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Promoting well-being in frail elderly people

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Part II
Design and test of an
intervention for increasing SMA
and well-being in frail elderly
people

Design, sample characteristics, and description of the intervention



In this chapter, the recruitment of the patients for the intervention study and the main characteristics of the sample are described, as well as the design and the used measurement instruments. In addition, a detailed description of the SMA intervention is given. The SMA intervention was tested in a randomized pre-post test design with two post-measurements (directly after, and after 4 months).

6.1 Patients

Patients were recruited between May 2001 and March 2003 in two settings: three wards of Internal Medicine of the University Hospital Groningen (specialties: General Internal Medicine, Rheumatology, Endocrinology, and Geriatrics) (clinic-based population), and the practice of a Family Practitioner (FP) in the Eastern part of the province of Groningen (the patients lived in the villages of Wedde, Wedderveer, Vriescheloo, Blijham, Veelerveen, Alteveer) (community-based population). Patients of 65 years and older were firstly selected using the Groningen Frailty Indicator (GFI). The GFI is a short, easy-to-administer 15-item screening instrument to determine a person's level of frailty. Further details on the GFI can be found in the section on measurement instruments. Patients with a score of 3 or more were included for further screening. The cut-off point was based on the judgments of clinical experts. The distribution of frailty in a normal population of community-dwelling elderly people is highly skewed, with about 53% scoring 2 or less (the maximum is 15) [1]. In a population of FP's patients of 75 years and older, this distribution is about the same, with 50% scoring 2 or less, and 75% scoring 3 or less. Therefore, a score of 3 indicates a moderate degree of frailty. The further screening consisted of checking if one of the exclusion criteria applied. These exclusion criteria were

- having cognitive impairments or dementia
- being delirious
- having a psychiatric disorder which could interfere with the intervention or would make the intervention impossible to apply (such as severe depression)
- having a very short life expectancy
- receiving other treatment or counseling which could interfere with the intervention (e.g., psychotherapy)
- being too ill.

Some of these exclusion criteria could be temporary for hospital patients - mainly the criteria of being too ill or delirious -, such that patients who were in the first instance excluded could be included later during their hospital admission. The medical attendants of the patients gave permission for the further screening of their patients. Screening was done by one of the trainers (the nurse) or by the primary investigator. After they were included in the study, patients were asked whether they agreed to take part. Those patients in the hospital who agreed and gave informed consent were randomly assigned to either the intervention or the control group. For the patients from the Family Practitioner's practice (FP's patients), this random assignment was done before patients were approached. Random assignment was done using sealed randomization envelopes following 'blocked randomization', such that within each group of six patients, three were assigned to the intervention group and three to the control group. Originally, the number of patients intended for inclusion in the study was 60 for each group (we aimed at a standardized effect of about .5, a power of 80%, and $\alpha = .05$, two-tailed). However, owing to problems with recruitment, these numbers had to be adjusted downward. Based on a new power analysis using the

variance in our main measurement scale (the SMAS-30) found in a large community sample (see Chapter 2), the number of patients sufficient for inclusion was adapted to 50 for each group (standardized effect of .5 and $\alpha = .05$, one-tailed, yielding a power of 78%).

In the hospital (including the Day Examination Center, the outpatient clinic, and the Rehabilitation Center), about 180 patients were screened using the GFI. Of these patients, 42 persons (33%) had a score below 3 and were excluded. Further screening revealed that about 13 patients had cognitive problems, 17 were too ill or had a bad prognosis, and 2 patients did not speak Dutch. Thirty patients could not be screened further because of very short hospital admissions. Thus, in the second phase of screening, 45% of the patients were excluded either because they met one of the exclusion criteria or because they could not be screened further. Of those who could be included in the study after Phase Two screening (76 persons), about 30 (39%) refused to participate. Forty-six patients were finally randomly assigned, which is about 25% of the total number of patients screened. Compared to, for instance, the FICSIT trials (several studies of frailty / injury prevention in elderly people [2]), this is quite good, though the refusal rate may be high in the hospital.

In the FP's practice, all patients of 75 years and older were screened using the GFI. Patients between 65 and 75 years of age were selected 'on face value' of frailty by the Family Practitioner for further screening. Of 148 patients of 75 years and older, 60 patients had a GFI score of 3 or higher. Of them, 24 patients were preliminarily excluded by the Family Practitioner because of cognitive problems (11 patients), death (4 patients), a bad prognosis (1 patient), and various other reasons (8 patients). Thirty-six patients were screened further and, of them, 30 (20% of the total number screened) finally participated (2 patients refused, 2 had cognitive problems, 2 were aphatic). Of 199 patients between 65 and 75 years of age, about 40 patients were screened, of whom 34 participated¹ (6 had a score below 3 on the GFI, had cognitive problems, or refused). In the FP's practice, unlike in the hospital, almost all people agreed to participate (refusal was only 6%). An overview of screening, inclusion, participation, and drop-out is given in Figure 6-1.

In total, 110 patients were randomly assigned. Of them, 39.4% were recruited in the hospital² (26 interventions, 20 controls); 60.6% were recruited in the FP's practice (30 interventions, 34 controls). Ninety-nine patients (90%, 49 interventions, and 50 controls) completed both pre-measurement (T0) and first post-measurement (T1). One patient dropped out before the pre-measurement; 10 patients did so between pre-measurement and first post-measurement. The reasons for drop-out were death (3 patients), severe illness (1), and refusal (6). Though the comparison was difficult

1. There was 1 protocol violation. In the control group, one partner of a respondent was allowed to participate with a GFI score of 1. In further analyses, we investigated how this protocol violation affected the outcomes.
2. Thirty patients of the wards of General Internal Medicine, 7 of the Day Examination Center, 2 of the outpatient clinic of Rheumatology, 7 of the Rehabilitation center.

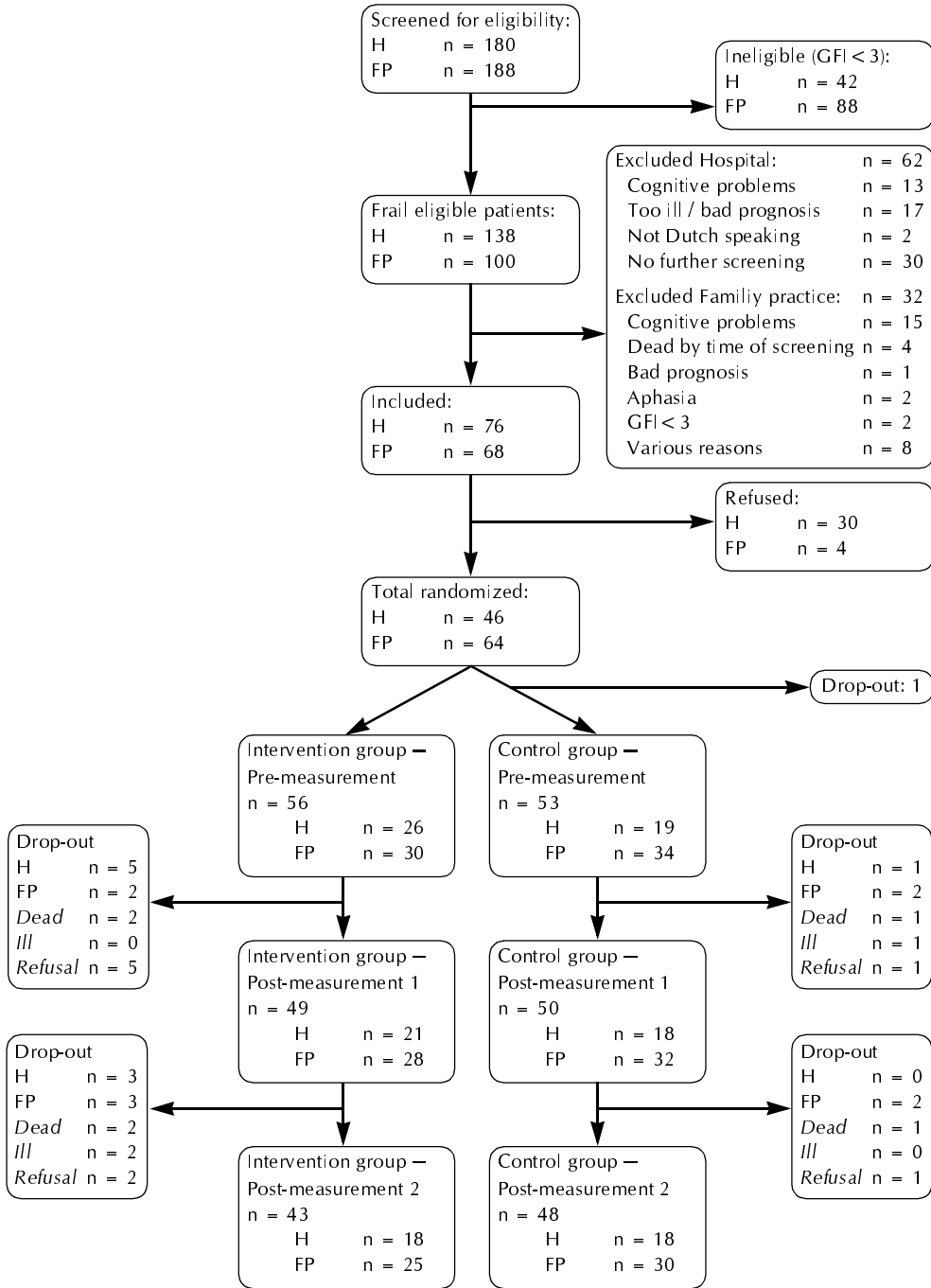


Figure 6-1. Overview of screening, inclusion, participation, and drop-out. H = hospital patients. FP = Family Practitioner's patients

because of the large differences between group sizes of patients and drop-outs, drop-outs seemed to be slightly older and frailer, had worse mobility, and lost weight more often. Between the first and the second post-measurements (T2), 8 patients dropped out because of death (3), severe illness (2), or refusal (3). Ninety-one patients (43 interventions and 48 controls) completed all three measurements.

Table 6-1. Baseline characteristics of the patients (percentages)

Characteristic	Intervention group	Control group	Overall
Mean age (SD)	75.7 (7.2)	74.4 (5.4)	75.0 (6.3)
Men	18.4	34.0	26.3
Married / Cohabiting	55.1	56.0	55.6
Widowed / Divorced	42.9	42.0	42.5
Never married	2.0	2.0	2.0
Living alone	40.8	44.0	42.4
Living with partner	46.9	50.0	48.5
Living with others	12.2	6.0	9.1
Living in independent house or apartment	59.2	78.0	68.7
Living in senior apartment	18.4	18.0	18.2
Living in sheltered accommodation	10.2	4.0	7.1
Living in residential home	12.2	0.0	6.1
Childless	12.2	6.0	9.1
No grandchildren	20.4	12.0	16.2
Reporting a 'life event' in last months	53.1	64.0	58.6

The mean age of the patients was 75 years ($SD = 6.3$; *median*: 73), with ages ranging from 66 to 89 years. Men made up 26.3% of the patients. The mean level of frailty was 5.4 (*median*: 5), ranging from 3 to 12. The distribution of frailty was slightly skewed to the left, which could be expected because of the distribution of frailty in the population. Twenty-five percent of the patients had a score of 4 or lower; 50% a score of 5 or lower; 75% a score of 7 or lower. Other characteristics of the patients are given in Table 6-1. Scores for the main measures of the three measurements are given per condition in Table 6-2. Table 6-1 and Table 6-2 seem to show some differences between the conditions.

The recruitment settings determined the geographical spread of the sample. Of the total T0-T1 sample, 86 patients were living in the province of Groningen, 5 in Friesland, 6 in Drente, 1 in Overijssel, and 1 in Noord-Brabant. Of the 86 patients living in the province of Groningen, 60 patients were recruited via the FP's practice and lived in 6 villages located near each other in Eastern Groningen (Wedde, Wedderveer, Blijham, Vriescheloo, Alteveer, and Veelerveen). Thus, many patients came from one specific geographical area. The region where the FP's patients lived is known to be a region

Table 6-2. Means for main concepts (SD) and paired T-Tests (p-values), per condition. Significant T-values are in bold

Concept	Intervention group					
	T0	T1	T2	t-value T0-T1	t-value T1-T2 ^a	t-value T0-T2 ^b
Frailty	5.5 (1.7)	4.6 (1.8)	4.9 (2.3)	3.68 (.001)	-1.23 (.227)	-8.22(<.001)
Overall SMA	18.8 (3.7)	19.2 (3.6)	19.2 (3.7)	-1.20 (.235)	1.29 (.204)	-1.15 (.258)
Multifunctionality	19.6 (7.0)	18.3 (6.4)	18.1 (6.2)	1.78 (.082)	1.49 (.144)	2.68 (.011)
Variety	15.6 (3.6)	16.3 (3.5)	16.6 (3.1)	-1.91 (.063)	-.18 (.859)	-2.47 (.018)
Positive Frame	19.3 (6.4)	19.7 (5.7)	19.7 (5.9)	-.68 (.499)	.096(.924)	-1.17 (.250)
Investment	18.0 (4.1)	18.1 (4.5)	18.0 (4.9)	-.34 (.734)	2.23 (.032)	.44 (.661)
Self-efficacy	23.3 (4.6)	24.4 (5.2)	24.3 (3.9)	-1.56 (.126)	.76 (.454)	-1.42 (.165)
Initiative	16.9 (4.5)	18.3 (4.5)	18.4 (5.5)	-3.03 (.004)	.47 (.641)	-2.09 (.042)
Overall Well-being	1.59 (.58)	1.76 (.53)	1.71 (.50)	-2.21 (.035)	.00(1.000)	-2.15 (.040)
Psychological Distress	2.02 (.54)	1.84 (.38)	1.83 (.34)	2.26 (.028)	.12 (.908)	2.10 (.042)
Neuroticism ^c	-	15.0 (2.9)	-	-	-	-
Mastery	3.10 (.85)	3.10 (.89)	3.21 (1.0)	-.06 (.956)	-.74 (.466)	-.86 (.396)
Loss-frame	2.69 (1.06)	2.58 (.98)	2.53 (.96)	.91 (.369)	-.39 (.701)	1.64 (.110)
Mobility ^d	8.7 (3.5)	8.8 (3.8)	8.9 (3.5)	-.47 (.642)	-1.10 (.277)	-1.01 (.317)

a. Because T2 contained fewer cases than did T0 and T1, the t-test was based on slightly different mean scores of T1 than those reported here.

b. A comparable argument holds for the tests T0 - T2.

c. Neuroticism was measured only at T1, because it was assumed to be a stable trait.

d. A higher mobility score indicates that mobility is more restricted (that is, worse).

with a low socioeconomic status, in which many people live quite isolated. We believe that many patients in the FP's population participated in the study 'because their doctor asked them to', so more with extrinsic than with intrinsic motivation.

Although Glasgow and Hampson [3] have shown that a community-based sample is comparable to a patient sample, in this study, the recruitment setting led to differences in the sample. The FP's patients were significantly less frail, and had higher overall well-being and less psychological distress than patients recruited in the hospital (see Table 6-3). Moreover, the FP's patients had a lower frequency of home nursing ($t = 1.79, p = .08$), were less often temporarily admitted to a nursing home ($\chi^2 = 8.44, p = .004$), had physiotherapy less often ($\chi^2 = 11.42, p = .001$), and had homecare ($\chi^2 = 3.98, p = .046$) and home nursing ($\chi^2 = 8.30, p = .004$) less often than did hospital patients. On the other hand, the FP's patients reported more life events, such as death of relatives, operations, and illnesses, during the past months ($\chi^2 = 10.74, p = .001$).

Concept	Control group					
	T0	T1	T2	t-value	t-value	t-value
				T0-T1	T1-T2 ^a	T0-T2 ^b
Frailty	5.0 (1.9)	4.6 (2.6)	4.4 (2.8)	1.70 (.096)	1.53 (.133)	-6.26(<.001)
Overall SMA	20.5 (4.2)	21.0 (3.9)	20.3 (4.2)	-1.44 (.158)	1.04 (.306)	.19 (.850)
Multifunctionality	21.6 (6.3)	20.7 (6.3)	20.3 (6.8)	1.61 (.115)	.03 (.974)	1.81 (.077)
Variety	17.6 (4.2)	18.8 (4.4)	17.6 (3.9)	-2.92 (.005)	2.42 (.019)	-.27 (.786)
Positive Frame	21.7 (5.2)	22.3 (4.5)	22.1 (4.6)	-1.45 (.152)	.12 (.903)	-.68 (.503)
Investment	18.6 (5.5)	19.2 (5.2)	19.1 (5.1)	-1.12 (.267)	-.29 (.773)	-1.21 (.232)
Self-efficacy	24.7 (5.2)	25.2 (4.2)	24.5 (5.1)	-.94 (.350)	1.19 (.242)	.03 (.974)
Initiative	18.8 (5.0)	19.5 (5.2)	18.3 (5.0)	-1.47 (.149)	1.61 (.114)	.89 (.380)
Overall Well-being	1.99 (.52)	1.95 (.53)	1.88 (.60)	.71 (.482)	-.51 (.612)	.43 (.667)
Psychological Distress	2.01 (.37)	1.93(34)	1.96 (.49)	1.40 (.167)	-1.24 (.221)	.54 (.589)
Neuroticism ^c	-	15.2 (3.2)	-	-	-	-
Mastery	3.31 (.95)	3.43 (.81)	3.40 (1.17)	-1.26 (.213)	.35 (.729)	-.94 (.353)
Loss-frame	2.22 (.92)	2.44 (1.00)	2.61 (1.06)	-2.35 (.023)	-1.40 (.168)	-2.97 (.005)
Mobility ^d	7.3 (3.4)	7.5 (3.3)	7.3 (3.3)	-.65 (.520)	1.0 (.325)	.47 (.642)

Two points concerning the composition of the sample needed extra attention in the analyses. First, the possible initial differences between the conditions could be expected to be related to the outcomes (for instance, the control group seemed to be higher in SMA). We had to take these possible differences into account by controlling for baseline levels. The second point concerns the differences between the patients recruited in the hospital and those recruited from the Family Practitioner's practice. The patients can be regarded as two sub-populations of the general population of 'moderately to severely frail elderly people'. All patients met the inclusion criteria, and could, therefore, be regarded as the target population of the intervention. If the effects of the intervention were to hold in both sub-populations, it would lend extra support to our model. However, when sampling patients from two different settings, we considered it important to take the effects of the setting into account in the analyses.

Table 6-3. Baseline differences between hospital patients and FP's patients in mean scores (SD) for main measures

Measure	Hospital		FP		t-value (p)	
Age	74.4	(6.6)	75.4	(6.2)	-.75	(.455)
Frailty	6.3	(2.0)	4.9	(1.9)	3.34	(.001)
Overall SMA	19.6	(3.8)	19.7	(4.3)	-.15	(.880)
Multifunctionality	21.5	(6.1)	20.1	(7.1)	1.03	(.307)
Variety	16.4	(3.8)	16.8	(4.2)	-.54	(.591)
Positive Frame	20.3	(6.8)	20.6	(5.3)	-.19	(.852)
Investment	17.9	(4.1)	18.5	(5.3)	-.61	(.544)
Self-efficacy	23.4	(4.6)	24.6	(5.1)	-1.11	(.268)
Initiative	17.9	(4.3)	17.8	(5.2)	.08	(.935)
Overall Well-being	1.5	(.5)	2.0	(.6)	-3.82	(< .001)
Psychological Distress	2.2	(.6)	1.9	(.3)	3.88	(< .001)
Neuroticism	15.0	(2.9)	15.2	(3.1)	-.36	(.719)
Mastery	3.2	(.9)	3.2	(.9)	-4.99	(.619)
Loss-frame	2.8	(1.1)	2.3	(.9)	-2.42	(.017)
Mobility ^a	9.9	(3.6)	6.8	(2.9)	4.68	(< .001)

a. A higher mobility score indicates that mobility is more restricted (that is, worse).

6.2 Measurement moments and interviewers

All patients were interviewed three times: pre-treatment after random assignment (T0), directly after the intervention or, for the control group, after 6 to 7 weeks (T1), and 4 months after the first post-treatment interview (T2; 6 months after baseline). Owing to several uncontrollable events – such as the illness of a patient – the intervals between the interviews differed between participants and were on average larger than planned. The interval between the first and the second interviews was on average 8.5 weeks (median 7 weeks), ranging from 4 to 14 weeks;³ the interval between the second and the third interviews was on average 19 weeks (median 18 weeks), ranging from 16 to 26 weeks. The patients for whom the period was very long were not influential cases in the analyses.

All patients were interviewed for the measurements, except for 4 patients who filled out some or all of the questionnaires themselves because of deafness or inability to schedule an interview. The measurements were done by the primary investigator and two trained interviewers, either in the hospital or at the patient's home.

3. For two patients, the period was up to 35 weeks because of illness.

6.3 Measures

Appendix III shows a scheme of the measurement scales and the concepts they were used to measure, for the pre-measurement and both post-measurements. Appendix IV gives the numbers of missing values for all (sub) scales.

6.3.1 Frailty

Frailty was measured using the Groningen Frailty Indicator (GFI) [4,5]. The GFI is a short, 15-item screening instrument to determine a person's level of frailty. It is easy to administer. The GFI is used to screen for loss of resources in 4 domains of functioning: physical (mobility functions, multiple health problems, physical fatigue, vision, hearing), cognitive (cognitive functioning), social (emotional isolation), and psychological (depressed mood and feelings of anxiety). Every item is scored either zero (no problems) or one (problems); scores are then summed. The sum scores range from 0 (*not frail*) to 15 (*severely frail*). As said above, the distribution of frailty in a population of community-dwelling elderly people is highly skewed. The GFI was used because it is the only known short screening instrument that screens for losses in all domains of functioning.

6.3.2 Self-management Abilities (SMA)

SMA was measured using the Self-Management Ability Scale (SMAS-30) (see Chapter 2). The overall scale is used to measure the level of SMA, which is an index for all self-management abilities together. The scale has a subscale of 5 items for every self-management ability. The subscales are interdependent and contribute to an overall score: SMA ($\alpha = .83$). Some subscales have a 5-point Likert scale for scoring, some a 6-point Likert scale. All scores are transformed to a 30-point scale.⁴ For every subscale, the average of the items is taken as sum score. The total SMA score is the average of the six subscale sum scores. For both the subscales and the total scale, a higher score implies higher SMA.

6.3.3 Subjective well-being

Two dimensions of well-being were measured. *Positive well-being* was measured using the SPF Instrument for the Level of well-being, the 15-item version (SPF-IL(s)), which is used to measure overall well-being [6]. This scale integrates both affective and cognitive components of well-being and measures levels of physical and social well-being ($\alpha = .78$). A higher score implies higher well-being. The SPF-IL(s) was used because it integrates the affective and cognitive components of well-being and conceptualizes well-being in the same way as the SMA intervention does (via well-being goals).

4. It has recently been decided to transform all subscales to a 100-point scale (see Chapter 2). However, all calculations in this dissertation except for those in Chapter 2 were done using a 30-point scale.

Negative well-being (or the absence of well-being) was measured using the General Health Questionnaire, the 12-item version (GHQ) [7]. This scale is used to measure psychological distress. The average of all items is taken as sum score, with a higher score indicating more psychological distress ($\alpha = .83$). The GHQ is a well-validated and well-known measure, which has been widely used (for instance, in Nestor-GLAS [8]). This facilitated the comparison of the results of this study with those of other studies.

6.3.4 Health care-use Questionnaire

Use of (health) care was measured using several questions about hospital visits, visits to the FP and specialists, nursing home admission, use of homecare and other services, et cetera. As no pre-existing scale could be used for this purpose, questions were designed for this study (Health Care Questionnaire, 19 questions). The Health Care Questionnaire covered 4 domains: 'Medical Care' (visits to FP, hospital admission, etc.), 'Paramedical Care' (physiotherapist, etc.), 'Rehabilitation' (temporary nursing home admission, etc.), and 'Care in the Home' (homecare, meals on wheels, etc.). Domain scores were created using Principal Component Analysis over the scores of the various questions. Illnesses were coded in a way comparable to that used in the Nestor-GLAS study [8]. The total number of diseases (physical and mental illnesses) was used as a continuous variable.

6.3.5 Mastery

Mastery was measured using Pearlin and Schooler's Mastery Scale [9], which is used to measure a general sense of mastery (control). This scale consists of 7 items to which people can agree or disagree on a 5-point Likert scale ($\alpha = .64$). Five items need to be reversed before computing a sum score by averaging the scores for the items. The higher the sum score, the higher a person's sense of mastery. The Mastery Scale is widely known and well validated, and has been used in research among elderly patients as well (for instance, in the Nestor-GLAS study or in LASA).

6.3.6 Loss-frame

This was operationalized using a 5-item version⁵ of the loss-perspective scale of Steverink [10] ($\alpha = .78$). This scale is used to measure people's expectations of the future fulfillment of the goals for physical and social well-being as they age. The scale is used to measure expectations of maintenance or loss, not of improvement or growth. Scoring is on a 5-point Likert scale. A lower score originally meant a stronger loss-

5. This 5-item version was developed on the basis of the data from three measurements in the Nestor-GLAS study [8]: T0 = 1993 (n = 737), T1 = 1994 (n = 617), and T3 = 1998 (n = 254). Five items were selected on face value, one for every first-order goal. All items were negatively worded. A comparison of Cronbach's alphas of the total scale to the five-item scale at all measurement times showed that alphas were comparable and satisfactory (T0: $\alpha = .93$ vs. $\alpha = .87$; T1: $\alpha = .89$ vs. $\alpha = .79$; T3: $\alpha = .91$ vs. $\alpha = .82$). Pearson correlations between the five-item version and the total scale were high (.94, .91, .91, respectively).

frame. To facilitate interpretation of the analyses, all scores were reversed such that a higher score indicated a stronger loss-frame. This scale was used because it is the only scale known for measuring expectations of the future fulfillment of the first-order goals for well-being.

6.3.7 Neuroticism

Neuroticism was assessed using the Neuroticism subscale of the Eysenck Personality Questionnaire (EPQ) [11]. This scale consists of 12 yes/no items for measuring neuroticism ($\alpha = .81$). Scores are added up. The higher the score, the more neurotic a person is. The Neuroticism subscale of the EPQ is often used and is well known, which facilitated comparison of the results of this study with those of other studies (for instance, with GLAS, and with another intervention study carried out in our research group).

6.3.8 Other variables

Other variables which can be regarded as (restrictions in) direct resources, such as health and living situation, and background variables were assessed using four items from the GARS about mobility [12], four subscales of the SF-20 (general health perceptions ($\alpha = .88$); restrictions in role functioning;⁶ restrictions in social activities; physical pain) [13], and several questions about marital status, living situation, living environment, shops and services for the elderly in the neighborhood, health status of the partner, contact with and proximity of children and grandchildren, driving a car, subjective income (that is, do people find that they have enough income to do what they want to do, or is this a problem), education, former profession, and religion. Questions were either taken from well-known, widely used, and well-validated scales (such as the SF-20), or designed for this study.

6.3.9 Random events

The last question was about random events that happened between the interviews and the intervention. These 'random events' are life events or other events that could have influenced the way people reacted to the intervention or that could have influenced well-being more than normally. Examples of such events are the illness of the patient or his / her partner, the deterioration of disability, the death of a member of the social network, holidays, the birth of grandchildren, relocation, or falls.

6. Because the two items used to measure restrictions in role functioning due to health were similar concerning the situation of elderly people, and because the answers in the first interviews to both items were the same, this subscale was restricted to only 1 item: "restrictions in work or household activities".

6.4 Intervention

6.4.1 Form

The underlying ‘Grip op het leven’⁷ intervention was an individual, partly tailor-made intervention that was delivered at home. This means that there was a general framework that was adapted to the specific situation of a patient and that stressed the themes within a module that are most relevant to a particular patient. By contrast, most existing intervention programs are group interventions. Group interventions have several benefits and effects which can be difficult to attain in an individual intervention, for example, good cost-effectiveness, exchange between patients who are in the same situation and have recognizable problems [14,15], and support from and modeling by other patients [16]. The goals of improving social well-being, such as behavioral confirmation, can be reached more easily in a group intervention, owing to its social nature. The reasons why we chose to design an individually delivered intervention, despite these advantages of group interventions, were the following. We believed that, for this category of frail elderly patients, a group intervention would be too strenuous. This has also been found in studies that describe ‘comprehensive geriatric assessment’ [e.g., 17-20]. In all these studies, individual approaches were adopted. In addition, in some studies, it has been found that non-participants in group interventions were mainly those patients whose condition was worst and who were the most disabled [see e.g., 21]. For people who are frail and whose physical condition is poor, traveling to a group setting and being in a group might be too exhausting. An individual intervention delivered at home is less strenuous, which could lower the threshold for taking part. Another reason for designing an individual intervention was the large heterogeneity in this group of frail elderly patients. Because frailty is a comprehensive concept including different domains of functioning, frail elderly people’s individual situations are heterogeneous. Their reserve capacities are small and heterogeneous, too. Because this reserve capacity was to be addressed in the intervention, an individual approach seemed the best because it can adapt to the situation of a particular patient. A last reason for choosing an individual approach was that a group intervention may yield effects on social goals, but possibly only because the participants are ‘in a group’ and not because of the intervention itself. On the other hand, an alternative for modeling, which occurs in a group, needs to be included in an individual intervention.

One of the things that this new intervention shared with existing ones was its educational character. Education, and consequently the supposed gain of knowledge, has been found to be important for self-management [22]. Without knowledge, people’s self-management capacity is not fully effective, because they do not know why it is beneficial to do what they do. Knowing the purpose increases the motivation. The educational character implied providing information, assignments, written role

7. GRIP is an acronym for Groningen Intervention Program. This is a program which comprises several interventions, in different formats. All interventions are called either ‘Grip op het leven’ or a comparable phrase containing GRIP.

models (role models have been found to be important for learning, see e.g., [23]), and home assignments. The intervention was a dialogue and practical co-working with patients. Its aim was to teach specific skills, or rather to educate people in them and to offer them as possibilities. Because the intervention focused on skills (namely, self-management abilities), it can be regarded as a skills training. However, because of the number of home visits, which was relatively small, it should be regarded as a mild form of training. The short and non-intensive character was chosen because of the frail condition of the patients. If such a modest training were to yield effect, it would indicate that there is much future potential in improving self-management abilities, provided the training is more intensive.

The intervention was a mixture of a professional-centered and a patient-centered approach. This mixture is often used in interventions. For example, Holman and Lorig [23] state that patients know best about the course of their disease, its impact, and the effect of treatment. The doctor, on the other hand, is the expert in the biological basis of the disease and the possibilities for treatment. In a similar way, we believe that scientists can contribute expertise in effective dimensions of self-management behavior in relation to the realization of well-being, whereas patients themselves know best about the specific contents of their goals for well-being and how they apply effective self-management behavior.

The intervention was delivered at home, or at the start of the intervention, sometimes in the hospital. The 'home visits' lasted one to one-and-half hours each. There were five to six visits in total, depending on how many problems patients had and how quickly they understand all themes of the home visits. The intervention was tailor-made within the home visits (modules). For patients who had few problems and understood everything quickly, much repetition was not necessary and the number of home visits was limited to 5. One or two extra visits were necessary for patients who had many problems. Mostly, the visits were weekly.⁸ If possible, the partner of the patient was involved. If the patient so desired, other persons from the patient's social network, such as children, were involved too. The trainer 'taught' the themes of the intervention to the patient in a dialogue in which information and advice were given. The themes were applied to the daily life of the patient and the active participation of the patient was stimulated. This made the intervention interactive. Patients were asked to do small home assignments, for instance, a plan to try to carry out for the following week. A workbook accompanied the home visits. The workbook consisted of three parts: one part with assignments used during the home visits; one with assignments patients were asked to do for the following home visit; and one with short summaries of the discussed themes. Every visit, the patients received some new pages for the workbook.

8. On average, patients received six visits. For patients who had few problems with self-management abilities and understood the content of the intervention quickly, five visits were enough ($n = 14$). Sometimes, more than six visits were thought necessary by the trainer ($n = 4$), with a maximum of 8 visits. The intervention period lasted on average 9 weeks, ranging from 4 to 13 weeks. For two patients, the intervention period lasted up to 34 weeks because of illness.

6.4.2 Content

General

In the intervention, the different self-management abilities were introduced. This was done by stressing the importance of positive thinking, self-efficacy, taking initiatives, taking care of a variety of resources, investing in resources, and taking care of the multifunctionality of resources. Moreover, the intervention applied these abilities directly to 'goals for realizing well-being'. Maybe it would not be possible to increase the quantity of the resources for achieving well-being, but it would be possible to enhance the quality of existing resources or to substitute existing resources with better ones.

Patients were taught to pay attention to the first-order goals for well-being: goals that most people need to realize to a certain degree to be happy and live a pleasant life. They were helped to apply these goals and to recognize them in their own lives. The trainer helped them to discover what they already did to reach the first-order goals and what they would like to change or add (if they wanted to change anything). The trainer then encouraged the patients to make these changes. This exercise expressed the partly professional-centered approach we took. We wanted to mix professional knowledge of the goals for well-being with people's own knowledge of the individual content of these goals. We believe that it does matter which goals patients choose, and that they can choose goals which are less beneficial to their well-being. This is stressed by Kasser and Ryan [24], too. They found that what is more beneficial is not reaching goals in itself, but reaching certain goals (they found intrinsic goals to be much more beneficial than extrinsic goals).

Goal setting played a large role in the intervention too. It was introduced as creating a plan, in small steps if necessary. Setting and achieving goals using a plan is an operationalization of Bandura's social cognitive theory, in which the mastery of skills (in this case, self-management abilities) is supposed to build confidence or self-efficacy [25-27]. Other parts of this skills mastery are feedback and problem solving, that is, adjusting a goal when it is unattainable. In our intervention, patients were encouraged to adjust plans and goals when these were unattainable. This is done in many interventions [see, e.g., 26]. In addition, in our intervention, people were encouraged to practice between sessions, for instance, by carrying out a plan. The importance of having the ability to practice between sessions with the learned behavior is stressed by others, too [see, e.g., 14].

Connected with goal setting and planning is the concept of self-efficacy. Self-efficacy is a cognitive factor that plays a role in the exercise of personal control over motivation. It determines which kinds of actions people want to undertake, how much energy they put into their efforts to achieve something, how long they can sustain effort, how vulnerable they are to stress when facing difficulties and failures, and so on [28]. In Bandura's theory, the mastering of skills increases self-efficacy. Self-efficacy is a prerequisite for, among other things, taking initiative. If people do not believe they are

competent to do something, they will not even try it. Self-efficacy, therefore, is one of the core self-management abilities to be increased and, it must be increased before some behavioral change can be expected [23]. Self-efficacy was introduced in the intervention as having confidence in one's plans and one's ability to achieve one's goal. To check if they had enough confidence in their plans, patients were asked to give themselves a score for the confidence they had in their ability to carry out their plans (confidence score). This is done in Lorig's intervention as well. If patients give their plan a low score, this implies either that their self-efficacy is low or that their goal is not realistic. They are then encouraged to change the plan in such a way that they will have more confidence in it. In this way, they adapt their goals to realistic ones. To increase self-efficacy, people are also encouraged to reward themselves when they have achieved their goals. Moreover, perceiving that one has successfully achieved one's goal contributes to happiness [24], perhaps through enhanced self-efficacy [29]. Rewarding oneself may intensify this. This was called 'dwelling on your successes', in our intervention.

Below, the specific content of each of the 6 modules (home visits) is described. Each of the modules addressed one or more self-management abilities and / or goals for well-being. Appendix V gives an overview of the modules (in Dutch).

Module 1

The first module started with a short explanation of the rationale of the intervention: elderly patients could be at risk of a decline in many domains of functioning and of losing their 'grip on life' because of health problems and their consequences for daily life. The goals of the intervention were to give advice on how to maintain autonomy and live as pleasant a life as possible, despite problems and restrictions; to give advice about keeping enough reserve capacity; to make patients realize which things are going well and to give advice on how to maintain this. The trainer made an overview of the patient's (health) problems, of the consequences of these problems, as well as of the things that were going well. After this introduction, the trainer briefly explained the outline of the intervention and introduced the workbook. The trainer pointed out the main themes of the intervention: goals that most people strive for in order to have as pleasant a life as possible ('*comfortable living*', '*pleasant activities*', '*good contacts with other people*', '*receiving and giving affection*', '*being proud of something*') (the goals for well-being); and the ways in which people can achieve these: '*thinking*' and '*doing*'. The patients were asked to think about the five goals and whether they recognized them in their own lives.

The intervention started with '*thinking*' (the cognitive part of SMA) - the thoughts that people have before they take action -, because this is seen as a precursor of patients' actions. 'Thinking' is of central importance for many other self-management abilities. In the first module, we tried to connect the 'thinking' theme with the patient's own situation through '*thoughts that hinder taking initiative*'. The way this was done was based on Rational Emotive Therapy (RET) [30,31]. RET teaches people to discover the sequence 'Thoughts → Feelings → Behavior' by themselves and to change hindering

thoughts into more realistic ones. We simplified this to a sequence of 'Thoughts → Behavior' and then especially to thoughts that hinder people from taking initiative. The trainer helped patients recognize these thoughts (if they had them) and see how they hindered their behavior. The trainer then helped them, if necessary, to replace these thoughts by 'better' ones, that is, thoughts that lead to taking initiative. Recognizing thoughts and replacing them was practiced during the home visits. Patients were asked to think of something that had happened during the past days and of the reasons why they did or did not do what they wanted to do. If they did not do what they wanted, they were asked to think of the reasons why and to find out if there was a thought hindering their actions. If possible, they were asked to replace this thought by one that would lead to action. The trainer also asked the patients to do a similar assignment for the following visit.

Module 2

In this module, the self-management abilities Positive Frame and Taking Initiatives were addressed. Module 2 started with discussing the home assignment and with repeating the theme 'thoughts that hinder'. Then, another aspect of thinking was addressed, namely, '*positive thinking*'. The aim of the intervention was to teach people to frame things positively. By doing so, we hoped that people would realize that they could achieve well-being and that this could be done by increasing or retaining their resources and improving the quality of their resources. A positive frame is better for investment behavior. Positive framing is done using certain cognitive coping strategies, which are grouped under the heading, 'think positively'. These strategies are used by many people and are effective in increasing well-being and coping with setbacks, especially in the short term [32]. Positive thinking is also closely related to optimism. Optimistic people turn to adaptive emotion-focused coping strategies, such as positive re-framing, when problem-focused coping does not work [33]. The intervention focused on ways of thinking positively about small negative events. Some events, such as the loss of a partner, are too distressing to be coped with in this way. For such events, the importance of acceptance and the process of mourning were stressed. For less negative events, the following cognitive coping strategies were briefly discussed: trying to see the positive side of negative things; looking at others who are worse off; thinking that the situation could always be worse; thinking of things one can still do (instead of only thinking of what one cannot do anymore); thinking that it will be better tomorrow; and not becoming discouraged by problems, but actively dealing with them. The trainer discussed whether patients used these strategies and how they felt when using them.

The second theme in Module 2 was the self-management ability '*taking initiatives*'. The trainer explained that 'thinking' is important, but not enough. Patients also need to do things. For 'doing', several tips were given in this and the following visits. The first tip given was 'taking initiative'. Patients were asked to decide what they wanted to change and take the initiative to do this, if necessary by asking help. The trainer discussed with the patients if *they* mostly took the initiative or if they mostly waited till *others* took the initiative, for instance, in contacts with others or in arranging pleasant

activities. The assignment for the following visit had the same content. Patients were asked to note in which situations they took initiative and in which situations they left this to other people.

Module 3

The third module addressed the self-management abilities Taking Initiatives and Self-efficacy, and the first-order goals Comfort and Stimulation. The module started with repeating the themes of Module 2 and with discussing the home assignment. The trainer then introduced two themes for which it is good to take initiative: 'comfortable living' (the well-being goal comfort) and 'pleasant activities' (the well-being goal stimulation). These are the best things that people can do in order to live as pleasantly as possible. The trainer introduced 'comfortable living' and 'pleasant activities' by giving examples and explaining why these things generally make people feel good. Examples of *comfortable living* are eating well, having a comfortable house with aids if necessary, relaxing and resting, relieving physical uneasiness, tidying up the house and making it cozy, and wearing nice clothes. An optional sub-theme of comfortable living is chronic pain. Because pain can have a major influence on how comfortably people live, this theme needs extra attention for patients who have (chronic) pain. Ways to cope with pain were discussed (such as relaxation, painkillers, distraction), as well as the importance of accepting pain and knowing what increases pain.

Examples of *pleasant activities* are walking or pottering as physically pleasant activities, and reading or doing crosswords as mentally pleasant activities. In addition, the trainer recommended a good balance between activity and rest. The trainer discussed with the patients what they did to live a comfortable life and engage in pleasant activities, and whether they wanted to add or change something. Patients who wanted to change things were encouraged to set goals.

An optional theme was '*hindering thoughts* for comfortable living and having pleasant activities'. This concerns the same thoughts as discussed in the first module, but then specifically applied to these two themes. If the trainer noticed that a patient had such thoughts, he addressed them in the same way as in Module 1. Otherwise, the theme was skipped.

Connected with '*doing*' is the theme '*making a plan*'. The trainer explained that it is easier to reach a goal or to take the initiative if one makes a concrete plan. In this plan, patients wrote down what they wanted to do, how often, and when, and how great their *confidence* was (confidence score). The trainer helped each patient to make a plan for one of his or her own goals. For people who did not want to change or add anything, the theme '*making a plan*' was introduced with examples. When choosing a goal and making a plan, it is important to choose something for which one is self-efficacious enough. That is, a person should have enough confidence that he or she can carry out this activity. Patients were encouraged to check their confidence in their plans by giving a confidence score. A score of 7 or higher meant they had enough confidence to carry out the plan; a lower score meant that confidence was too low. In

that case, the trainer helped the patients to adapt their plans in such a way that they would have enough confidence. For the following visit, patients were asked to carry out the plans they had made.

Module 4

In this module, the self-management ability Self-efficacy and the first-order goals Affection, Behavioral confirmation, and Status were addressed. As all modules, the fourth one started with repetition and with discussion of the home assignment. Coupled with the evaluation of carrying out the plan are the following themes: making attainable and realistic plans, and dividing large goals or plans into small steps (stepwise plan). These themes refer to two reasons for failure of an intended plan: either the plan was not realistic, or it was too large to carry it out at once.

Making attainable and realistic plans is important to increase the chance of success. Success in carrying out a plan is important to strengthen self-efficacy. Patients were encouraged to check how attainable and realistic their plans and intentions were by giving a score for confidence. Those who had unattainable plans were encouraged to replace them with more realistic ones. This was done because it is not beneficial to strive too long for goals that are unattainable [33]. It has been found that people who are able to adjust their goals flexibly are less vulnerable to developmental stress [34]. Even if certain goals are unattainable, a sense of control can be maintained by shifting preferences and goals in such a way that they are compatible with resources and (situational) constraints [35].

Another way of reaching a large goal is by dividing it into small steps and trying to attain these steps one by one, by making a *stepwise plan*. This also applies when people want to train for something, for instance, walking. Making such a stepwise plan is comparable to ‘problem-solving skills’, which are taught in many (self-management) interventions [see e.g., 14].

The stepwise plan was applied to the other three goals that we advised patients to strive for in order to live as pleasant a life as possible: genial contacts with others, giving and receiving affection, and being proud of something (the well-being goals of behavioral confirmation, affection, and status, respectively). The trainer introduced these goals by giving examples and explaining why these things generally make people feel good. *Having genial contacts with other people* means, among other things, belonging to a group, receiving the attention of others, and others’ liking what one does. Genial contacts can be obtained, for instance, by visiting others or by doing activities in a group, such as a club. *Giving and receiving affection* involves more than just genial contacts with others. It means having a close bond with others – with confidants or friends. Affection is important to prevent loneliness and unhappiness, and to cope with negative feelings and experiences. It can be gained, for instance, by contact with loved ones, by having a personal talk with people, by showing affection for another person, and by building up and maintaining friendships. *Being proud of something*, finally, is important because it can be beneficial if people distinguish

themselves from others in a positive way. This often leads to gaining the respect and esteem of others. People can be proud of things they have, for instance, a nice house or their grandchildren, or of things they can do, for instance, a hobby. The trainer discussed with the patients whether they recognized these three goals (genial contacts, affection, being proud) and what they did to achieve these goals. The trainer also asked whether they wanted to change or add something to these goals in their lives. Patients who wanted to change or add things were encouraged to set goals.

An optional theme was '*hindering thoughts* for genial contacts with others, giving and receiving affection, and being proud of something'. This concerned the same thoughts as discussed in the first module, but then specifically applied to these three themes. If the trainer noticed that a patient had such thoughts, he addressed them in the same way as in Module 1. Otherwise, the theme was skipped.

Next, patients were encouraged to make a stepwise plan for one of the three goals of this module. Patients were asked to define the steps needed to carry out the plan, decide in which order they wanted to take these steps, how often, and when, and when they wanted to have finished all steps. In addition, they were asked to give a confidence score for the plan.

The last theme of Module 4 was '*dwelling on success*'. Patients were encouraged to reward themselves when they had a (small) success. People tend to let losses weigh heavier than gains [36], and tend to pay attention only to things that fail, not to things that succeed. However, paying attention to successes increases confidence in one's ability to do something; that is, it increases self-efficacy.

For the following visit, patients were asked to carry out (part of) the stepwise plan, or to work on another goal if there was no stepwise plan. In addition, they were asked to dwell on successes they had had (things that went well) and to write them down.

Module 5

Module 5 started with repetition and with discussion of the home assignment. This module was mostly about ways to *build up and keep reserves*. This involves the self-management abilities Variety, Multifunctionality, and Investment. Variety is coupled with the process of 'substitution'. It was introduced as having more ways to reach one's goals and replacing one way by another (substitution and compensation). Patients were asked to think about activities or contacts they had to give up temporarily or permanently, and whether they 'replaced' them or not. *Replacing activities and contacts* is easier when people have a number of activities and contacts, because then they have *reserve possibilities*. These reserve possibilities may be *other ways to reach goals*, which lead to the same or almost the same level of well-being (of course, some things cannot fully be replaced, for instance, a friend who dies). The trainer helped the patients to discover whether they had a number of ways to reach each of the five well-being goals. If, for one or more of the goals, patients had only one way, the trainer encouraged them to think of reserve ways for these goals.

The second theme in this module was multifunctionality, here called '*combining*' ('killing two birds with one stone'). The trainer explained that it is efficient to have activities with which more than one goal is realized at the same time. For many people, this is a pleasant way to realize well-being. The trainer asked the patients if they recognized this combining and whether and how they did that. Connected with the theme '*combining*' is the theme '*do not combine too much*' ('do not put all eggs in one basket'). The trainer explained that combining is a good way to realize well-being, but that combining too much makes people vulnerable. If people have only one person (mostly a partner) with whom they reach all well-being goals, and they lose this person, they lose all their activities, contacts, et cetera, at once. It is better to have contact with a number of people with whom one can do different activities. The trainer asked the patients whether they combined too much in this way and, if so, how they could change that.

The last theme of this module was '*investment*'. This means doing things which yield results in the long term (such as having enough activities to prevent boredom). It also means maintaining what one already has (such as regularly visiting or calling people with whom one has good contact, to maintain the contact). The trainer helped the patients to discover if they invested enough, if they would like to invest more, and how they could do that.

For the last visit, patients were asked to write down what was of most use to them during the visits and to consider what they would like to discuss again.

Module 6

Module 6 started with a short discussion of the home assignment. The trainer then briefly repeated and summarized all themes that had been discussed during the visits. The patients' own plans, lists of goals, and resources, and other things that were discussed during the visits, were connected with the themes again. Following this, the trainer discussed with the patients whether they found it necessary and possible to go on with the themes and recommendations of the intervention in the future. If so, the trainer discussed how they intended to do this. If necessary, patients could call the trainer for advice or help, over a period of four months. However, they were encouraged not to call too often, because they should not become dependent on the trainer.

6.4.3 The trainers

In this study, a geriatric nurse and a psychologist in training (a student) gave the intervention. The trainers were trained by extensively discussing the content of each module and role playing each module several times. In addition, the second trainer (the student) accompanied the first trainer several times to observe how to give the training.

6.5 Analysis

Specific analyses are described in each chapter separately. However, we would like to make some general remarks concerning the analyses of the intervention data. Because of the composition of the sample and the possible baseline differences, the baseline levels of all measures and the setting in which the patients were recruited were taken into account. For 4 patients (all belonging to the intervention group), the interviewers doubted whether the interviews were valid. One patient (a control respondent) caused a protocol violation, because he had a GFI score of 1 at inclusion. All analyses were carried out both with and without these five cases to see whether they influenced the analyses. Because there were no substantial differences between the analyses with and without the five cases, and the five cases were not influential, as could be concluded from examining Cook's Distances and Centered Leverage Values, the results of the analyses including the five cases are reported. Influential cases in univariate and multivariate analyses were investigated by examining Cook's Distances and Centered Leverage Values, and were excluded in the main analyses.

For all analyses, assumptions of normality and homogeneity of variances were assessed graphically and analytically. Both Kolmogorov-Smirnov tests and normal Q-Q-plots showed that the assumption of a normal distribution of the scores did not hold for almost all measures. This implies that the results of the main analyses, which were based mostly on the assumption of normality, should be interpreted with caution. Transforming the different dependent variables (log, quadratic, and square root transformations) did not yield other results and did not lead to increased explained variances. Apparently, the non-normality of the scores did not severely violate the results. Therefore, analyses are reported with the untransformed scores. In most uni- and multivariate analyses, the error variances could be considered homogeneous.

Missing values were imputed using SOLAS [37], a program for multiple imputation, using the predictive model-based method with ordinary least squares regression. Eight data files with complete cases were created, in which missing values were imputed using a regression model of the imputation variable on a set of covariates. The covariates included the variables to which the imputation variable was expected to relate [38] (such as the same variables from other measurement moments) and gender, age, condition, population, and interviewer, which were probably related to the number or the pattern of missing values. All main analyses were done using the non-imputed and the 8 imputed files. Secondary and non-parametric analyses were done using the non-imputed file only.

All analyses were carried out using SPSS 10.0.7. [39] and MSV DISTs [40].

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