0.12 (0.32)        |                                |        | −0.13 (0.19)                      |                                          |        |
| Family support for PA | Intervention | 34          | 0.48 (0.10)         | 0.27 (0.23)                    | 0.25   | 0.51 (0.07)                       | 0.36 (0.18)                              | 0.05   |
|                 | Control     | 17          | 0.21 (0.22)         |                                |        | 0.15 (0.16)                       |                                          |        |
| Family cohesion | Intervention | 34          | 0.93 (0.85)         | 2.5 (1.3)                      | 0.06   | 1.1 (0.70)                        | 3.0 (1.2)                               | 0.02   |
|                 | Control     | 17          | −1.5 (0.99)         |                                |        | −1.9 (0.90)                       |                                          |        |
| Family problem-solving communication, total | Intervention | 34          | 0.35 (0.67)         | 0.12 (1.3)                     | 0.93   | −0.06 (0.65)                      | 1.4 (1.4)                               | 0.32   |
|                 | Control     | 17          | 0.47 (1.1)          |                                |        | 1.3 (1.09)                       |                                          |        |
| Family problem-solving communication, affirming | Intervention | 34          | −0.41 (0.40)        | 1.2 (0.66)                     | 0.08   | −0.62 (0.35)                      | 1.8 (0.70)                               | 0.01   |
|                 | Control     | 17          | 0.76 (0.18)         |                                |        | 1.2 (0.56)                       |                                          |        |
| Family problem-solving communication, incendiary | Intervention | 34          | −0.76 (0.36)        | 1.1 (0.80)                     | 0.19   | −0.51 (0.35)                      | −0.31 (0.81)                             | 0.71   |
|                 | Control     | 17          | 0.29 (0.74)         |                                |        | −0.21 (0.68)                      |                                          |        |

\(^a\)Values for mean differences between groups of family partners were adjusted for baseline value, diastolic blood pressure, gender, and values for perceived stress, depressive symptoms, family problem solving and communication total score, and frequency of making dinner at home. A negative value indicates a decrease compared with baseline; positive value indicates an increase. PA, physical activity.
“Family Time” component. We knew this would be a limitation when we designed the study but felt given the absence of published interventions, it was more important to first show weight loss effectiveness. Moreover, we allowed many types of family members to partner with the index participant, and because of the very small subgroup numbers we were unable to test differences in outcomes by family partner relationships. Our culturally-appropriate, but broad definition of “family” introduced wide variability in the family behavioral context, with some dyads sharing the same home (and behavioral context), and others not. This broad definition, however, reflects African American life and may have facilitated implementation of our intervention.

Conclusion
Our positive findings make an important contribution to a limited literature on family-centered research for chronic disease management among African Americans and strongly support the effectiveness of a family-centered approach. Important research questions that remain include: which family member(s) should be involved, when should they be involved, and how should they be involved in diabetes self-management (and weight loss) interventions. Further testing of these family-centered adaptations, while addressing longer-term weight loss maintenance, represents a logical next step. Expanding this family-centered research base could potentially improve intervention outcomes among African Americans burdened by diabetes and obesity.

Acknowledgments
Authors are indebted to the family pairs who committed to Family PALS. The authors also acknowledge the mentorship of Dr. Pegge Dilworth-Anderson and assistance of Larry Johnston, Agna Boass, and student interns Kina Smith, Kelsey Blaine, Abby Furr, and Jasmine Burroughs.

© 2016 The Obesity Society

References
1. Must A, McKrow NM. The disease burden associated with overweight and obesity. In: De Groot LJ, Chrousos G, Dungan K, et al., eds. Endotext (Internet). MDText.com, Inc.: South Dartmouth, MA; 2000.
2. Knowler WC, Barrett-Conner E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 2002;346:393-403.
3. Wing RR, Lang W, Wadden TA, et al. Benefits of modest weight loss in improving cardiovascular risk factors in overweight and obese individuals with type 2 diabetes. Diabetes Care 2011;34:1481-1486.
4. Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. U.S. Department of Health and Human Services: Atlanta, GA; 2014.
5. Colberg SR, Albert AI, Blissmer BJ, et al. Exercise and type 2 diabetes: American College of Sports Medicine and the American Diabetes Association: joint position statement. Exercise and type 2 diabetes. Med Sci Sports Exerc 2010;42:2282-2303.
6. Narayan KM, Boyle JP, Thompson T, Sorensen SW, Williamson DF. Lifetime risk for diabetes mellitus in the United States. JAMA 2003;290:1884-1890.
7. Ogden CL, Carroll MD, Flegal KM. Prevalence of obesity in the United States. JAMA 2014;312:189-190.
8. Wingo BC, Carson TL, Ard J. Differences in weight loss and health outcomes among African Americans and whites in multicentre trials. Obes Rev 2014;15(Suppl 4):48-61.
9. Fitzgibbon ML, Tussing-Humphreys LM, Porter JS, Martin IK, Odoms-Young A, Sharp LK. Weight loss and African-American women: a systematic review of the behavioural weight loss intervention literature. Obes Rev 2012;13:193-213.
10. West DS, Elaine Prewitt T, Bursac Z, Felix HC. Weight loss of black, white, and Hispanic men and women in the Diabetes Prevention Program. Obesity (Silver Spring) 2008;16:1413-1420.
11. Samuel-Hodge CD, Johnson CM, Braxton DF, Lackey M. Effectiveness of diabetes prevention program translations among African Americans. Obes Rev 2014;15(Suppl 4):107-124.
12. McLeod VC, Hill NE, Dodge KA, eds. African American Family Life: Ecological and Cultural Diversity. Guilford Press: New York; 2005.
13. Kumaniskyka SK, Whitt-Glover MC, Gary TL, et al. Expanding the obesity research paradigm to reach African American communities. Prev Chronic Dis 2007;4:A112.
14. Fisher L, Chesla CA, Bartz RJ, et al. The family and type 2 diabetes: a framework for intervention. Diabetes Educ 1996;24:599-607.
15. Chesla CA, Fisher L, Mallan JT, et al. Family and disease management in African-American patients with type 2 diabetes. Diabetes Care 2004;27:2850-2855.
16. Samuel-Hodge CD, Gizlice Z, Cai J, Brantley PJ, Ard JD, Svetkey LP. Family functioning and weight loss in a sample of African Americans and whites. Ann Behav Med 2010;40:294-301.
17. Kumaniskyka SK, Wadden TA, Shults J, et al. Trial of family and friend support for weight loss in African American adults. Arch Intern Med 2009;169:1795-1804.
18. Torenholz R, Schwennesen N, Williaing I. Lost in translation—the role of family in interventions among adults with diabetes: a systematic review. Diabetes Med 2014;31:15-23.
19. McLean N, Griffin S, Toney K, Hardeman W. Family involvement in weight control, weight maintenance and weight-loss interventions: a systematic review of randomised trials. Int J Obes Relat Metab Disord 2003;27:987-1005.
20. Wing RR, Marcus MD, Epstein LH, Jawad AA. “family-based” approach to the treatment of obese type II diabetic patients. J Consult Clin Psychol 1991;59:156-162.
21. Thomas S, Reading J, Shephard RJ. Revision of the Physical Activity Readiness Questionnaire (PAR-Q). Can J Sport Sci 1992;17:338-345.
22. Hollis JF, Gullion CM, Stevens VJ, et al. Weight loss during the intensive intervention phase of the weight-loss maintenance trial. Am J Prev Med 2008;35:118-126.
23. Svetkey LP, Stevens VJ, Brantley PJ, et al. Comparison of strategies for sustaining weight loss: the weight loss maintenance randomized controlled trial. JAMA 2008;299:1139-1148.
24. Svetkey LP, Harsha DW, Vollmer WM, et al. Premier: a clinical trial of comprehensive lifestyle modification for blood pressure control: rationale, design and baseline characteristics. Ann Epidemiol 2003;13:462-471.
25. Johnson DW. Social interdependence: interrelationships among theory, research, and practice. Am Psychol 2003;58:934-945.
26. Vaux A. Social Support: Theory, Research, and Intervention. Praeger Publishers: New York; 1988.
27. Standards of medical care in diabetes—2015: summary of revisions. Diabetes Care 2015;38(Suppl 1):S4.
28. Martire LM, Lustig AP, Schulz R, Miller GE, Helgeson V. Is it beneficial to involve a family member? A meta-analysis of psychosocial interventions for chronic illness. Health Psychol 2004;23:599-611.
29. Hartmann M, Bazner E, Wild B, Eiser I, Herzog W. Effects of interventions involving the family in the treatment of adult patients with chronic physical diseases: a meta-analysis. Psychother Psychosom 2010;79:136-148.
30. Samuel-Hodge CD, Cene CW, Corsino L, Thomas C, Svetkey LP. Family diabetes matters: a view from the other side. J Gen Intern Med 2013;28:428-435.
31. Samuel-Hodge CD, Johnson LF, Gizlice Z, et al. Randomized trial of a behavioral weight loss intervention for low-income women: the Weight Wise Program. Obesity (Silver Spring) 2009;17:1891-1899.
32. Ware JER, Turner-Bowker DM, Gandek B. User’s Manual for the SF-12v2® Health Survey (With a Supplement Documenting SF-12® Health Survey), QualityMetric Inc.: Lincoln, RI; 2008.
33. Van Gaal L, Scheen A. Weight management in type 2 diabetes: current and emerging approaches to treatment. Diabetes Care 2015;38:1161-1172.
34. Campbell TL. Improving health through family interventions. In: Crane DR, Marshall ES, eds. Handbook of Families & Health. Sage Publications: Thousand Oaks, CA, 2006;379-395.
35. Armour TA, Norris SL, Jack L Jr, Zhang X, Fisher L. The effectiveness of family interventions in people with diabetes mellitus: a systematic review. Diabetes Med 2005;22:1295-1305.