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Title: Translating the Diabetes Prevention Program to Primary Care: A Pilot Study

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Abstract: Background: Research on the translation of efficacious lifestyle change programs to prevent type 2 diabetes into community or clinical settings is needed.

Objectives: The primary purpose of this pilot study was to examine the reach, implementation, and efficacy of a 6-month lifestyle program implemented in primary care by nurse practitioners (NP) for adults at risk for type 2 diabetes.

Method: NP sites (n=4) were randomized to an enhanced standard care program (1 NP and 1 nutrition session) or a lifestyle program (enhanced standard care and 6 NP sessions). NPs recruited adults at-risk for diabetes from their practice (n=58) with an acceptance rate of 70%.

Results: The program reached a diverse, obese, moderately-low income sample. NPs were able to successfully implement the protocols; however, the average length of the program was 9.3 months. Attendance was high (98%) and attrition low (12%). NPs were easily able to adopt the educational, behavioral and psychosocial strategies of the intervention. Motivational interviewing was more difficult for NPs. Mixed-model repeated measures analysis indicated significant trends or improvement in both groups for nutrition and exercise behavior. Participants of the lifestyle program

demonstrated trends for better HDL as well exercise behavior compared to enhanced standard care participants. Twenty-five percent of lifestyle participants met treatment goals of 5% weight loss compared to 11% of standard care participants.

Discussion: A lifestyle program can be implemented in primary care by NPs, reach the targeted population, and be modestly successful. Further research is indicated.

April 25, 2008

Molly Dougherty, PhD, RN, FAAN
Editor, *Nursing Research*
University of North Carolina
School of Nursing
Chapel Hill, N.C.

Dear Dr. Dougherty:

Enclosed is a manuscript, "Translating the Diabetes Prevention Program to Primary Care: A Pilot Study" to be considered for publication in *Nursing Research*. This manuscript reports on a pilot study that translated the Diabetes Prevention Program (DPP) collaboratively with nurse practitioners for implementation in their primary care practices. Previous research translating the DPP has been with group-based programs and with one-group designs. This study was an experimental design and demonstrates the potential of an individualized approach to diabetes prevention as well as the feasibility of the program being provided by nurse practitioners. I believe it is a timely and important topic of potential interest to the readership of the journal.

While it is a pilot study, there were numerous processes and outcomes to report; thus this manuscript is submitted as a full length manuscript, per our previous email communication. This manuscript includes only original material, has not been published elsewhere, nor has it been submitted for publication at another journal. There are no conflict of interests and all ethical standards have been adhered to in the conduct of the study.

Thank you for considering this manuscript for publication. Please do not hesitate to contact me with any questions.

Sincerely,

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Translating the Diabetes Prevention Program to Primary Care: A Pilot Study

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1 Translating the Diabetes Prevention Program to Primary Care: A Pilot Study

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5 type 2 diabetes into community or clinical settings is needed.

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7 and efficacy of a 6-month lifestyle program implemented in primary care by nurse practitioners
8 (NP) for adults at risk for type 2 diabetes.

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10 nutrition session) or a lifestyle program (enhanced standard care and 6 NP sessions). NPs
11 recruited adults at-risk for diabetes from their practice (n=58) with an acceptance rate of 70%.

12 Results: The program reached a diverse, obese, moderately-low income sample. NPs were able
13 to successfully implement the protocols; however, the average length of the program was 9.3
14 months. Attendance was high (98%) and attrition low (12%). NPs were easily able to adopt the
15 educational, behavioral and psychosocial strategies of the intervention. Motivational
16 interviewing was more difficult for NPs. Mixed-model repeated measures analysis indicated
17 significant trends or improvement in both groups for nutrition and exercise behavior. Participants
18 of the lifestyle program demonstrated trends for better HDL as well exercise behavior compared
19 to enhanced standard care participants. Twenty-five percent of lifestyle participants met
20 treatment goals of 5% weight loss compared to 11% of standard care participants.

21 Discussion: A lifestyle program can be implemented in primary care by NPs, reach the targeted
22 population, and be modestly successful. Further research is indicated.

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24

1 T2D (T2D) is emerging as a public health epidemic of the 21st century with
2 approximately 17 million persons affected in the United States. Ethnic minorities have a
3 disproportionate risk and are twice as likely as non-Hispanic whites of similar age to develop
4 T2D (Centers for Disease Control and Prevention [CDC], 2004). T2D is the leading cause of
5 blindness, renal failure, and nontraumatic amputation in adults in the U.S. In addition, T2D
6 increases the risk of cardiovascular disease and stroke 2- to 4-fold (CDC, 2004). These
7 complications often occur concomitantly and contribute to extensive disability, personal
8 suffering, and significant societal costs. In the U.S., the economic costs associated with diabetes
9 in 2007 were estimated to be \$174 billion (American Diabetes Association, 2008). Therefore,
10 the greatest opportunity in addressing the personal and societal burden of T2D is to prevent the
11 development of the disease.

12 Recent evidence demonstrates that individuals at risk for T2D can be identified and
13 delayed, if not prevented through lifestyle change programs. International trials have
14 demonstrated a 31-58% reduction in the incidence of T2D for adults with impaired glucose
15 tolerance (IGT) who participated in lifestyle change programs of weight reduction and physical
16 activity compared to a control group (Pan et al., 1997; Tuomilehto et al., 2001). Most recently,
17 the Diabetes Prevention Program (DPP), a large clinical trial in the U.S. with an ethnically
18 diverse sample of adults, provided evidence on the dramatic decrease in progression from IGT to
19 T2D with a lifestyle change program (Knowler et al., 2002).

20 Results from these lifestyle change trials emphasize the importance of lifestyle in the
21 prevention of T2D. A strong correlation was seen between the ability to prevent T2D and the
22 degree to which participants made the recommended lifestyle changes (Tuomilehto et al., 2001).
23 Also encouraging from a translational perspective was that the lifestyle change goals that

1 contributed to diabetes prevention in these studies were quite modest. Participants were
2 counseled to lose 5-7% of body weight, reduce fat intake to <30%, reduce saturated fat intake to
3 <10%, increase fiber intake to 15gm/1000kcal, and exercise for 30 minutes 5-7 days per week.
4 These modest lifestyle changes also reduced the magnitude of cardiac risk factors of participants
5 (i.e., hypertension) (Tuomilehto, et al., 2001). The challenge remains as to how to provide
6 research-based lifestyle change programs to at-risk populations that are aligned with current
7 health care systems. The DPP was a proof of principle study demonstrating the ability to delay
8 T2D with lifestyle change and therefore provided extreme measures to promote lifestyle change
9 (ie., frequent sessions, free sneakers) that are not easily translated into community or clinical
10 settings.

11 Approaches to translate diabetes prevention programs into different settings have been
12 investigated. A systematic review of community-based interventions to prevent or delay T2D (9
13 studies targeting adults) reported variable programs with very modest improvements in
14 outcomes. The majority of studies in this review used one-group designs, were programs that
15 were not based on the DPP, with few measuring plasma glucose or insulin resistance (Satterfield
16 et al., 2003). More recently, group-based lifestyle programs translating the DPP to the
17 community have demonstrated preliminary efficacy in terms of participants meeting weight loss
18 goals (Laatikasen et al., 2007; Seidel et al., 2008) and improving glucose tolerance and lipid
19 profiles (Laatikasen et al., 2007) in one-group designs. Experimental research evaluating the
20 translation of the DPP into community or clinical settings is indicated.

21 Primary care represents a setting to screen at-risk adults and implement interventions to
22 prevent T2D. Primary care practices typically provide health care for a large percentage of the
23 population and have the ability to follow-up with patients over time. In addition, many have

1 established relationships with patients, which may enhance the delivery and receptivity of the
2 recommended lifestyle changes. However, lifestyle change counseling has been reported to be
3 difficult to accomplish in many primary care settings. Providers report pessimism about the
4 motivation of patients to change their lifestyles, skepticism about the efficacy of brief lifestyle
5 change counseling, limited time to provide lifestyle change counseling, limited training on
6 effective counseling techniques, and low reimbursement rates (Kristeller & Hoerr, 1997; Larme
7 & Pugh, 1998).

8 Nurse practitioners (NPs) represent an overlooked yet ideal health professional to
9 implement lifestyle change counseling in primary care. There are currently over 85,000 certified
10 registered NPs in the United States with the majority certified in family or adult specialties
11 (77%) (American Academy of Nurse Practitioners, 2002). NPs have been reported to be
12 particularly cost-effective in preventive care due to their expertise in counseling, health
13 education, and case management (Hummel & Pirezada, 1994). In providing care to adults with
14 T2D, NPs were more likely to provide health education about nutrition, weight, and exercise to
15 adults with T2D compared to physicians (Lenz, Mundinger, Hopkins, Lin, & Smolowitz, 2002).
16 In addition, many NPs provide health care for individuals who would be otherwise underserved
17 (Fairbanks, Montoya & Viens, 200). Therefore, NPs may represent health professionals with
18 access to adults at risk for T2D and the expertise to implement a diabetes prevention program.

19 Designing studies to test the translation of a research-based program (with established
20 efficacy in clinical trials) into the healthcare setting requires consideration of broad processes
21 and outcomes of care. The RE-AIM (Reach, Efficacy, Adoption, Implementation, Maintenance)
22 model was the organizing framework of this study as it was developed for use in evaluating the
23 effectiveness of health behavior programs in terms of public health significance (Glasgow, Vogt,

1 cluster randomization and repeated measures to evaluate the reach, implementation, and
2 preliminary efficacy of the modified lifestyle program.

3 Sample

4 A convenience sample of 4 NP primary care practice sites were recruited from a regional
5 practice-based research network for NPs in New England through a mailed invitation (22 %
6 response rate). NPs declined due to ongoing research, patients non-English speaking, or time.
7 The network has 68 members with 80% certified as family NPs (56%) or adult NP's (24%)
8 providing care for ethnically and racially diverse adults. A cluster randomization procedure
9 using a computerized table of random numbers randomized 4 sites: 2 sites into the lifestyle
10 change program and 2 sites into an enhanced standard care program. Each site had a different
11 distribution of NPs working with study participants (site 1 and 3 had 2 NPs for the duration of
12 the study, site 2 had one NP, and site 4 had 2NPs, with the second NP replacing the first one due
13 to illness).

14 Procedure

15 NPs recruited a convenience sample of 58 adults at-risk for T2D from their practices (31
16 treatment and 27 control group participants). The sample size for this pilot study was determined
17 by a power analysis, recruiting 20% of what would be necessary for a clinical trial testing the
18 intervention. Inclusion criteria included: 1) age 21 or older; 2) medically stable and safe to
19 exercise; 3) at risk for IGT, metabolic syndrome, or T2D; and 4) able to speak English. Potential
20 participants were considered at risk if they were overweight or obese ($BMI \geq 25\text{kg}/\text{m}^2$) and were
21 age 45 years or older. Adults younger than 45 years and overweight or obese were also
22 considered at risk if they had any other risk factor for T2D (family history of T2D, history of
23 gestational diabetes or giving birth to a baby ≥ 9 pounds, of an ethnic group at high risk for T2D,

1 hypertension, or lipid abnormalities of high tryglicerides and low-density lipoproteins, and low
2 high-density lipoproteins). Exclusion criteria included: current participation in a commercial diet
3 program or treatment of IGT with metformin. IRB approval was obtained from all institutional
4 review boards associated with the study.

5 Interventions

6 Enhanced Standard Care. After informed consent and baseline data collection, all
7 participants (regardless of group assignment) received written information about diabetes
8 prevention, a 20-30 minute individual session with their NP on the importance of a healthy
9 lifestyle for the prevention of T2D, and a 45-minute individual session with a nutritionist hired
10 for the study. The goals of the standard care approach were similar to the DPP and represented
11 the current treatment recommendation for individuals at risk for T2D. Specifically, participants
12 were encouraged to follow a healthy diet (limit calories; limit fat; limit processed foods); to lose
13 5-7% of their initial weight through diet and exercise; and to increase their exercise gradually
14 with a goal of at least 30 minutes of exercise (ie., walking) 5 days per week. Training for NPs at
15 the sites randomized to enhanced standard care only and study nutritionists consisted of a 2-hour
16 education session reviewing the study protocols. Monthly meetings were conducted to discuss
17 any implementation questions.

18 Lifestyle Change Program. The lifestyle change program for this pilot study was based on
19 the protocol for the DPP (Diabetes Prevention Research Group, 1999). The goals for this
20 program were identical to enhanced standard care; however, the approach was more intensive
21 and based on behavioral science evidence which recognizes the difficulty inherent in diet and
22 exercise lifestyle change. The lifestyle change program intended to maximize success by
23 providing: a) culturally relevant education on nutrition, exercise, and T2D prevention;

1 b) behavioral support in collaboratively identifying lifestyle change goals and problem-solving
2 barriers to change; c) motivational interviewing when participants were unable to achieve
3 lifestyle goals; and d) psychosocial support. Training for NPs at the sites randomized to the
4 lifestyle program consisted of training on the enhanced standard care protocol, self-study
5 (reading and a 45 minute DVD on motivational interviewing), two 2-hour workshops on
6 motivational interviewing (before study, at 3 months), a 2-hour education session reviewing the
7 lifestyle program protocols, and monthly meetings with the primary investigator. Consultation
8 with an expert on motivational interviewing was available throughout the study. Study
9 nutritionists provided nutrition sessions at all sites and were blinded to the site assignment.

10 NPs who worked at the lifestyle program sites participated in the modification process of
11 the lifestyle protocol which was aimed at maintaining key elements of the DPP while
12 simultaneously enhancing the ability to implement the protocol in their practice settings. The
13 changes made to the DPP protocol for this study were: a reduction of the number of in-person
14 sessions from 16 over 6 months to 6 in-person sessions and 5 phone sessions over 6 months, as
15 well as the revision of some content to be provided for participants to complete at home. In-
16 person sessions were also structured to be provided in a 20-minute office visit. All educational
17 content of the DPP was provided; however, content was abbreviated and the nutritional content
18 was revised slightly. The lifestyle protocol used in this study is provided in Table 1. Over the 6
19 months of the intervention, participants were to receive approximately 3 hours of in-person NP
20 support and 1 hour of NP phone support in contrast to 12-16 hours of individual sessions in the
21 DPP core curriculum.

22 Outcome Measures

23 Data were collected at the individual (participant) and organizational (NP and site) levels

1 at scheduled time points throughout the study in order to evaluate the reach, implementation, and
2 preliminary efficacy of the lifestyle program. All data were collected by trained research
3 assistants blinded to group assignment with the exception of glucose tolerance, insulin resistance
4 and lipids, which were collected by experienced lab personnel at each site and sent to one
5 laboratory for analysis.

6 Reach. Recruitment rates were documented for each NP practice. Demographic and
7 clinical data were collected using a standard form (i.e., age, gender, SES, ethnicity, health
8 history).

9 Implementation. *Participant Measures* of implementation consisted of attendance,
10 attrition, and a satisfaction survey. The satisfaction survey was a 7-item summated scale
11 modified from the Diabetes Treatment Satisfaction Survey (Bradley, 1994) to evaluate a diabetes
12 prevention program. Adequate internal consistency has been reported with the original scale
13 ($\alpha=.82$) and was demonstrated with the modified scale in this study ($\alpha=.86$).

14 *Organizational Measures* of implementation consisted of NP and nutrition session
15 documentation forms which were created with components of each session itemized. The
16 percent of protocol implementation was calculated by dividing the number of protocol items by
17 the number of protocol items completed per session. NPs were also interviewed at 3 and 6
18 months to address issues of implementation.

19 Efficacy. Efficacy data were collected on clinical outcomes (weight loss, waist
20 circumference, insulin resistance, and lipid profiles), behavioral outcomes (nutrition and
21 exercise), psychosocial outcomes (depressive symptoms), and participant satisfaction. All data
22 were collected at baseline, 3, and 6 months with the exception of laboratory data which were
23 collected at baseline and 6 months and the satisfaction survey which was collected at 6 months.

1 *Weight loss* was the primary outcome and was calculated as % weight loss from baseline
2 to 6 months. *Insulin resistance* (IR) was an additional primary clinical outcome. After an 8 hour
3 fast, subjects had fasting insulin and glucose levels drawn, ingested a standard glucose load (75
4 gm), and had insulin and glucose drawn at 120 minutes. IR was assessed using the homeostasis
5 model assessment (HOMA) which has been shown to be a good approximation ($r=.35$, $p<.05$) of
6 more complex tests (metabolic clearance rate for glucose) (Wallace, Levy & Matthews, 2004).
7 [fasting insulin (uIU/ml) x fasting glucose (mmol/l)/22.5]. Glucose at 120 minutes assessed
8 glucose tolerance (GTT). *Waist circumference and lipid profiles* were secondary clinical
9 outcomes. *Waist circumference* was measured by positioning a tape measure snugly midway
10 between the upper hip bone and the uppermost border of the iliac crest. In very overweight
11 participants, the tape was placed at the level of the umbilicus (Klein et al., 2007). *Lipid profiles*
12 (*LDL, HDL, total cholesterol, total triglycerides*) were determined using fasting venous blood.

13 *Diet and exercise health promoting behaviors* were measured with the exercise and
14 nutrition subscales of the Health Promoting Lifestyle Profile II (8 and 9 items respectively)
15 which has items constructed on a 4-point Likert scale (Walker, Sechrist, & Pender, 1987). This
16 instrument has been used in diverse samples and demonstrates adequate internal consistency ($r=$
17 0.70 to 0.90 for sub-scales) (Jefferson, Melkus, & Spollett, 2000). The alpha coefficients for the
18 exercise and nutrition subscales in this study were $.86$ and $.76$ respectively.

19 Psychosocial data were collected on depressive symptoms as measured by the Center for
20 Epidemiologic Studies – Depression Scale (CES-D), a widely used scale (Radloff, 1977). The
21 CES-D consists of 20 items that address depressed mood, guilt/worthlessness, helplessness or
22 hopelessness, psychomotor retardation, loss of appetite and sleep disturbance. Each item is rated
23 on a scale of 0 to 3 in terms of frequency during the past week. The total score may range from 0

1 to 60, with a score of 16 or more indicating impairment. High internal consistency, acceptable
2 test-retest reliability, and good construct validity have been demonstrated (Posner *et al.* 2001).
3 The alpha coefficient was .93 for the CES-D in this sample.

4 Data Analysis

5 Data were entered into databases (Microsoft Access or Excel) via an automated Teleform
6 system. Mean substitution was employed for missing data of individual items on instruments (up
7 to 15%). If >15% of items were missing (rare), the sub-scale or scale was coded as missing data.
8 Descriptive statistics were calculated using frequency distributions and appropriate summary
9 statistics for central tendency and variability (SAS). The two groups were compared on major
10 variables to make certain that the cluster random assignment equally distributed the sample.
11 Variables unequally distributed were controlled for in subsequent analyses.

12 Reach and implementation were analyzed with descriptive statistics and content analysis of
13 NP interviews and process notes. The hypothesis that at-risk adults who received the lifestyle
14 change program would demonstrate better clinical, behavioral, and psychosocial outcomes than
15 at-risk adults who received an enhanced standard care control program was tested using an intent
16 to treat repeated measures mixed modeling procedure (PROC MIXED, SAS). Each model had
17 fixed effects (group assignment, income, race, month, and month by group interaction with age
18 as a covariate) and random effects (intercept and site for dependent variables with two evaluation
19 time points; intercept, site, and month for dependent variables with three evaluation points). The
20 main effect of time was estimated, which described the average monthly change in outcomes
21 across both groups; and treatment by time interaction, which compared the rates of monthly
22 change between treatment and control groups. Because it was possible that significant main
23 effects or interaction effects would not be found due to the sample size, identification of trends

1 of significance (e.g., $p < .20$) and effect sizes were examined. Participant satisfaction was
2 analyzed with t-test analysis.

3 Results

4 Reach

5 Fifty-eight participants were enrolled between April and August, 2006 and the study
6 ended in September, 2007. There was a 70% response rate to in-person recruitment at NP
7 practices and a 12% attrition rate at 6 months (Figure 1). Those who did not complete the study
8 were younger, had higher BMI, and lower low-density lipoproteins ($p < .05$).

9 The sample represented diverse (52% White), primarily female (92%), obese,
10 moderately-low income adults at risk for T2DM (Table 2). Thirty-three percent of the sample
11 reported elevated depressive symptoms. There were no statistically significant differences
12 between groups at baseline on clinical, behavioral, or psychosocial variables. There were more
13 Black participants in the treatment group in contrast to more Hispanic participants in the control
14 group ($p = .01$). More participants in the treatment group had moderately-low income compared
15 to low income in the control group ($p = .01$).

16 Implementation of the intervention

17 Attendance for in-person sessions was high at 96%. Completion of phone calls for the
18 lifestyle program was problematic with only a 37% success rate due to difficulty scheduling and
19 making phone appointments (both providers and participants). Implementation of the lifestyle
20 program took 9.3 months compared to the outlined protocol of 6.5 to 7 months due to NP
21 illnesses, rescheduling of participant appointments, and the end of the year holidays. The
22 protocols for in-person sessions were implemented with moderately good success.

23 Implementation of the standard care NP protocol was 80%, implementation of the standard care

1 nutrition protocol was 92%, and NP implementation of the lifestyle protocol was 76%. NPs of
2 the lifestyle program reported confidence in the ability to implement the educational and
3 behavioral strategies of goal setting and problem-solving. All NPs reported that motivational
4 interviewing was the most challenging aspect of the protocol to implement; however, they
5 consistently worked at improving their skills for the duration of the study. Protocol
6 implementation increased over time. NPs requested additional training and expert consultation
7 throughout the course of the study. Time was also a factor that contributed to difficulty
8 implementing the protocol. NPs reported that study participants often discussed psychosocial
9 issues within the context of lifestyle change (eg. stress of job), and this required time in sessions
10 which sometimes precluded the ability to complete all aspects of the protocol.

11 Preliminary efficacy of the intervention

12 Clinical Outcomes. Results of the mixed model analyses for all outcomes are reported in
13 Table 3. Participants in the lifestyle program demonstrated trends for greater percent weight loss
14 ($p=.08$) and higher HDL levels ($p=.21$) over participants in the enhanced standard care program.
15 Figure 2 depicts mean percent weight change from baseline between the two groups. At six
16 months, twenty-five percent of lifestyle participants achieved a weight loss goal of 5% compared
17 to 11% of standard care participants. HOMA levels demonstrated a trend to increase over time
18 in both groups ($p=.11$). There were no significant differences or trends with respect to other
19 clinical variables.

20 Behavioral Outcomes. Participants in both groups demonstrated improvement over time
21 in nutrition behavior ($p=.001$). Both groups also demonstrated a significant monthly increase in
22 exercise behavior ($p=.001$), with lifestyle participants demonstrating trends toward greater
23 improvement in exercise ($p=.08$).

1 Psychosocial and Satisfaction Outcomes. While there was a decrease in depressive
2 symptoms over time, this change was not significant. Participants of the lifestyle program were
3 more satisfied with the program compared to standard care participants ($t=2.06$; $p=.05$).

4 Effect of 5% Weight Loss on Clinical Outcomes

5 Mixed model analysis comparing participants with 5% weight loss, regardless of group
6 assignment, to participants who did not achieve 5% weight loss supported the beneficial effect of
7 weight loss with respect to a decrease or a decreasing trend in HOMA ($p=.10$), GTT ($p=.02$),
8 insulin at 120 minutes ($p=.001$), LDL ($p=.10$), triglyceride ($p=.14$), and cholesterol ($p=.07$).
9 Both groups improved their exercise ($p=.001$) and nutrition behaviors ($p=.001$), with a greater
10 rate of increase in exercise among participants who achieved 5% weight loss ($p=.01$).

11 Discussion

12 Results of this study support the feasibility of implementing a diabetes prevention
13 program by NPs in a primary care setting to adults at-risk for T2D. Study participants were
14 primarily female, of diverse race/ethnicity, obese, sedentary, of low to moderately-low income,
15 and with elevated depressive symptoms which is representative of adults at-risk for T2D.

16 Successful reach and implementation of study protocols are important results of this
17 study. There was high attendance for in-person sessions and low attrition, critical elements to
18 improving diabetes prevention efforts in vulnerable populations. Previous research
19 implementing behavioral or psychological intervention research into primary care has
20 demonstrated high attrition (30-40%) and considerable implementation issues (Zayes et al.,
21 2004). While there were some notable issues in the implementation of study protocols in this
22 study (ie., difficulty completing phone sessions, longer duration of program, frequent
23 rescheduling of participant appointments), protocol implementation of in-person sessions was

1 very good. NPs were able to successfully implement an enhanced standard care and a lifestyle
2 program aimed at T2D prevention within the context of primary care (ie., 20 minute sessions)
3 and without considerable training. Future dissemination of this program will be facilitated as
4 NPs in both groups reported high levels of confidence in implementing the educational and
5 behavioral strategies subsumed within the programs. Motivational interviewing was the only
6 behavioral strategy that NPs in the lifestyle program expressed lack of confidence. The finding
7 that NPs were able to easily implement many aspects of a lifestyle program is important, as
8 lifestyle counseling has been reported to be difficult to implement by primary care physicians.

9 Preliminary efficacy results of the lifestyle program indicate modest improvements with
10 respect to clinical and behavioral outcomes. Twenty-five percent of lifestyle participants
11 achieved a 5% weight loss goal compared to 11% of participants in standard care. These results
12 were obtained with a lifestyle program of much shorter duration than the DPP (4 hours vs. 12-16
13 hours) which is considerably less costly and potentially more acceptable to practitioners and
14 participants. Weight loss of 5-7% in adults at risk for T2D improves glucose tolerance and
15 consistently has been shown to reduce the risk for T2D (Colman et al., 1995; Rana, Li, Manson
16 & Hu, 2007). Modest weight loss was a strong predictor of T2D risk reduction in the DPP, with
17 a 16% reduction in diabetes risk per kilogram of weight loss (Hammon et al., 2006).

18 Both lifestyle participants and standard care participants demonstrated improvements in
19 diet and exercise behavior over time, additional behaviors shown to decrease T2D risk (Hammon
20 et al., 2006). However, lifestyle participants demonstrated a trend toward greater improvements
21 in exercise behavior. This finding is important as increasing exercise has been the primary
22 behavior associated with risk reduction for type 2 diabetes, often in combination with weight
23 loss. In the DPP, diabetes risk decreased as nutrition, exercise, and weight loss goals were met.

1 However, meeting the exercise goal (of 150 minutes per week) was more critical than meeting
2 the nutrition goal in reducing diabetes incidence (Hammon et al., 2006). Exercise decreases
3 glucose-stimulated insulin production, increases insulin sensitivity, and decreases abdominal
4 adiposity, all risk factors for IGT and T2D (Bloem & Chang, 2008; Pratley et al., 2000). In a
5 prospective study with adults at-risk for T2D, a protective effect of exercise was observed, even
6 in adults with high BMI and glucose levels (Hu et al., 2004).

7 More than 50% of all Americans are not engaging in regular exercise or physical activity
8 with 25% reporting no leisure time physical activity (Zoeller, 2007). Participants in this study
9 were not physically active at baseline, with only 34 % reporting an exercise goal of 150 minutes
10 per week. Thus, lifestyle programs that provide at-risk adults with strategies to safely initiate
11 and maintain exercise are critical to T2D prevention. The increased intensity of the lifestyle
12 program in this study appears to have enhanced participants' ability to engage in exercise.

13 Nutrition behaviors also play an important role in T2D risk reduction. Both groups in
14 this study improved nutrition behaviors over time. Providing educational and behavioral
15 strategies on nutrition and physical activity are foundational aspects to diabetes prevention
16 programs. Meeting nutritional goals has been associated with weight loss maintenance which
17 has been shown to improve diabetes risk factors (Avenell et al., 2004). Strategies to support
18 weight loss as well as insulin sensitivity are important in T2D prevention. The beneficial effect
19 of weight loss in adults at risk for diabetes was supported in this study as participants with a 5%
20 weight loss demonstrated clinically significant improvements on important clinical outcomes of
21 glucose, insulin resistance, and lipids as well as exercise behavior.

22 While this study was a pilot study that focused on the reach and implementation as well
23 as preliminary efficacy, inadequate power precludes strong conclusions or clinical implications.

1 Clearly NPs represent a health care provider able to implement a diabetes prevention program in
2 a primary care setting; however, the intervention protocol requires further development and
3 testing. Future research will be aimed at increasing the intensity of the intervention while
4 simultaneously considering the structure and processes of primary care. Eliminating phone
5 sessions, introducing email contacts, providing additional in-person sessions, addressing elevated
6 depressive symptoms, encouraging family participation at sessions, and developing a
7 maintenance component to the program are revisions that are currently in progress. Previous
8 research strongly supports increasing the intensity of behavioral interventions to increase the
9 potential for weight reduction and maintenance (Norris et al., 2005). The challenge remains to
10 identify the settings and sessions required. NPs typically provide ongoing follow-up care for
11 adults at risk for T2D, thus, a maintenance component to this lifestyle program appears feasible.
12 In addition, enhanced motivational interviewing training for NPs is also indicated.

13 Conclusion

14 With the increasing prevalence of obesity and T2D risk, many adults would benefit from
15 a preventive intervention. Yet, intensive lifestyle interventions are not easily implemented in the
16 current health care system. Research is needed to evaluate less intensive interventions that take
17 into consideration issues of reach and implementation as well as intervention efficacy. Results
18 demonstrate a collaborative process of translating the DPP into the primary care setting, with
19 NPs taking part in shaping and implementing the intervention protocol. While this was a small
20 pilot study from one geographical area, with a relatively short program duration, preliminary
21 results with respect to reach, implementation, and efficacy support further development and
22 testing of this lifestyle program.

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Figure 1. Consort Table

Figure 2. Weight Change From Baseline (%) by Group

Table 1.

Lifestyle Protocol

Session	Topic
NP session 1A	Welcome to the Lifestyle Balance Program. Highlighted study goals: 7% weight loss and 150 minutes of weekly physical activity.
NP session 1B	Healthy Eating. Emphasized the importance of a regular meal pattern and eating slowly. Used the Food Guide Pyramid as a model for healthy eating and compared personal eating patterns to these recommendations. Recommended specific low-fat, low-calorie substitutes at each level of the food pyramid.
Take-home	Healthy Eating Part II. More information on low-fat, healthy eating.
NP session 2	Get Started Being Active. Discussed physical activity and importance to weight loss. Helped participants learn to set incremental exercise goals.
Take-home	Get Started Being Active Part II. More information on the benefits of exercise and how to exercise safely.
NP session 3	Tip the Calorie Balance. Discussed the fundamental principle of energy balance and what it takes to lose 1-2 pounds per week.
Take-home	Take Charge of What's Around You. Introduced the principle of stimulus control and ways to identify cues in the home environment that lead to unhealthy food and activity choices.
NP session 4A	Talk Back to Negative Thoughts. Practiced identifying common patterns of

self-defeating, negative thoughts and ways to counter these thoughts with positive statements.

NP session 4B The Slippery Slope of Lifestyle Change. Stressed that slips are normal and learning to recover quickly is the key to success.

Take-home Four Keys to Healthy Eating Out. Introduced four basic skills for managing eating away from home: anticipating and planning ahead, positive assertion, stimulus control, and making healthy food choices.

NP session 5 You Can Manage Stress. Highlighted the importance of coping with stress, including stress caused by the Lifestyle Program.

Take-home Make Social Cues Work *for* You. Presented strategies for managing problem social cues, e.g., being pressured to overeat, and helped participants learn social cues to promote healthy behaviors.

NP session 6 Ways to Stay Motivated. Enhanced motivation to maintain behavior change by reviewing participants' personal reasons for joining the Lifestyle Program and by recognizing personal successes thus far

Take-home Ways to Stay Motivated Part II.

Table 2.

Characteristics of Subjects at Baseline by Treatment Group

Characteristic	Treatment (n=31)	Control (n=27)	p-value
<i>Age, years</i>			
Mean (\pm SD)	48.2 (12.4)	43.2 (13.2)	0.1415*
<i>Sex</i>			
Male, n (%)	3 (50.0)	3 (50.0)	1.0000 [#]
Female, n (%)	28 (53.8)	24 (46.2)	
<i>Race</i>			
White, n (%)	15 (57.7)	11 (42.3)	0.0116[#]
Black, n (%)	14 (70.0)	6 (30.0)	
Hispanic, n (%)	2 (16.7)	10 (83.3)	
<i>Income</i>			
< \$19,999, n (%)	1 (9.1)	10 (90.9)	0.0176[#]
\$20,000 - \$39,999, n (%)	12 (70.6)	5 (29.4)	
\$40,000 - \$59,999, n (%)	7 (58.3)	5 (41.7)	
\$60,000 - \$99,999, n (%)	7 (70.0)	3 (30.0)	
\$100,000 and greater, n (%)	4 (50.0)	4 (50.0)	
<i>Clinical Variables</i>			
HOMA**	5.6 (3.1)	5.7 (5.4)	0.5942*
Glucose ₁₂₀ (mg/dl)	119.1 (40.9)	109.8 (36.1)	0.3670*
LDL (mg/dl)	123.0 (38.0)	109.7 (33.4)	0.1164*

HDL (mg/dl)	48.6 (13.1)	43.7 (11.0)	0.1295*
BMI (kg/m ²)	40.0 (9.0)	37.4 (7.0)	0.2262*
Waist (inches)	45.3 (7.8)	42.6 (6.9)	0.1720*

Behavioral Variables

Physical Activity	1.8 (0.5)	1.9 (0.6)	0.7747*
Minutes of Exercise/Week	139.7 (191.3)	129.5 (139.7)	0.8162*
< 150 minutes, n (%)	22 (57.9)	16 (42.1)	0.4130 [#]
Nutrition (HPLP range 0-4)	2.4 (0.6)	2.4 (0.5)	0.6695*
CES-D (range 0 – 60)	12.1(10.7)	14.9 (13.6)	0.3890*
≥ 16 total score, n (%)	10 (52.6)	9 (47.4)	1.0000 [#]

* Student's t-test; [#] Fisher's Exact test;
 ** Log-Transformed for Analysis

Table 3.

Estimates of Monthly Change in Outcome in Treatment and Control Groups

Characteristic	Control group rate of change	Treatment group rate of change	p-value ¹	p-value ²	Group effect size at 6 months
<i>Clinical Variables</i>					
Percent Change in Weight	0.13	-0.42	0.45	0.08	0.33
HOMA**	0.02	0.01	0.11	0.61	0.14
Glucose 120 minutes (mg/dl)	1.50	0.28	0.30	0.48	0.03
Insulin 120 minutes (μU/ml) **	0.01	-0.03	0.59	0.29	0.05
LDL (mg/dl)	-0.14	0.07	0.94	0.87	0.28
HDL (mg/dl)	0.17	0.60	0.03	0.21	0.24
BMI (kg/m ²)	-0.02	-0.03	0.55	0.97	0.11
Waist (inches)	-0.03	-0.19	0.33	0.35	0.28
<i>Behavioral Variables</i>					
Physical Activity	0.05	0.10	<.0001	0.08	0.24
Nutrition	0.04	0.03	0.001	0.63	0.02
CES-D (range 0 – 60)	-0.01	-0.34	0.40	0.42	0.01

** Log-Transformed for Analysis

¹ p-value for main effect of time (month) across both groups

² p-value for interaction of treatment and time (month)

Table 4.

Estimates of Monthly Change in Outcomes in Group with 5% Weight Loss at 6 Months

vs Group with <5% Weight Loss at 6 Months

Characteristic	Rate of change in <5% weight loss group	Rate of change in 5% weight loss group	p-value ¹	Group effect size at 6 months
<i>Clinical variables</i>				
HOMA **	0.02	-0.03	0.10	0.45
Glucose 120 minutes (mg/dl)	1.94	-2.98	0.02	0.64
Insulin 120 minutes (μU/ml)**	0.02	-0.14	0.0001	1.43
LDL (mg/dl)	0.34	-2.38	0.10	0.50
HDL (mg/dl)	0.45	-0.02	0.30	0.44
Triglyceride (mg/dl) **	0.003	-0.03	0.14	0.59
Cholesterol (mg/dl)	0.78	-3.22	0.07	0.59
Waist (inches)	-0.07	-0.24	0.38	0.24
<i>Behavioral variables</i>				
Physical activity	0.05	0.15	0.01	0.87
Nutrition (HPLP range 0-4)	0.03	0.04	0.62	0.29
CES-D (range 0 – 60)	-0.14	-0.53	0.46	0.17

** Log-Transformed for Analysis

² p-value for interaction of treatment and time (month)

Figure 1

Consort Table

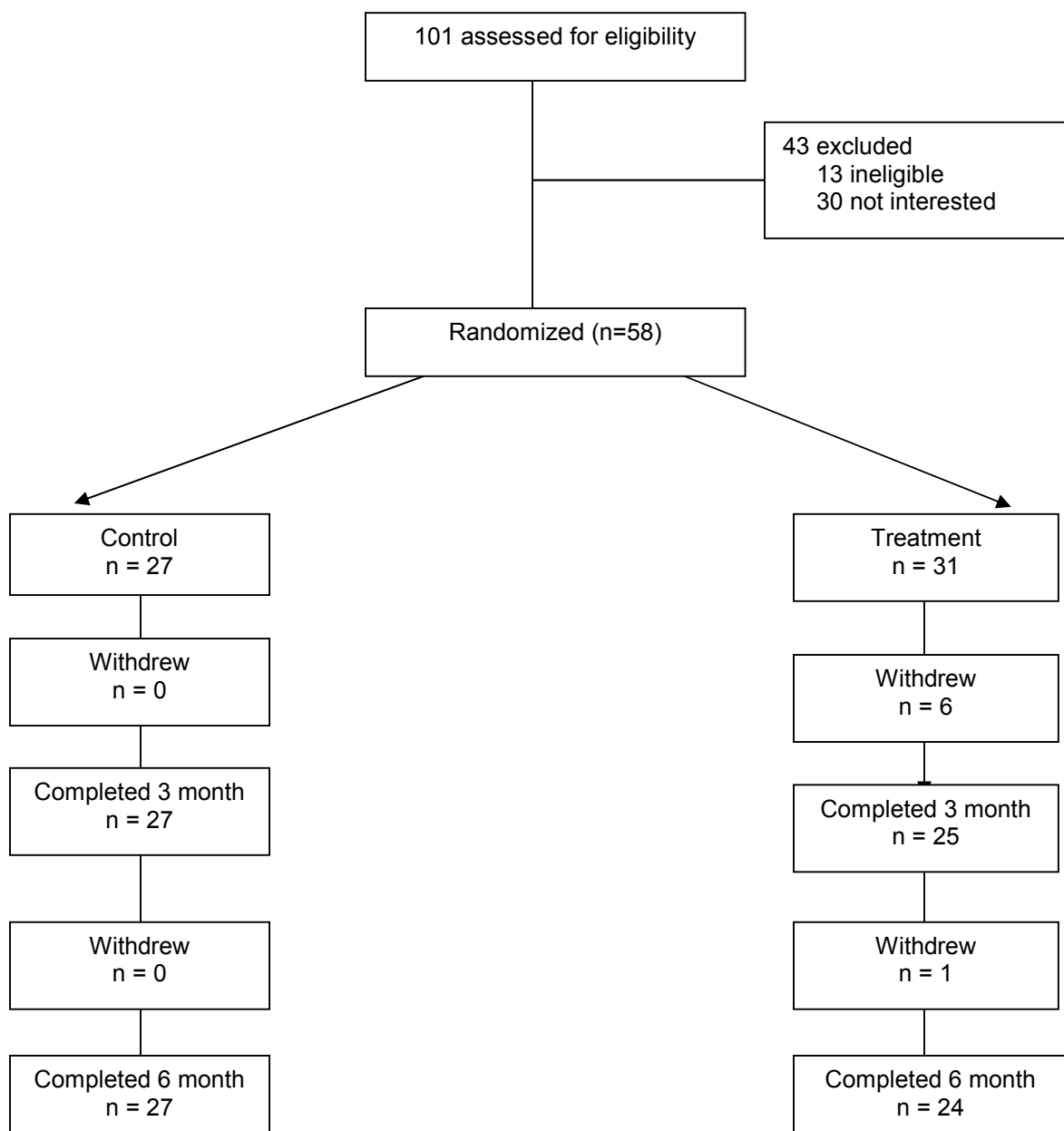


Figure 2

Weight Change From Baseline (%) by Group

