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Response Rates in a Nursing Intervention Longitudinal Study on Vulnerable Elderly Patients

Steve Strupeit, PhD[1,*], Arne Buss, BA, MScN[2]

Professor, Department 11, Applied Social Sciences, University of Applied Sciences Munich, Am Stadtpark 20, 81243 München, Germany

Research Associate, Department 11, Applied Social Sciences, University of Applied Sciences Munich, Am Stadtpark 20, 81243 München, Germany.

Corresponding Author:** ***Steve Strupeit, *Professor, Department 11, Applied Social Sciences, University of Applied Sciences Munich, Am Stadtpark 20, 81243 München, Germany.* ***Email:*** *strupeit @hm.edu.*

Abstract

Introduction: *In the present study we sought to calculate the response rate in an experimental trial on a vulnerable elderly population and to examine reasons for nonparticipation. Additionally we aimed to determine the response rate of a later subsequent study were the same cohort was re-recruited.*

Materials and Methods: *The number of all eligible patients was collected to determine the sample size. Then the response rate was calculated by dividing the number of eligible patients by the number of participants. Analysis of reasons for refusal was conducted descriptively by checking patient records.*

Results and Discussion: *In the first study the overall response rate was 25.2% compared to 52% in the subsequent study was. There were several reasons for refusal, such as feeling over challenged or interference with privacy. The findings of this study revealed that when recruiting participants for long-term intervention studies vulnerable elderly populations, especially women, tend to show low response rates, in particular for the intervention group.*

Conclusions: *Researchers in this field should be aware of this issue and the risk of a nonresponse bias. Re-recruiting may increase response rate.*

Keywords: *Response rate; Recruitment; elderly; Nursing intervention; Longitudinal study*

1. Introduction

Recruitment of study participants can carry risks that may threat external validity. One bias that can occur during the recruitment is the nonresponse bias. A nonresponse bias (or response bias) is a bias that can result when a non-random subset of people invited to participate in a study fail to participate [1]. A nonresponse bias is related to the response rate. The response rate is the number of people participating in a study relative to the number of people sampled [1]. The higher the response rate the lower is the risk for a nonresponse bias. Polit & Beck [1] state that "a response rate greater than 65% is probably sufficient for most purposes, but lower response rates are the norm."

In several studies the authors sought to calculate the response rates and identify characteristics separating participants from nonparticipants or reasons for refusal. Lahmann et al. [2] in their prevalence study calculated response rates of 80.2% (2002) and 76.3% (2003) respectively. Puts et al. [3] in a study on cancer patients determined a response rate of 72%.

There were numerous reasons for refusal, such as lack of acceptance, a lack of attendence [2], fear, lack of time [3], or feeling too ill or too healthy [3, 4].

Experimental studies examining the effects of educational interventions on quality of life or functional status in elderly people show response rates of 30.9% [5], 59.6% [6], 62.6% [7], 77.1% [8], or 99.6% [9]. However in some studies it is not comprehensible why the authors differentiate between eligible patients and patients fulfilling inclusion criteria. Thus the sample sizes are not clear. If the authors reported reasons for nonparticipation these were refusal or decline to participate [5, 6, 7] or lack of consent [8].

In the present study we sought to calculate the response rate in an experimental trial on a vulnerable elderly population and to examine reasons for nonparticipation.

Additionally we aimed to determine the response rate of a later subsequent study were the same cohort was re-recruited in order to compare both response rate.

2. Materials and Methods

2.1. The Study Project

The Longitudinal Urban Cohort Ageing Study (LUCAS) is a cohort study of community-dwelling seniors complemented by specific studies of geriatric patients or diseases (Dapp et al. 2012). Within the LUCAS-study seven sub-projects are being conducted, approaching specific populations and research fields and questions three of which have contributed to this study.

The study Subproject "Immobility in old patients – trans-sectional care aspects (FALLEN): Nurse-driven counseling (reinforcement)" aimed at developing and testing the effectiveness of a concept to maintain and facilitate mobility in aged and old-aged multimorbid people in and after hospital discharge. The Intervention comprised nurse-delivered guidance, consultation, and training. The intervention was provided during clinical stay as well as post discharge and comprised inpatient consultation, home visitations and phone calls. Effectiveness of the intervention was evaluated by using a quasi-experimental study design (study 1). The main outcomes measured were mobility (functional status) and quality of life[10].

For a second project phase, the intervention was evaluated and adapted. It was then carried out outpatient and its effectiveness on functional status and quality of life was tested by using a randomized controlled trial design (study 2).

2.2. Ethical Approval

The study protocol was approved by the Ethics Commission of the Medical Association of Hamburg (PV2972).

2.3. Participants and Recruitment

The participants were recruited from the Albertinen- Haus geriatric rehabilitation facility in Hamburg, Germany. The inclusion criteria were an established diagnosis of functional mobility impairment of the musculoskeletal system or stroke (ICD-10: S00-T98 [except T36-87], T89, T88, T90-T95, T98, M00-M99, I61, I63, or I66), age older than 60 years, no spatial or temporal orientation deficits, no function-impairing cognitive impairments, the ability to communicate (motorically, cognitively, and psychologically), the ability to speak German, residence in Greater Hamburg (home or nursing home), and the provision of written informed consent. The exclusion criteria were a score of less than 25 points on the MMSE and discharge within the first week of the study. Additionally, individuals with a disease expected to lead to death during the study period were excluded from the study. A physician was consulted to identify these individuals. This criterion typically affected patients receiving palliative care. The average length of hospitalization among these patients was three weeks.

Two study nurses, two research associates, and student assistants recruited the participants. In a first phase the study nurses daily collected data from newly admitted patients and checked it for eligibility. Then the study nurses, supervised by the research associates, decided which patient finally was eligible to participate in the study. The eligible patients then were informed about participation. When written consent was given by the patients they were included in the study and baseline data were collected. Reasons for refusal and events leading to nonparticipation were standardized recorded.

2.4. Data Analysis

Data were analyzed by using descriptive methods. Data from patient records were digitalized and proportions of participants and nonparticipants were calculated. Analysis of reasons for refusal was conducted descriptively by checking patient records.

3. Results And Discussion

3.1. Participants Characteristics

Table 1 shows the characteristics of the study participants according to group allocation. There was a higher proportion of male participants in the intervention group and participants in the control group had a better overall quality of life.

Table1. *Baseline characteristics according to group*

	Intervention group	**Control group**	**Sig. (if applicable) (p^1)**
n[2] (%)	39 (31.8)	85 (68.2)	
Mean age, y (SD[3])	83.72 (6.87)	83.44 (8.71)	.052
Sex, n (%)			.000

Male	34 (87.2)	28 (32.9)	
Female	5 (12.8)	57 (67.1)	
Birthplace, n (%)			.663
Germany	36 (94.7)	75 (92.6)	
Other	2 (5.3)	6 (7.4)	
Marital status, n (%)			.139
Married	9 (23.1)	29 (35.8)	
Single	2 (5.1)	8 (9.9)	
Divorced	7 (17.9)	6 (7.4)	
Widowed	20 (51.3)	38 (46.9)	
Education, n (%)			.322
Secondary school Level I (up to 10th grade)	23 (59.0)	57 (70.3)	
Secondary school Level II (beyond 10th grade)	14 (35.9)	20 (24.8)	
Other	2 (5.1)	4 (4.9)	
Professional education (Berufsabschluss), n (%)			.852
Vocational training	23 (60.5)	50 (61.7)	
University degree	6 (15.8)	12 (14.8)	
Other	1 (2.6)	3 (3.7)	
No professional education	8 (21.1)	16 (19.8)	
Barthel Index	63.97 (21.71)	68.37 (21.95)	.951
WHOQOL-BREF[4]			
Overall	36.86 (19.65)	44.33 (24.15)	.018
Physical	48.35 (15.61)	47.90 (17.35)	.725
Psychological	57.56 (18.69)	58.73 (18.32)	.650
Social	75.21 (18.16)	70.83 (19.88)	.306
Environmental	62.15 (12.66)	65.20 (13.90)	.836
Self-efficacy	25.97 (5.13)	26.10 (6.25)	.121
MMSE[5]	27.97 (2.15)	27.98 (1.60)	.640
MNA[6]	22.76 (3.75)	21.78 (3.37)	.716

[1]p-value; [2]Number; [3]Standard Deviation; [4]World Health Organization Quality of Life-BREF; [5]Mini-Mental State Examination; [6]Mini Nutritional Assessment

3.2. Response Rates

For the first study, overall 492 patients fulfilled the eligibility criteria. Of these 124 patients gave consent to participate in the study. Thus the overall response rate (for both groups) was 25.2%. Male patients showed to be considerably more willing to participate in the study (48.8%), compared to female patients (17.0%). The response rate for the intervention group recruitment was lower (13.5%) compared to the control group (42.1%). Whereas about half of the men (51.5%) were more willing to participate in the intervention group only few women gave consent for participation (2.2%). For the control group response rates between male and female patients were comparable (see Table 2).

For the second Phase (study 2), 125 individuals from the original participants were re-recruited. Of these 65 individuals gave consent to participate in the study, indicating a response rate of 52% (see Table 3).

Table2. *Response rates study 1*

	Overall			Intervention Group			Control Group		
	Overall	**Women**	**Men**	**Overall**	**Women**	**Men**	**Overall**	**Women**[1]	**Men**
Fulfilled inclusion criteria (n)	492	365	127	290	224	66	202	141	61
Participated in the study (n)	124	62	62	39	5	34	85	57	28
Response rate (%)	25.2%	17.0%	48.8%	13.5%	2.2%	51.5%	42.1%	40.4%	45.9%

[1]Number

Table3. *Response rates study 2*

	Overall
Fulfilled inclusion criteria (n[1])	125
Participated in the study (n)	65
Response rate (%)	52%

[1]*Number*

3.3. Reasons for Nonparticipation/Refusal

Reasons for refusal were recorded in the intervention group recruitment. Overall there were numerous reasons. The patients stated that they feel over challenged (n = 5), do not want to receive home visits (n = 4), do not want to be under obligation (n = 4), do not want to reveal personal data (n = 3), are not interested in the intervention (n = 4), feel too young (n = 2), or refused to participate after talking to their relatives (n = 2).

During the recruitment for the second phase the nonparticipants stated that their relatives do not agree with a participation (n = 3), that they are not interested (n = 5), or that they do not want to receive home visits from strangers (n = 1). Thirteen individuals died and the other nonparticipants either did not state any reasons for refusal or could not be contacted.

The aim of the study was to calculate the response rate and to examine reasons for nonparticipation.

The overall response rate (intervention and control group) in the present study was 25.2%. compared to other studies examining a similar population (Desroisiers et al. 2007, Jerant et al. 2009, Andersen et al. 2002, Harrington et al. 2010) our response rate was considerably low. Bakas et al. (2009) showed a comparable response rate in their study. A low response rate may increase the risk of a nonresponse bias. Thus a non-random subset of our population may have been excluded in our study. As we examined a vulnerable population this may have led to such a low proportion of participants. Our sample consisted of elderly people who just have experienced a severe impact (i.e. stroke or fracture) leading to a decrease in their functional status. This may have influenced their decision not to participate in any study. To address this issue in further studies on this population it could beneficial to perform recruitment when patients already received rehabilitation. In this study we performed recruitment at admission. Our data show that functional status of the participants was lowest at admission and increased afterwards [10]. Patients may be more willing to participate when their functional status has improved. Additionally, the relation between the recruiters and the patients could have influenced the patients' decision because the study nurses who carried out the recruitment were not part of the clinic staff. It could have been more beneficial if the clinicians or other staff members had performed recruitment. Moreover the patients had to do deal with paperwork if they wished to participate because participants had to sign five documents in order to give consent. As especially female patients showed a low response rate (overall and in the control group recruitment) this seems to apply to women in particular. Moreover the lowest response rate was found for the intervention group recruitment. About half of the male patients and more than 95% of the female patients refused to participate in the intervention group. This may have been caused by the character of the intervention which required active participation and availability for a longer time. Additionally the intervention comprised personal contact in terms of home visits phone calls which could have been perceived as an interference with privacy. This stays in line with the nonparticipants reasons for refusal. Some of them stated that they feel over challenged, do not want to receive home visits, or do not want to reveal personal data. However reasons for nonparticipation could be collected from only few patients. Qualitative interviews were planned to evaluate reasons for nonparticipation but could not be performed because the ethics commission did not approve application. To address concern over interference with privacy researchers could phone refusers by using interview guides [11].

Additionally we aimed to determine the response rate of a later subsequent study were the same cohort was re-recruited in order to compare both response rate.

When the same participants from the first phase were recruited for the second phase, the response rate showed to be about twice as high as the response rate in the first phase. Thus it can be concluded that individuals from the population examined who already took part in a similar study, are more likely to give consent to participate. These individuals may have been

more aware of what they are confronted with. Additionally it can be assumed that they are more willing to participate because they already know the study nurses and therefore build confidence.

4. CONCLUSIONS

To address issues of low response rates in elderly vulnerable populations in studies with comprehensive long-term interventions, researchers should consider possible reasons for nonparticipation. Vulnerable elderly populations, especially women, often do not want to participate in studies, in particular in intervention groups. As low response rates cannot be avoided all researchers should be aware of the risk of a non response bias. When re-recruiting former study participants for a subsequent study this may increase the response rate.

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