

**Nursing Interventions for Improving Health Outcomes of Older African American
Women with Type 2 Diabetes**

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1 Background - Type 2 diabetes affects one in five African American women over the age of
2 60, who face distinct challenges in managing their diabetes self care. Therefore, culturally-
3 sensitive, tailored self-care interventions need to be developed and tested for this
4 population.

5 Objectives - We compare a tailored, four visits, in-home symptom-focused diabetes
6 intervention with and without booster telephone calls to an attentional control intervention
7 focusing on skills training for weight management and diet.

8 Methods - 180 African American women (>55 years old, Type 2 diabetes mellitus >1 year,
9 HbA1c >7%) randomly assigned to the symptom focused or weight/diet intervention were
10 evaluated at baseline, 3, 6 and 9 months.

11 Results - HbA1c declined significantly in the whole sample, .57%, with no differences
12 between study arms. Participants in the booster arm decreased HbA1c by .76%. Symptom
13 distress, perceived quality of life, impact of diabetes, and self-care activities also improved
14 significantly for the whole sample with no significant differences between study arms.

15 Discussion - Parsimonious interventions of 4 in-person visits yielded clinically significant
16 decreases in HbA1c. Although the weight/diet intervention was intended as an attentional
17 control, its positive impacts suggest it met a need in this population. Since the content of
18 the two interventions were effective despite different approaches, a revised symptom-
19 focused intervention that incorporates weight/diet skills training may offer even better
20 results.

21 Key words - diabetes, African American, symptoms

22

Background

1
2 Over seven percent of adults in the U.S. have been diagnosed with diabetes, and
3 diabetes-related care now accounts for 11% of all U.S. health care expenditures (American
4 Diabetes Association [ADA], 2005). Type 2 diabetes disproportionately affects African
5 Americans, who are almost twice as likely to have the disease, less likely to have good
6 glycemic control, and have a higher incidence of diabetes complications when compared to
7 Caucasian Americans (ADA, 2005; Saydah, Cowie, Eberhardt, De Rekeneire, & Narayan,
8 2007; Selbey et al., 2007). Diabetes poses a particular burden for African American women
9 over the age of 60; 20% of whom are diagnosed with diabetes (ADA, 2005). Many older
10 African American women live in poverty, adding to their burden in managing their care.
11 Those who live in rural areas face further challenges due to the shortage of health care
12 providers, lack of transportation, and limited community-based resources to support their
13 self-care (Stoodt & Lengerich, 1993).

14 The goal of diabetes management is to improve glycemic control and thereby
15 prevent or delay the onset of complications (ADA, 2008). The cornerstone of management
16 is self-care, which consists of an often complex regimen of meal planning, daily foot care,
17 regular physical activity, weight control, administration of insulin or oral medications, and
18 self-monitoring of blood glucose. An individual's culture, resources, and functional
19 abilities affect their approach to self-care. Therefore, self-care management interventions
20 are more effective when they attend to these differences (ADA, 2008; Sarkisian, Brown,
21 Norris, Wintz, & Mangione, 2003). Yet few interventions tailored to the needs of older,
22 rural African American women have been developed. Researchers have demonstrated the
23 effectiveness of diabetes self-care interventions tailored for African Americans (Anderson

1 et al., 2005; Anderson-Loftin et al., 2005; Feathers et al., 2005; Keyserling et al., 2002;
2 Mayer-Davis et al., 2004) and the elderly, but have not focused on the distinct needs of
3 African Americans who are also elders (Falkenberg, Elwing, Göransson, Hellstrand, &
4 Riis, 1986; Funnell, Arnold, Fogler, Merritt, & Anderson, 1997; Gilden, Hendryz, Clar,
5 Casia, & Singh et al., 1992; Glasgow et al., 1992; Halter, Anderson, & Herman, 1993). Only
6 three studies have tested self-care interventions for older African Americans; all were
7 tested with urban populations, and two had small samples (Agur-Collins, Kumanyika, Ten
8 Have, & Adams-Campbell, 1997; Jaber, Halapy, Fernet, Tummalapalli, & Diwakaran,
9 1996; Mazzuca et al., 1986). In this report, we present a test of the effectiveness of a
10 symptom-focused approach to diabetes self-care tailored for older African American
11 women as compared to a more traditional skills-based approach. We also assess the effect
12 of a telephone booster follow-up for the symptom-focused approach.

13 ***A Symptom-Focused Approach to Diabetes Self-care Management***

14 The conceptual model for the symptom-focused intervention is based on the
15 University of California at San Francisco Symptom Management Model (Dodd,
16 Miaskowski, & Paul, 2001; UCSF Symptom Management Group, 1994) and one developed
17 to manage symptoms of HIV infection in women (Miles et al., 2003). The development of
18 the conceptual model and how it was used to guide the design of the study and intervention
19 is described elsewhere (Author, 2008, in press). Symptom-focused interventions have
20 demonstrated effectiveness at reducing symptom distress and improving health behaviors
21 for a broad range of conditions (Chiou, Kuo, Chen, Wu, & Lin, 2005; Given et al., 2004;
22 Taylor, 1999; Wassem & Dudley, 2003; Zimmerman et al., 2007). People with diabetes
23 experience symptoms acutely and chronically throughout the course of their disease

1 distress, and perceived quality of life. We also evaluated the impact of a booster
2 intervention on sustaining the effects of the symptom-focused intervention.

3 **Methods**

4 This study used a randomized controlled three-group experimental design with
5 2/3 of subjects randomly assigned to the intervention, and 1/3 to the attentional control
6 (weight/diet) program. At the end of their intervention, 1/2 of the symptom-focused
7 intervention participants were randomly assigned to receive the telephone booster.

8 ***Sample***

9 The sample consisted of 180 African American women recruited from health care
10 centers, health department clinics, and primary care practices serving the target population.
11 The inclusion criteria for the study were female gender, age 50 and older, African-
12 American ethnicity as defined by the participant, type 2 diabetes for greater than 1 year,
13 and HbA_{1c} greater than 7%. A_{1c} less than 7% is the current standard established by the
14 American Diabetes Association for acceptable glycemic control (ADA, 2008). Participants
15 were required to have access to a telephone and be English speaking.

16 ***Symptom - Focused Intervention***

17 The symptom-focused intervention was a teaching/counseling intervention
18 delivered by a nurse in the participant's home over a series of four bi-monthly visits. The
19 intervention was guided by four modules addressing Symptoms of Hyperglycemia,
20 Symptoms of Hypoglycemia, Numbness and Tingling in the Feet/Foot Pain, and Prevention
21 of Cardiovascular Symptoms. These modules were based on symptom clusters identified in
22 our previous research (Stover et al., 2001). Each module was composed of: 1) a brief
23 overview of the symptom, 2) assessment parameters, 3) goals for the intervention, 4)

1 symptom management strategies, and, 5) materials on the prevention of symptoms. The
2 nurse individualized the intervention by allowing participants to choose in which order to
3 address symptoms and what management strategies to use. This approach covered not only
4 the symptoms participants were experiencing but also other symptoms of diabetes they
5 may encounter.

6 ***Telephone Booster***

7 Three months after completion of the intervention, participants in the booster arm
8 received four telephone calls at approximately 2-3 week intervals with the spacing of the
9 calls covering a 12-week interval similar to that of the intervention. To build on the
10 therapeutic relationship formed during home visits, the calls were made by the same
11 intervention nurse that made the home visits, using an established protocol. The purpose of
12 the telephone booster was to reinforce the strategies developed during home visits, engage
13 in problem-solving, provide motivation/encouragement, and encourage reframing and
14 adjustment as needed.

15 ***Attentional Control Intervention***

16 The attentional control was a weight/diet intervention consisting of four modules
17 addressing Weight Maintenance (two modules), Modifying Fat, and Modifying Sodium in
18 the diet. These modules included skill-based strategies to enhance diabetes self-care (such
19 as label reading) but did not directly address symptoms. An important component of the
20 learning modules was practice exercises, shopping lists and recipes. The modules also were
21 individualized, allowing participants to choose which content areas to address and what
22 management strategies to use. This intervention was a skills-based, “how-to” approach
23 similar to traditional diabetes education.

1 *Measurement*

2 We assessed the interventions' effects on the study outcomes (metabolic control,
3 symptom distress, perceived quality of life and self-care practices). *Metabolic control* was
4 assessed by HbA1c, a measure of the participant's weighted average blood glucose level
5 over the preceding 2-3 months (Lebovitz, 1998). *Symptom distress* was measured by the
6 Diabetes Symptom Distress Scale, a 20-item instrument measuring the presence of 20
7 diabetes-related symptoms and the amount of distress caused by these symptoms
8 (Cronbach's alpha .86 for the distress scale). The distress score correlated well with other
9 diabetes specific measures: $r=0.62$ ($P<.01$) with PAID, and $r=0.51$ ($p<.01$) with the mental
10 well-being score and $r=0.53$ ($p<.01$) with the social well-being score of Diabetes-related
11 Quality of Life. The distress score changed consistently with changes in HbA1c over 9
12 months ($p=.02$), demonstrating its ability to measure changes due to treatment.

13 Quality of life was measured by two diabetes-specific measures. *Diabetes-related*
14 *Quality of Life* was measured with the Quality of Life in Diabetes Scale, a measure of
15 diabetes-related quality of life developed for use with older, rural African Americans which
16 focuses on the effects of diabetes self-care regimens, symptoms, and complications on an
17 individual's mental and social wellbeing (Elasz et al., 2000). This 27-item instrument has
18 two subscales measuring quality of life in two domains: mental well-being and social well-
19 being; scores range between 1 and 4, where 4 is the highest quality of life. Cronbach's
20 alpha is 0.83 for the mental well-being scale and 0.93 for the social well-being scale. The
21 instrument has received extensive validation from focus groups and in structured interviews
22 with African American women (Elasz et al., 2000). Other aspects of quality of life were
23 measured by the Problem Areas in Diabetes survey (PAID) (Polonsky et al., 1995;

1 Polonsky et al., 2005). The *PAID* is a 20-item instrument in which each item represents an
2 area of diabetes-related psychosocial distress such as worry, frustration, anger,
3 interpersonal distress and coping concerns. The PAID is scored on a scale of 0-100 where
4 higher scores indicate greater problems. Concurrent validity was established by significant
5 correlations between the PAID and diabetes-coping strategies (Welch, Jacobson, &
6 Polonsky, 1997). The PAID has high internal reliability with a Cronbach's alpha of .95.
7 *Diabetes self-care practices* were measured by the Diabetes Self-Care Practices
8 questionnaire (Skelly et al., 1995) a self-report of daily diabetes-related self-care practices
9 in five regimen areas: diet, medications/insulin, home glucose monitoring (HGM) physical
10 activity/exercise and foot care. Performance is rated by the percent of time the practice was
11 performed: 0, 25, 50, 75 or 100% of the time. To improve the stability of the analysis, the
12 responses were grouped into compliant (100 and 75%) and non-compliant (50, 25 and 0%).

13 All of these instruments were reviewed by members of the investigative team and
14 Community Advisory Board for cultural relevance and acceptability and pilot tested with
15 African American participants to assess readability and ease of administration.

16 ***Intervention Procedures***

17 IRB approval was obtained from the Institutional Review Board at The University
18 of North Carolina at Chapel Hill. After meeting the inclusion criteria and providing
19 informed consent, participants were randomized to the test or attentional control
20 intervention arm and completed the baseline study questionnaires during two initial visits.
21 This was followed at two-week intervals by four home visits delivered by a registered
22 nurse during which participants received either the symptom-focused or weight/diet
23 attentional control intervention. Visits in the home lasted about 60 minutes ($X = 63.5$, $SD =$

1 12.02). Data collection visits conducted by a research assistant were made at 3 months (2
2 weeks after the last intervention visit), 6 months and 9 months. A booster telephone
3 intervention consisting of 4 monthly telephone calls was provided between months 6 and 9
4 to symptom-focused participants chosen randomly at month 6. This was delivered by the
5 same nurse who had conducted the home intervention.

6 ***Data Analysis***

7 To preserve the integrity of the randomized trial, each participant was analyzed in
8 the study arm to which they were randomized, regardless of degree of adherence to their
9 intervention or whether they were observed at all of the data collection times. For HbA1c,
10 Diabetes Symptom Distress, Diabetes Related Quality of Life, and Problem Areas in
11 Diabetes, hypotheses regarding changes in outcome due to assignment to symptom-focused
12 (SF/B), symptom-focused without booster (SF), or the weight/diet attentional control (WD)
13 were tested with linear mixed models. Three hypotheses were examined to assess the
14 immediate and longer term effect of the symptom-focused intervention relative to the
15 weight/diet intervention, and the effect of the telephone booster: 1) over the intervention
16 period, (baseline to month 3), outcomes improved more for the combined SF/B and SF
17 participants than for WD. 2) Over the entire study period to month 9, the outcome
18 improved more for SF/B participants than for SF and WD, and SF improved more than WD
19 and 3) between 6 and 9 months, the outcome improved more for SF/B participants than for
20 only SF participants.

21 For each outcome, the appropriate covariance structure was identified by
22 examination of the observed autocorrelations and by comparing values of Aikake's
23 Information Criteria (AIC) that resulted from specifying different structures. To allow for

1 variations in the actual times between observations, time was represented by the number of
2 days elapsed from the baseline measurement. Quadratic and cubic terms for time were
3 included in initial models to represent possible non-linear effects and were dropped from
4 subsequent models if they were non-significant.

5 For self-care practices, generalized linear models were used to estimate models
6 similar to those for the health outcomes but with time represented by the data collection
7 point (1 for the baseline measurement to 4 for the 9 month measure). Generalized
8 estimating equations were employed to model the repeated measurements.

9 **Findings**

10 Of the 308 potential participants screened, 180 (58%) met the inclusion criteria and
11 were enrolled. The primary reason potential participants were deemed ineligible was
12 HbA1c levels below the 7% level required for inclusion. The typical study participant was
13 67 years old, widowed, residing in her own home, with a history of diabetes for 12 years, a
14 HbA1c of 8.3% and less than a high school education. Her total family income was less
15 than \$15,000 per year. She was taking 8.4 prescribed medications daily and received
16 Medicare. This typical participant presented with an average of 8.2 (SD 4.1) symptoms
17 related to diabetes and had previously received diabetes education primarily from her
18 healthcare provider via printed materials. As detailed in Table 1, baseline values of patient
19 characteristics and outcomes were equivalent across the three treatment groups with the
20 exception of educational level and the PAIDS score.

21 ***Retention***

22 The overall retention rate at 9 months was 90.6%. Retention rates for the 4
23 evaluation visits were 97% for time 1, 96% for time 2, 93% for time 3 , and 91% for time

1 4. Seventeen (17) women did not complete all four evaluation points. The reasons for
2 attrition were: died (n=7), depressed/ill (n=1), moved out of state (n=1), lost to follow-up
3 (n=7), and procedural error (n=1). The likelihood of completing the study was not related
4 to initial treatment assignment: 90.8% of the SF (symptom-focused) and SF/B (symptom-
5 focused with booster) participants completed the study compared to 88.3% of the WD
6 (weight/diet) participants, chi-square (1)=0.51, p=0.47. Completion of the study also was
7 not related to the primary physiological outcome, glycemic control. Mean and standard
8 deviation of HbA1c levels at enrollment were 7.97 (1.57) for those who did not complete
9 the study versus 8.32 (1.63) for those who did finish, F (1,178) =0.70, p=0.40.

10 ***Metabolic control, symptom distress and perceptions of quality of life***

11 *Metabolic control* - The mean HbA1c was 8.3% (SD 1.6) at baseline. As seen in
12 Figure 1, over the 9-month study period, there was a significant decline in HbA1c decline
13 from baseline for the entire sample (p=0.01), but there were no significant differences in
14 the amount of decline between the study arms. During the intervention period between
15 baseline and 3 months, the decline was greater for the combined SF + SF/B participants
16 than for WD participants (p=0.04). The SF/B and WD groups experienced some degree of
17 increase in HbA1c between 3 months and 6 months after which both group means declined
18 at 9 months to their lowest point during the study. Between 3 and 6 months the mean for SF
19 participants did not change, after which it rose, but remained below baseline level. The
20 SF/B participants improved significantly compared to SF participants during the period of
21 booster follow-up (from 6 to 9 months, p=0.04). Participants receiving the booster
22 decreased their HbA1c by .76% over the nine months of the study.

1 *Symptom Distress* – Symptom distress declined throughout the study period for all
2 treatment groups, more sharply for SF/B and WD than for SF participants. On average
3 participants across treatment groups reported a significant decrease in symptom distress at
4 9 months as compared to baseline ($p<0.01$), but the hypothesized differences in decline
5 between the treatment groups were not seen. Likewise, comparisons of change from
6 baseline to 3 months between SF + SF/B and WD, and between SF/B and SF from 6 to 9
7 months were not significant.

8 *Perceptions of quality of life* were measured by the *Diabetes-related Quality of Life*
9 *scale* and the *Problem Areas in Diabetes scale (PAIDS)*:

10 *Diabetes-related Quality of Life* – There was a significant increase in the mean
11 scores for mental and social well-being for the entire sample over the study period but there
12 were no difference between study arms in the amount of increase. No differences in the
13 amount of increase were observed from baseline to 3 months between SF+SF/B and WD,
14 and from 6 to 9 months between SF/B and SF.

15 *Problem Areas in Diabetes (PAIDs)* – Over the study period the decrease in PAIDS
16 score in the total sample was significant ($p<0.01$), but no differences were observed
17 between the treatment groups. No differences in change between baseline and 3 months
18 were observed between SF+SF/B and WD. Participants in the booster arm showed greater
19 improvement than participants in the other symptoms management arm during the 6 to 9
20 month period, demonstrating a significant effect for the booster ($p=.04$).

21 *Diabetes Self-Care Practices* - We also examined participants' self-care practices
22 using the Diabetes Self-Care Practices questionnaire (Skelly et al., 1995). Based on our
23 previous research, we considered each of the diabetes regimen areas separately (diet,

1 exercise, insulin/oral medication, HGM and foot care). Treatment assignment had no
2 significant effect on changes in adherence for any of the self-care practices. This was true
3 for comparing SF+SF/B to WD from baseline to 3 months, comparing all 3 treatments from
4 baseline to 9 months, and for SF+B vs SM from 6 to 9 months. However, the total sample
5 improved in their self-care in regard to diet, oral medications, and foot care over the course
6 of the study ($p < .05$ for each outcome). There were no significant changes over time in
7 regard to physical activity, insulin use or home glucose monitoring. The self-care practices
8 that improved over the course of the study did not mediate the effects of the study on
9 HbA1c, diabetes-related quality of life, or symptom distress. However, compliance with
10 diet was positively correlated with the mental well-being scale of the Diabetes-related
11 Quality of Life instrument.

12 **Discussion**

13 *Effects on Health Outcomes*

14 Over the nine months of the study, self-care practices, metabolic control, symptom
15 distress, and quality of life improved for the entire sample. The average drop in HbA1c for
16 the entire sample was .57%, and the maximum drop was in the symptom management
17 participants that received the telephone booster. Their HbA1c decreased by .76%. The
18 observed decreases were a clinically important level of improvement for an intervention of
19 4 in-person contact hours and four telephone calls. However, the study found no
20 differences in change between the symptom-focused and diet/weight (attentional control)
21 interventions. The absence of differences may be explained if improvements in outcomes
22 were caused by both the treatment and control intervention or if they were the result of
23 extraneous factors. It is our contention that both the symptoms intervention and the

1 weight/diet interventions were effective. To persuasively make this case, we first address
2 the *potential role of extraneous factors*.

3 Multiple extraneous factors can affect outcomes and threaten the validity of study
4 findings. Potential threats to validity most relevant to the present study include *reactivity of*
5 *measurement, contamination, history effects, and other measurement issues* (Becker,
6 Roberts, & Voelmeck, 2003).

7 *Reactivity of measurement* refers to the effect that study measures themselves can
8 have on an individual's knowledge and behaviors. A central purpose of the symptom-
9 focused intervention was to teach participants about diabetes symptoms. By measuring
10 symptom distress in all study participants, we may have raised weight/diet participants'
11 awareness of the relationship between their symptoms and diabetes as well. Since the
12 instrument used to measure symptom distress lists 18 symptoms, it might be especially
13 prone to educating participants compared to instruments that ask more general questions.
14 However, the number of symptoms reported declined as well as the level of symptom
15 distress. Since increased awareness of and knowledge about diabetes related symptoms
16 would be expected to increase the reports of symptoms and their associated distress, it
17 seems that reactivity of measurement would work against an observed decline in those
18 measures. Thus, we cannot rule out the possibility that the study measurements had some
19 impact on participants' diabetes-related behaviors but that would not account for the
20 decline in symptoms and symptom related distress. Reasons for reactivity to measurement
21 in other instruments are not readily apparent and reactivity is not relevant to HbA1c.

22 *Contamination* occurs when participants in the control group are exposed to
23 components of the intervention. We designed the study to minimize opportunities for

1 contamination. Different nurses were used to deliver the symptom management and the
2 attentional control interventions. The PI met weekly with the intervention nurses for both
3 the symptom management and weight/diet interventions separately to discuss any problems
4 and issues with delivery of their intervention. Over the course of the study, she also made
5 shared visits with all the intervention nurses to observe the fidelity of their delivery of the
6 intervention which they were assigned to deliver.

7 *History* refers to contextual factors occurring at the same time as the intervention
8 that effect outcomes in study participants in both the test and control arms of the study. For
9 example, release of a new diabetes treatment could improve outcomes independent of the
10 intervention. We feel that improvement from baseline to 9-months was not a historical
11 effect, but that real improvement occurred due to the interventions. Evidence for this is that
12 the baseline values for new participants' outcomes did not improve significantly as the trial
13 progressed. An improvement in the population during the course of the trial would be
14 expected to be seen in the baseline measurements since the cases were not newly
15 diagnosed. Additionally, the outcome for statistical analysis was improvement from
16 personal baseline, and assignment to the study arms was balanced over time, so any
17 historical effects would have to operate in a very odd pattern to produce a confounding
18 result over an enrollment period of three years. The most likely source of improvement that
19 could confound the study would be the introduction of new medications, however, that
20 would be expected to affect all study arms equally. Researchers examining the question of
21 whether glycemic control has improved overall in recent years report conflicting findings.
22 Hendry (2004) found no improvement in the control of glycemic levels among adults with
23 diabetes who participated in NHANES III compared to those who participated in NHANES

1 1999-2002 (Hendry, 2004). Hoerger, Gregg, Segel, and Saadine (2008) found a trend in
2 decline in glycemic levels in NHANES participants comparing 1999-2000; 2001-2002 and
3 2003-2004. However, these levels did not approach a decline of .76% and were more
4 prominent in younger participants.

5 *Other measurement issues* include social desirability bias and the use of self-report
6 as participants often wish to present themselves in the best light. While this could account
7 for improvement in self-care practices, it could not account for the improvement in HbA1c.

8 ***Why did both interventions work?***

9 One explanation for the effectiveness of both the test and attentional control
10 interventions is that both were effective in changing behaviors and improving health
11 outcomes. The effectiveness of both may be that they were both tailored and
12 individualized. It may also be due to the use of two different but effective approaches. Both
13 interventions were individualized in that they were delivered in the home at a day and time
14 convenient for the participants. While the objectives and content of the two interventions
15 and strategies used to meet the objectives differed (different mechanisms), the interventions
16 both focused on the distinct experience and personal needs of participants, who were
17 encouraged to select the management strategies best suited to their personal situation. This
18 individualization may be more important than the actual content delivered. Also, both the
19 interventions provided the opportunity to answer questions one-to-one and receive support
20 in a non-threatening environment as opposed to participating with a group of strangers and
21 having to acknowledge problems with diabetes publicly. This contrasts with the more
22 common mode of delivery of formal diabetes education in a group format over 10-12
23 weeks. Both interventions also were tailored for use with older, rural African American

1 women. The content and mode of delivery of the interventions were based on exploratory
2 work and further refined through pilot work and consultation with a community advisory
3 board (Leeman et al., 2008).

4 Although the objectives and content of the two interventions and strategies used to
5 meet the objectives were different, both may have been effective. A central objective of the
6 Symptoms intervention was to teach participants to recognize and interpret symptoms so
7 they could better use their experience of symptoms as a guide to self-care (Teel et al.,
8 1997). The central objective of the attentional control intervention was to teach specific
9 self-care skills and provide opportunities to practice them. The skills taught include
10 counting carbohydrates, label reading, determining portion sizes, healthy types of fat, and
11 strategies to reduce saturated fat in the diet. In the Symptom intervention, self-care skills
12 are one of several management strategies that are addressed but not taught in depth as the
13 attentional control intervention. Reviews of diabetes self-care education have found that
14 skills training, combined with practice is an effective approach to improving self-care
15 (ADA, 2008). Discussions with the intervention nurses over the course of the study as well
16 as review of their field notes emphasize how well participants responded to the specific
17 skill training and exercises, particularly in regards to diet.

18 We designed our attentional control to focus on diet with the expectation that it
19 would be ineffective as many individuals with diabetes have listened to advice to watch
20 their weight for years without making the necessary changes in their behavior. We then
21 developed a diet-focused intervention that had many advantages over the education
22 typically offered in that it was individualized and tailored, providing one-to-one training,
23 feedback, and practice opportunities in women's homes.

1 participants indicate that the interventions were well received by participants. The study
2 findings suggest that the symptom-focus and weight/diet approaches can be combined into
3 a revised intervention with the potential for a greater effect on outcomes.

4 It is also timely to study the effects of delivery setting by comparing the in-home
5 delivery of the intervention with delivery at a point of care in the community, such as a
6 community health center, hospital clinic, mobile care facility or private medical practice.
7 This real-world translation of the study would provide useful data for health care providers
8 and yield a better understanding of the critical elements of the intervention that contribute
9 to improved health outcomes.

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Table 1: Baseline Patient Characteristics by Study Group

	All	Symptom Intervention with Booster (a)	Symptom Intervention (b)	Weight Management / Diet (c)	Comparisons
Age					ns
<i>n</i>	174	55	60	59	
<i>Median</i>	67.0	65.0	68.5	68.0	
<i>Q1,Q3</i>	62.0,74.0	62.0,71.0	61,73.5	63.0,75.0	
Age at diagnosis					ns
<i>n</i>	166	52	59	55	
<i>Median</i>	54	54	54	55	
<i>Q1,Q3</i>	45,61	47,60	40,61	45,64	
Years with diagnosis					ns
<i>n</i>	168	51	60	57	
<i>M</i>	12	12	15	12	
<i>SD</i>	6,21	6,17	7,25	5,23	
HbA1C					ns
<i>n</i>	180	59	61	60	
<i>M</i>	8.29	8.30	8.44	8.11	
<i>SD</i>	1.62	1.64	1.63	1.61	
Complications					ns
<i>n</i>	175	56	60	59	
<i>Median</i>	4.0	4.0	4.0	4.0	
<i>Q1,Q3</i>	3.0,5.0	2.5,5.5	3.0,5.0	3.0,5.0	
Symptoms	172	55	59	58	ns
<i>n</i>	8.10	7.82	7.98	8.50	
<i>M</i>	4.09	4.30	3.65	4.35	
<i>SD</i>					
Diabetes medication					ns
<i>N</i>	174	55	60	59	
<i>% None</i>	2	4	2	0	
<i>% Oral</i>	44	45	42	46	
<i>% Insulin</i>	18	18	17	17	
<i>% Both</i>	36	33	40	36	
Income					ns
<i>N</i>	170	53	59	58	
<i>Median category</i>	< \$10,000	\$10-14,000	< \$10,000	\$10-14,000	
Education					(b)&(c) < (a)
<i>N</i>	172	53	60	59	
<i>% <HS</i>	51	36	60	56	
<i>% HS</i>	22	26	22	19	

	<i>% >HS</i>	27	38	18	25	
Mental quality of life						ns
	<i>N</i>	172	55	59	58	
	<i>M</i>	2.55	2.67	2.43	2.56	
	<i>SD</i>	0.69	0.60	0.70	0.77	
Social quality of life						ns
	<i>N</i>	171	55	59	57	
	<i>M</i>	3.25	3.41	3.19	3.17	
	<i>SD</i>	0.66	0.57	0.67	0.71	
PAIDS						(c) > (a)
	<i>N</i>	165	51	56	58	
	<i>M</i>	2.28	2.05	2.31	2.44	
	<i>SD</i>	0.83	0.56	0.75	1.05	

Figure 1: Mean HbA1c at Each Data Collection Point, by Treatment

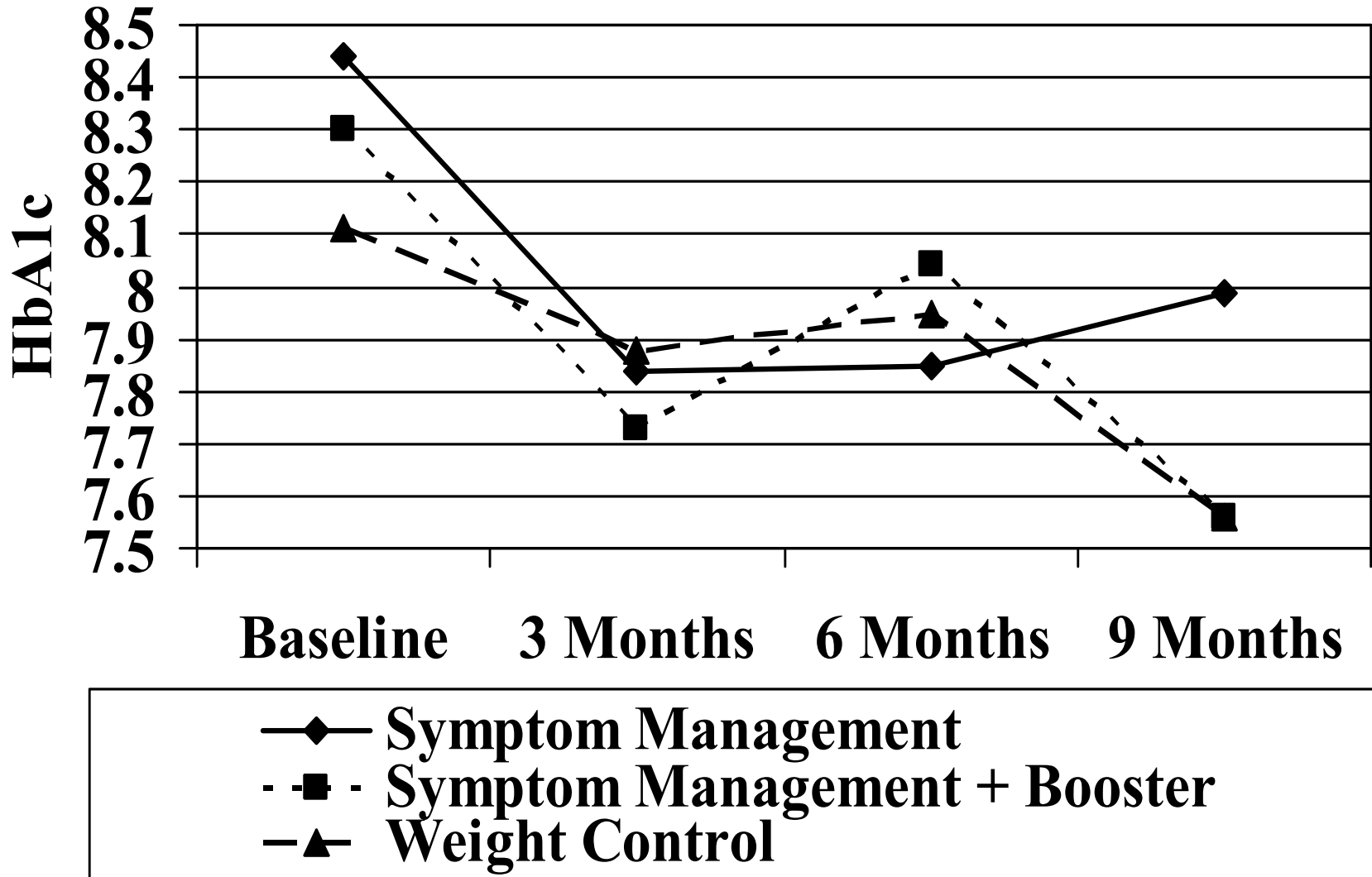
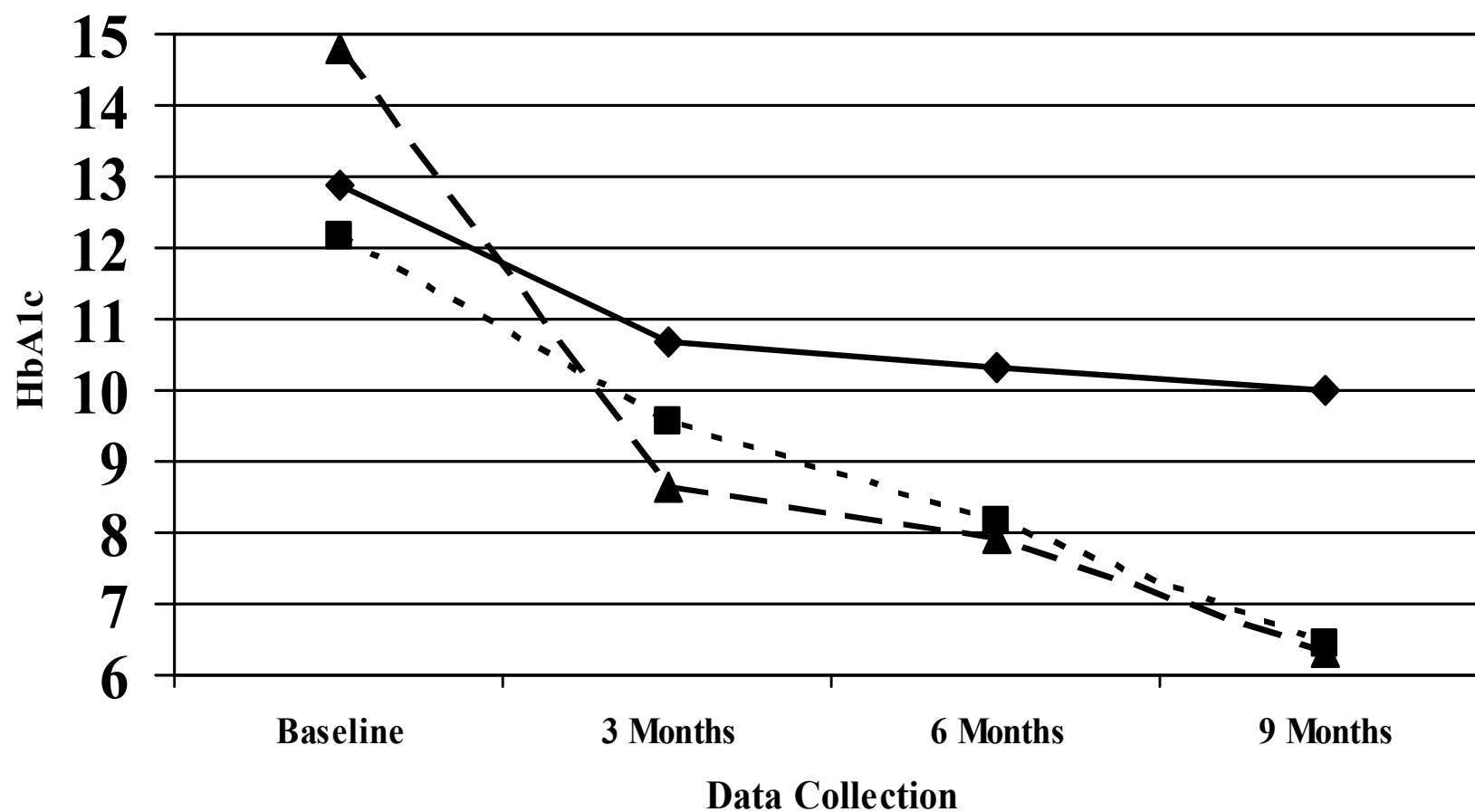
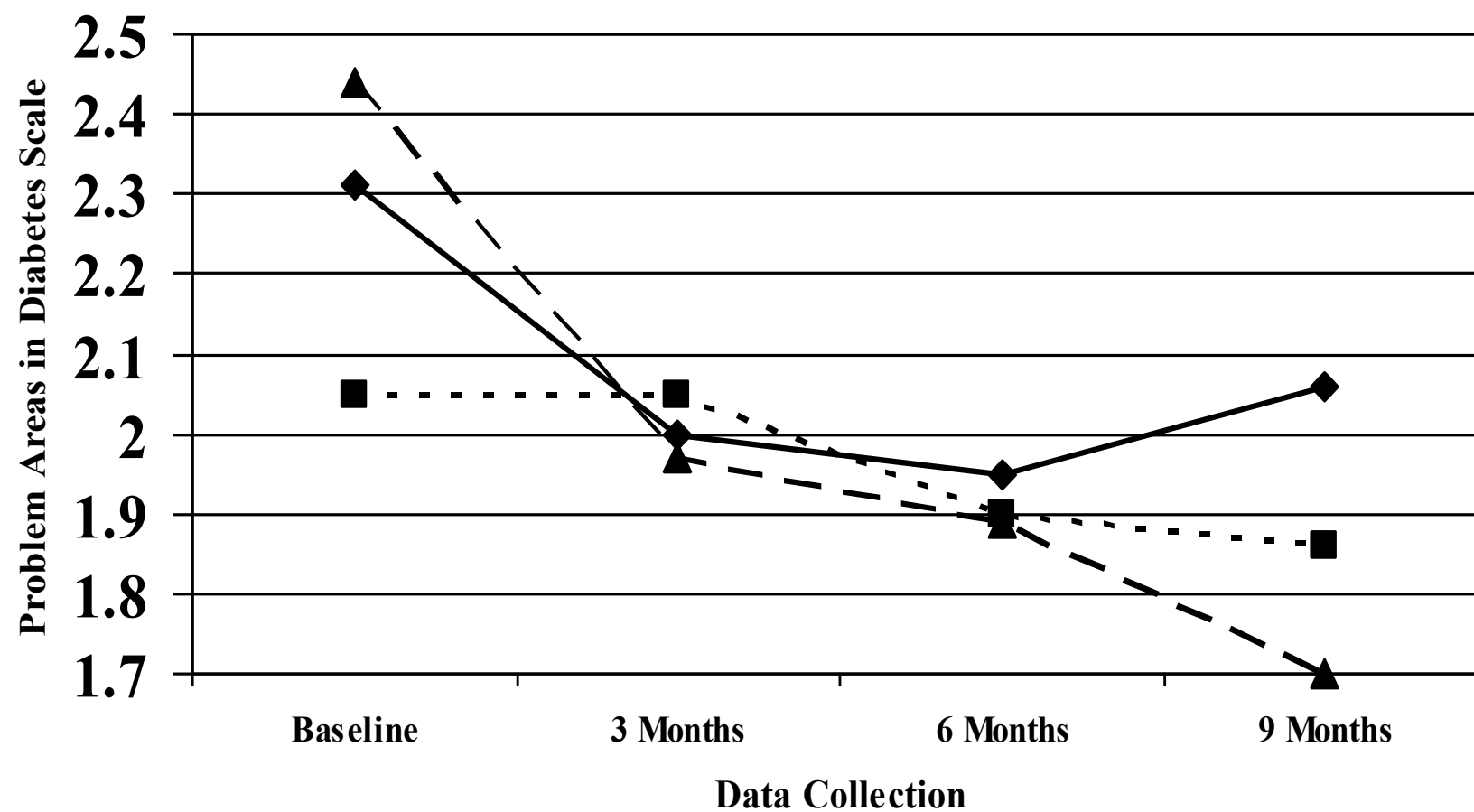


Figure 2: Mean Symptom Distress at Each Data Collection, by Treatment



—◆— Symptom Management - ■- Symptom Management + Booster -▲- Weight Control

Figure 3: Mean of Problem Areas in Diabetes Scale at Each Data Collection, by Treatment



—◆— Symptom Management - ■ - Symptom Management + Booster -▲- Weight Control