

## Challenges in the performance of real-life studies in older patients: focus on long-term care facilities

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### Abstract

Research on geriatric conditions and atypical disease presentation in poorly studied patients' groups is becoming increasingly important. Aim of the present investigation was addressing prevalence and prognostic significance of aortic valve stenosis (AVS) in older residents of long-term care facilities (LTCF). For the planned recruitment of 500 LTCF guests of a German metropolitan area, study investigators were trained and in the performance of a cardiologic examination and of the comprehensive geriatric assessment-based multidimensional prognostic index (MPI). After five attempts to obtain permission to conduct the study in 30 institutions, patients' recruitment was stopped with 22 participants included from one institution. AVS was suspected in two patients, in agreement with the reported prevalence data. The MPI value correlated with social support ( $P=0.002$ ) and geriatric syndromes ( $P=0.004$ ). This structured attempt at investigating presence and prognostic signature of AVS in older LTCF guests was challenged by logistic obstacles strongly hindering diagnosis of potentially treatable conditions which, if undisclosed, negatively impact on survival and quality of life.

### Introduction

By 2060, an aged population and thus an increase of the prevalence of frailty, disabili-

ty, atypical disease presentation, morbidity and chronic conditions is expected.<sup>1-3</sup> As result, the likelihood of needing long-term care will increase.<sup>4</sup> Residents of long-term care facilities (LTCF) have a high prevalence for coexisting physical and mental illnesses as well as for frailty.<sup>5,6</sup> Multimorbidity is highly common as are geriatric syndromes (GS).<sup>5</sup> Therefore, they are a group of patients highly vulnerable due to their health conditions and multidimensional frailty so they might be more exposed to adverse outcomes after stressors - as unfortunately shown during the coronavirus disease 2019 (COVID-19) pandemic.<sup>7,8</sup>

Associated with ageing-related multimorbidity, aortic valve stenosis (AVS) is a disease predominantly occurring in patients of advanced age.<sup>9</sup> It arises predominantly in patients of advanced age as calcific AVS.<sup>9</sup> However, a substantial proportion - around 50% - of patients with severe AVS is asymptomatic at the time of first diagnosis.<sup>10</sup> Older patients, in particular, may not develop classic symptoms.<sup>11</sup> The appearance of symptoms, nonetheless, indicates a clinically significant stenosis and the need for prompt intervention.<sup>11</sup> Due to a reduced quality of life and life expectancy attributed to AVS, it is essential to determine the cardiovascular risk and discuss the benefits and risks of either regular check-ups, drug or interventional therapy based on current guidelines.<sup>9,11,12</sup> Therefore, classification and correct diagnosis are especially important in choosing the right approach based on severity and symptoms of the AVS.<sup>12</sup>

Various studies have determined the prevalence of AVS for patients of advanced age with values between 3-12%.<sup>9-11,13</sup> Due to the population's increasing average of age, the absolute number of patients with AVS will rise substantially in the future. Underdiagnosing, atypical presentation, coexistence of GS, and functional loss in vulnerable populations drastically challenge the traditional algorithms as far as diagnosis and management are concerned. Therefore, the present study was designed to investigate presence and severity of AVS in LTCF and affiliated assisted living facility (ALF) residents as well as the role of a patient-centered approach in disclosing factors associated with AVS usually escaping traditional clinical paths but highly influencing disease trajectories.

In particular, the comprehensive geriatric assessment (CGA)-based multidimensional prognostic index (MPI) was used<sup>14-17</sup> to assess prognostic information in relation to the overall health condition of the LTCF residents. As the study was highly challenged in its conduction, the encountered obstacles as important results of the investi-

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Ethical standards: the study was performed in accordance with the 1964 Declaration of Helsinki and its later amendments. The ethics committee of the University of Cologne, Germany approved the study protocol (Vote EK 17-442 on 14.12.2017). The study is registered at the German Clinical Trials Register (DRKS00016957).

Informed consent: informed consent was obtained from institutions, patients, or, from their legal caregiver.

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gation are here reported and described to draw the attention of the scientific - medical community on often neglected aspects of geriatric care research.

## Materials and Methods

### Registration, participant consent and ethics

The study was performed in accordance with the 1964 Declaration of Helsinki and its later amendments. The ethics committee of the University of Cologne, Germany approved the study protocol (EK 17-442 from 14.12.2017).

### Clinical training

Study investigators received training on the CGA-based MPI as well as on cardiac auscultation. A standardized curriculum was conducted in the Cardiology Department of the University Hospital of Cologne (30 min theory, 40 min practical instruction, 2 h auscultation with echocardiographic control, 90 min examination for heart murmurs on cardiology ward, 120 min additional training in a skills lab). The acquired skills were tested in a single-blinded examination and judged to be satisfactory for the purpose of the study.

### Patients

The study was implemented as a prospective, observational study and started in November 2017. Since then, 30 different LTCF with in total 3000 possible participants were contacted to ask for cooperation. Written, telephone and personal approaches were chosen to establish contact. Only in 2019, after approval of the *Arbeiterwohlfahrt (AWO) Regionalverband Rhein-Erft & Euskirchen e.V.*, an association of five LTCF in the Cologne area, agreed to participate. A screening phase on approximately 500 patients aged 65 years and older living in the institution was initiated. The investigation begun in one of these LTCF, in which lived, at the time, approximately 130 people aged 65 years and older. Concerning potential participation residents of ALF were personally approached, whereas residents of LTCF and their family members were asked via letters. A personal request was not possible due to data protection regulations.

The inclusion criteria were age of  $\geq 65$  years and living in a LTCF/ALF. The exclusion criteria were defined as absence of language abilities and informed consent, refusal of participation, age  $< 65$ , chronic life-threatening and end-of-life conditions as well as withdrawal. In the survey,  $n=106$

were excluded due to refusal to participate,  $n=2$  due to age  $< 65$ . Therefore, of the 130 patients living in the LTCF, only 22 could be recruited between May 2019 and September 2019 (Figure 1).

### Clinical assessments

All participants underwent a CGA-based MPI calculation. The MPI contains different domains queried by the questionnaires listed below: activities of daily living (ADL), instrumental activities of daily living (IADL), mini-nutritional assessment short form (MNA-SF), short portable mental status questionnaire (SPMSQ), cumulative illness rating scale (CIRS), Exton-Smith scale, the social support (VSOC) - as well as the number of drugs taken and their living conditions as previously described.<sup>15</sup> Based on the questionnaires presented, the MPI generates continuous values between 0 and 1, reflecting one of three risk grades for mortality, (re)hospitalization and institutionalization (MPI-1 0.0-0.33=low risk, MPI-2 0.34-0.66=moderate risk, MPI-3 0.67-1.0=severe risk).<sup>14</sup> MPI captures the physical, psychological, functional, and socioeconomic aspects of patients and is validated for one month and one year after assessment.<sup>14</sup> Furthermore, the MPI has been proved to be the only available selected mortality index based on multidimensional information.<sup>16</sup>

In addition, geriatric resources (GR) and syndromes (GS),<sup>14</sup> as well as patients' pain level based on the verbal rating scale (VRS) were determined.<sup>18</sup> Finally, cardiac symptoms were gathered, blood pressure and pulse were measured, and an auscultation of the heart was conducted as described

above. A verification of the auscultatory findings suggestive of AVS was planned by means of an echocardiography.

A 3-/6-/12-month follow-up was performed via telephone concerning survival, reason, and number of visits at the general practitioner (GP), use of home care services, hospitalizations, falls and number of medications.

### Statistical analysis

The analysis was performed using IBM SPSS 26 and 27 (statistical Package for Social Sciences, SPSS Inc., Chicago, IL, version 26.0 and 27.0) software.

Relative frequencies and absolute numbers were used to describe categorical variables as well as mean (standard deviation, SD) and median (interquartile range, IQR) for continuous variables. As univariate test the Chi-squared was used to explore frequencies. All continuous variables were tested for normal distribution using the t-test or the Kolmogorov-Smirnov test. P-values  $< 0.05$  were considered to indicate statistical significance, anyhow, they are to be assessed critically due to the small number of cases.

## Results

### Demographics

The study included 22 LTCF/ALF residents, full datasets were available for 19 [85.0 (IQR 9) years, 17 women thereof 7 in MPI-1, 8 in MPI-2, 2 in MPI-3]. Since only 2 patients belonged to the MPI-3, MPI-2 and -3 were merged for further analyses.

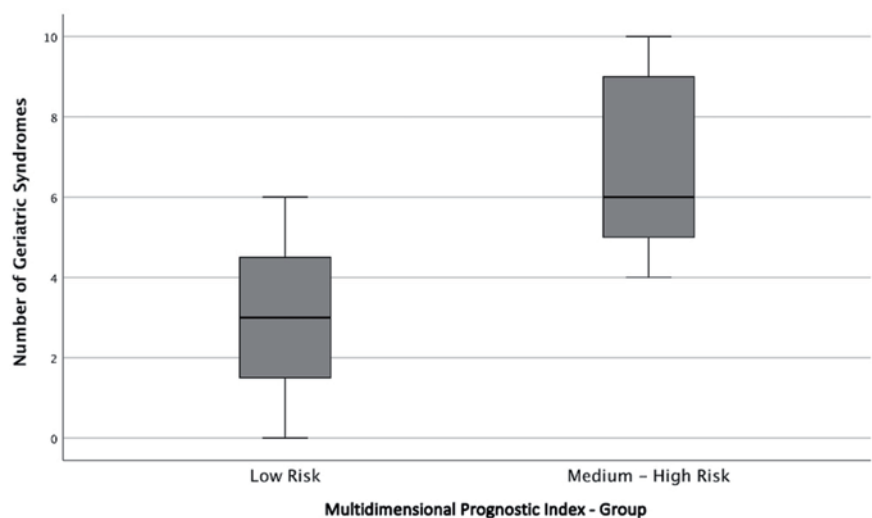


Figure 1. Boxplot multidimensional prognostic index group - Number of geriatric syndromes.

The following can be stated concerning the age in both MPI groups: MPI-1 with a mean of 84.6 years (SD 8.5) and MPI-2/-3 with 83.9 years (SD 3.4).

Of the data presented, 5 were collected in LTCF and 14 in ALF. Of these, residents of the LTCF were mainly in MPI-2/-3 (4 of 5 living in LTCF), while in ALF residents are categorized equally into MPI-1 and MPI-2/-3 (7 each) (Table 1).

### Geriatric conditions

MPI-1 showed a mean of drugs taken of 3.4 (SD 2.4), in MPI-2/-3 8.3 (SD 2.2). Psychotropic drug use and the MPI value were significantly correlated ( $P=0.004$ ) (Table 1).

Pain intensity could not be assessed in 5 patients, while no pain in 2 patients, mild pain in 6 patients, moderate pain in 4 and

severe pain in 2 could be observed (Table 1).

The four most common GR were living conditions ( $n=21$ ), financial ( $n=18$ ), social ( $n=14$ ) and intellectual resources ( $n=13$ ) (Table 2). Regarding the distribution of the MPI risk groups in terms of the number of GR, a mean of 7.4 resources was observed in MPI-1 (SD 2.7), whereas the mean in MPI-2/-3 was 5.1 (SD 2.1).

Concerning the GS, instability ( $n=18$ ),

**Table 1. Demographics and aortic valve stenosis related to multidimensional prognostic index groups.**

	TotalN=19	MPI-1N=8	MPI-2/-3N=11	P-value
Female, N	17	7	10	0.811
Ageing subgroups, N				
- Young-old (65-74 years)	1	1	0	0.274
- Older-old (75-84 years)	8	2	6	
- Oldest-old ( $\geq 85$ years)	10	5	5	
BMI category, N				
- Normal weight	9	3	6	0.429
- Pre-obesity	1	1	0	
- Obesity	8	3	5	
Level of education requirement, N				
- Auxiliary/semi-skilled	9	5	4	0.716
- Functional professional	5	1	4	
- Complex specialized	2	1	1	
- High complex	2	1	1	
Living situation, N				
- In long term care facility	5	1	4	0.243
- In assisted living	14	7	7	
Grade of care, N				
- None	4	3	1	0.139
- Grade of care 1	1	1	0	
- Grade of care 2	6	2	4	
- Grade of care 3	3	0	3	
<b>Geriatric conditions</b>				
Medication risk group, N				
- Low (0-3 medications)	5	4	1	0.013
- Medium (4-7 medications)	7	4	3	
- High ( $>7$ medications)	7	0	7	
Psychopharmaceutic use, N	9	1	8	0.004
CIRS score group, N				
- Low (0 pathology)	1	1	0	0.116
- Medium (1-2 pathologies)	6	4	2	
- High ( $\geq 3$ pathologies)	12	3	9	
Verbal rating scale - pain, N				
- Self-assessment not possible	5	2	3	0.946
- No pain	2	1	1	
- Slight pain	6	3	3	
- Excessive pain	5	1	3	
- Severe pain	2	1	1	
Relation Ger. Syn. (GS)/Res. (GR), N				
- GS>GR	4	0	4	0.043
- GS<GR	14	8	6	
Physical mobility, N	15	8	7	0.008
Cognitive impairment, n	2	0	2	0.231
Hospitalization last 12 months, N	6	1	5	0.127
Falls last 12 months, N	8	2	6	0.198

To be continued on next page

incontinence (n=14), sensorial impairment (n=12) and polypharmacy (>6 different drugs per day, n=11) were the most common syndromes observed (Table 2). In addition, a mean of 3.0 GS was found in MPI-1 (SD 2.1) with 6.8 in MPI-2/-3 (SD 2.2). Analysis of variance of GS in relation to the MPI groups was found to be significant (Kruskal-Wallis-Test: 0.004; Figure 1).

Additionally, the relation between GS and GR (GS> or <GR) in correlation with the MPI group showed a tendency towards significance (O=0.043) (Table 2). Furthermore, the mean VSOC Score in MPI-1 was 28.1 (SD 44.5) and in MPI-2/-3 109.5 (SD 75.3). A significant correlation of MPI groups in relation to the VSOC Score could be determined (Kruskal-Wallis-Test: 0.002).

### Follow-up

Patients in MPI-2/-3 were more frequently hospitalized during the follow-up period than those in MPI-1. Regular visits to the GP occurred throughout the follow-up, both in the entire patient group and in the respective MPI groups. Falls resulted more frequent in MPI-2/-3 persons.

The number of patients falling under

**Table 1. Continued from previous page.**

	TotalN=19	MPI-1N=8	MPI-2/-3N=11	P-value
<b>Aortic valve stenosis</b>				
Systolic heart murmur, N	2	1	1	0.811
<b>Follow-up</b>				
Hospitalization, N				
- After three months	4	2	2	0.679
- After six months	2	0	2	0.190
- After twelve months	2	1	1	1.000
Visit general practitioner, N				
- After three months	7	3	4	0.921
- After six months	9	3	6	0.320
- After twelve months	6	3	3	1.000
Falls, N				
- After three months	1	0	1	0.377
- After six months	3	1	2	0.735
- After twelve months	0	0	0	-
Medication risk group after 12 months, N				
- Low (0-3 medications)	1	1	0	0.350
- Medium (4-7 medications)	5	2	3	
- High (>7 medications)	1	0	1	
Death after 12 months, N				
	2	0	2	0.197
Loss to follow-up, N (%)				
- In long term care facility (LTCF)	0	0	0	0.845
- In assisted living	9	4	5	

MPI, multidimensional prognostic index. Analysis for descriptive statistics using crosstabs in IBM SPSS 26/27; For this analysis, the data of 19 patients with detectable MPI of the 22 patients recruited in a long-term care facility (LTCF) were used (n=3 without detectable MPI), merge of MPI-2/-3.

**Table 2. Analysis of geriatric conditions in relation to the frequency of occurrence.**

	Frequencies (the four most common each)		
	Yes (n)	No (n)	Missing (n)
<b>CIRS</b>			
- Eye-ear-nose-throat	20	1	1
- Vascular	18	3	1
- Musculoskeletal/skin	15	6	1
- Endocrine-metabolic	13	8	1
<b>Geriatric syndromes</b>			
- Instability	18	4	0
- Incontinence	14	8	0
- Sensorial impairment	12	7	3
- Polypharmacy	11	11	0
<b>Geriatric resources</b>			
- Living condition	21	1	0
- Financial	18	1	3
- Social	14	6	2
- Intellectual	13	6	3

CIRS, cumulative illness rating scale; descriptive analysis of the frequency of the above parameters using IBM SPSS 26/27, listing the four most common entities with absolute frequency and valid percent. For this analysis, the data of all 22 persons recruited in the long-term care facility (LTCF) were included.

each medication risk groups (low 0-3, medium 4-7, high >7 drugs) were distributed evenly at the time of recruitment (5 in MPI-1, 7 in MPI-2 and 7 in MPI-3,  $P=0.013$ ). Whereas, the 12-month follow-up showed a clear increase in the group with medium risk category (5 out of 7 patients surveyed in the follow-up in medium medication risk category,  $P=0.350$ ). Overall, mortality rate was 2 out of 22, both deaths were recorded in 12 month follow up in MPI-2/3 group ( $P=0.197$ ). A loss to follow-up was observed in 9 out of 22 cases. Of those, all were living in the ALF, while in LTCF all patients could be tracked (Table 1).

### Aortic valve stenosis

Systolic heart murmur was found in 2 of 22 patients screened for AVS. In both cases, no previous diagnosis of AVS was known. According to the MPI risk group, one case belonged to MPI-1 and the other to MPI-2/-3. This results in a frequency of 10.5% for the occurrence of AVS (Table 1). In the case in which the patient belonged to MPI-2/-3 the symptoms angina pectoris, dizziness and fatigue could be determined, as well as the death of the patient after one year. Whereas the other belonging to MPI-1 showed no specific or non-specific symptoms for the AVS.

### Termination of the study

The study was stopped on October 24<sup>th</sup>, 2019, due to recruitment challenges on different levels ranging from participants' and their legal guardians' uncertainty to concerns on LTCFs' side. Reasons given for rejecting participation by LTCF were staff shortage and the thereby existing workload even if no participation on part of the staff was planned for conducting the survey. While actions were initiated to adjust once again the recruitment strategy, these were finally hindered by the COVID-19 outbreak.

## Discussion

Although the small number of participants obviously limits the informative value of the present observations, these are largely consistent with previous studies of older adults admitted to other healthcare settings. Most importantly, the results did deliver new information on a substantial issue of geriatric care - *i.e.*, the management potential of common age-related clinical conditions if the personalized approach is used. As the study was stopped due to social and logistic barriers, which is per se an interesting result within an aging population worldwide, the first hints concerning disease

characterization in LTCF/ALF residents are worth being shared for the purpose of research outlook. As described previously, also in the present setting's collective the number of GS display a prognostic signature.<sup>14,19,20</sup> Together with the observation of the (expected) larger number of higher MPI scores in LTCF than in ALF as well as the correlation between accommodation in LTCF vs ALF and the MPI score.<sup>19</sup>

Regarding the cardiac symptoms related to AVS as well as the distribution regarding the MPI, no significant statements could be made due to the small number of cases. Still, the resulting prevalence of 10.5% falls within the range of 3-12% to be expected based on literature research.<sup>9,11,13</sup> Concerning diseases of the heart valves, the MPI seems to provide additional information on mortality risk beyond established cardiovascular risk factors. This additional risk stratification makes valuable individual information available and supports well-founded decision-making about the treatment modality.<sup>21,22</sup> With a special focus on the AVS, this connection should be evaluated in further studies.

The lack of significant results at follow-up is probably due to the large number of additional data missing. The incidence of the loss to follow-up cases occurring only in patients living in the ALF was presumably caused by the changing of residence to the affiliated/another LTCF or death of the participants. Since all patients included in the ALF were living alone at the time of the survey, the reason for the loss to follow-up could not be determined by relatives, caregivers, or proxy respondents.

Although the main objective of the study of investigating prevalence and prognostic signature of AVS in connection to the MPI in a large LTCF/ALF residents collective could not be achieved, this study shades some light on challenges associated to better characterizing vulnerable persons such as those residing in nursing homes. The importance of studies in LTCF derives mainly from the rising age of the population, its frail nature, and the expected increase in the number of residents of LTCF.<sup>1,2</sup> Additionally, the current SARS-CoV-2 pandemic dramatically uncovered the highest risk which this population is exposed at.<sup>20,23</sup>

The observations gathered during the present study generated discussion points about the reasons for those challenges. These are considered a potentially important starting point for designing further similar studies. On one hand, further development of evidence bases to successfully conducting CGA-based studies and their effectiveness across healthcare settings is need-

ed.<sup>24</sup> In nursing homes in particular, further studies are to be encouraged to strengthen the informative value of CGA-based studies in this specific setting.<sup>6</sup> On the other hand, translating between trial and real-world settings as well as between different clinical settings is described to be challenging. Therefore, to ensure successful realization, definition of precise ways of implementation and responsibilities is crucial.<sup>24</sup>

One major problem hindering the success of our investigation was the lack of crosstalk between research actors and facilities. Further exchange on the topic and planning of a potential implementation was in most cases not even possible due to an early cancellation on side of the LTCF. Despite requests to over 30 LTCF with a total number of about 3000 residents, only one regional association agreed to participate. Still, a total amount of around 500 senior citizens residing in facilities would have been available for recruitment. The number of actual participants ( $n=22$ ) out of 130 residents of the LTCF where the study was started, however, was significantly lower. (Figure 2) A recent study in Germany included 1329 LTCF participants older than 60 years. Out of 5519 guests of 149 LTCF, 1451 persons living in 42 residences could be included. Therefore, the final participation was around 25% of all potential guests.<sup>25</sup> A very strong implementation strategy was carried out to yield this number of participants. It appears that striving for closer cooperation with the LTCF and/or the umbrella organization, meeting and close communication with care managers and the staff, as well as early clarification via staff concerning whether the inhabitants want to participate. Furthermore, information evenings and a Germany-wide recruitment might be strategies to enhance recruitment success in LTCF in Germany.<sup>25</sup>

During implementation staff shortage was a major problem, as feared additional workload was the main reason given for refusing participation on side of the LTCF. Nevertheless, evidence suggests nurses to play an important role in research studies as their involvement increased patient recruitment and to be considered an important link between investigator and study participant.<sup>26</sup> Especially in nursing homes and new facilities, where implementation is described as more complicated than on specialized wards, teamwork is cited as vital for implementation.<sup>24</sup> Therefore, another starting point might be an organizational direction to generate more professionals with interest, skills, and attitudes suitable for care of older people.<sup>24</sup>

Optimizing the survey environment might also lead to higher percentages of

participation and lower period needed for recruitment. Especially a non-medical atmosphere encourages participation, as well as a health oriented, non-stigmatizing community setting. Therefore, a collaboration between medical and non-medical departments and community agencies is crucial for a successful recruitment.<sup>27</sup> Additionally, interaction as a multidisciplinary team, especially in not geriatric-specialized wards, as well as an organizational

change are named to be essential to successfully conducting a study.<sup>24</sup>

Another challenge which is considered serious in implementing a study, was the lack of adequate information of possible participants, their guardians and the LTCF. Gaining consent to participation in research investigations is complex and requires a great deal of soft skills from the investigators, ability to communicate and share knowledge, as well as health literacy from

patients' and caregivers' side.<sup>28</sup> To the latter add cooperative effort and organizational skills from the institutional side.<sup>29</sup> Moreover, through appropriate information, negative connotations of being old and feelings of discrimination can be avoided to enable participation without fear of stigmatization.<sup>24</sup>

The lack of understanding elements of the informed consent occurred as another challenge. When patients were interviewed

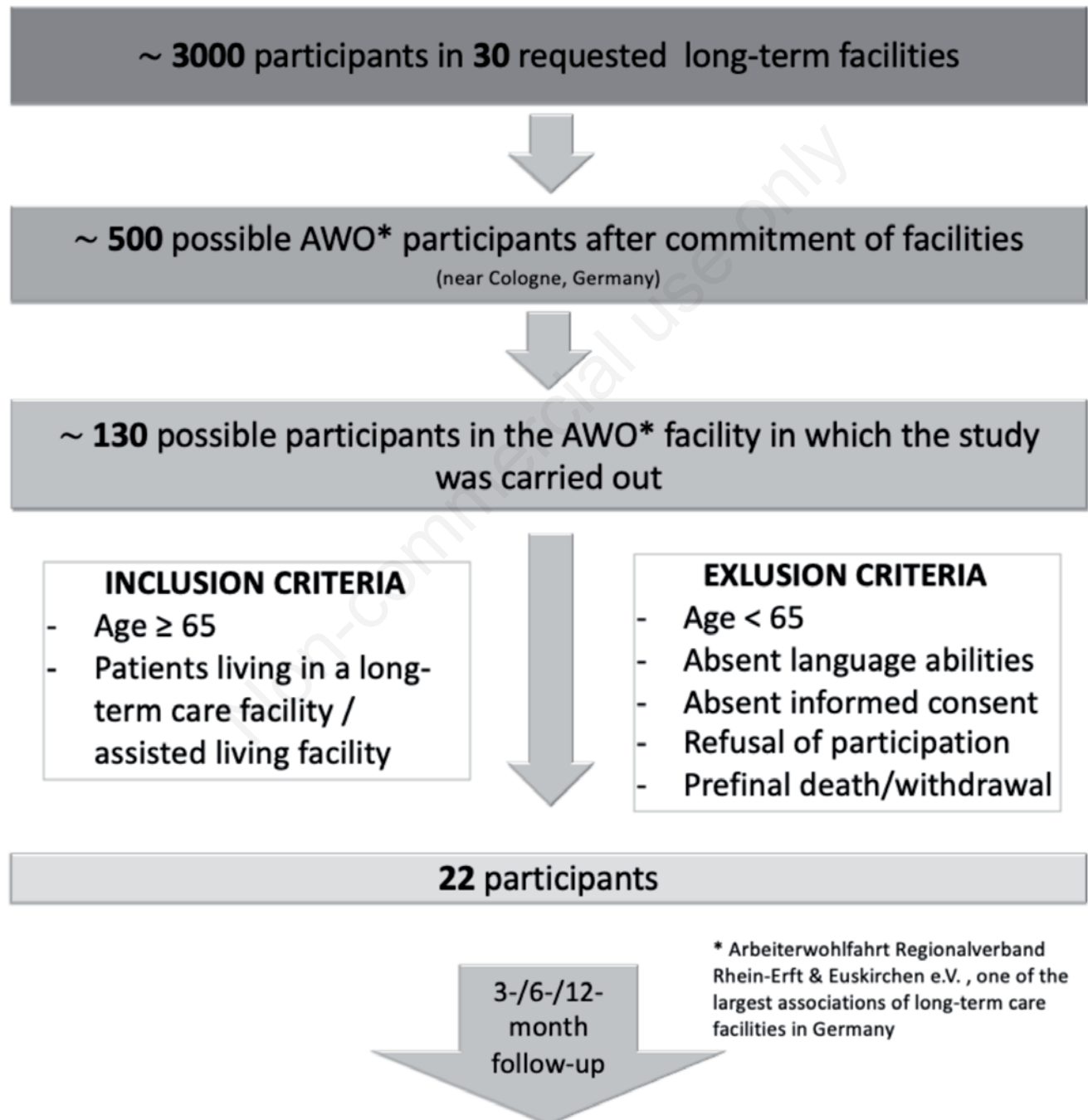


Figure 2. Development of the number of participants. AWO, *Arbeiterwohlfahrt*.

after signing the informed content, a clear lack of knowledge about the content of the document became apparent.<sup>30</sup> Thus, another possibility to increase participation would have been a less complicated, shortened declaration of content better adapting to the respondents' preconditions.

The so called 'Know-Do'-gap describes a need to implement existing knowledge in clinical practice.<sup>24</sup> Understanding the questionnaire itself and the importance of studies in the field of Geriatrics and Gerontology and their implementation is only possible when a basis of knowledge, interest and educational effort is present since the likelihood of participation depends on the understanding of the importance and the main points of the study.<sup>24,28,29</sup>

The challenges of conducting a study are many and could hinder the identification of main treatable diseases that severely affect health resources and the quality of life of advanced aged patients. Bridging the gap in knowledge and a closer collaboration between research institutions and the LTCF could raise awareness and provide better protection for vulnerable groups such as LTCF residents.

## Conclusions

Conducting studies in LTCF could facilitate the important identification of treatable diseases in advanced age, which have profound implications for health care resources and patients' quality of life. The challenges faced when performing a real-life study in LTCF/ALF trace back to several underlying problems and should be addressed through targeted healthcare actions.

Anyhow as interesting insights a valid association between the Numbers of GS and the MPI as well as a correlation between accommodation in LTCF vs ALF and the MPI, along with a significant association of psychotropic drug use and the MPI could be gained.

However, these results are limited by the small number of participants and need confirmation in further studies. The limited number of participants can be attributed to the lack of staff capacity and the resulting work overload as well as the small number of participating institutions could have negative impact on the implementation. Furthermore, integrating possible partici-

pants and all persons involved in decision-making processes and a closer cooperation between research institutions and the LTCF might have helped to overcome challenges. The most crucial challenge, however, is the lack of sufficient knowledge and interest on side of possible participants and other persons involved. Therefore, more educational effort is urgently required to create awareness and to ensure better care for vulnerable groups as residents of LTCF.

To summarize, the following points can be mentioned as suggestions for improvement (Figure 3):

- Recognizing and minding the 'Know-Do' gap;
- Enlarging the range of audience and the number of participating institutions;
- Closer cooperation and effective communication with all persons involved;
- Integration of all persons involved in decision-making processes;
- Clarification of benefits;
- Dissemination events to improve the meaning of self-efficacy, self-competence, and self-management;
- Value based care and understanding of personal needs as basic requirement.

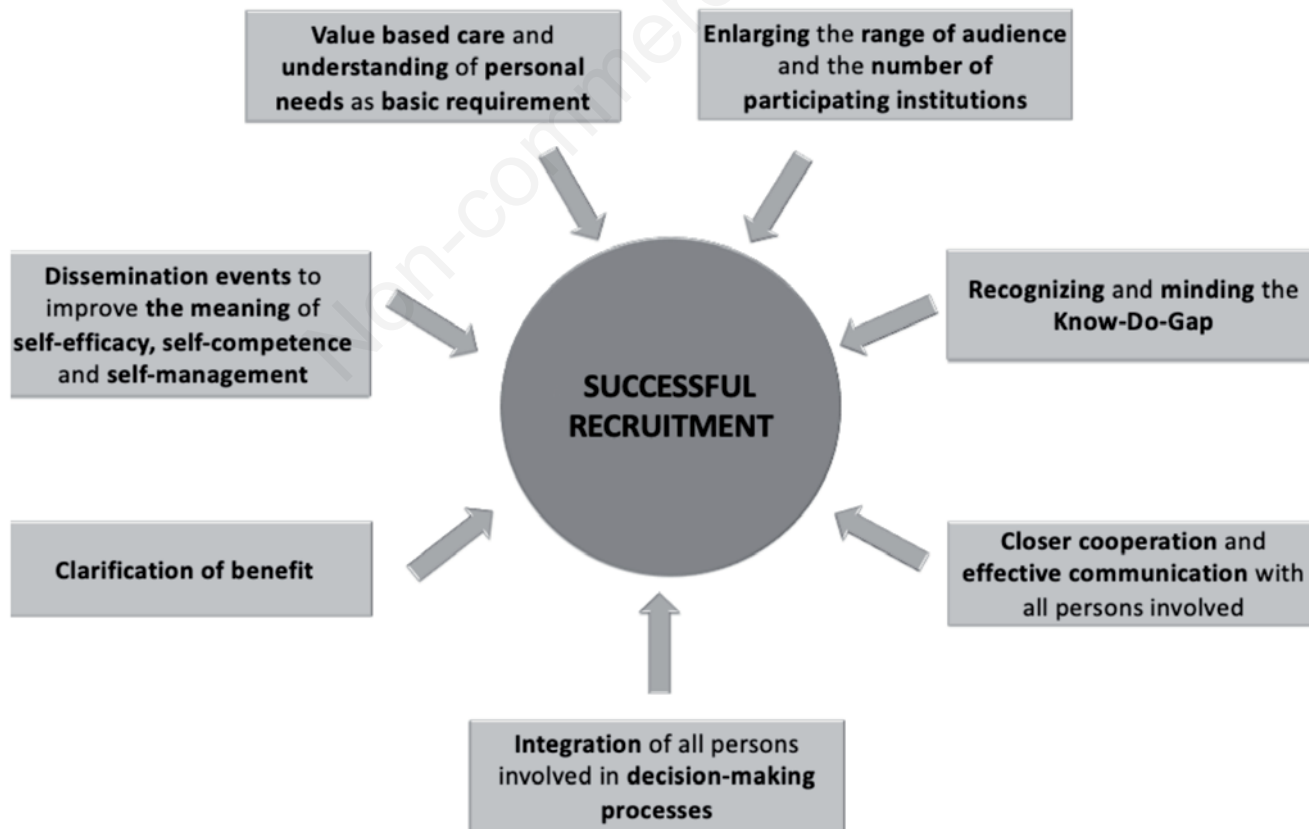


Figure 3. Strategies for successful recruitment.

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