The intensive improvement program consists of instruction and support in diabetes self-management coupled with intensification of glycemic medications, including insulin. It is provided by nurse practitioners and supervised by a practicing diabetologist. The educational content includes diet, exercise, self-monitoring of blood glucose and medication adherence as well as instruction in preventive measures such as foot care and screening for complications. Upon completion of the program, only those subjects referred to the improvement program for poor glycemic control (HbA1c>8%) and who obtained control (HbA1c<8% and at least an absolute 1% decline in HbA1c) during the program were recruited. Only subjects aged 18–75 years of age were included. Pregnant women were excluded.

Randomization

Two weeks after completion of the improvement program, a research assistant contacted patients and gave them a brief explanation of the study. The subjects were then invited to participate in the study if they met the defined inclusion criteria. A research assistant confirmed eligibility. After informed consent was obtained, patients were randomly assigned to one of three study arms. Randomization applied permuted block scheme for balancing interval, varying randomly among 3, 6, 9 and12 according to the outcome of a computer generated random number. This ensured that the cumulative number of assignments to each treatment would be in balance after each block of assignments had been made. The allocation sequence was written by the statistician involved with the trial. Once treatment arm status was assigned by the research assistant, subjects in the intervention arms were assigned a study nurse practitioner. Due to the nature of this intervention, blinding of participants, investigators and study nurse practitioners was not possible. See Figure 1 for enrollment and randomization scheme.

Intervention

The intervention consists of a phone contact by a nurse practitioner with a referral to a dietitian if nutrition self-care is perturbed. The characteristics of the intervention are described in Table 1 using a diabetes intervention taxonomy previously characterized[29] The duration of each contact was monitored. During the first session, shared goal setting was established and referred to or modified during subsequent contacts. The method and content of the phone contacts varied based on the assessment. If there were no problems related to glycemic control or self-care behaviors identified, then Protocol 1 was followed (see Figure 2). If a problem was identified, Protocol 2 was followed (see Figure 2). The intervention does not vary between the treatment arms; only the frequency of the intervention varies.

Protocol 1 is characterized by anticipatory planning for potential lapses, including practicing a coping skill, and also offers self-efficacy enhancement through positive reinforcement, short-term goal setting and cognitive rewards. If a self-care problem was identified then protocol 2 was followed. The subject was asked to identify the source of the struggle. If readily identified, the interviewer employed a 5 step problem solving paradigm: 1) Define problem clearly, 2) Brainstorm strategies, 3) Choose a strategy, 4) Develop an action plan and 5) Try it and revise as needed. If a subject was unable to identify a reason for deteriorating self-care behavior, motivational interviewing was employed largely as a diagnostic modality[30] Subjects were asked to assess the importance of and their confidence in correcting the lapse behavior. The individ-

Table 1: Intervention Structure

Setting	One-on-One
Delivery	Phone contact
Teaching Methods	Shared goal setting Problem solving Cognitive re-framing Diaries
Content	Diet Exercise Self-monitoring of blood glucose Medication management
Provider	Diabetes certified nurse educator with a dietician referral if diet self-care is perturbed
Tailoring of intervention to an assessment	Yes
Modification of intervention with follow-up	Yes
Intensity of intervention	
Number of episodes	Arm 2: 8 Arm 3: 24
Duration of episodes	Measured as part of study protocol
Duration of study	24 months
Initial supplement given	No