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## Self-management for chronically ill older people

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*Document Version*

Publisher's PDF, also known as Version of record

*Publication date:*

2006

[Link to publication in University of Groningen/UMCG research database](#)

*Citation for published version (APA):*

Elzen, H. A. (2006). *Self-management for chronically ill older people*. [Thesis fully internal (DIV), Rijksuniversiteit Groningen]. s.n.

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# 7

## **Do older patients who refuse to participate in a self-management intervention in the Netherlands differ from older patients who agreed to participate?**

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Submitted

## **Abstract**

### **Background and Aims**

Refusal of patients to participate in an intervention program is an important problem in clinical trials but, in general, researchers devote relatively little attention to it. In this article a comparison is made between patients who agreed to participate in a self-management intervention (participants) and those who refused (refusers) after having been personally invited. Compared to other studies of refusers, in the present study a considerable amount of information was obtained from the refusers with regard to their personal characteristics and their reasons to refuse, because all potential participants were invited personally.

### **Methods**

Older patients from a Dutch outpatient clinic were invited to participate in a self-management intervention, and their characteristics were assessed. Demographic data were collected, as well as data on physical and social functioning. People who refused to participate were asked to give their reasons to refuse.

### **Results**

Of the 361 patients who were invited to participate, 267 (74%) refused participation. These refusers were more restricted in their mobility, lived further away from the location of the intervention and more often had a partner compared to the participants. No differences were found in level of education, age, or gender. The main reasons given by the respondents for refusing participation were lack of time, travel distance, and transportation problems.

### **Conclusions**

As in many studies, the refusal rate in this study is high, and seems to be related to physical mobility, travel distance, and social support. These findings can be used to make the recruitment process more effective, for example by offering transportation to the location of the intervention.

## 7.1 Introduction

Refusal of patients to participate in an intervention program is an important problem in clinical trials [1-3]. Many researchers have to deal with this problem, but relatively few devote explicit attention to it. Retaining a low number of participants can, among other things, threaten the statistical power of the study. If we know beforehand which patients are more likely to refuse participation, measures can be taken to encourage their participation. Why is it that so many patients who are potential participants refuse to participate in what are often well developed interventions? Are patients who refuse to participate in a self-management intervention different from the patients who agreed to participate?

As the number of older people with chronic conditions increases, the number of (randomized) clinical trials in which older participants are involved will probably also increase. These trials often concern intervention studies, aimed at evaluating self-management programs, and the demands made on participants in self-management evaluation studies are, in general, relatively large. For example, patients have to travel to a hospital on several occasions, to meet with other patients in group sessions. For many patients this may, indeed, be a burden, but we still know relatively little about which patients refuse and how they differ from participants.

Most of the literature on older patients who refuse participation concerns health promotion intervention studies. In this literature, two definitions are used for older people who do not want to participate, namely refusers [4] and non-participants [4-7]. From the literature it is also clear that people who do not want to participate are usually older [5;6;8-10], have a lower level of education [4;5;7;9], show less health- or protection-related behavior such as use of seat belts or owning smoking alarms [11], are more likely to smoke [7], have a lower level of physical or mental health [4;5;7;9;11;12], are more likely to live further away from the study location [6;8;10], are more likely to experience time constraints [5;10], and perceive more social support in everyday and problem situations [13]. The results with regard to gender are less consistent. Some studies found that refusers are more likely to be male [5], others found that they were more likely to be female [4;7] while others again found that there was no difference [6].

This article aims to add to this literature by comparing patients who refused to participate (refusers) and patients who agreed to participate (participants), after they had been invited to participate in a self-management intervention program. Because all the patients were invited personally, we were able to

gather a considerable amount of information with regard to characteristics and reasons to refuse participation.

As said before, the demands of participating in a self-management intervention are rather high. With regard to the self-management intervention described in this chapter, participation required willingness to travel to a hospital on six occasions, once a week, to meet with 10 to 15 other patients in group sessions with a duration of two and a half hours. Therefore, we first expected that people with more physical problems, such as mobility problems, or more chronic diseases, would be more likely to refuse participation. Secondly, we asked the participants to come to the location of the intervention themselves, without providing transportation. Therefore, we expected that people who lived further away would be more likely to refuse participation, because they needed more time to travel. Thirdly, during the recruitment we asked people if they would like to participate in a “course”. Therefore, because a course implies education and learning, we expected that people with a low level of education would be more likely to refuse participation, because they might be deterred by this educational aspect. Fourthly, the self-management intervention for which the patients in this study were recruited was a group intervention, and being with a group of fellow-sufferers can be a source of social support. Therefore, we expected that people who experienced a lack of support would be more likely to participate, and that people who receive enough social support will refuse participation more often. We had no expectations with regard to age, because people over 60 are rather heterogeneous with regard to physical resources and other resources: age itself is not the best predictor of functioning [14]. We also had no specific expectations with regard to gender, since we had no reason to expect to find differences between men and women in their willingness to participate in a self-management intervention. However, we did compare the groups with regard to both age and gender.

## **7.2 Methods**

The procedures, research risks, and associated safeguards for this study were approved by the Independent Review Board of the University Medical Center Groningen.

### *7.2.1 Subjects*

In the period from May 2003 to May 2004, potential participants were invited to participate in a self-management intervention program. This intervention

consisted of six weekly meetings in groups of 10-15 patients [15]. Potential participants were selected on the basis of their medical records and personally invited in four wards of the Internal Medicine outpatient clinic at the University Medical Center Groningen, i.e., General Internal Medicine, Rheumatology, Endocrinology, and Lung Diseases. Eligibility criteria were: age 59 or older; a heart disease (angina pectoris or heart failure), or a lung disease (COPD or asthma), or arthritis, or diabetes, because these are the most common chronic diseases among older people; ability to communicate adequately in Dutch; experiencing problems with regard to ways of coping with their disease; physically able to attend a six-week course. Patients with a life-expectancy of less than one year, or already attending a disease-specific self-management program, or participating in another study, or who were permanent residents of a nursing home, were excluded. Patients with other diseases in addition to a heart disease, lung disease, arthritis, or diabetes were also eligible for participation.

### *7.2.2 Procedure*

During the patient's visit to one of the four wards of the hospital, his/her physician was notified by means of a small note in the medical record that this patient was considered to be eligible for the self-management intervention, and thus eligible to be invited to participate by the primary researcher (HE). The physician then only asked the patient if (s)he had time, after the appointment, to answer some questions asked by a researcher. If the patient gave verbal consent, a short interview took place with the primary researcher. During this interview, the Groningen Frailty Indicator (GFI) questions were asked to collect as much information as possible about all patients, i.e., including the refusers [14;16]. The GFI is a short, easy-to-administer 15-item instrument that assesses four domains of functioning: basic functions (3 items), physical functioning (7 items), social functioning (3 items), and psychological functioning (2 items). Because not all eligibility criteria could be derived from the medical records, for instance whether or not the patient was experiencing problems in coping with his or her disease, or whether the patient was physically able to attend a six-week course, this information was obtained during the interview. At the end of this interview, if the patient was considered to be eligible, (s)he was invited to participate in a study on the effects of a self-management program for chronically ill older people. The patients were given information about the content of the program, for instance how to deal with fatigue or communicate with a physician, and the procedure of the study was explained, i.e., that the

participants would be randomly assigned to an intervention or a control group, and that they would have to fill in questionnaires on three occasions. Patients who refused to participate were asked, by means of an open-ended question, to give their reason. These reasons were categorized later on in the study.

### 7.2.3 Measures

In order to test our hypotheses, we used the relevant items of the GFI, i.e., those concerning physical functioning and social functioning. These items are shown in Table 7.1.

Table 7.1 Items of the Groningen Frailty Indicator (GFI) concerning physical and social functioning

<b>Physical functioning</b>	
<i>Mobility</i>	
Are you able to carry out these tasks single-handed without any help? (The use of aids such as a walking stick, walking frame, or wheelchair, is considered as independent)	
1	Shopping
2	walking around outside (around the house or to the neighbors)
3	dressing and undressing
4	going to the toilet
<i>Physical fitness</i>	
5	What score do you give yourself for physical fitness? (scale 0 to 10)
<i>Comorbidity</i>	
6	Do you take 4 or more different types of medicine?
<b>Social functioning</b>	
7	Do you sometimes experience an emptiness around you?
8	Do you sometimes miss people around you?
9	Do you sometimes have the feeling of being left alone?
Scoring:	
Question 1 – 4:	independent = 0; dependent = 1
Question 6:	no = 0; yes = 1
Question 7-9:	no = 0; sometimes and yes = 1

Each item is scored either zero (no problems) or one (problems), except for physical fitness, which has a score ranging from 0-10. The four mobility items together form a sub-scale, which yields an overall mobility score, and the three social items form a sub-scale, which yields an overall social functioning score. The data included the variables travel distance (kms), level of education (with five categories from 1=elementary to 5=university), and having a partner (yes/no). The latter variable was also used as an indicator for social support. Data on age and gender was also collected.

#### *7.3.4 Statistical Analyses*

First, the refusers and participants were compared by means of bivariate analyses. *T*-tests were used for continuous variables, such as age. The variables partner and gender, and the 1-item variables of the GFI were analyzed with Pearson's Chi-square test or Fischer's Exact test. Mann-Whitney tests were used to compare the two groups with regard to travel distance and level of education. Secondly, logistic regression analysis was used to predict refusal of participation. All analyses were performed in SPSS 12.0.2. [17].

### **7.3 Results**

#### *7.3.1 Subjects*

Of the 492 patients who had the short interview with the primary investigator, 131 (26.6%) were not considered to be eligible for the self-management intervention, and were therefore not invited to participate (Figure 7.1). The most important reasons for non-eligibility were that the patient did not experience problems in coping with the disease (n=83), or that the patient was physically unable to attend a six-week course (n=17). Other reasons were: living in a nursing home (n=3); inability to communicate adequately in Dutch (n=2); admission to a hospital or rehabilitation center (n=5); or participating in another study (n=2). During the recruitment process it became clear that certain other patients were also not eligible for participation: patients who were cognitively impaired (n=8), patients with severely impaired vision or hearing (n=5), patients with certain personality characteristics, such as being too talkative, which made them unsuitable for group sessions (n=5), and patients who had recently been discharged from a psychiatric hospital (n=1).



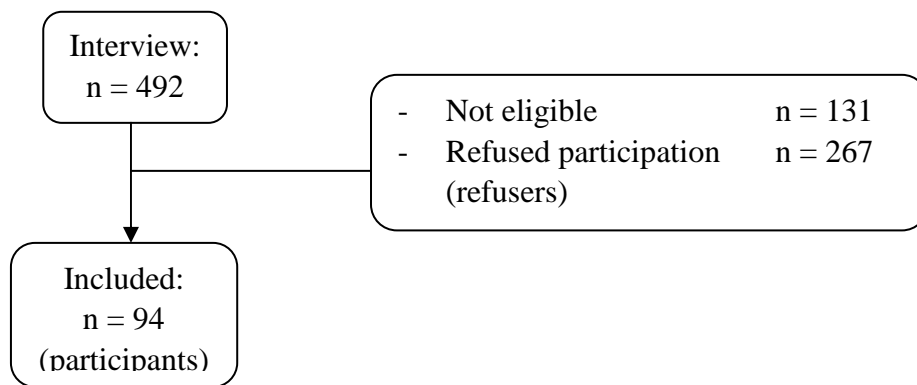


Figure 7.1 Enrolment procedure

Table 7.2 presents the characteristics of the refusers and the participants with regard to physical functioning, travel distance, level of education, partner status, social functioning, age, and gender.

Of the 361 patients who were invited, 267 refused participation (74.0%). With regard to physical functioning, there was only a significant difference in mobility between the two groups. Refusers had significantly more problems relating to mobility than the participants. No differences were found with regard to physical fitness or comorbidity. The finding concerning physical fitness is unexpected, because the refusers and the participants differed in their mobility problems.

A difference was found with regard to travel distance, i.e., refusers lived significantly further away. No statistically significant differences were found between refusers and participants with regard to education. It should be noted that the level of education of only a relatively small number of patients was known, namely 73 refusers and 72 participants. With regard to marital status significantly more refusers than participants had a partner. No differences were found with regard to social functioning, and there were also no differences between refusers and participants with regard to age or gender.

To summarize, our expectations with regard to physical problems were partly confirmed, i.e., refusers had more problems with mobility than the participants, but there were no differences in physical fitness or comorbidity. Our expectation with regard to travel distance was confirmed, i.e., refusers lived further away than the participants. However, our expectation with regard to education, was not confirmed, i.e., refusers did not have a lower level of education than the participants, and our expectation with regard to social support was only partly confirmed, i.e., more refusers had a partner.

Table 7.2 Characteristics of refusers and participants

Characteristics	Refusers				Participants				P-value*
	% (N)	M	SD	Range	% (N)	M	SD	Range	
N		267				94			
<i>Physical functioning</i>									
Mobility score		0.44	0.71	0-3		0.17	0.41	0-2	0.000 <sup>  </sup>
Physical fitness score		6.1	1.53	1-10		6.1	1.30	0-8	0.977
Comorbidity <sup>‡</sup>	77.2 (206)				81.9 (77)				0.335
Travel distance (km)									0.031
<= 10 <sup>‡</sup>	33.3 (89)				45.7 (43)				
>10 - <= 20 <sup>‡</sup>	23.6 (63)				18.1 (17)				
>20 - <= 30 <sup>‡</sup>	9.7 (26)				11.7 (11)				
>30 - <= 40 <sup>‡</sup>	13.9 (37)				13.8 (13)				
> 40 <sup>‡</sup>	19.5 (52)				10.6 (10)				
Education <sup>†</sup> (N)	73				72				0.106
Elementary <sup>‡</sup>	1.4 (1)				5.6 (4)				
Primary <sup>‡</sup>	19.2 (14)				30.6 (22)				
Secondary <sup>‡</sup>	68.5 (50)				51.4 (37)				
Tertiary <sup>‡</sup>	8.2 (6)				12.5 (9)				
University <sup>‡</sup>	2.7 (2)				-				
Partner (%)	85.2 (225) <sup>§</sup>				64.9 (61)				0.000 <sup>  </sup>
Social functioning		.96	1.09	0-3		1.17	1.18	0-3	.109
Age		69.0	6.22	59-86		68.6	5.71	60-87	0.589
Gender									0.769
Male	39.0 (104)				37.2 (35)				

\* P-value of t-tests, Chi-square tests, or Mann-Whitney test

† Classification based on Statistics Netherlands (CBS, 2005)

‡ Given are percentages of people (N)

§ n = 264

<sup>||</sup>sign  $\alpha = .05$  (2-tailed)

However, no differences were found in social functioning. We did not have any specific expectations with regard to age or gender, but no differences were found.

In order to know which of all the measured variables predict refusal of participation, a binary logistic regression analysis was performed (Table 7.3). All variables were included, with (non-)participation as the dependent variable. Because the level of education of only a relatively small number of patients was known, this variable was excluded from the analysis. The analysis showed that mobility ( $B=-1.006$ ,  $p=0.000$ ) and having a partner ( $B=-1.127$ ,  $p=0.000$ ) were

significantly related to participation. Travel distance was not a significant predictor in this analysis.

Table 7.3 Binary logistic regression

	<b>B</b>	<b>S.E.</b>	<b>Wald</b>	<b>df</b>	<b>Sig.</b>	<b>Exp(B).</b>
Mobility score	-1.006	.288	12.207	1	.000	.366
Physical fitness score	-.066	.094	.492	1	.483	.936
Comorbidity	.532	.332	2.578	1	.108	1.703
Travel distance	-.124	.089	1.962	1	.161	.883
Partner	-1.127	.314	12.888	1	.000	.324
Social functioning	.050	.120	.173	1	.677	1.051
Age	-.026	.022	1.375	1	.241	.974
Gender	-.175	.276	.401	1	.527	.804
Constant	2.218	1.724	1.656	1	1.986	9.192

### 7.3.2 Reasons for refusing participation

Eighty percent of the refusers gave a reason for refusing participation (n=218). The main were: no time to attend a six-week course (19.3%), travel distance too far (19.3%), transportation problems (12.4%), no need to attend a course (10.1%), and attending a course is too strenuous (7.8%). So, two main groups of refusers could be distinguished: those who had no time to attend a six-week course (n=42), and those who lived too far away from the course location (n=42). Because we were curious about the characteristics of these two groups, we performed some explorative analyses. First, we compared the two groups with regard to all variables. It appeared that the refusers who “lived too far away” did, indeed, live further away from the course location ( $Z=-5.141$ ,  $p=0.000$ ), but more of them had a partner ( $\chi^2=4.100$ ,  $p=0.043$ ), and more of them were female ( $\chi^2=6.039$ ,  $p=0.014$ ), compared to the refusers who “had no time”. Each of the groups was also, separately, compared to the participants. The refusers who “lived too far away” lived further away, and more of them had a partner, compared to the participants (respectively  $Z=-6.028$ ,  $p=0.000$  and  $\chi^2=13.583$ ,  $p=0.000$ ), but no differences were found between the refusers who “had no time” and the participants.

## 7.4 Discussion

The aim of this study was to compare the patients who refused participation in a self-management intervention with the patients who agreed to participate. We collected demographic data, as well as data on physical and social functioning from all patients who were invited to participate in the intervention. We assumed that, on average, refusers would have more physical problems, live further away, have a lower level of education, and receive more social support. We had no specific expectation with regard to age and gender.

As is the case in many studies, the 74.0% rate of non-participation in this study was high, but it was even higher than in most intervention studies with an older study population, in which it varies from 7 to 50% [1;4-6;9]. However, it was comparable to the rate of non-participation in the study carried out by Chang et al. [10], which concerned a 15-week relaxation response intervention, in which 65% of the screened patients refused participation. It is not quite clear why the rate of non-participation in our study was so high. One possible explanation might be that the recruitment strategy differed from that of most other studies, especially with regard to the way in which patients were invited to participate (usually by telephone or by letter in other studies), and the fact that the patients were only invited to participate once (usually more than once in most studies). Besides, in our study, potential participants first were approached by their physician. In other studies, potential participants often first receive a letter signed by their physician, and were then contacted by a researcher. On the other hand, however, a lower rate of non-participation could have been expected because the recruitment strategy in this study concerned a time and effort-consuming face-to-face procedure.

In accordance with our expectations, differences were found between refusers and participants with regard to physical functioning. This finding is also in accordance with the findings of Van Heuvelen et al. [13], who reported that the participants in their study were functionally and physically more active. It could, however, be that especially these people with mobility problems could have benefited most from the program. No differences were found in physical fitness or comorbidity. With regard to physical fitness, this is remarkable, because there was a difference in mobility problems. Apparently, physical fitness was assessed on the basis of something other than mobility. An explanation for finding no difference with regard to comorbidity might be that we included patients aged 59 or older with one or more chronic diseases. In this population of chronically ill older patients comorbidity is very common, as is

illustrated by our data, which show that, on average 79% of the patients experienced comorbidity.

Also in accordance with our expectations, the two groups differed with regard to travel distance. Therefore, one way to make the recruitment process more successful could be to have more than one course location, so that patients can participate in a self-management intervention closer to their home. Contrary to our expectations, no differences were found between refusers and participants with regard to level of education. However, a significant difference was found with regard to one aspect of social support, i.e., more of the refusers had a partner, compared to the participants. This finding also seems to be in accordance with the findings of Van Heuvelen et al. [13], who reported that the participants in their study perceived less social support. As expected, it seems that a partner can provide social support in coping with a chronic disease, which implies that there is less need to participate in a self-management program [18]. With regard to the social functioning scale no differences were found. It might, however, be that the items of this scale are more related to social loneliness, whereas not having a partner more relates to emotional loneliness [19;20]. A logistic regression analysis showed that, of all the variables, mobility and having a partner had a unique association with (non-) participation.

The main reasons given by the respondents for refusing participation were no time to attend a six-week course, travel distance too far, transportation problems, no need to attend a course, and attending a course is too strenuous. When comparing the two main groups of refusers, i.e., “having no time” and “living too far away”, the latter group did, indeed, live further away from the course location, more of them had a partner, and more of them were female. This supports what was observed during the interviews, namely that women frequently mentioned that they depended on their husband for transportation, because they themselves did not have a driver’s license. These women might have refused participation because they did not want to burden their husband with driving them to the course location for six consecutive weeks. This potential problem could be solved by providing some kind of meeting or activity for the husbands while the women attend the course. No differences were found between the participants and the refusers who “had no time”. The refusers who “lived too far away” did, indeed, live further away, but also more of them had a partner, compared to the participants. Again, future studies could provide more than one course location, closer to the homes of the participants, or could offer transportation.

Some limitations of our study should be mentioned. First, although we included quite a number and variety of variables in order to distinguish refusers from participants, we did not gather information about motivational or psychological reasons for (non-)participation. However, these reasons could be related to the variables measured in our study. Future research should take this into consideration. Secondly, a question that arises from our results is why do certain patients participate in the intervention even though they would be expected to refuse participation because, for example, they have mobility or transportation problems. This should be investigated in future research.

## **7.5 Conclusions**

As in many studies, the rate of non-participation in this study was high. Refusal in this study seemed to be related to physical mobility, to travel distance, and to social support. As a consequence, the participants who were included in our self-management intervention were only a selection of the target population. In future self-management intervention studies the above-mentioned characteristics of refusers should be taken into account, for example by offering transportation or providing some kind of activity for the partners of people who are unable to drive themselves.

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