



DETERMINING FEASIBILITY OF AN INTERVENTION: DEFINITIONS AND PROCESS

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BACKGROUND

Limited participation in health promotion activities is noted in people with diabetes, even though lifestyle changes have been found to be essential in decreasing the risk of complications of the disease. Barriers to health promotion in people with diabetes have been identified through qualitative research¹ and surveys^{2,3} and include:

- Lack of knowledge
- Lack of coordinated care
- Feelings of helplessness, depression, and lack of confidence
- Feeling tired

Participation in regular physical activity is strongly associated with lower risk for cardiovascular events in subjects with diabetes,⁴ and several small studies have demonstrated improved glycemic control following aerobic and resistance exercise in people with diabetes.^{5,6} However, exercise remains an underutilized therapy.⁶ Dietary recommendations have consistently been found to reduce weight and improve glucose control in people with diabetes.⁷⁻⁹ However, interventions that incorporate intense, supervised exercise with customized dietary interventions and education are absent from the literature. Further, exercise interventions at the frequency (3-5 days per week) recommended by ACSM for individuals with type 2 diabetes⁴ have not been studied. Determining the feasibility of an intervention is an often-stated goal of pilot research, but the concept of feasibility and the process for

PURPOSE STATEMENT

Using the example of an intense, customized health promotion program for people with diabetes, we sought to provide a template for the determination of whether an intervention is feasible, focusing specifically on the analysis of recruitment, retention, and adherence.

Table 1. Description of Intervention

Week	# sessions	Total aerobic time (min) and intensity (%VO ₂ R)	Total strength training repetitions	Education session	Nutrition session
Week 1	3	40 @ 50%	10 reps	Setting goals	Diabetes Food Pyramid
Week 2	3	30 @ 50%	20 reps	Monitoring ABC's of diabetes	Self-monitoring diet intake
Week 3	3	60 @ 50%	10 reps	Healthy and happy feet	Modify favorite recipes
Week 4	4	60 @ 50%	20 reps	Risk factors for stroke and CVD	Taste test new items
Week 5	4	60 @ 60%	20 reps	Family support day	Be a fat detective
Week 6	4	60 @ 60%	30 reps	Stress management	Healthy snacks
Week 7	4	80 @ 60%	30 reps	Accessing health information	Four keys to eating out
Week 8	4	80 @ 60%	30 reps	Preventing depression	Modify favorite recipes
Week 9	4	80 @ 70%	30 reps	Building healthy relationships	Taste test new items
Week 10	4	100 @ 70%	30 reps	Graduation ceremony	Review goals

METHODS

The feasibility of an intense, comprehensive health promotion program with aerobic and strength training, dietary counseling, and education were assessed in this study. During a 6-month period, our goal was to enroll 20 subjects in the 10-week health promotion intervention to identify recruitment, retention, and adherence issues that would be relevant to implement this intervention in a future large study.

Subjects: To be enrolled in the study, subjects had to be diagnosed with type 2 diabetes, age 40-70 years old, and receive documentation from their physician that they were medically stable to participate in a supervised exercise program. Exclusion criteria:

- (1)Serious, symptomatic medical problems
- (2)Current active involvement in regular exercise
- (3)Open wounds on the feet
- (4)Not able to ambulate independently
- (5)Stroke or other central nervous system pathology

Recruitment Strategies:

Subjects were recruited for this study through flyers posted at local diabetes clinics & safety net clinics, distributed at health fairs, and via broadcast email at the medical center. We also contacted subjects who were known to us through previous studies.

Intervention:

The 10-week program included education, exercise, and nutrition components (see Table 1). The program was implemented with small cohorts of subjects to promote the development of a supportive network. The weekly time commitment ranged from 3 – 5.5 hours per week. Subjects were offered a \$50 stipend at the midpoint and \$50 at the completion of the study (total of \$100) to help with transportation expenses.

Statistical Approach:

Recruitment. Recruitment was assessed by tracking the number of potential subjects assessed for eligibility, those who were excluded because of subject inclusion criteria, and those who declined to participate.

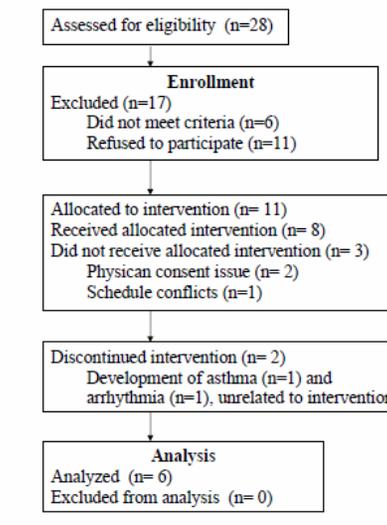
Retention. Information on retention was acquired by tracking the number of subjects who discontinue the intervention during the study along with their reasons.

Adherence. For the subjects that complete the study, the % of total sessions attended were documented. We also conducted focus group "exit interviews" at the end of the intervention to gather feedback on recruitment, retention and adherence issues.

RESULTS



Figure 1. Modified CONSORT Flowchart



Recruitment. We distributed hundreds of flyers in the community, but only 1 enrolled subject was recruited by this method. The other subjects were recruited via university broadcast email (n=5), previous study contacts (n=3), and word of mouth (n=2).

Retention. Of the 11 subjects entered into the study, 5 (45%) did not complete the 10-week intervention.

*2 subjects: physician did not sign medical release because of concern about liability for undiagnosed medical concerns
*1 subject: conflicts with work schedule

*1 subject: developed seasonal asthma

*1 subject: developed cardiac arrhythmia after 7 weeks of intervention that was detected by our study personnel

Adherence. The 6 subjects who completed the study attended an average of 95.5% of all scheduled sessions (range 89-100%), for 37 total sessions over 10 weeks. Exit interview comments were very positive:

"The length of the program was just right; long enough to establish new habits and skills, but short enough to fit into my schedule."

"I'm more energetic, happy, relaxed, optimistic."

"Setting goals have helped me in other ways to get more sleep, cutting down caffeine, and watching less TV."

"This is so far beyond any diabetes classes I've ever attended, it would be worth the cost to pay for it out of pocket"

Subject Characteristics. The subjects (2 males/4 females, age 60.2±4.7) were all Caucasian. At entry into the study, they were obese (BMI 33.8±7) with mild symptoms of neuropathy, well-controlled blood glucose (glycosolated hemoglobin or A1C 6.7±0.6), and poor aerobic fitness (VO₂peak 15.5±3.3 ml/kg/min).

CONCLUSIONS

This systematic approach to analysis of feasibility revealed significant issues with recruitment and retention that would need to be addressed for future studies. Future research should incorporate more aggressive recruitment strategies to connect directly with potential subjects rather than relying on distribution of flyers. Other suggestions are to modify the physician consent letter and offer flexible times for the sessions. The high levels of adherence indicate that the intervention was feasible for this subset of subjects.

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