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Who participates in Diabetes Self-management Interventions?

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ABSTRACT

Purpose: The purpose of this study was to examine reasons for nonparticipation and drop out in a diabetes self-management intervention.

Methods: A total of 468 recently screen-detected patients, receiving usual care or intensive pharmacological treatment, were invited and randomized into either a control or intervention condition, consisting of a brief self-management course. A nonresponse survey was conducted, and participants, nonparticipants, and dropouts were compared on sociodemographic variables, diabetes attitudes, and self-care.

Results: A total of 227 patients consented and were allocated to the control (n = 108) or intervention group (n = 119). Two hundred forty-one patients declined participation, 41 dropped out, and 78 completed the intervention. Major reasons for refusal and drop out were hesitancy toward research and practical barriers. Nonparticipants were less educated and reported higher self-management, while participation also varied by treatment and disease duration: intensively treated patients were more likely to participate in their first year, and usual-care patients participated more often 2 to 3 years after diagnosis. Dropouts had a lower education level but did not differ on any other measure.

Conclusion: Participants, nonparticipants, and dropouts did not differ in their attitudes toward diabetes, but the intervention did attract patients with lower self-care. Variations in participation by treatment and disease duration suggest that patients prefer self-management interventions at different times depending on their medical treatment. Finally, education appears to be the most important factor determining participation. Alternative strategies are needed to attract and retain patients with low education.

Many studies have appeared to investigate how patients with type 2 diabetes can be motivated and supported in achieving optimal self-care. Such intervention studies commonly take the form of randomized controlled trials (RCTs), which are generally recognized as the most reliable method of determining treatment effects, as their design ideally keeps selection bias to a minimum. However, the success of an RCT stands or falls with the recruitment of an adequate and representative sample. In practice, studies often encounter serious difficulties in recruiting enough patients, increasing costs and workload, reducing statistical power, and ultimately increasing the potential for selection bias.^{1,2} The CONSORT statement emphasizes the importance of adequately describing the recruitment phase in the publication of RCTs.³ Nevertheless, problems with recruitment and retainment remain notoriously underreported.⁴ This undermines the external validity of RCTs, making it unclear which patients participated and under which conditions the treatment can be applied.^{5,6} While many interventions in diabetes are quite successful in achieving short-term change, their method is often poorly described, and there is some concern that such interventions are primarily meeting the needs of specific subgroups. In particular, those who are concerned about their health recognize the need for change and are already well under way to achieving proper self-management.^{6,7} A more thorough study of the recruitment process could therefore help researchers, clinicians, and policy makers alike to assess the validity of the RCT, understand which subgroups are underrepresented, and improve recruitment strategies accordingly.⁸

Several reviews have focused on the attitudes and characteristics of patients unwilling or unable to participate in RCTs.^{1,6-12} Reasons for refusal, nonresponse, and drop out include lack of time, lack of interest, preferences for specific treatments, uncertainties about the effectiveness and demands of the intervention, and poor understanding of the study design. How the intervention is communicated is therefore of crucial importance.² Furthermore, the same disease and treatment may be viewed differently by those who choose to participate and those who do not.⁶ Finally, looking at sociodemographic characteristics, participants are generally older, married, and have a higher socioeconomic status and education level than nonparticipants.^{1,6} Participation in diabetes interventions follows the general pattern, with an underrepresentation of younger adults, females, ethnic minorities, and less educated patients.⁷

This article addresses these issues of recruitment and retainment in the study "Beyond Good Intentions," an RCT examining the effectiveness of a brief self-management intervention for patients recently diagnosed with type 2 diabetes during a population screening.¹³ Recruitment in this population faced a number of potential challenges. First, newly diagnosed patients are relatively asymptomatic, and evidence suggests that they tend to downplay their illness and treatment, which could also negatively influence their decision to take part in the study.¹⁴ Participants could thus include only those patients who take their disease seriously and are already actively involved in their self-care. Furthermore, the study took place in a rural area and among an elderly group of patients, who may be less inclined to participate in a study that requires travel and evening classes. Recognizing these potential challenges, the current authors chose to explicitly investigate participation in their intervention, looking beyond sociodemographic differences to uncover reasons for refusal and diabetes-related attitudes and behavior among nonparticipants and dropouts. Two questions will be addressed:

1. Why do patients not participate in the RCT, and do they differ from patients who do participate?
2. Why do patients drop out of the intervention, and do they differ from patients who complete the course?

METHOD

Context

The behavioral intervention Beyond Good Intentions recruited patients from the Dutch ADDITION study, a multicenter RCT evaluating both the feasibility of a population-based

screening program for type 2 diabetes and the effectiveness of a target-driven approach to reduce cardiovascular risk in people with screen-detected diabetes.¹³ Patients (aged 50 to 70 years) had been screened between 2002 and 2004 and were randomly assigned to receive either intensive, multifactorial pharmacological treatment (target-driven tight control of blood glucose, cholesterol, and blood pressure, including prescription of aspirin and angiotensin-converting enzyme [ACE] inhibitors) or usual care since diagnosis. The study Beyond Good Intentions ultimately wished to examine whether a behavioral intervention was effective on top of and apart from ADDITION's pharmacological intervention.

The behavioral intervention consisted of an evening course including 2 (1-hour) individual sessions and 4 (2-hour) biweekly group meetings (n = 6-8), spread over 12 weeks. During the sessions, various domains of self-care (including diet, exercise, and medication) were discussed, and patients were stimulated to formulate, plan, and carry out personally relevant goals with regard to each theme. A 5-step plan formed the core of the program. Based on theories of proactive coping and self-regulation, it included elements of anticipation, goal setting, planning, problem solving, and evaluation to help patients move beyond their intentions to achieve and maintain optimal self-care. Led by a trained nurse, the course had a strong patient-centered focus and included group assignments and individual homework.¹⁵

Procedure

The study Beyond Good Intentions began in 2004, after receiving approval from the medical ethics committee of the University Medical Center Utrecht. All patients included in ADDITION who were not suffering from other serious physical or mental illnesses were invited to participate. In total, 468 patients from 70 general practices received a standard letter via their physician, including an information brochure and consent form. The brochure contained information about the study, the randomization process, and the course's structure to inform patients about the expected outcomes, demands, and (low) risk involved. A second letter was sent out to all nonresponders after 5 weeks. The mailing was carried out from the university, and the general practices received personal visits to explain the study in more detail and raise commitment.

Participants.

After consent, participants were randomly allocated to an intervention or control group (Figure 1). The former were offered a self-management course free of charge; the latter received a brochure on self-care. Both groups were asked to complete 3 questionnaires: at baseline, after 3 months (postcourse), and at 12 months.

Participants in the intervention condition were allocated to different course groups depending on their medical treatment (intensive vs usual care) and their time since diagnosis (<1 year vs 2-3 years). Courses were ideally located in or near patients' villages and on evenings during which most could participate. Patients who missed a session were contacted by telephone to catch up. If patients missed 2 or more sessions, they were labeled as dropouts.

[FIGURE 1]

Nonparticipants.

Patients who did not wish to participate were asked to return the consent form and indicate their reasons for refusal. As it was considered important to understand which patients do not participate and why, the researchers contacted patients who had either not responded or refused without explanation and asked them if they would be willing to take part in a brief telephone interview. All patients were called a maximum of 3 times and on various days and times to maximize response. A research assistant not otherwise involved in the project conducted the interview.

Measurements

Information on demographic characteristics (age, gender, partner status, ethnicity, education level, and employment status), treatment (intensive vs usual care), and time since diagnosis had been collected previously for all patients included in ADDITION.

Participants of the intervention study were asked to complete a baseline questionnaire before the start of the course. Patients who participated in the nonresponse survey were interviewed to explore their reasons for refusal, including an abbreviated form of the baseline questionnaire to limit the researchers' intrusiveness. Both the questionnaire and the interview included similar instruments assessing health threat perceptions, self-efficacy, and self-management behavior, described in more detail below.

Perceptions of health threat were assessed identically in both groups using 2 scales measuring perceived seriousness and perceived vulnerability for diabetes, following recent studies that found that general perceptions of seriousness do not necessarily translate into feelings of personal vulnerability.^{14,16} The perceived seriousness scale was based on the diabetes illness representations questionnaire and used 3 items to explore beliefs about the seriousness of diabetes in general.¹⁷ With regard to perceived vulnerability, the authors translated the seriousness scale into 4 questions assessing patients' beliefs about the seriousness of their own diabetes and their worry about the consequences that diabetes may have for their health. The Cronbach was .67 for the seriousness scale and .94 for the vulnerability scale, while correlations between the 2 scales were low (Spearman $r = 0.27$, $P < .01$), supporting the use of these scales as independent measures of threat perception.

Self-management behavior was assessed in participants using the Summary of Diabetes Self-care Activities Measure, revised according to Toobert et al.¹⁸ The scale includes 10 items covering general diet, specific diet, exercise, blood glucose testing, foot care, and smoking. For each domain, patients were asked, "Over the last 7 days, how often did you....," yielding an average score between 0 and 7. In the nonresponse group, assessment was limited to 4 items, covering the 2 core domains of self-care behavior, notably, general diet and exercise. For comparative purposes, analyses were limited to the 4-item scale. The Cronbach was .71 for the entire sample.

The questionnaire for participants also included a self-efficacy measure adapted and validated for Dutch diabetes patients.^{19,20} The instrument assesses self-efficacy in performing both general and domain-specific self-care behaviors. The scale includes 12 items, beginning with "How confident are you that you can....," with answers ranging from 1 (not at all) to 7 (totally confident). The Cronbach was .84 in the present sample. The nonresponse survey included a similar but single-item measure of self-efficacy, that is, "How confident are you that you can do all the necessary tasks needed to manage your disease?" using a similar scale to rate levels of confidence. Given the different assessments of self-efficacy, differences between participants and nonparticipants could not be analyzed statistically and were interpreted with care.

Analyses

In a number of steps, recruitment and retention rates were described, reasons for refusal and drop out were summarized, and participants and nonparticipants, dropouts, and course completers were compared, using t tests and 2 tests where appropriate. Initial participation was examined first, describing nonparticipants' reasons for refusal and comparing their sociodemographic characteristics and diabetes-related outcomes with participants. In addition, as the researchers were interested in the differential effectiveness of their intervention for patients based on treatment intensity and disease duration, it was also examined whether participation rates varied by these 2 factors. Second, retention rates were examined, reasons for drop out were summarized, and dropouts were compared with participants who completed the course, based on the variables mentioned above. Given the explorative nature of the analyses, all results significant at the .05 level are reported.

RESULTS

Nonparticipants Versus Participants

Of the 468 invited patients, 227 (49%) initially agreed to participate (Figure 1). Of the 241 nonparticipants, 71 patients returned the consent form with clear reasons for refusal, 60 patients refused with no additional comments, and 110 patients did not respond. These latter 2 groups were approached for the nonresponse survey. Of these 170 patients, 125 (74%) took part in this survey, of which 120 completed the entire interview. Patients had no reservations toward participating in the interview, and only 2 patients refused to participate, while 43 (25%) could not be reached. As such, there was basic demographic information on all nonparticipants, reasons for refusal from 196 (81%), and additional information on diabetes attitudes and behavior from 120 (50%) nonparticipants (Table 1). This final group of 120 patients was representative for the entire sample of nonrespondents in demographic measures (data not shown).

One of the most important reasons for refusal was lack of interest in research (36%). A further 36% cited practical reasons for not participating: 22% indicated a lack of time, while some 14% had logistical concerns with regard to the course, including lack of transportation, concerns about costs, and problems with courses being given in the evening. A further 16% referred to specific personal circumstances such as illness, caring for others, or a prolonged vacation. Finally, 25% of nonparticipants saw no additional benefit in taking the course: 13% considered their diabetes to be under control or very mild, while 12% were satisfied with the level of care they were receiving. However, only 6% of all nonparticipants mentioned this as their most important reason.

With regard to demographic measures, nonparticipants were less educated than participants ($T = 4.9$, $P < .001$), but there were no other significant differences (Table 1). With regard to diabetes-related measures, nonparticipants reported higher self-management ($T = 3.1$, $P < .01$), but there were no differences with regard to perceived seriousness or vulnerability. In self-efficacy, nonparticipants' scores on the single-item measure were relatively high (mean, 5.4) but appeared to be quite similar to that of participants (mean, 5.6), taking differences in measurements into account. Finally, significant differences were found when both time since diagnosis and treatment intensity were taken into account ($2 = 10.0$, $P < .05$); notably, participants included more usual-care patients diagnosed 2 to 3 years previously (30%) and less intensively treated patients diagnosed 2 to 3 years previously (20%). Put in other words, among those diagnosed 2 to 3 years previously, 60% (68/113) of usual-care patients participated compared to 39% (45/114) of intensively treated patients. Participation rates were about 47% among those diagnosed less than 1 year previously.

[TABLE 1]

Dropouts Versus Course Completers

After consent, the 227 participants were randomly allocated to the intervention ($n = 119$) or control ($n = 108$) condition. In the intervention group, 30 (25%) patients dropped out before the course began (early drop out), while 11 (14%) dropped out during the course (late drop out). In the control group, 6 patients dropped out after randomization. This left 78 patients in the intervention condition and 102 patients in the control condition (Figure 1).

In the control group, 5 patients dropped out as they had reservations regarding the length or content of the questionnaires, and 1 patient died during the study. In the intervention condition, patients dropped out for different reasons. Of the 30 who dropped out immediately after randomization, 10 patients would have liked to participate but could not because the course was too far away and/or they lacked transportation. Ten patients cited personal reasons, including illness, caring for others, or time constraints. Three patients indicated they did not want to participate in hindsight, and 3 would have preferred the control condition. Three patients from ethnic minorities had difficulty with the language, while 1 patient found

the course too challenging. Eighteen of these patients filled out the baseline questionnaires (18/30).

Of the 11 patients who dropped out during the intervention, 4 were too busy with other activities and missed more than 2 sessions, 4 patients became ill, and 1 intervention had to be discontinued because of small group size, losing 3 patients. Ten of these patients completed the baseline questionnaire (10/11).

Comparing the 78 course completers with 41 dropouts (Table 2), completers were significantly more educated than dropouts ($T = 3.4$, $P < .01$), but they did not differ significantly on any other demographic or diabetes-related measure. Figure 2 illustrates the importance of education for participation, revealing a near-perfect linear relationship between education level on one hand and nonparticipation and drop-out rates on the other ($r = 0.95$ and 0.93 , respectively; $P < .01$). Finally, the differential pattern based on time since diagnosis and treatment intensity also appeared here, but differences were not significant.

[FIGURE 2]

[TABLE 2]

CONCLUSION AND DISCUSSION

A number of conclusions can be drawn from this study, which examined the recruitment and retention process of a randomized, controlled, behavioral intervention trial for patients with type 2 diabetes. First, the nonresponse interview reveals that nonparticipants and dropouts did not take their disease less seriously, while participants actually reported lower self-management behavior. Furthermore, looking at patients' reasons for refusal and drop out, these primarily included practical reasons and often had more to do with patients' attitudes toward research than with their diabetes per se. Second, participation rates varied depending on the patient's treatment intensity and time since diagnosis; notably, intensively treated patients were more willing to participate early on in their disease, and usual-care patients were more likely to participate some years after diagnosis. Finally, education was found to be the single most important factor differentiating between those who participated in and completed the intervention and those who did not. These findings and their implications will be discussed in more detail below.

A major issue in this study was that newly diagnosed patients would not be concerned about their condition and would therefore not participate.^{14,21} Indeed, patients in the study generally did not perceive their condition to be threatening, and this could explain the relatively low participation rate. Unexpectedly, however, it was found that neither nonparticipants nor dropouts took their diabetes less seriously than participants and course completers, and very few considered this to be their main reason for refusal. Furthermore, it was also found that nonparticipants and dropouts were not less involved in their self-care. In fact, participants actually reported lower self-management levels, which suggests that the intervention was successful in attracting patients who were more in need of improvement. At any rate, the study does not support the view that the same disease and treatment are viewed differently by those who choose to participate and those who do not.⁶

Rather, the reasons mentioned by nonparticipants and dropouts primarily relate to practical issues and attitudes toward research. While many nonparticipants were retired, they often had numerous responsibilities at home and in the community and thus had only limited time to participate. Many were also reluctant to take part in evening classes or travel to other villages. Commuting can be a real obstacle for elderly patients in rural communities who may be frail and less flexible with regard to transportation. Many patients were also reluctant to take part in research; they did not want to commit themselves to a 12-month study, were hesitant about filling out personal questionnaires, or did not believe in the value of participating in research. Very few patients were outright negative, however. Indeed, while it

is generally accepted that medical research is important, people become more hesitant when they themselves are approached, perhaps because it is unclear to them that the advantages of participating outweigh the personal costs.⁹

This study also finds that patients may appreciate interventions at different times, depending on their treatment. Intensively treated patients were more likely to participate within 1 year after diagnosis; usual-care patients were more likely to participate some years later. This is particularly interesting to this study, which focuses on the differential effectiveness of a self-management intervention, based on these 2 variables. The researchers have previously found that newly diagnosed patients' emotional and cognitive outcomes varied by both their treatment intensity and their time since diagnosis: patients who received intensive treatment experienced more distress and less self-efficacy in the first year after diagnosis, and usual-care patients experienced more distress and less self-efficacy 2 to 3 years after diagnosis.²² The fact that usual-care patients were more willing to participate in and complete the course 2 years after diagnosis could very well reflect their emotional and cognitive status in which they are looking for additional support to deal with their diabetes. Similarly, as intensively treated patients become more experienced and less distressed, they may be less inclined to participate. The lack of data on emotional measures among nonrespondents does allow for a full multivariate analysis, but it was discovered that nonrespondents showed similar interaction effects with regard to self-efficacy (data not shown). This suggests that treatment intensity may play a role in whether and when patients are inclined to seek support in dealing with their illness.

Finally, the authors consider the most important finding of this study to be the difference in education levels between those who participate and those who do not. The more educated the patient, the more likely he or she was to participate in and complete the intervention. This finding agrees with other studies, which also find that patients with a lower level of education are particularly difficult to recruit for research and educational programs.^{1, 2, 9, 10} These individuals generally find written materials (brochures) less appealing, have more difficulty understanding the goals and designs of the study, have more difficulty understanding what is expected of them, and may also be more uncertain of their capacity to participate. That said, lower education levels may also reflect a general lower socioeconomic status; less flexibility in terms of work, finances, and transportation could make it more difficult for these patients to participate. Indeed, practical issues were a major reason for refusal and drop out. Given that type 2 diabetes is more prevalent in those with a lower socioeconomic background,²³ one must conclude that self-management interventions are missing a significant proportion of diabetes patients, an undesirable situation that needs to be addressed.

A first question is then, how does one get these patients to participate in self-management interventions? It has been suggested that different strategies are needed to attract different groups of patients.⁶ Thus, patients with lower education need more time and face-to-face contact to discuss and understand the study, and they may also be more influenced by their physicians.² Recognizing these issues, the researchers tried to keep the information as simple as possible and stimulated the general practitioner to discuss the study with their patients. Nevertheless, relatively few patients with a primary education (8% of participants had only primary education compared to 29% of nonparticipants) were attracted. Recent studies have focused on reaching less privileged groups and have found that community-based programs specifically designed to meet the needs of the subpopulation can be quite successful in recruiting and retaining these patients.²⁴ A more community-based approach could be a more successful strategy, but it is not always an option in a rigidly designed RCT, which needs to take ethical considerations into account.

A second question is how to keep less educated patients in the intervention. These patients were not only more difficult to recruit but were also more likely to drop out. This could be due to the cognitive nature of the course, which includes considerable written material, self-reflection, and planning. However, a preliminary evaluation showed that patients with lower

education levels evaluated the course very highly, did not find it difficult, and showed considerable improvement.¹⁵ Furthermore, only 1 patient found the course too challenging, while most dropped out for practical reasons. This suggests to us that the intervention itself is not the problem. Rather, the question appears to be how to make the course more attractive for less educated patients and which conditions are required to help these patients complete the course. One alternative could be to downplay the reflection and planning and emphasize the practical exercises and group discussions. Other alternatives could be planning the intervention around those who lack socioeconomic flexibility, keeping financial costs to a minimum, and ensuring that the course is near the patient's home and at times when he or she can participate.

This study has limitations and strengths. It focused on a relatively rural population of patients with screen-detected type 2 diabetes and included relatively less women (45% in this study compared to 51% in the general population with diabetes) and relatively few patients from ethnic minorities.²⁵ In contrast, in other studies, it was not found that these groups were less willing to participate, although the present findings do reveal that ethnic patients had more difficulty with the course. The particular strength of this study was its inclusion of a relatively large number of nonparticipants, looking beyond their sociodemographic characteristics to include reasons for refusal and diabetes-related attitudes and behavior.

IMPLICATIONS

This study gives more insight into which patients participate in self-management interventions. First, self-management interventions do not necessarily attract and retain only patients who take their disease seriously and are already actively involved in their self-care; rather, practical barriers and ambiguity toward research are important factors undermining patients' willingness to participate. How the intervention is communicated is therefore of paramount importance, and researchers should address patients' concerns and ensure that conditions are as ideal as possible. Second, a patient's treatment intensity is decisive in whether and when he or she is willing to participate, which also indicates the importance of timing. Finally, it must unfortunately also be concluded that interventions are not reaching those with a lower educational background. It may not be necessary to develop different interventions, but different strategies do need to be developed to reach these patients and convince them that these interventions are worthwhile.

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REFERENCES

1. Ross S, Grant A, Counsell C, Gillespie W, Russel I, Prescott R. Barriers to participation in randomised controlled trials: a systematic review. *J Clinical Epidemiol.*1999; 52:1143 -1156
2. Larzeler RE, Kuhn BR, Johnson B. The intervention selection bias: an unrecognized confound in intervention research. *Psychol Bull.* 2004;130:289 -303.
3. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet.*2001; 357:1191 -1194
4. Britton A, McKee M, Black N, McPherson K, Sanderson C, Bain C. Threats of applicability of randomised trials: exclusions and selective participation. *J Health Serv Res Policy.*1999; 4:112 -121.
5. Rothwell PM. External validity of randomised controlled trials: "to whom do the results of this trial apply." *Lancet .* 2005;365:82 -93.
6. Hunninghake DB, Darby CA, Probstfield JL. Recruitment experience in clinical trials: literature summary and annotated bibliography. *Control Clin Trials.* 1987;8:6s -30s.

7. Glasgow RE, Toobert DJ, Hampson SE. Participation in outpatient diabetes education program: how many patients take part and how representative are they? *Diabetes Educ.* 1991; 17:376 -380
8. Froehlicher ES, Lorig K. Editorial: who cares about recruitment anyway? *Patient Educ Couns.* 2002; 48:97
9. Ellis PM. Attitudes towards and participation in randomised clinical trials in oncology: a review of the literature. *Ann Oncol.* 2000;11:939 -945.
10. Torgerson DJ, Klaber-Moffet J, Russel IT. Patient preferences in randomised trials: threat or opportunity, *J Health Serv Res Policy.* 1996;1:194 -197.
11. Featherstone K, Donovan JL. Random allocation or allocation at random? Patients perspectives on participation in a randomised controlled trial. *Br Med J.* 1998;317:1177 -1180.
12. Toobert DJ, Strycker LA, Glasgow RE, Bagdade JD. If you build it will they come? Reach and adoption associated with a comprehensive lifestyle management program for women with type 2 diabetes. *Patient Educ Couns.* 2002;48:99 -105.
13. Lauritzen T, Griffin S, Borch-Johnsen K, Wareham NJM, Wolffenbuttel BH, Rutten G. The ADDITION study: proposed trial of the cost-effectiveness of an intensive multifactorial intervention on morbidity and mortality among people with type 2 diabetes detected by screening. *Int J Obes Relat Metab Disord.* 2000;24:S6 -S11.
14. Adriaanse MC, Snoek FJ, Dekker JM, van der Ploeg HM, Heine RJ. Screening for type 2 diabetes: an exploration of subject's perceptions regarding diagnosis and procedure. *Diabetes Med.* 2002; 19:1 -6.
15. Thoolen BJ, de Ridder D, Bensing J, Gorter K, Rutten G. Beyond good intentions: the development and evaluation of a proactive self-management course for patients recently diagnosed with type 2 diabetes. *Health Educ Res.* Epub ahead of print February 7, 2007 . DOI: 10.1093/her/cyl160.
16. Das EHHJ. *How Fear Appeals Work: Motivational Bias in the Processing of Fear-Arousing Health Communications.* Utrecht, the Netherlands: Utrecht University; 2001.
17. Skinner TC, Howells L, Greene S, Edgar K, McEvelly A, Johansson A. Development, reliability and validity of the diabetes illness representations questionnaire. *Diabetes Med.* 2003; 20:283 -289.
18. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care.* 2000;23:943 -950.
19. Lorig K, Stewart A, Ritter P, Gonzales V, Laurent D, Lynch J. *Outcome Measures for Health Education and Other Health Care Interventions.* Thousand Oaks, Calif: Sage; 1996 .
20. Kuijter RG, de Ridder DTD. Discrepancy in illness-related goals and quality of life in chronically ill patients: the role of self-efficacy. *Psychol Health.* 2003;18:313 -330.
21. Adriaanse MC, Snoek FJ. The psychological impact of screening for type 2 diabetes. *Diabetes Metab Res Rev.* 2006; 22:20 -25.
22. Thoolen BJ, de Ridder D, Bensing J, Gorter K, Rutten G. Psychological outcomes of screen-detected patients with type 2 diabetes: the influence of time since diagnosis and treatment intensity. *Diabetes Care.* 2006;29:2257 -2262.
23. Banks J, Marmot M, Oldfield Z, Smith JP. Disease and disadvantage in the United States and in England. *JAMA.* 2006; 295:2037 -2045.
24. Uitewaal P, Bruijnzeels P, de Hoop T, Hoes A, Thomas S. Feasibility of diabetes peer education for Turkish type 2 diabetes patients in Dutch general practice. *Patient Educ Couns.* 2004; 53:359 -363.
25. Poos MJJC, Eysink PED, Gommer AM, van der Wilk EA, Harbers MM. Diabetes mellitus. Omvang van het probleem. In: *Volksgezondheid Toekomst Verkenning, Nationaal Kompas Volksgezondheid.* Bilthoven, RIVM, 2004.

TABLES AND FIGURES

Figure 1: Beyond good intentions: patient recruitment through the various phases of the intervention study (participants) and non-response survey (nonparticipants).

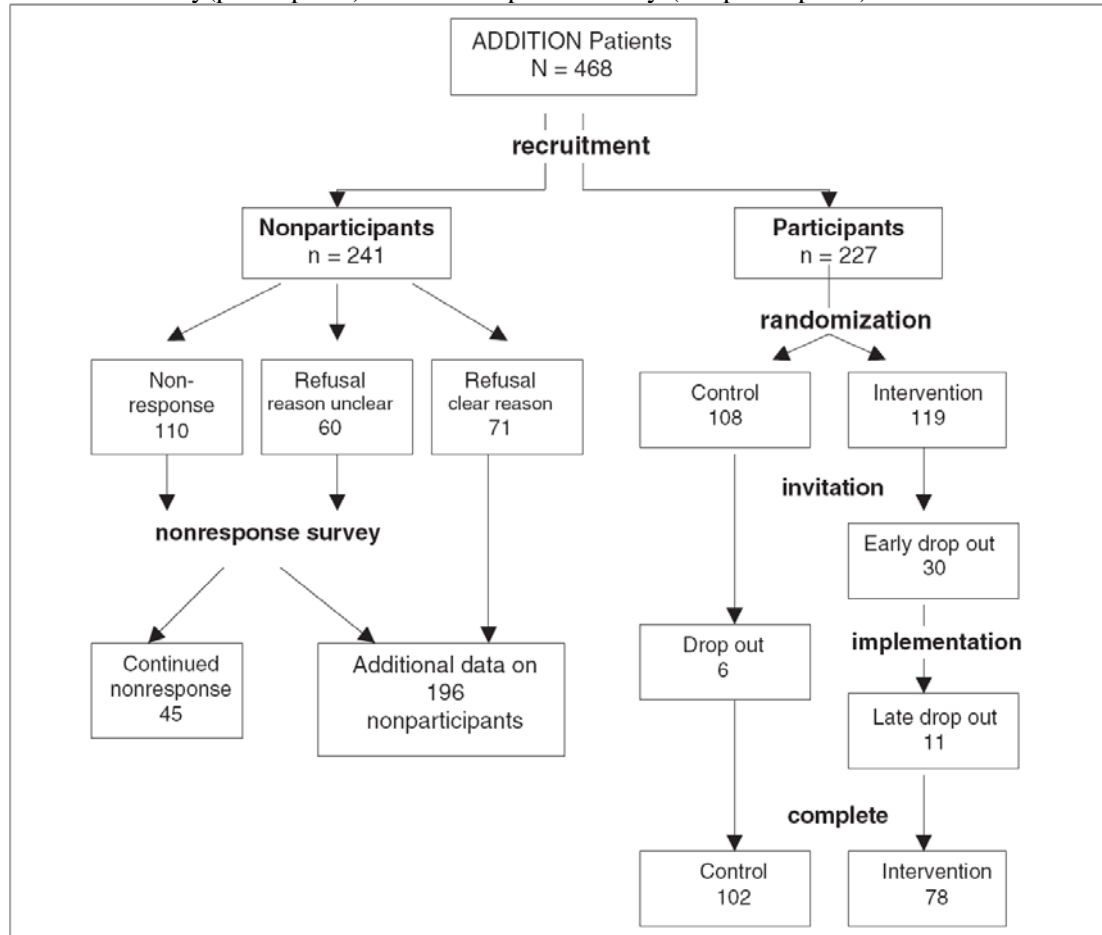


Table 1

Comparing Participants With Nonparticipants on Patient Characteristics and Diabetes-Related Measures

	Participants (n = 227)	Nonparticipants (n = 241)	Group Differences*
Patient characteristics			
Age, mean (SD)	61.7 (5.3)	62.3 (5.2)	ns
Gender, % male	58	52	ns
Partner status, % partner	87	83	ns
Ethnic minorities, % (n)	5 (11)	3 (6)	ns
Education level (1-6), mean (SD) [†]	3.1 (1.6)	2.4 (1.4)	$T = 4.9, P < .001$
% Employed	28	25	ns
Diabetes-related measures, mean (SD)[‡]			
Seriousness (1-5)	3.2 (1.0)	3.3 (0.7)	ns
Vulnerability (1-5)	2.6 (1.1)	2.5 (0.9)	ns
Self-efficacy (1-7) [§]	5.6 (1.0)	5.4 (1.1)	— [§]
Self-management (1-7)	4.6 (1.2)	4.9 (1.0)	$T = -3.1, P < .05$
Treatment × disease duration, % (n)			
Intensive, diagnosed <1 y	27 (62)	28 (68)	$\chi^2 = 10.0, P < .05$
Intensive, diagnosed 2-3 y	20 (45)	29 (69)	
Usual care, diagnosed <1 y	23 (52)	25 (59)	
Usual care, diagnosed 2-3 y	30 (68)	19 (45)	
ns = not significant. * χ^2 or t test. Significant at the $P < .05$ level. [†] Level of education ranging from 1 = primary to 6 = higher education. [‡] Item measured in nonresponse survey (125). Not known for entire group. [§] Not statistically comparable because of different measurements. Percentage of total participants; n = number of participants per subgroup.			

Table 2

Comparing Course Completers With Patients Who Dropped Out Based on Patient Characteristics and Diabetes-Related Measures

	Course Completers (n = 78)	Dropouts (n = 41)	Group Difference*
Patient characteristics			
Age, mean (SD)	61.9 (4.9)	60.6 (5.9)	ns
Gender, % male	63	56	ns
Partner status, % partner	91	82	ns
Education level (1-6), mean (SD) [†]	3.6 (1.7)	2.5 (1.4)	$T = 3.4, P < .01$
Ethnic minorities, %	6	8	ns
% Employed	31	28	ns
Diabetes-related measures, mean (SD)[‡]			
Seriousness (1-5)	3.2 (1.0)	3.3 (1.0)	ns
Vulnerability (1-5)	2.7 (1.1)	2.8 (1.2)	ns
Self-efficacy (1-7)	5.7 (1.3)	5.9 (1.5)	ns
Self-management (1-7)	4.5 (1.2)	4.6 (1.3)	ns
Treatment × disease duration, % (n)			
Intensive, diagnosed <1 y	24 (19)	26 (12)	ns
Intensive, diagnosed 2-3 y	16 (12)	31 (12)	
Usual care, diagnosed <1 y	22 (18)	23 (9)	
Usual care, diagnosed 2-3 y	38 (29)	21 (8)	
ns = not significant. * χ^2 or t test. Significant at the $P < .05$ level. [†] Level of education ranging from 1 = primary to 6 = higher education. [‡] Twenty-nine of 41 participants completed baseline questionnaires.			

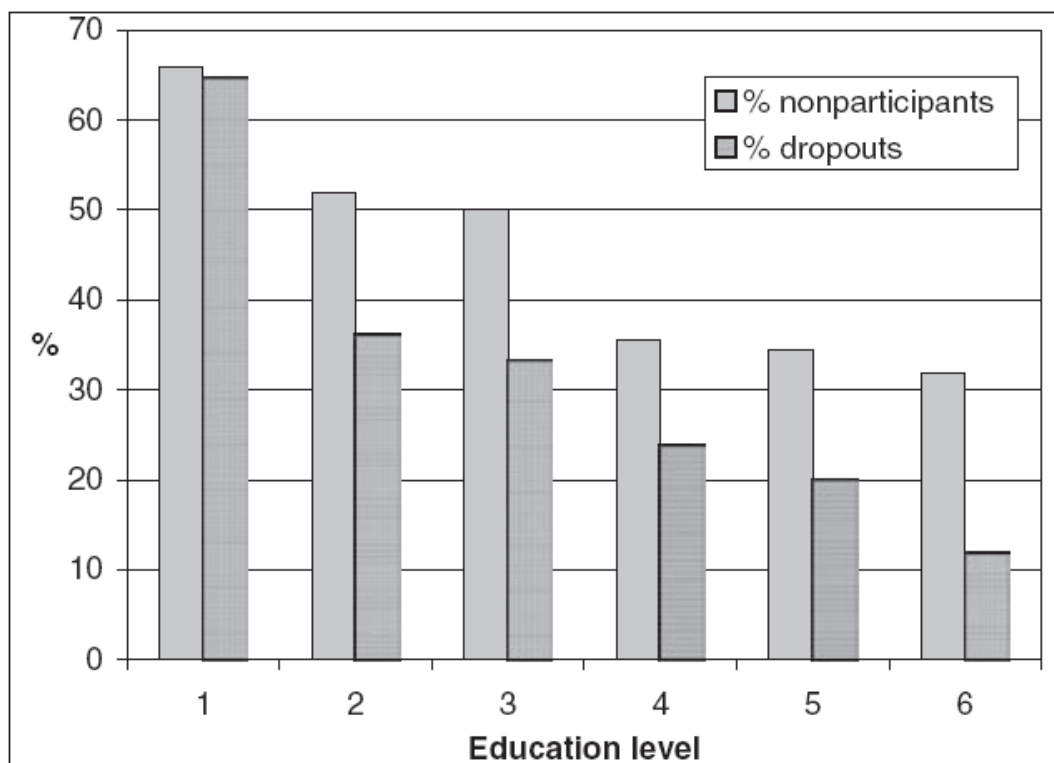


Figure 2. Nonparticipation and drop-out rates by education level (1 = primary education to 6 = higher education).