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Family PARTners in Lifestyle Support (PALS): Family-Based Weight Loss for African American Adults with Type 2 Diabetes

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Trial Registration: [Clinicaltrials.gov](https://clinicaltrials.gov) #NCT01324011

Abstract

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 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 20 weeks 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 –5.0 kg, $p < .0001$ (–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 (–3.9 kg (SI) vs. –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.

Keywords

obesity; family support; intensive behavioral lifestyle intervention; weight loss intervention; diabetes self-management

Introduction

Obesity is estimated to account for 64–74% 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 overweight and obese persons 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 are 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 to white participants(8)(9)(10)(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 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 overweight/obese African American adults with type 2 diabetes and an overweight/obese family partner 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 to delayed intervention 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 21–75 years; self-reported diagnosis of type 2 diabetes; BMI between 25–47 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, 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 (PAR-Q)(21) was used to screen participants for the ability to safely engage in moderate intensity PA. Participants with a positive PAR-Q were required to obtain written clearance from their clinician prior to participating in the PA component of the study intervention. The study was conducted at both the University of North Carolina at Chapel Hill (UNC) 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 pre-screened prospective participants by phone for study eligibility and motivation to participate. Since randomization to the study required paired participants, during the pre-screening 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 delayed intervention (DI) control group. Permuted 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 minutes 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 minutes/week of moderate-intensity PA(5). Participant incentives were also included; points were earned for reaching weekly behavioral goals (self-monitoring, fruits and vegetables servings, calories, PA). At sessions #8 and #19, earned points could be redeemed for items such as exercise DVDs, hand held weights, small kitchen appliances, and bathroom scales. For the delayed intervention 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.

A “Family Time” component (Table 1) was included in every other group sessions. This was a 20-minute 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 of weight change(10,31) and 15% anticipated attrition rate. We estimated enrolling 75 index participants (50 in intervention arm and 25 in delayed intervention 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-square and t-tests. For the analysis of the primary outcome, we used a simple t-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 comprised the study sample. Table 2 shows baseline characteristics of study participants. Overall, 81% of participants were females, with a mean age of 51 years, educational attainment of 15 years, and nearly half with annual household incomes between \$30,000 to < \$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

Post-intervention, we obtained weight data from 89% (96/108) of participants overall (90% (65/72) among SI, and 86% (31/36) in the DI group). Participants lost to follow-up were significantly younger than those assessed (43 vs 52 years; $p<.01$). 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 kg, $p<.$

0001, with a mean weight loss of -3.6 kg among SI and a 1.4 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 kg, $p=.0001$. In the analysis of weight change among completers (Table 3 and Figure 2), the adjusted mean difference in weight between groups was -5.7 kg, $p<.0001$ (4.3 kg loss (SI) vs. 1.4 kg gain (DI)). Among SI index participants, 42% ($14/33$) lost at least 5% of initial weight, compared to 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 kg among those attending all 20 sessions, -5.9 kg for those attending 17 or more sessions, and -1.1 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 mm Hg systolic and -5.3 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 kg (SI) and -1.0 kg (DI), for a mean difference of -2.9 kg, $p=.02$. The adjusted mean difference between groups was -3.7 kg, $p=.006$ (-4.1 kg (SI) and -0.5 kg (DI)). Among SI family partners, 38% ($12/32$) lost at least 5% of initial body weight. Overall, among both SI family partners and index participants, 28% of completers ($18/65$) lost at least 7% of initial body weight, and 40% ($26/65$) 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 kg among those attending all 20 sessions, -4.3 kg for those attending 14 or more sessions, and -1.1 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 ($p=.05$).

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 to DI. Similarly, significant

improvements were seen in family cohesion and support among SI compared to 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 to DI the adjusted differences were mostly marginally significant. In contrast, among family members the only significant adjusted difference between SI vs. 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 (-5.7 vs. -3.3 .kg, respectively; $p=0.11$). 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 -2.2 and -2.5 kg (at 1 year and 9 months, respectively), while a third reported -3.0 kg weight loss (at 6 months) among African Americans (39% of sample). Family PALS weight loss of -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 one 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) (-3.4 kg vs. -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 delayed intervention 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 don't know what the difference in weight loss would be if Family PALS was compared to a similar intervention *without* active participation of family partners and the "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 sub-group 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 represent logical next steps. Expanding this family-centered research base could potentially improve intervention outcomes among African Americans burdened by diabetes and obesity.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Study Importance Questions

What is already known about this subject?

- Family-centered lifestyle interventions have been shown to be effective in chronic disease management, yet very few studies specifically target high risk minority or African American populations.
- There is a strong evidence base for behavioral weight loss intervention in the prevention and treatment of diabetes, but African Americans (particularly women) have shown suboptimal rates of success.

What does this study add?

- This study addresses an area with no published research – family-centered behavioral weight loss interventions among African American adults with diabetes.
- It complies with several recommendations from recent reviews of family-centered interventions for diabetes and weight management. These include: starting with a theory-informed intervention; obtaining input from experts in the field of psychology or family therapy; and evaluating outcomes among family members.

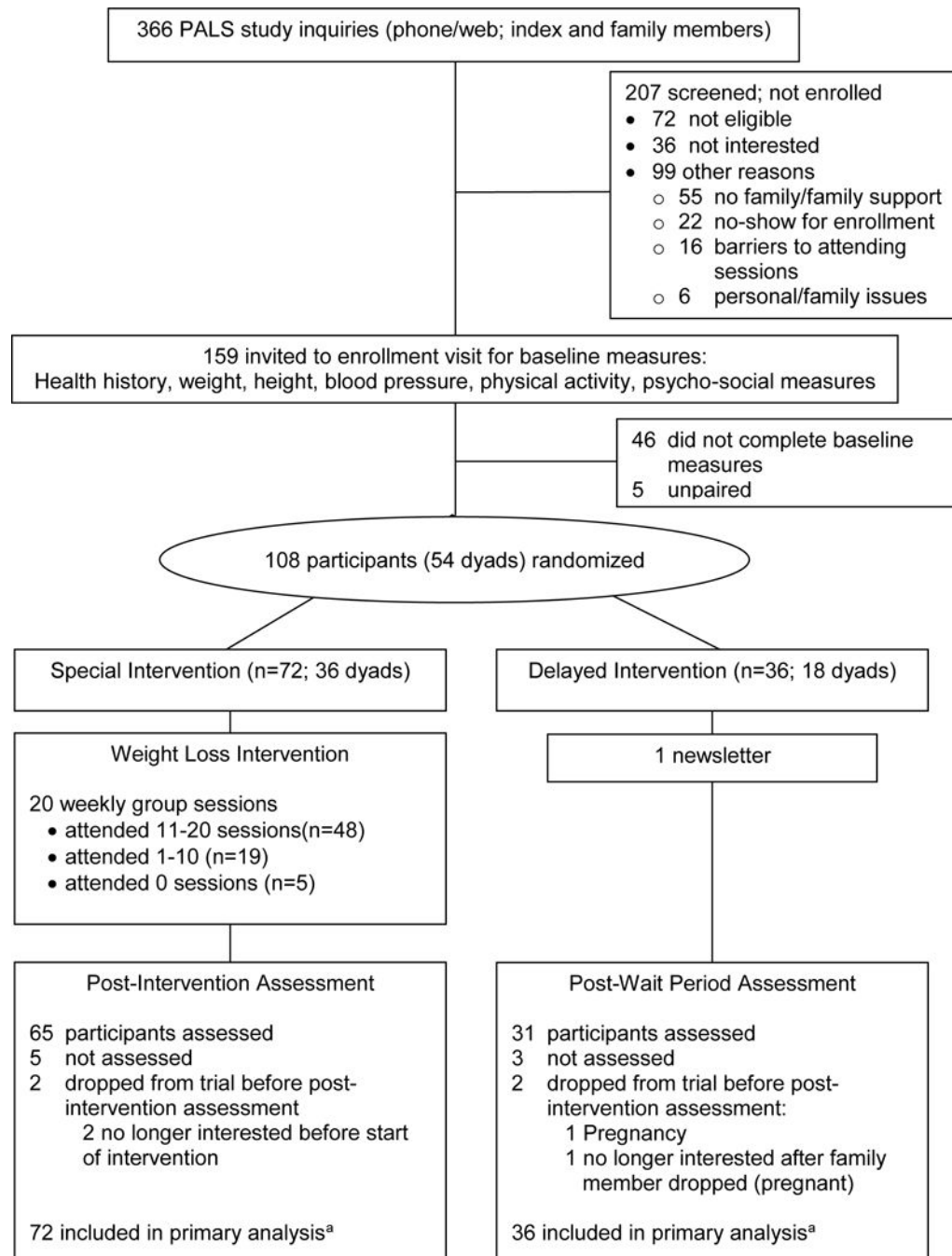


Figure 1. Study flow diagram

^aIndex = participant in dyad with diagnosed diabetes. Both participants in the dyad had to complete baseline measures before randomization. Only index participants (n=54) included in primary analysis of weight loss. Returnees included in secondary analyses.

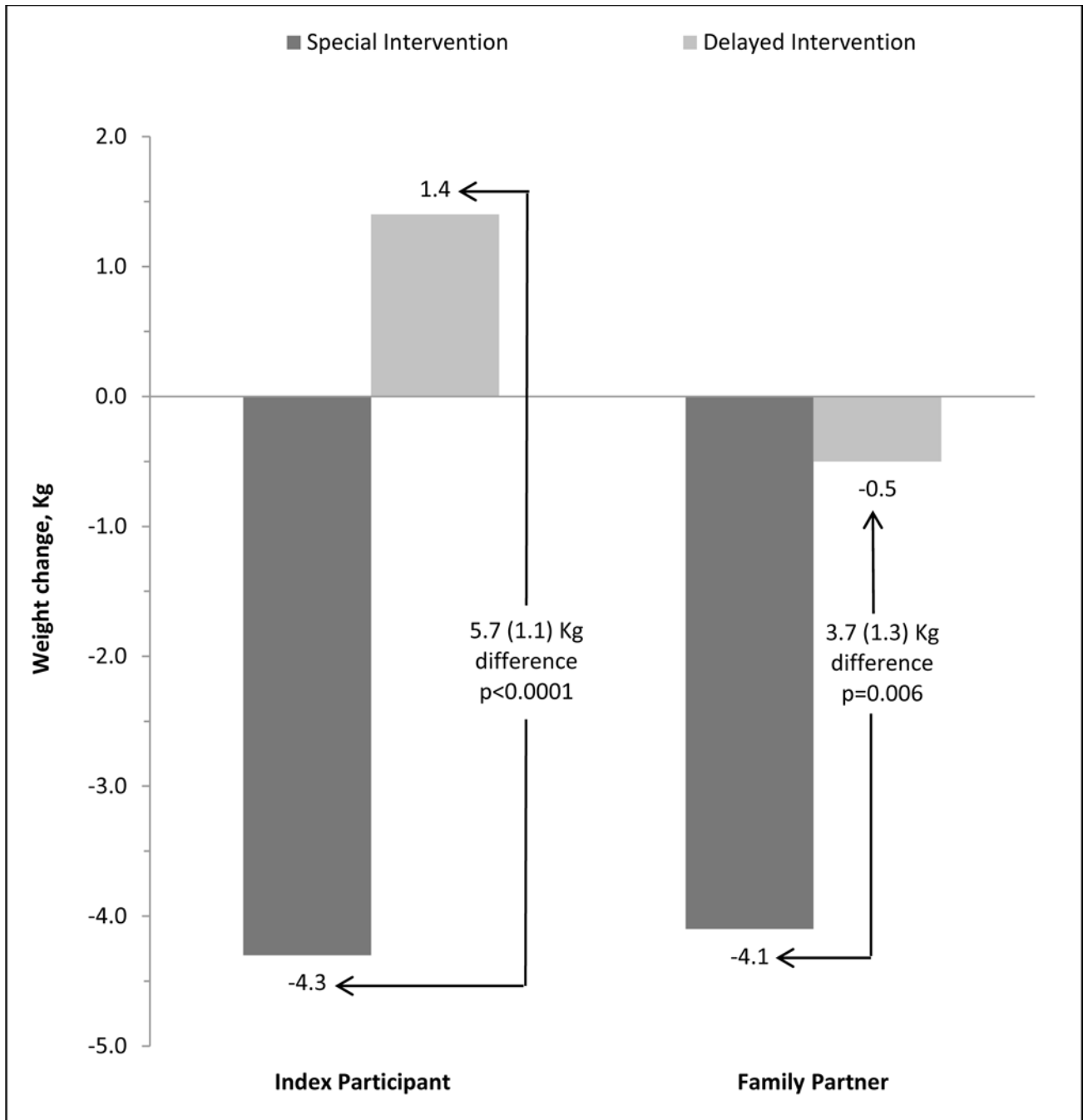


Figure 2. Adjusted mean difference in weight outcomes between SI and DI groups (completers) Values are means (SE). Mean differences between groups of *index* participants were adjusted for baseline value, diastolic blood pressure, and weekly frequency of eating breakfast. Mean differences between groups 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, frequency of making dinner at home.

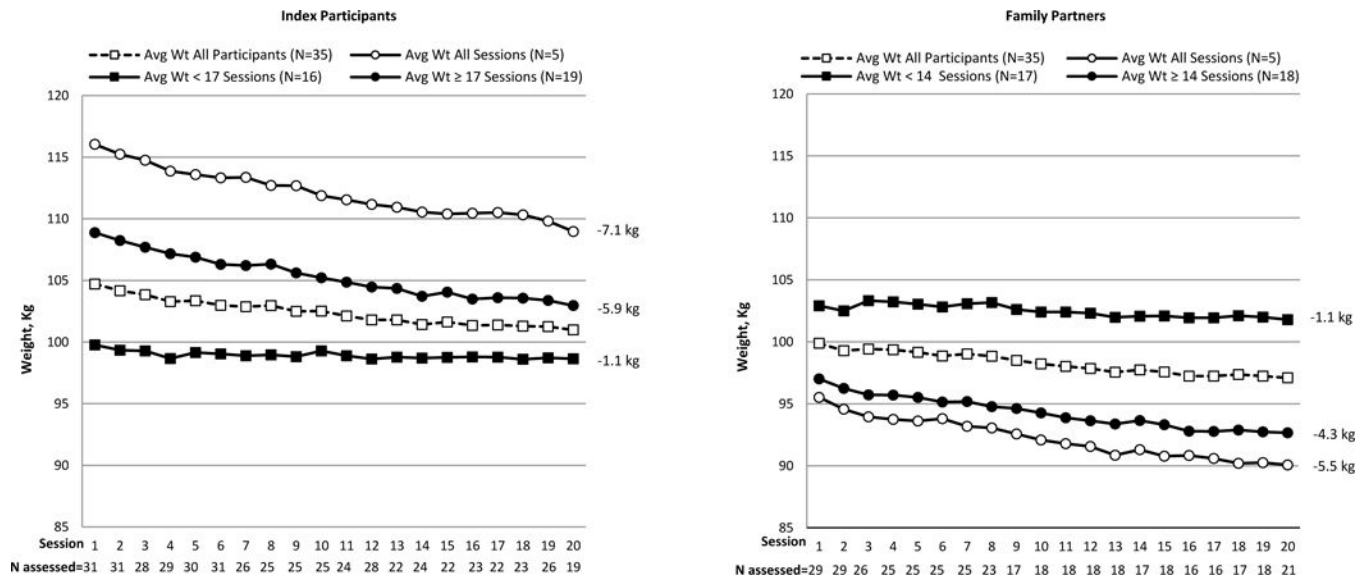


Figure 3. Weight change by attendance at weekly sessions among index and family participants (completers)

Time points (weeks) for weight assessment are depicted on the horizontal axis. Week 20 session is the end of the randomized trial. Last weight is brought forward for those with missing values. Four lines show weight loss among completers attending all sessions, those above and below the median number of sessions attended, and the average.

TABLE 1

“Family Time” component of the PALS intervention^a

Session Number	“Family Time” – Topics	Behavioral target area(s)
1	Introduction to Family Goals (Connect, Communicate, Cope)	<ul style="list-style-type: none"> Strengthening family ties by encouraging family members to set goals for <i>connecting</i> and <i>communicating</i> well with each other, and using good <i>coping</i> strategies to deal with family stress
3	Family Goals and PAL Wishes	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> Discuss how family communications can influence mood, thoughts, and behaviors. This segment addresses <i>emotional management</i> (e.g., in the context of food policing by family members).
15	Listening and I-Statements	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Practice skills in better family communication (general and/or diabetes specific) using a family collage to facilitate discussion.
19	My Family Now	<ul style="list-style-type: none"> Share progress in reaching ‘family goals’ made at the 1st session Share successes, challenges, and plans for the future.

^aThis 20-minute intervention component was incorporated into every other session of the 20 week intervention. Participants were provided with a worksheet one 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.

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TABLE 2

Participant characteristics^a

Characteristic	Index Participants (n=54)	Family Partners (n=54)	Special Intervention		Delayed Intervention	
			Index (n=36)	Family (n=36)	Index (n=18)	Family (n=18)
Demographic						
Age, years	54	48	55	46	53	50
Female, n (%)	40 (74)	47 (87)	27 (75)	34 (94)	13 (72)	13 (72)
Educational achievement, years	14.8	15.3	15.0	15.7	14.5	14.9
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/m ²	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, ^c mm Hg	77	80	78	81	75	76

Characteristic	Index Participants (n=54)	Family Partners (n=54)	Special Intervention		Delayed Intervention	
			Index (n=36)	Family (n=36)	Index (n=18)	Family (n=18)
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 (83)	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, 5 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

Characteristic	Index Participants (n=54)	Family Partners (n=54)	Special Intervention		Delayed Intervention	
			Index (n=36)	Family (n=36)	Index (n=18)	Family (n=18)
Unresolved diabetes conflict, mean score ^g	1.7	-	1.7	-	1.8	-

^aData are expressed as means (SD) unless otherwise indicated. PA, Physical Activity

^bIndex (n=6) and family partners (n=12) chose not to provide income information

^cDiastolic blood pressure was the only variable significantly different ($p < .05$) between SI and DI.

^dComposite score for self-monitoring blood glucose, PA, dietary, and medication adherence, 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.

TABLE 3

Secondary study outcomes: Index participants change from baseline to 20 weeks and mean differences between groups (completers)^a

Outcome	Index Participants							
	Study Group	No. Assessed	Change in mean (SE)	Difference between groups (SE)	P-Value	Adjusted change from baseline (SE)	Adjusted difference between groups (SE)	Adjusted P-Value
Weight, kg ^b	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)			1.4 (0.87)		
BMI, kg/m ²	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)			0.44 (0.30)		
A1c, %	Intervention	33	-0.45 (0.19)	-0.71 (0.38)	0.07	-0.51 (0.15)	-0.89 (0.43)	0.04
	Control	16	0.26 (0.34)			0.38 (0.38)		
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 (2.3)		
Diastolic blood pressure, mm Hg	Intervention	33	-6.7 (1.7)	-5.3 (2.5)	0.04	-6.3 (1.6)	-4.2 (2.7)	0.13
	Control	16	-1.3 (2.0)			-2.1 (1.9)		
Fruit and vegetables 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)		
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)		
Vigorous intensity physical activity, (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)		
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)		
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)		
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)		
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)			-0.01 (0.12)		

Outcome	Index Participants							
	Study Group	No. Assessed	Change in mean (SE)	Difference between groups (SE)	P-Value	Adjusted change from baseline (SE)	Adjusted difference between groups (SE)	Adjusted P-Value
Diabetes self-care Composite 7-day score	Intervention	33	3.9 (0.89)	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)		
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)		
Family support for PA	Intervention	32	0.62 (0.17)	0.91 (0.23)	0.0003	0.55 (0.16)	0.69 (0.21)	0.002
	Control	15	-0.29 (0.17)			-0.15 (0.14)		
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 (0.99)			-1.6 (0.73)		
Family problem-solving communication, total	Intervention	34	2.0 (0.67)	1.4 (1.3)	0.29	2.3 (0.67)	2.3 (1.3)	0.08
	Control	16	0.63 (1.1)			0.0 (1.1)		
Family problem-solving communication, Affirming	Intervention	34	1.0 (0.38)	0.72 (0.64)	0.27	1.2 (0.36)	1.1 (0.60)	0.07
	Control	16	0.31 (0.54)			0.03 (0.46)		
Family problem-solving communication, Incendiary	Intervention	34	-1.1 (0.72)	-0.75 (0.79)	0.35	-1.2 (0.46)	-1.3 (0.83)	0.14
	Control	16	-0.31 (0.72)			0.03 (0.70)		
Unresolved family diabetes conflict	Intervention	34	-0.44 (0.17)	-0.35 (0.23)	0.14	-0.49 (0.09)	-0.53 (0.27)	0.06
	Control	16	-0.09 (0.17)			0.03 (0.24)		

^aValues for mean differences between groups of *index* participants were adjusted for baseline value, diastolic blood pressure, and weekly frequency of eating breakfast. A negative value indicates a decrease compared to baseline; positive value indicates an increase. Intervention = special intervention (SI); Control = delayed intervention (DI); PA = physical activity

^bWeight values are for completers only. ITT values for the primary outcome of weight change among index participants appear in the text.

Secondary study outcomes: Family partners change from baseline to 20 weeks and mean differences between groups (completers)^a

TABLE 4

Outcome	Family Partners							
	Study Group	No. Assessed	Change in mean (SE)	Difference between groups (SE)	P-Value	Adjusted change from baseline (SE)	Adjusted difference between groups (SE)	Adjusted P-Value
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 vegetables 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	-0.05 (0.32)			0.03 (0.34)		
Recreational walk time (self-report), min/wk	Intervention	32	60.0 (26.9)	10.0 (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 physical activity, (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)		

Outcome	Family Partners							
	Study Group	No. Assessed	Change in mean (SE)	Difference between groups (SE)	P-Value	Adjusted change from baseline (SE)	Adjusted difference between groups (SE)	Adjusted P-Value
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)		

^aValues 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, frequency of making dinner at home. A negative value indicates a decrease compared to baseline; positive value indicates an increase. Intervention = special intervention (SI); Control = delayed intervention (DI)