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Needs-based provision of medical care to nursing home residents: protocol for a mixed-methods study

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1 **Needs-based provision of medical care to nursing home residents: protocol for a**
2 **mixed-methods study**

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3 52 **Abstract**
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5 53 **Introduction** Nursing home residents typically have greater needs for medical care than
6
7 54 community-dwelling elderly. However, restricted cognitive abilities and limited mobility may
8
9 55 impede their access to GPs and medical specialists. The provision of medical care in nursing
10
11 56 homes may therefore be inappropriate in some areas of medical care. The purpose of this
12
13 57 mixed-methods study is to systematically assess, evaluate and explain met and unmet medical
14
15 58 care needs in German nursing homes and to develop solutions where medical care is found to
16
17 59 be inappropriate.
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19

20 60 **Methods and analysis** First, Statutory Health Insurance claims data are analyzed to identify
21
22 61 differences in the utilization of medical care between nursing home residents and community-
23
24 62 dwelling elderly with and without need for long-term care. Second, the health status and
25
26 63 medical care of 500 nursing home residents are assessed and evaluated to quantify met and
27
28 64 unmet medical care needs. Third, qualitative expert interviews and case conferences and,
29
30 65 fourth, quantitative analyses of linked data are used to provide structural, case-specific and
31
32 66 generalizable explanations of inappropriate medical care among nursing home residents.
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34 67 Fifth, a modified Delphi study is employed to develop pilot projects aiming to improve
35
36 68 medical care in nursing homes.
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39 69 **Ethics and dissemination** This study was approved by the Ethics Committee of the
40
41 70 University of Bremen. Research findings are disseminated through presentations at national
42
43 71 and international conferences and publications in peer-reviewed scientific journals.
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46 72 **Trial registration number** DRKS00012383
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78 **Article Summary**

79 **Strengths and limitations of this study**

- 80 • Based on longitudinal Statutory Health Insurance claims data, cross-sectional data
81 collected in nursing homes, expert interviews and case conferences the provision of
82 medical care is analyzed for the first time in relation to individual medical care needs
83 among nursing home residents in Germany.
- 84 • The mixed-methods designs allows a comprehensive assessment, evaluation and
85 explanation of met and unmet medical care needs in nursing homes.
- 86 • Participatory approaches involving GPs, medical specialists, nursing home staff,
87 Statutory Health Insurance employees, nursing home residents and relatives are used
88 to increase the acceptance and effectiveness of pilot projects to be developed to
89 improve medical care where it is found to be inappropriate.
- 90 • Differences in the willingness to participate among nursing homes and nursing home
91 residents may result in a selective study population.
- 92 • Focusing on nursing homes located in the federal state of Bremen and members of one
93 local Statutory Health Insurance fund may limit the generalizability of the study
94 results.

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103 **Introduction**

104 Nursing home residents may not receive appropriate medical care since restricted cognitive
105 abilities and limited mobility may impede their access to GPs and medical specialists¹⁻³.

106 Moreover, nursing home residents typically suffer from multimorbidity, frailty, cognitive
107 impairments and polypharmacy, resulting in diverse medical care needs that compound the
108 challenge of providing appropriate medical care⁴⁻⁷.

109 Empirical studies support this view, indicating inappropriate medical care provision in
110 nursing homes for the treatment of visual and hearing impairments⁸⁻¹⁰, oral health care^{1 2 11}
111 ¹², pain treatment¹³ and drug prescriptions^{2 14-17}. Atramont et al., furthermore, found nursing
112 home admission to be negatively associated with some forms of outpatient care¹⁸ and
113 positively associated with psychotropic and antibacterial drug use¹⁹.

114 There is, however, hardly any empirical evidence on explanations of inappropriate medical
115 care provision in nursing homes. In this regard, a health technology assessment report
116 concluded that there is not sufficient data available to allow recommendations to be drawn on
117 how medical care provision in German nursing homes can be improved².

118 Given this lack of evidence, the proposed research project aims to systematically assess,
119 evaluate and explain met and unmet medical care needs in German nursing homes and to
120 develop solutions where medical care is found to be inappropriate. The specific aims are: (1)
121 to identify differences in the utilization of medical care between a) nursing home residents, b)
122 community-dwelling elderly in need for long-term care and c) community-dwelling elderly
123 without need for long-term care; (2) to quantify met and unmet medical care needs of nursing
124 home residents; (3) to provide structural and case-specific explanations of inappropriate
125 medical care provision in nursing homes; (4) to provide explanations of inappropriate medical
126 care provision that are generalizable to the total population of nursing home residents; and (5)
127 to develop pilot projects aiming to improve medical care provision in nursing homes.

128 **Methods and analysis**

129 This mixed-methods study is running from April 1, 2017 to March 31, 2020. It is structured
130 into five steps (figure 1). In step 1, Statutory Health Insurance (SHI) claims data are analyzed
131 in order to identify differences in the utilization of medical care between nursing home
132 residents and community-dwelling elderly with and without the need for long-term care. Such
133 differences in the utilization of medical care may indicate, but not prove, inappropriate
134 medical care provision in nursing homes. Thus, in step 2, nursing home residents' health
135 status and utilization of medical care are assessed and evaluated to quantify met and unmet
136 medical care needs with respect to vision, hearing, oral health and Parkinson's disease. In
137 steps 3 and 4, qualitative expert interviews and case conferences as well as quantitative
138 methods are used to provide structural, case-specific and generalizable explanations of
139 inappropriate medical care in nursing homes. In step 5, a modified Delphi study is used to
140 generate ideas on how to improve the provision of medical care in nursing homes.
141 Consequently, at least two pilot projects are developed and implemented in one nursing home
142 to test for practicability. In the following sections, each step is described in detail.

143

144 **Step 1: Analysis of SHI claims data**

145 SHI claims data from AOK Bremen/Bremerhaven, a local SHI fund, are analyzed to identify
146 differences in the utilization of medical care that indicate inappropriate medical care provision
147 in German nursing homes. The available data comprise information on sex, age, in- and
148 outpatient care as well as on long-term care use. All diagnoses are coded according to the
149 German Modification of the International Classification of Diseases, 10th Revision (ICD-10-
150 GM) and can be differentiated according to GPs and medical specialties in the outpatient
151 setting.

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3 152 From 245,000 insured persons, a subsample of 68,718 insured persons aged 60 years and over
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5 153 is drawn. For this subsample, the morbidity status of each insured person is defined by 31
6
7 154 disease categories related to at least one of 13 examined medical specialties (table 1).
8

9 155

11 156 **Table 1 Disease categories and related medical specialties used to define the individual**
12
13 157 **morbidity status of insured persons examined in step 1**

| No. | Disease categories | ICD-10-GM 2015 codes | Related medical specialties* |
|-----|---|-----------------------------|---|
| 01 | Hypertensive diseases | I10-I15 | Internal medicine, cardiology |
| 02 | Ischemic heart diseases | I20-I52 | Internal medicine, cardiology |
| 03 | Metabolic disorders | E70-E90 | Internal medicine |
| 04 | Arthropathies | M00-M25 | Internal medicine, orthopedics |
| 05 | Diabetes mellitus | E10-E14 | Internal medicine |
| 06 | Dorsopathies | M40-M54 | Orthopedics |
| 07 | Disorders of thyroid gland | E00-E07 | Internal medicine |
| 08 | Vascular diseases | I70-I89 | Internal medicine, cardiology |
| 09 | Organic, including symptomatic, mental disorders; other degenerative diseases of the nervous system | F00-F09; G30-G32 | Neurology/psychiatry |
| 10 | Diseases of esophagus, stomach and duodenum; hernia; other diseases of intestines | K20-K31; K40-K46; K55-K64 | Internal medicine |
| 11 | Chronic lower respiratory diseases | J40-J47 | Internal medicine, pulmonology |
| 12 | Mood (affective) disorders | F30-F39 | Neurology/psychiatry |
| 13 | Cerebrovascular diseases | I60-I69 | Internal medicine, neurology/psychiatry |
| 14 | Neurotic, stress-related and somatoform disorders | F40-F48 | Neurology/psychiatry |
| 15 | Symptoms and signs involving the urinary system; other diseases of urinary system | R30-R39; N30-N39 | Gynecology, urology |
| 16 | Diseases of the eye and adnexa | H00-H59 | Ophthalmology |
| 17 | Renal failure | N17-N19 | Internal medicine, nephrology |
| 18 | Osteopathies and chondropathies | M80-M94 | Orthopedics |
| 19 | Diseases of the ear and mastoid process | H60-H95 | Otorhinolaryngology |
| 20 | Mononeuropathies; polyneuropathies and other disorders of the peripheral nervous system | G56; G57; G58; G59; G60-G64 | Internal medicine, neurology/psychiatry |
| 21 | Diseases of male genital organs | N40-N51 | Urology |
| 22 | Dermatitis, eczema, melanoma and other malignant neoplasms of skin | L20-L30; C43-C44 | Dermatology, surgery |
| 23 | Noninflammatory disorders of female genital tract | N80-N98 | Gynecology |
| 24 | Other disorders of the skin and subcutaneous tissue | L80-L99 | Dermatology |
| 25 | Extrapyramidal and movement disorders | G20-G26 | Internal medicine, neurology/psychiatry |
| 26 | Mental and behavioral disorders due to psychoactive substance use | F10-F19 | Neurology/psychiatry |
| 27 | Cerebral palsy and other paralytic syndromes | G80-G83 | Internal medicine, neurology/psychiatry |
| 28 | Obesity and other hyperalimentation; Malnutrition | E65-E68; E40-E46 | Internal medicine |
| 29 | Schizophrenia, schizotypal and delusional disorders; disorders of adult personality and behavior | F20-F29; F60-F69 | Neurology/psychiatry |
| 30 | Functional impairments | U50-U52 | Internal medicine, Orthopedics |

| | | | |
|----|----------|--|----------------------|
| 31 | Injuries | S00-S09; S10-S19; S20-S29; S30-S39; S40-S49; S50-S59; S60-S69; S70-S79; S80-S89; S90-S99; T08-T14 | Orthopedics, surgery |
|----|----------|--|----------------------|

158 *Due to the availability of data, dentistry had to be analyzed separately and is therefore not presented.

159

160 Zero-inflated poisson regression analyses as well as linear and logistic regression analyses are
161 conducted to investigate the resulting 45 combinations of disease categories and related
162 medical specialties separately. Each regression model includes only those insured persons
163 who are diagnosed in the examined disease category. The dependent variable is the number of
164 outpatient visits in the related medical specialty in 2015. Independent variables are the
165 remaining 30 disease categories, age, sex, region, death, care setting and dummy variables as
166 a combination of the obtained level of care and the care setting.

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168 **Step 2: Assessment of nursing home residents**

169 The standardized assessment focuses on vision, hearing, oral health and Parkinson's disease.

170 It consists of two parts: First, the individual health status and medical care provision of 500

171 nursing home residents are assessed. Second, the provision of medical care is evaluated for

172 each resident to determine met and unmet medical care needs.

173 Residents are eligible for assessment if a) they are in need for long-term care, b) are aged 60

174 and over, c) have been residing in a nursing home located in the federal state of Bremen for at

175 least 12 months and d) are a member of the AOK Bremen/Bremerhaven. Eligible residents (or

176 their legal guardians) are recruited by the participating nursing homes and approached for

177 informed consent.

178 The standardized assessment is carried out by trained study nurses and includes: (1)

179 examinations of residents, (2) self-assessments by residents, (3) proxy-assessments by

180 residents' care nurses and (4) reviews of medical charts (table 2).

181

Table 2 Instruments used to assess cross-sectional data in step 2

| Category | Instrument | Source* | | | |
|---------------------------------|---|---------|---|---|---|
| | | E | S | P | R |
| Area of medical care | | | | | |
| Vision | Visual test ²⁵ | X | | | |
| | Questionnaire for individual rating of vision and use of visual aids | | X | X | |
| Hearing | Chart review for vision-related diagnoses (e.g. age-related macular degeneration, cataract) and relevant comorbidities (e.g. diabetes mellitus) | | | | X |
| | Whispered voice test ²⁶ | X | | | |
| | Questionnaire for individual rating of hearing and use of hearing devices | | X | X | |
| Oral health | Chart review for hearing-related diagnoses (e.g. presbycusis) | | | | X |
| | Oral Health Assessment Tool (OHAT) ²⁷ and Oral Health Impact Profile (OHIP) ²⁸ | X | | | |
| | Questionnaire for individual rating of dental problems as well as availability and use of dentures | | X | X | |
| Parkinson's disease | Chart review for oral health-related diagnoses (e.g. gingivitis) | | | | X |
| | Chart review for diagnosis of Parkinson's disease, prescribed medications and contacts to medical specialists (e.g. neurologists) and/or therapists (e.g. physiotherapists) | | | | X |
| General health status | | | | | |
| Health-related quality of life | Short-Form Health Survey (SF-12) ²⁹ | | X | X | |
| Depression | Geriatric Depression Scale (GDS) ^{30 31} | | X | | |
| | Cornell Scale for Depression in Dementia (CSDD) ³² | | | | X |
| Functional and cognitive status | Mini-Mental State Examination ³³ | | X | | |
| | Extended Barthel-Index ³⁴ | | | | X |
| Nutrition | Mini-Nutritional Assessment Short Form (MNA-SF) ³⁵⁻³⁸ | | | | X |
| Vital signs | Chart review for vital signs and falls | | | | X |
| Level of care | Chart review for level of care | | | | X |
| Additional data | | | | | |
| Utilization of medical care | Questionnaire and chart review for diagnoses, prescriptions of medication and aids, contacts to and organization of general and specialized care, hospitalization, contacts to duty doctors and emergency calls | | X | X | |
| Sociodemographic data | Questionnaire and chart review for age, sex, education, marital status, migrant status and relatives | | X | X | |
| Nursing home characteristics | Questionnaire** for size, number of employees and residents, location-related information | | | | X |

*E = examinations of residents; S = self-assessed by residents; P = proxy-assessed by residents' care nurses; R = reviewed in medical charts

** This questionnaire is completed by administrative employees of the respective nursing home.

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3 188 Additionally, health-related aspects (e.g. quality of life and depression) are assessed as well as
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5 189 structural factors relating to the participating nursing homes (e.g. numbers of employees and
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7 190 residents) that may act as explanatory variables of medical care.

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9 191 Based on these data, a geriatrician, a GP and where necessary a medical specialist of the
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11 192 corresponding field (i.e. an ophthalmologist, an ENT specialist, a dentist or a neurologist)
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13 193 determine case by case whether or not medical care needs are met.

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17 18 195 **Step 3: Expert interviews and case conferences**

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20 196 Semi-structured expert interviews and case conferences are used to identify structural and
21
22 197 case-specific explanations of inappropriate medical care provision in nursing homes. Expert
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24 198 interviews are conducted with nursing home staff, physicians, people in need for long-term
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26 199 care and informal caregivers who provide informed consent. The number of interviews is
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28 200 determined by the principal of theoretical saturation. All interviews are recorded on tape,
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30 201 transcribed and analyzed using content analysis²⁰. The results provide a framework for the
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32 202 subsequent case conferences, which are conducted for a selected subsample of nursing home
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34 203 residents assessed in step 2.

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37 204 The case conferences are held with the consenting nurses and, where necessary, the
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39 205 consenting physicians and other health professionals involved in the provision of nursing and
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41 206 medical care of the respective resident. Twenty residents with appropriate medical care and
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43 207 twenty residents with inappropriate medical care are randomly selected for each field of
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45 208 medical care (i.e. vision, hearing, oral health and Parkinson's disease). The case conferences
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47 209 are based on a summarized presentation of the health status and medical care provision of the
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49 210 respective resident. Using problem-centered group interviews²¹, the conference members
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51 211 then discuss, case by case, factors that foster or inhibit the provision of needs-based medical
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53 212 care.

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214 **Step 4: Analysis of linked data, non-response analysis and extrapolation**

215 In step 4, primary data assessed in step 2 and SHI claims data covering the years 2014-2018
216 are linked at the individual level. The linked data are analyzed to identify generalizable
217 factors that impact the provision of medical care:

218 First, retrospective and prospective regression analyses are conducted. Retrospective analyses
219 are used to identify factors in the utilization of medical care that impact the quantified met
220 and unmet medical care needs of nursing home residents. Prospective analyses are used to
221 investigate the impact of the standardized assessment conducted in step 2 on the utilization of
222 medical care.

223 Next, a non-response analysis is conducted. SHI claims data of 1,500 residents are analyzed to
224 identify systematic differences between responders and non-responders (e.g. in the
225 distribution of age, sex, morbidity and long-term care level as well as in the duration of stay in
226 long-term care and nursing homes).

227 Third, prevalence of met and unmet medical care needs is extrapolated. Findings are projected
228 to a) all nursing home residents insured by the AOK Bremen/Bremerhaven, b) all nursing
229 home residents of the federal state of Bremen and c) all nursing home residents of Germany.

230

231 **Step 5: Modified Delphi study and pilot projects**

232 Based on the factors identified that may explain inappropriate medical care in steps 3 and 4, a
233 modified Delphi study is then carried out. The technique is used with stakeholders from the
234 fields of nursing and medical care and comprises three rounds. The first round is based on
235 face-to-face focus group discussions, while the second and third rounds each consist of semi-
236 structured online surveys. Each survey takes about 20 minutes to complete and is online for
237 up to 2 weeks.

238 In the first round, a convenience sample of homogeneous and heterogeneous focus groups of
239 consenting stakeholders (i.e., nursing home staff, GPs, medical specialist, SHI employees,

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3 240 nursing home residents and relatives) generate ideas on how medical care provision to nursing
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5 241 home residents can be improved. The focus groups are led by experienced project researchers,
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7 242 who feed the results of steps 3 and 4 into the discussions. Based on the ideas generated, the
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9 243 project researchers draft at least two pilot projects.

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11 244 In the second round, the experts are given descriptions of these potential pilot projects and
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13 245 rate them with respect to their feasibility and effectiveness for improving medical care of
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15 246 nursing home residents. These ratings are summarized and distributed back to all experts.
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17 247 In the third round, the experts re-rate the projects based on the rating results from the previous
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19 248 round. This is expected to result in a more consensual decision. Taking the results of this last
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21 249 round into account, the concept of the pilot projects is revised and implemented in one
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23 250 nursing home to test for practicability. A systematic evaluation of the pilot projects is planned
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25 251 in a follow-up study.
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31 253 **Discussion**

32
33 254 This mixed-methods study broadens the limited evidence on the needs-based provision of
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35 255 medical care in nursing homes. It systematically assesses, evaluates and explains met and
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37 256 unmet medical care needs in nursing homes and takes first steps toward improvement.
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39 257 Up to now, several studies have described differences in the utilization of medical care
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41 258 between nursing home residents and community-dwelling elderly with and without need for
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43 259 long-term care^{2 22-24}. None of these, however, has evaluated whether such differences reflect
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45 260 unmet medical care needs at the individual. Neither have differences in the utilization of
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47 261 medical care been explained by prevailing structures that may be changed.
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49 262 The present mixed-methods study addresses this evidence gap: Based on longitudinal SHI
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51 263 claims data, cross-sectional data collected in nursing homes as well as transcripts of expert
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53 264 interviews and case conferences, differences in the utilization of medical care are identified,
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55 265 met and unmet medical care needs are quantified, explanations of inappropriate provision of
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3 266 medical care are provided and pilot projects are developed aiming to improve the provision of
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5 267 medical care where it is found to be inappropriate. Participatory approaches involve GPs,
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7 268 medical specialists, nursing home staff, SHI employees, nursing home residents and relatives.
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9 269 This is expected to result in strong acceptance and effective pilot projects which will be
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11 270 systematically evaluated in a follow-up study.

12
13 271 There are, however, some limitations to consider. First, in the present study, all nursing homes
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15 272 in the federal state of Bremen are invited to participate and to recruit nursing home residents
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17 273 for study participation. Differences in the willingness to participate among nursing homes and
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19 274 nursing home residents may result in a selective study population. The claims-based non-
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21 275 response analysis, however, permits the identification of structural differences between
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23 276 participants and non-participants. Second, the study focuses on nursing homes located in the
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25 277 federal state of Bremen and members of one local SHI fund. Therefore, the generalizability of
26
27 278 research findings may be limited.

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29
30 279 In conclusion, the findings from this study enhance our knowledge of met and unmet medical
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32 280 care needs in nursing homes. The pilot projects provide a first step towards a sustainable
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34 281 improvement of medical care in German nursing homes. Therefore, it is expected that the
35
36 282 findings are highly relevant for many stakeholders from the fields of nursing and medical
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38 283 care.

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42 43 285 **Ethics and dissemination**

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46 286 The Ethics Committee of the University of Bremen approved this study on November 23,
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48 287 2017. All eligible nursing home residents and all nursing home staff are informed in detail
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50 288 about the study. Informed consent is obtained from all included nursing home residents (or
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52 289 their legal guardians where applicable). Informed consent is also obtained from all persons
53
54 290 included in the expert interviews, case conferences and Delphi study. Dissemination strategies

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3 291 include presentations at national and international conferences and publications in peer-
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5 292 reviewed scientific journals.
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10
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12
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18 298 **Footnotes**

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20 299 **Contributors:** JC, TK, ASchw, GS, KW-O, AG and HR designed the study. MS, TK, CT,
21
22 300 ASchw and HR specified the analysis of longitudinal SHI claims data. MS, FH, DK, ASchw,
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24 301 SK, GS, KW-O, AG and HR specified the collection of cross-sectional primary data. JC, MS,
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26 302 FH, DG, ASchw, CT, ASchw and SK wrote the first draft of the protocol which was critically
27
28 303 revised by TK, GS, KW-O, AG and HR. All authors approved the final version of the
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30 304 protocol.
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32

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34
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36

37 307 **Competing interests:** None declared.
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42 309 **Figures**

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44 310 See separate file (Figure_1.TIF)
45

46 311 **Figure 1 Conceptual framework of the mixed-methods study**

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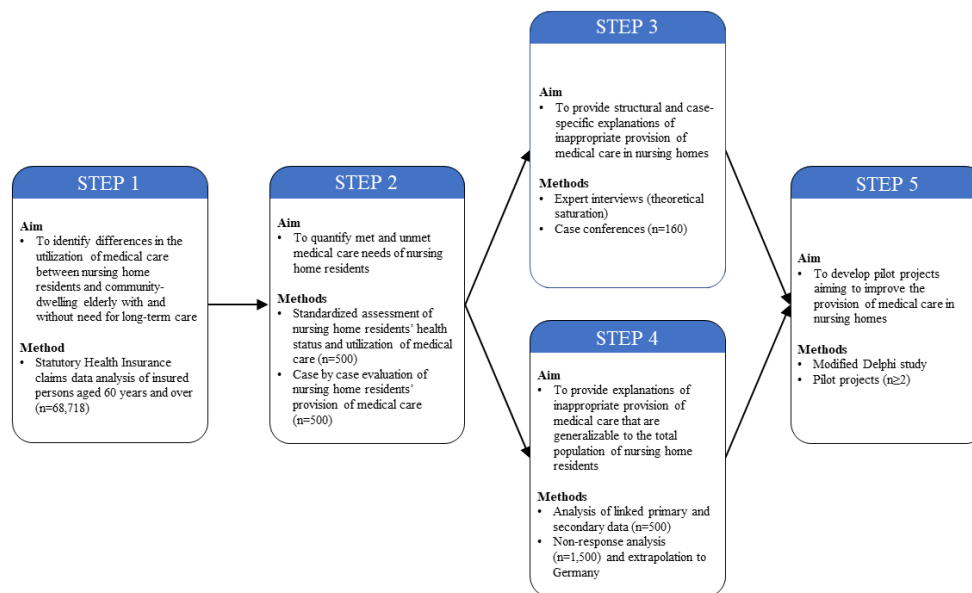


Figure 1 Conceptual framework of the mixed-methods study

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BMJ Open

Needs-based provision of medical care to nursing home residents: protocol for a mixed-methods study

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| Primary Subject Heading: | Health services research |

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|----------------------------|--|
| Secondary Subject Heading: | Geriatric medicine, Ophthalmology, Ear, nose and throat/otolaryngology, Dentistry and oral medicine, Neurology |
| Keywords: | Medical care, Nursing homes, Needs assessment, Administrative claims, Health services research |
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3 **1 Needs-based provision of medical care to nursing home residents: protocol for a**
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5 **2 mixed-methods study**

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3 **52 Abstract**
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5 **53 Introduction** Nursing home residents typically have greater needs for medical care than
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8 **54** community-dwelling elderly. However, restricted cognitive abilities and limited mobility may
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10 **55** impede their access to general practitioners and medical specialists. The provision of medical
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12 **56** care in nursing homes may therefore be inappropriate in some areas of medical care. The
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14 **57** purpose of this mixed-methods study is to systematically assess, evaluate and explain met and
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16 **58** unmet medical care needs in German nursing homes and to develop solutions where medical
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18 **59** care is found to be inappropriate.

21 **60 Methods and analysis** First, Statutory Health Insurance claims data are analyzed to identify
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23 **61** differences in the utilization of medical care between nursing home residents and community-
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25 **62** dwelling elderly with and without need for long-term care. Second, the health status and
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27 **63** medical care of 500 nursing home residents are assessed and evaluated to quantify met and
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29 **64** unmet medical care needs. Third, qualitative expert interviews and case conferences and,
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31 **65** fourth, quantitative analyses of linked data are used to provide structural, case-specific and
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33 **66** generalizable explanations of inappropriate medical care among nursing home residents.
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35 **67** Fifth, a modified Delphi study is employed to develop pilot projects aiming to improve
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37 **68** medical care in nursing homes.

42 **69 Ethics and dissemination** This study was approved by the Ethics Committee of the
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44 **70** University of Bremen. Research findings are disseminated through presentations at national
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46 **71** and international conferences and publications in peer-reviewed scientific journals.

49 **72 Trial registration number** DRKS00012383
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3 78 **Article Summary**
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5 79 **Strengths and limitations of this study**
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- 8 80 • Based on longitudinal Statutory Health Insurance claims data, cross-sectional data
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10 81 collected in nursing homes, expert interviews and case conferences the provision of
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12 82 medical care is analyzed for the first time in relation to individual medical care needs
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14 83 among nursing home residents in Germany.
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17 84 • The mixed-methods designs allows a comprehensive assessment, evaluation and
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19 85 explanation of met and unmet medical care needs in nursing homes.
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22 86 • Participatory approaches involving general practitioners, medical specialists, nursing
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24 87 home staff, Statutory Health Insurance employees, nursing home residents and
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26 88 relatives are used to increase the acceptance and effectiveness of pilot projects to be
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28 89 developed to improve medical care where it is found to be inappropriate.
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31 90 • Differences in the willingness to participate among nursing homes and nursing home
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33 91 residents may result in a selective study population.
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36 92 • Focusing on nursing homes located in the federal state of Bremen and members of one
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38 93 local Statutory Health Insurance fund may limit the generalizability of the study
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40 94 results.
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103 **Introduction**

104 Nursing home residents may not receive appropriate medical care since restricted cognitive
105 abilities and limited mobility may impede their access to general practitioners (GPs) and
106 medical specialists.[1-3] Moreover, nursing home residents typically suffer from
107 multimorbidity, frailty, cognitive impairments and polypharmacy, resulting in diverse medical
108 care needs that compound the challenge of providing appropriate medical care.[4-7]
109 Empirical studies support this view, indicating inappropriate medical care provision in
110 nursing homes for the treatment of visual and hearing impairments,[8-10] oral health
111 care,[1,2,11,12] pain treatment[13] and drug prescriptions.[2,14-17] Atramont et al.,
112 furthermore, found nursing home admission to be negatively associated with some forms of
113 outpatient care[18] and positively associated with psychotropic and antibacterial drug use.[19]
114 There is, however, hardly any empirical evidence on explanations of inappropriate medical
115 care provision in nursing homes. In this regard, a health technology assessment report
116 concluded that there is not sufficient data available to allow recommendations to be drawn on
117 how medical care provision in German nursing homes can be improved.[2]
118 Given this lack of evidence, the proposed research project aims to systematically assess,
119 evaluate and explain met and unmet medical care needs in German nursing homes and to
120 develop solutions where medical care is found to be inappropriate. The specific aims are: (1)
121 to identify differences in the utilization of medical care between a) nursing home residents, b)
122 community-dwelling elderly in need for long-term care and c) community-dwelling elderly
123 without need for long-term care; (2) to quantify met and unmet medical care needs of nursing
124 home residents; (3) to provide structural and case-specific explanations of inappropriate
125 medical care provision in nursing homes; (4) to provide explanations of inappropriate medical
126 care provision that are generalizable to the total population of nursing home residents; and (5)
127 to develop pilot projects aiming to improve medical care provision in nursing homes.

128 **Methods and analysis**

129 This mixed-methods study is running from April 1, 2017 to March 31, 2020. It is structured
130 into five steps (figure 1). In step 1, Statutory Health Insurance (SHI) claims data are analyzed
131 in order to identify differences in the utilization of medical care between nursing home
132 residents and community-dwelling elderly with and without the need for long-term care. Such
133 differences in the utilization of medical care may indicate, but not prove, inappropriate
134 medical care provision in nursing homes. Thus, in step 2, nursing home residents' health
135 status and utilization of medical care are assessed and evaluated to quantify met and unmet
136 medical care needs with respect to vision, hearing, oral health and Parkinson's disease. In
137 steps 3 and 4, qualitative expert interviews and case conferences as well as quantitative
138 methods are used to provide structural, case-specific and generalizable explanations of
139 inappropriate medical care in nursing homes. In step 5, a modified Delphi study is used to
140 generate ideas on how to improve the provision of medical care in nursing homes.
141 Consequently, at least two pilot projects are developed and implemented in one nursing home
142 to test for practicability. In the following sections, each step is described in detail.

143

144 **Step 1: Analysis of SHI claims data**

145 SHI claims data from AOK Bremen/Bremerhaven, a local SHI fund, are analyzed to identify
146 differences in the utilization of medical care that indicate inappropriate medical care provision
147 in German nursing homes. The available data comprise information on sex, age, in- and
148 outpatient care as well as on long-term care use. All diagnoses are coded according to the
149 German Modification of the International Classification of Diseases, 10th Revision (ICD-10-
150 GM) and can be differentiated according to GPs and medical specialties in the outpatient
151 setting.

152 From 245,000 insured persons, a subsample of 68,718 insured persons aged 60 years and over
153 is drawn. Insured persons with missing or invalid information on demographic characteristics

154 (n = 124) are not considered. For this subsample, the morbidity status of each insured person
 155 is defined by 31 disease categories related to at least one of 13 examined medical specialties
 156 (table 1).

157

158 **Table 1 Disease categories and related medical specialties used to define the individual**
 159 **morbidity status of insured persons examined in step 1**

| No. | Disease categories | ICD-10-GM 2015 codes | Related medical specialties* |
|-----|---|-----------------------------|---|
| 01 | Hypertensive diseases | I10-I15 | Internal medicine, cardiology |
| 02 | Ischemic heart diseases | I20-I52 | Internal medicine, cardiology |
| 03 | Metabolic disorders | E70-E90 | Internal medicine |
| 04 | Arthropathies | M00-M25 | Internal medicine, orthopedics |
| 05 | Diabetes mellitus | E10-E14 | Internal medicine |
| 06 | Dorsopathies | M40-M54 | Orthopedics |
| 07 | Disorders of thyroid gland | E00-E07 | Internal medicine |
| 08 | Vascular diseases | I70-I89 | Internal medicine, cardiology |
| 09 | Organic, including symptomatic, mental disorders; other degenerative diseases of the nervous system | F00-F09; G30-G32 | Neurology/psychiatry |
| 10 | Diseases of esophagus, stomach and duodenum; hernia; other diseases of intestines | K20-K31; K40-K46; K55-K64 | Internal medicine |
| 11 | Chronic lower respiratory diseases | J40-J47 | Internal medicine, pulmonology |
| 12 | Mood (affective) disorders | F30-F39 | Neurology/psychiatry |
| 13 | Cerebrovascular diseases | I60-I69 | Internal medicine, neurology/psychiatry |
| 14 | Neurotic, stress-related and somatoform disorders | F40-F48 | Neurology/psychiatry |
| 15 | Symptoms and signs involving the urinary system; other diseases of urinary system | R30-R39; N30-N39 | Gynecology, urology |
| 16 | Diseases of the eye and adnexa | H00-H59 | Ophthalmology |
| 17 | Renal failure | N17-N19 | Internal medicine, nephrology |
| 18 | Osteopathies and chondropathies | M80-M94 | Orthopedics |
| 19 | Diseases of the ear and mastoid process | H60-H95 | Otorhinolaryngology |
| 20 | Mononeuropathies; polyneuropathies and other disorders of the peripheral nervous system | G56; G57; G58; G59; G60-G64 | Internal medicine, neurology/psychiatry |
| 21 | Diseases of male genital organs | N40-N51 | Urology |
| 22 | Dermatitis, eczema; melanoma and other malignant neoplasms of skin | L20-L30; C43-C44 | Dermatology, surgery |
| 23 | Noninflammatory disorders of female genital tract | N80-N98 | Gynecology |
| 24 | Other disorders of the skin and subcutaneous tissue | L80-L99 | Dermatology |
| 25 | Extrapyramidal and movement disorders | G20-G26 | Internal medicine, neurology/psychiatry |
| 26 | Mental and behavioral disorders due to psychoactive substance use | F10-F19 | Neurology/psychiatry |
| 27 | Cerebral palsy and other paralytic syndromes | G80-G83 | Internal medicine, neurology/psychiatry |
| 28 | Obesity and other hyperalimentation; Malnutrition | E65-E68; E40-E46 | Internal medicine |
| 29 | Schizophrenia, schizotypal and delusional disorders; disorders of adult personality and behavior | F20-F29; F60-F69 | Neurology/psychiatry |
| 30 | Functional impairments | U50-U52 | Internal medicine, Orthopedics |

31 Injuries

S00-S09; S10-S19; S20-S29;
S30-S39; S40-S49; S50-S59;
S60-S69; S70-S79; S80-S89;
S90-S99; T08-T14

Orthopedics, surgery

160 *Due to the availability of data, dentistry had to be analyzed separately and is therefore not presented.

161

162 Zero-inflated Poisson regression analyses are conducted to investigate the probability
163 (component I) and intensity (component II) of medical care for the resulting 45 combinations
164 of disease categories and related medical specialties separately. Each regression model
165 includes only those insured persons who are diagnosed in the examined disease category and
166 have valid information on all variables included in the model. The dependent variable is the
167 number of outpatient visits in the related medical specialty in 2015. Independent variables are
168 the remaining 30 disease categories, age, sex, region, death, care setting and dummy variables
169 as a combination of the obtained level of care and the care setting. In a sensitivity analysis, the
170 probability and intensity of medical care is investigated using logistic and linear regression
171 analyses, respectively.

173 **Step 2: Assessment of nursing home residents**

174 The standardized assessment focuses on vision, hearing, oral health and Parkinson's disease.
175 It consists of two parts: First, the individual health status and medical care provision of 500
176 nursing home residents are assessed. Second, the provision of medical care is evaluated for
177 each resident to determine met and unmet medical care needs.

178 Residents are eligible for assessment if a) they are in need for long-term care, b) are aged 60
179 years and over, c) have been residing in a nursing home located in the federal state of Bremen
180 for at least 12 months and d) are a member of the AOK Bremen/Bremerhaven. The total
181 number of eligible nursing home residents is approximately 1,800. Assuming a realistic
182 response rate of 25-30% results in approximately 500 study participants. The recruitment
183 strategy comprises two stages: At stage one, the total number of nursing homes located in the

1
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3 184 federal state of Bremen is approached for participation. At stage two, eligible residents (or
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5 185 their legal guardians) are recruited by the nursing homes agreeing to participate and
6
7 186 approached for informed consent. In case of reaching considerably less than 500 participants,
8
9 187 the recruitment strategy may be extended to the federal state of Lower Saxony to ensure that
10
11 188 enough nursing home residents with met and unmet medical care needs are included in the
12
13 189 explanation of inappropriate medical care provision (steps 3 and 4).
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17 190 The standardized assessment is carried out by trained study nurses and includes: (1)
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19 191 examinations of residents, (2) self-assessments by residents, (3) proxy-assessments by
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21 192 residents' care nurses and (4) reviews of medical charts (table 2).
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Table 2 Instruments used to assess cross-sectional data in step 2

| Category | Instrument | Source* | | | |
|---------------------------------|---|---------|---|---|---|
| | | E | S | P | R |
| Area of medical care | | | | | |
| Vision | Visual test[20] | X | | | |
| | Questionnaire for individual rating of vision and use of visual aids | | X | X | |
| | Chart review for vision-related diagnoses (e.g. age-related macular degeneration, cataract) and relevant comorbidities (e.g. diabetes mellitus) | | | | X |
| Hearing | Whispered voice test[21] | X | | | |
| | Questionnaire for individual rating of hearing and use of hearing devices | | X | X | |
| | Chart review for hearing-related diagnoses (e.g. presbycusis) | | | | X |
| Oral health | Oral Health Assessment Tool (OHAT)[22] and Oral Health Impact Profile (OHIP)[23] | X | | | |
| | Questionnaire for individual rating of dental problems as well as availability and use of dentures | | X | X | |
| | Chart review for oral health-related diagnoses (e.g. gingivitis) | | | | X |
| Parkinson’s disease | Chart review for diagnosis of Parkinson’s disease, prescribed medications and contacts to medical specialists (e.g. neurologists) and/or therapists (e.g. physiotherapists) | | | | X |
| General health status | | | | | |
| Health-related quality of life | Short-Form Health Survey (SF-12)[24] | | X | X | |
| Depression | Geriatric Depression Scale (GDS)[25,26] | | X | | |
| | Cornell Scale for Depression in Dementia (CSDD)[27] | | | | X |
| Functional and cognitive status | Mini-Mental State Examination[28] | | X | | |
| | Extended Barthel-Index[29] | | | | X |
| Nutrition | Mini-Nutritional Assessment Short Form (MNA-SF)[30-33] | | | | X |
| Vital signs | Chart review for vital signs and falls | | | | X |
| Level of care | Chart review for level of care | | | | X |
| Additional data | | | | | |
| Utilization of medical care | Questionnaire and chart review for diagnoses, prescriptions of medication and aids, contacts to and organization of general and specialized care, hospitalization, contacts to duty doctors and emergency calls | | | X | X |
| Sociodemographic data | Questionnaire and chart review for age, sex, education, marital status, migrant status and relatives | | | X | X |
| Nursing home characteristics | Questionnaire** for size, number of employees and residents, location-related information | | | | X |

*E = examinations of residents; S = self-assessed by residents; P = proxy-assessed by residents’ care nurses; R = reviewed in medical charts
** This questionnaire is completed by administrative employees of the respective nursing home.

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3 216 Additionally, health-related aspects (e.g. quality of life and depression) are assessed as well as
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5 217 structural factors relating to the participating nursing homes (e.g. numbers of employees and
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7 218 residents) that may act as explanatory variables of medical care.

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10 219 Based on these data, a geriatrician and a GP jointly determine case by case whether or not
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12 220 medical care needs in the areas of vision, hearing, oral health and Parkinson's disease are met.
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14 221 In cases of uncertainties or discrepancies, geriatricians and GPs may decide to consult a
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16 222 medical specialist of the corresponding field (i.e. an ophthalmologist, an ear, nose and throat
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18 223 (ENT) specialist, a dentist or a neurologist) who independently determines whether or not
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20 224 medical care needs in the respective area are met. The process of evaluating met and unmet
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22 225 medical care needs is based on standardized guidelines and is tested and adjusted before final
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24 226 application. All physicians are trained on how to evaluate met and unmet medical care needs.
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26 227 Intercoder reliability is assessed for a subsample of 50 nursing home residents.
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32 33 229 **Step 3: Expert interviews and case conferences**

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35 230 Semi-structured expert interviews and case conferences are used to identify structural and
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37 231 case-specific explanations of inappropriate medical care provision in nursing homes. Expert
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39 232 interviews are conducted with nursing home staff, physicians, people in need for long-term
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41 233 care and informal caregivers who provide informed consent. The number of interviews is
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43 234 determined by the principal of theoretical saturation. All interviews are recorded on tape,
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45 235 transcribed and analyzed using content analysis.[34] The results provide a framework for the
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47 236 subsequent case conferences, which are conducted for a selected subsample of nursing home
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49 237 residents assessed in step 2.

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52 238 The case conferences are held with the consenting nurses and, where necessary, the
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54 239 consenting physicians and other health professionals involved in the provision of nursing and
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56 240 medical care of the respective resident. Twenty residents with appropriate medical care and
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58 241 twenty residents with inappropriate medical care are randomly selected for each field of
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3 242 medical care (i.e. vision, hearing, oral health and Parkinson's disease). The case conferences
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5 243 are based on a summarized presentation of the health status and medical care provision of the
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7 244 respective resident. Using problem-centered group interviews,[35] the conference members
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10 245 then discuss, case by case, factors that foster or inhibit the provision of needs-based medical
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12 246 care.

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16 17 248 **Step 4: Analysis of linked data, non-response analysis and extrapolation**

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19 249 In step 4, primary data assessed in step 2 and SHI claims data covering the years 2014-2018
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21 250 are linked at the individual level. The linked data are analyzed to identify generalizable
22
23 251 factors that impact the provision of medical care:

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25 252 First, retrospective and prospective regression analyses are conducted. Retrospective analyses
26
27 253 are used to identify factors in the utilization of medical care that impact the quantified met
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29 254 and unmet medical care needs of nursing home residents. Prospective analyses are used to
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31 255 investigate the impact of the standardized assessment conducted in step 2 on the utilization of
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33 256 medical care.

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37 257 Next, a non-response analysis is conducted. SHI claims data of 1,800 residents are analyzed to
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39 258 identify systematic differences between responders and non-responders. Chi-square tests are
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41 259 used to identify differences in the distribution of age groups, sex, morbidity and long-term
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43 260 care levels. Differences in the mean duration of stays in long-term care and nursing homes are
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45 261 identified using t-tests.

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49 262 Third, prevalence of met and unmet medical care needs is extrapolated. Controlling for
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51 263 systematic differences between responders and non-responders identified in the non-response
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53 264 analysis, prevalence of met and unmet medical care needs is projected to all nursing home
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55 265 residents insured by the AOK Bremen/Bremerhaven. Using official statistics, systematic
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57 266 differences in the distribution of age groups, sex and long-term care levels between nursing
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60 267 home residents insured by the AOK Bremen/Bremerhaven and the total population of nursing

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3 268 home residents in the federal state of Bremen are identified. Taking into account identified
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5 269 differences, the prevalence of met and unmet medical care needs is then projected to all
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7 270 nursing home residents of Bremen. Finally, the prevalence is projected to all nursing home
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9 271 residents of Germany controlling for identifiable differences in the distribution of age groups,
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11 272 sex and long-term care levels between nursing home residents in Bremen and Germany.
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16 17 274 **Step 5: Modified Delphi study and pilot projects**

18
19 275 Based on the factors identified that may explain inappropriate medical care in steps 3 and 4, a
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21 276 modified Delphi study is then carried out. The technique is used with stakeholders from the
22
23 277 fields of nursing and medical care and comprises three rounds. The first round is based on
24
25 278 face-to-face focus group discussions, while the second and third rounds each consist of semi-
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27 279 structured online surveys. Each survey takes about 20 minutes to complete and is online for
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29 280 up to 2 weeks.

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33 281 In the first round, a convenience sample of homogeneous and heterogeneous focus groups of
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35 282 consenting stakeholders (i.e., nursing home staff, GPs, medical specialist, SHI employees,
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37 283 nursing home residents and relatives) generate ideas on how medical care provision to nursing
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39 284 home residents can be improved. The focus groups are led by experienced project researchers,
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41 285 who feed the results of steps 3 and 4 into the discussions. Based on the ideas generated, the
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43 286 project researchers draft at least two pilot projects.

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47 287 In the second round, the experts are given descriptions of these potential pilot projects and
48
49 288 rate them with respect to their feasibility and effectiveness for improving medical care of
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51 289 nursing home residents. These ratings are summarized and distributed back to all experts.

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53 290 In the third round, the experts re-rate the projects based on the rating results from the previous
54
55 291 round. This is expected to result in a more consensual decision. Taking the results of this last
56
57 292 round into account, the concept of the pilot projects is revised and at least two pilot projects
58
59 293 are implemented simultaneously in one nursing home to test for practicability. To minimize
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3 294 the risk of contamination effects, the pilot projects are implemented in different areas of the
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5 295 nursing home. A systematic evaluation of the pilot projects is planned in a follow-up study.
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10 297 **Patient and public involvement**

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12 298 Nursing home residents and the public were not involved in the development of the research
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14 299 question and outcome measures as well as in the design of and the recruitment to the study.
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17 300 Nursing home residents are involved in the standardized assessments of vision, hearing, oral
18
19 301 health, health-related quality of life, depression as well as functional and cognitive status
20
21 302 (self-assessments). Furthermore, nursing home residents and relatives are involved in the
22
23 303 expert interviews, the modified Delphi study and the development of pilot projects. The
24
25 304 results of the standardized assessment are summarized and disseminated to the participating
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27 305 nursing homes (i.e. the results are not directly disseminated to the participating residents). The
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29 306 results of the expert interviews, the modified Delphi study and the development of pilot
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31 307 projects are disseminated to the participating nursing home residents and relatives.
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37 309 **Discussion**

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40 310 This mixed-methods study broadens the limited evidence on the needs-based provision of
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42 311 medical care in nursing homes. It systematically assesses, evaluates and explains met and
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44 312 unmet medical care needs in nursing homes and takes first steps toward improvement.
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47 313 Up to now, several studies have described differences in the utilization of medical care
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49 314 between nursing home residents and community-dwelling elderly with and without need for
50
51 315 long-term care.[2,36-38] None of these, however, has evaluated whether such differences
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53 316 reflect unmet medical care needs at the individual level. Neither have differences in the
54
55 317 utilization of medical care been explained by prevailing structures that may be changed.
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58 318 The present mixed-methods study addresses this evidence gap: Based on longitudinal SHI
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60 319 claims data, cross-sectional data collected in nursing homes as well as transcripts of expert

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3 320 interviews and case conferences, differences in the utilization of medical care are identified,
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5 321 met and unmet medical care needs are quantified, explanations of inappropriate provision of
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7 322 medical care are provided and pilot projects are developed aiming to improve the provision of
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10 323 medical care where it is found to be inappropriate. Participatory approaches involve GPs,
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12 324 medical specialists, nursing home staff, SHI employees, nursing home residents and relatives.
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14 325 This is expected to result in strong acceptance and effective pilot projects which will be
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16 326 systematically evaluated in a follow-up study.
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18 327 There are, however, some limitations to consider. First, in the present study, all nursing homes
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20 328 in the federal state of Bremen are invited to participate and to recruit nursing home residents
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22 329 for study participation. Differences in the willingness to participate among nursing homes and
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24 330 nursing home residents may result in a selective study population. The claims-based non-
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26 331 response analysis, however, permits the identification of structural differences between
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28 332 participants and non-participants. Second, the study focuses on nursing homes located in the
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30 333 federal state of Bremen and members of one local SHI fund. Therefore, the generalizability of
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32 334 research findings may be limited.
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35 335 In conclusion, the findings from this study enhance our knowledge of met and unmet medical
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37 336 care needs in nursing homes. The pilot projects provide a first step towards a sustainable
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39 337 improvement of medical care in German nursing homes. Therefore, it is expected that the
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41 338 findings are highly relevant for many stakeholders from the fields of nursing and medical
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341 **Ethics and dissemination**

342 The Ethics Committee of the University of Bremen approved this study on November 23,
343 2017. All eligible nursing home residents and all nursing home staff are informed in detail
344 about the study. Informed consent is obtained from all included nursing home residents (or
345 their legal guardians where applicable). Informed consent is also obtained from all persons

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3 346 included in the expert interviews, case conferences and Delphi study. Dissemination strategies
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5 347 include presentations at national and international conferences and publications in peer-
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7 348 reviewed scientific journals.
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13
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29

30 358

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32
33
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35
36 361 ASchw and HR specified the analysis of longitudinal SHI claims data. MS, FH, DK, ASchm,
37
38 362 SK, GS, KW-O, AG and HR specified the collection of cross-sectional primary data. JC, MS,
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40 363 FH, DG, ASchm, CT, ASchw and SK wrote the first draft of the protocol which was critically
41
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3 370 **Figures**
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6 371 See separate file (Figure_1.jpg)
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8 372 **Figure 1 Conceptual framework of the mixed-methods study**
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For peer review only

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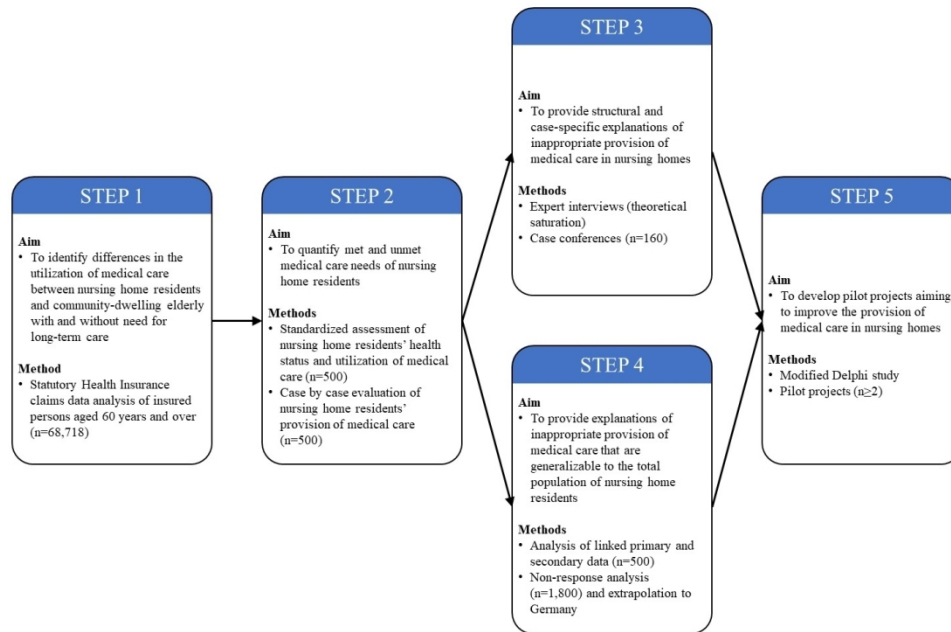


Figure 1 Conceptual framework of the mixed-methods study

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BMJ Open

Needs-based provision of medical care to nursing home residents: protocol for a mixed-methods study

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| Keywords: | Medical care, Nursing homes, Needs assessment, Administrative claims, Health services research |
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SCHOLARONE™
Manuscripts

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3 1 **Needs-based provision of medical care to nursing home residents: protocol for a**
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6 2 **mixed-methods study**

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3 **52 Abstract**
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5 **53 Introduction** Nursing home residents typically have greater needs for medical care than
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8 **54** community-dwelling elderly. However, restricted cognitive abilities and limited mobility may
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10 **55** impede their access to general practitioners and medical specialists. The provision of medical
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12 **56** care in nursing homes may therefore be inappropriate in some areas of medical care. The
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14 **57** purpose of this mixed-methods study is to systematically assess, evaluate and explain met and
15
16 **58** unmet medical care needs in German nursing homes and to develop solutions where medical
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18 **59** care is found to be inappropriate.

19
20
21 **60 Methods and analysis** First, Statutory Health Insurance claims data are analyzed to identify
22
23 **61** differences in the utilization of medical care between nursing home residents and community-
24
25 **62** dwelling elderly with and without need for long-term care. Second, the health status and
26
27 **63** medical care of 500 nursing home residents are assessed and evaluated to quantify met and
28
29 **64** unmet medical care needs. Third, qualitative expert interviews and case conferences and,
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31 **65** fourth, quantitative analyses of linked data are used to provide structural, case-specific and
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33 **66** generalizable explanations of inappropriate medical care among nursing home residents.
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35 **67** Fifth, a modified Delphi study is employed to develop pilot projects aiming to improve
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37 **68** medical care in nursing homes.

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40 **69 Ethics and dissemination** This study was approved by the Ethics Committee of the
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42 **70** University of Bremen. Research findings are disseminated through presentations at national
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44 **71** and international conferences and publications in peer-reviewed scientific journals.

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47 **72 Trial registration number** DRKS00012383
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3 78 **Article Summary**
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5 79 **Strengths and limitations of this study**
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- 8 80 • Based on longitudinal Statutory Health Insurance claims data, cross-sectional data
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10 81 collected in nursing homes, expert interviews and case conferences the provision of
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12 82 medical care is analyzed for the first time in relation to individual medical care needs
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14 83 among nursing home residents in Germany.
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17 84 • The mixed-methods designs allows a comprehensive assessment, evaluation and
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19 85 explanation of met and unmet medical care needs in nursing homes.
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22 86 • Participatory approaches involving general practitioners, medical specialists, nursing
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24 87 home staff, Statutory Health Insurance employees, nursing home residents and
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26 88 relatives are used to increase the acceptance and effectiveness of pilot projects to be
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28 89 developed to improve medical care where it is found to be inappropriate.
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31 90 • Differences in the willingness to participate among nursing homes and nursing home
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33 91 residents may result in a selective study population.
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36 92 • Focusing on nursing homes located in the federal state of Bremen and members of one
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38 93 local Statutory Health Insurance fund may limit the generalizability of the study
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40 94 results.
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103 **Introduction**

104 Nursing home residents may not receive appropriate medical care since restricted cognitive
105 abilities and limited mobility may impede their access to general practitioners (GPs) and
106 medical specialists.[1-3] Moreover, nursing home residents typically suffer from
107 multimorbidity, frailty, cognitive impairments and polypharmacy, resulting in diverse medical
108 care needs that compound the challenge of providing appropriate medical care.[4-7]
109 Empirical studies support this view, indicating inappropriate medical care provision in
110 nursing homes for the treatment of visual and hearing impairments,[8-10] oral health
111 care,[1,2,11,12] pain treatment[13] and drug prescriptions.[2,14-17] Atramont et al.,
112 furthermore, found nursing home admission to be negatively associated with some forms of
113 outpatient care[18] and positively associated with psychotropic and antibacterial drug use.[19]
114 There is, however, hardly any empirical evidence on explanations of inappropriate medical
115 care provision in nursing homes. In this regard, a health technology assessment report
116 concluded that there is not sufficient data available to allow recommendations to be drawn on
117 how medical care provision in German nursing homes can be improved.[2]
118 Given this lack of evidence, the proposed research project aims to systematically assess,
119 evaluate and explain met and unmet medical care needs in German nursing homes and to
120 develop solutions where medical care is found to be inappropriate. The specific aims are: (1)
121 to identify differences in the utilization of medical care between a) nursing home residents, b)
122 community-dwelling elderly in need for long-term care and c) community-dwelling elderly
123 without need for long-term care; (2) to quantify met and unmet medical care needs of nursing
124 home residents; (3) to provide structural and case-specific explanations of inappropriate
125 medical care provision in nursing homes; (4) to provide explanations of inappropriate medical
126 care provision that are generalizable to the total population of nursing home residents; and (5)
127 to develop pilot projects aiming to improve medical care provision in nursing homes.

128 **Methods and analysis**

129 This mixed-methods study is running from April 1, 2017 to March 31, 2020. It is structured
130 into five steps (figure 1). In step 1, Statutory Health Insurance (SHI) claims data are analyzed
131 in order to identify differences in the utilization of medical care between nursing home
132 residents and community-dwelling elderly with and without the need for long-term care. Such
133 differences in the utilization of medical care may indicate, but not prove, inappropriate
134 medical care provision in nursing homes. Thus, in step 2, nursing home residents' health
135 status and utilization of medical care are assessed and evaluated to quantify met and unmet
136 medical care needs with respect to vision, hearing, oral health and Parkinson's disease. In
137 steps 3 and 4, qualitative expert interviews and case conferences as well as quantitative
138 methods are used to provide structural, case-specific and generalizable explanations of
139 inappropriate medical care in nursing homes. In step 5, a modified Delphi study is used to
140 generate ideas on how to improve the provision of medical care in nursing homes.
141 Consequently, at least two pilot projects are developed and implemented in one nursing home
142 to test for practicability. In the following sections, each step is described in detail.

143

144 **Step 1: Analysis of SHI claims data**

145 SHI claims data from AOK Bremen/Bremerhaven, a local SHI fund, are analyzed to identify
146 differences in the utilization of medical care that indicate inappropriate medical care provision
147 in German nursing homes. The available data comprise information on sex, age, in- and
148 outpatient care as well as on long-term care use of 245,000 insured persons (i.e. 34.7% of the
149 total population in the federal state of Bremen). The data represent 51.8% of the population of
150 community-dwelling individuals with need for long-term care and 54.9% of the population of
151 nursing home residents in Bremen. All diagnoses are coded according to the German
152 Modification of the International Classification of Diseases, 10th Revision (ICD-10-GM) and
153 can be differentiated according to GPs and medical specialties in the outpatient setting. In

1
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3 154 Germany, the Federal Joint Committee defines which services are reimbursed by the SHI
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5 155 ensuring that all SHI insured persons are treated according to the current standard of care.[20]
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7 156 SHI claims data comprise all diagnoses coded by physicians for reimbursement purposes of
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9 157 services with clear benefits. Services with unclear benefits, which have to be paid out of
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11 158 pocket, are not included.
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13 159 From the 245,000 insured persons, a subsample of 68,718 insured persons aged 60 years and
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15 160 over is drawn. Insured persons with missing or invalid information on demographic
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17 161 characteristics (n = 124) are not considered. For this subsample, the morbidity status of each
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19 162 insured person is defined by 31 disease categories related to at least one of 13 examined
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21 163 medical specialties (table 1).
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Table 1 Disease categories and related medical specialties used to define the individual morbidity status of insured persons examined in step 1

| No. | Disease categories | ICD-10-GM 2015 codes | Related medical specialties* |
|-----|---|-----------------------------|---|
| 01 | Hypertensive diseases | I10-I15 | Internal medicine, cardiology |
| 02 | Ischemic heart diseases | I20-I52 | Internal medicine, cardiology |
| 03 | Metabolic disorders | E70-E90 | Internal medicine |
| 04 | Arthropathies | M00-M25 | Internal medicine, orthopedics |
| 05 | Diabetes mellitus | E10-E14 | Internal medicine |
| 06 | Dorsopathies | M40-M54 | Orthopedics |
| 07 | Disorders of thyroid gland | E00-E07 | Internal medicine |
| 08 | Vascular diseases | I70-I89 | Internal medicine, cardiology |
| 09 | Organic, including symptomatic, mental disorders; other degenerative diseases of the nervous system | F00-F09; G30-G32 | Neurology/psychiatry |
| 10 | Diseases of esophagus, stomach and duodenum; hernia; other diseases of intestines | K20-K31; K40-K46; K55-K64 | Internal medicine |
| 11 | Chronic lower respiratory diseases | J40-J47 | Internal medicine, pulmonology |
| 12 | Mood (affective) disorders | F30-F39 | Neurology/psychiatry |
| 13 | Cerebrovascular diseases | I60-I69 | Internal medicine, neurology/psychiatry |
| 14 | Neurotic, stress-related and somatoform disorders | F40-F48 | Neurology/psychiatry |
| 15 | Symptoms and signs involving the urinary system; other diseases of urinary system | R30-R39; N30-N39 | Gynecology, urology |
| 16 | Diseases of the eye and adnexa | H00-H59 | Ophthalmology |
| 17 | Renal failure | N17-N19 | Internal medicine, nephrology |
| 18 | Osteopathies and chondropathies | M80-M94 | Orthopedics |
| 19 | Diseases of the ear and mastoid process | H60-H95 | Otorhinolaryngology |
| 20 | Mononeuropathies; polyneuropathies and other disorders of the peripheral nervous system | G56; G57; G58; G59; G60-G64 | Internal medicine, neurology/psychiatry |
| 21 | Diseases of male genital organs | N40-N51 | Urology |

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|----|--|---|---|
| 22 | Dermatitis, eczema; melanoma and other malignant neoplasms of skin | L20-L30; C43-C44 | Dermatology, surgery |
| 23 | Noninflammatory disorders of female genital tract | N80-N98 | Gynecology |
| 24 | Other disorders of the skin and subcutaneous tissue | L80-L99 | Dermatology |
| 25 | Extrapyramidal and movement disorders | G20-G26 | Internal medicine, neurology/psychiatry |
| 26 | Mental and behavioral disorders due to psychoactive substance use | F10-F19 | Neurology/psychiatry |
| 27 | Cerebral palsy and other paralytic syndromes | G80-G83 | Internal medicine, neurology/psychiatry |
| 28 | Obesity and other hyperalimentation; Malnutrition | E65-E68; E40-E46 | Internal medicine |
| 29 | Schizophrenia, schizotypal and delusional disorders; disorders of adult personality and behavior | F20-F29; F60-F69 | Neurology/psychiatry |
| 30 | Functional impairments | U50-U52 | Internal medicine, Orthopedics |
| 31 | Injuries | S00-S09; S10-S19; S20-S29; S30-S39; S40-S49; S50-S59; S60-S69; S70-S79; S80-S89; S90-S99; T08-T14 | Orthopedics, surgery |

*Due to the availability of data, dentistry had to be analyzed separately and is therefore not presented.

Descriptive analyses are conducted in two steps. First, the prevalence of each single disease category in 2015 is determined among the groups of nursing home residents, community-dwelling elderly in need for long-term care and community-dwelling elderly without need for long-term care. Second, for the 45 combinations of disease categories and related medical specialties, the proportion of prevalent cases with an outpatient visit in the related medical specialty in 2015 is calculated among the three groups (i.e. nursing home residents as well as community-dwelling elderly with and without need for long-term care). Lower proportions of prevalent cases with an outpatient visit in the related medical specialty may indicate, but not prove, unmet medical care needs.

Poisson regression analyses are conducted to investigate the intensity of medical care for the 45 combinations of disease categories and related medical specialties separately. In cases of overdispersion, negative binomial regression and in cases of excess zeros, zero-inflated Poisson regression or zero-inflated negative binomial regression analyses are conducted. Each regression model includes only those insured persons who are diagnosed in the examined disease category and have valid information on all variables included in the model. The

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3 184 dependent variable is the number of outpatient visits in the related medical specialty in 2015.
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5 185 Independent variables are age (in five-year groups), sex and dummy variables as a
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7 186 combination of the obtained level of care (no long-term care dependency, level 1, level 2,
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9 187 level 3 of long-term care dependency) and the care setting (community, nursing home). To
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11 188 take account of differences in morbidity and mortality that likely impact the number of
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13 189 outpatient visits, the remaining 30 disease categories and death are included as control
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15 190 variables. Multicollinearity between variables is evaluated on the basis of the variance
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17 191 inflation factor.
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23 193 **Step 2: Assessment of nursing home residents**

24 194 The standardized assessment focuses on vision, hearing, oral health and Parkinson's disease.
25
26 195 It consists of two parts: First, the individual health status and medical care provision of 500
27
28 196 nursing home residents are assessed. Second, the provision of medical care is evaluated for
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30 197 each resident to determine met and unmet medical care needs.
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32 198 Residents are eligible for assessment if a) they are in need for long-term care, b) are aged 60
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34 199 years and over, c) have been residing in a nursing home located in the federal state of Bremen
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36 200 for at least 12 months and d) are a member of the AOK Bremen/Bremerhaven. The total
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38 201 number of eligible nursing home residents is approximately 1,800. The recruitment strategy
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40 202 comprises two stages: At stage one, the total number of nursing homes located in the federal
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42 203 state of Bremen is approached for participation by the research team (i.e. no sampling strategy
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44 204 is applied). At stage two, all eligible residents (or their legal guardians) are invited for
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46 205 participation and approached for informed consent by the nursing homes agreeing to
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48 206 participate (i.e. also no sampling strategy is applied). We expect that not all nursing homes
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50 207 and not all nursing home residents agree to participate and assume to reach 25-30% of the
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52 208 approximately 1,800 eligible nursing home residents, resulting in a study population of 500
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3 209 nursing home residents. In case of reaching considerably less than 500 participants, the
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5 210 recruitment strategy may be extended to the federal state of Lower Saxony.
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7 211 The standardized assessment is carried out by trained study nurses and includes: (1)
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9 212 examinations of residents, (2) self-assessments by residents, (3) proxy-assessments by
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11 213 residents' care nurses and (4) reviews of nursing records (table 2). The examination of
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13 214 residents comprises the application of a visual test,[21] a whispered voice test[22] and the
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15 215 Oral Health Assessment Tool (OHAT).[23] During the self-assessments, nursing home
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17 216 residents are asked, inter alia, to rate their vision, hearing and oral health as well as whether
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19 217 they use a visual aid, a hearing device or dentures. Further questions relate to their general
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21 218 health status. The residents' self-assessments are complemented by the proxy-assessments in
22
23 219 which the residents' care nurses are asked the same or comparable questions. Information
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25 220 regarding the utilization of medical care (e.g. contacts to general and specialized care),
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27 221 sociodemographic data and nursing home characteristics are obtained from the residents' care
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29 222 nurses and nursing records.
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235 **Table 2 Instruments used to assess cross-sectional data in step 2**

| Category | Instrument | Source* | | | |
|---------------------------------|--|---------|---|---|---|
| | | E | S | P | R |
| Area of medical care | | | | | |
| Vision | Visual test[21] | X | | | |
| | Questionnaire for individual rating of vision and use of visual aids | | X | X | |
| | Review of nursing records in terms of vision-related diagnoses (e.g. age-related macular degeneration, cataract) and relevant comorbidities (e.g. diabetes mellitus) | | | | X |
| Hearing | Whispered voice test[22] | X | | | |
| | Questionnaire for individual rating of hearing and use of hearing devices | | X | X | |
| | Review of nursing records in terms of hearing-related diagnoses (e.g. presbycusis) | | | | X |
| Oral health | Oral Health Assessment Tool (OHAT)[23] | X | | | |
| | Oral Health Impact Profile (OHIP)[24] | | X | | |
| | Questionnaire for individual rating of dental problems as well as availability and use of dentures | | X | X | |
| | Review of nursing records in terms of oral health-related diagnoses (e.g. gingivitis) | | | | X |
| Parkinson's disease | Review of nursing records in terms of diagnosis of Parkinson's disease, prescribed medications and contacts to medical specialists (e.g. neurologists) and/or therapists (e.g. physiotherapists) | | | | X |
| General health status | | | | | |
| Health-related quality of life | Short-Form Health Survey (SF-12)[25] | | X | X | |
| Depression | Geriatric Depression Scale (GDS)[26,27] | | X | | |
| | Cornell Scale for Depression in Dementia (CSDD)[28] | | | X | |
| Functional and cognitive status | Mini-Mental State Examination[29] | | X | | |
| | Extended Barthel-Index[30] | | | X | |
| Nutrition | Mini-Nutritional Assessment Short Form (MNA-SF)[31-34] | | | X | |
| Vital signs | Review of nursing records in terms of vital signs and falls | | | | X |
| Level of care | Review of nursing records in terms of level of care | | | | X |
| Additional data | | | | | |
| Utilization of medical care | Questionnaire for and review of nursing records in terms of diagnoses, prescriptions of medication and aids, contacts to and organization of general and specialized care, hospitalization, contacts to duty doctors and emergency calls | | | X | X |
| Sociodemographic data | Questionnaire for and review of nursing records in terms of age, sex, education, marital status, migrant status and relatives | | | X | X |
| Nursing home characteristics | Questionnaire** for size, number of employees and residents, location-related information | | | | X |

*E = examinations of residents; S = self-assessed by residents; P = proxy-assessed by residents' care nurses; R = reviewed in nursing records

** This questionnaire is completed by administrative employees of the respective nursing home.

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3 240 Additionally, health-related aspects (e.g. quality of life and depression) are assessed as well as
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5 241 structural factors relating to the participating nursing homes (e.g. numbers of employees and
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7 242 residents) that may act as explanatory variables of medical care.

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10 243 The assessed data are summarized in individual case reports. These case reports comprise
11
12 244 information on age, sex, level of care, date of nursing home admission, in- and outpatient
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14 245 medical care, diagnoses, medication, aids, vital signs, falls, the result of the visual test and
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16 246 self-reported use of visual aids, the result of the whispered voice test and self-reported use of
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18 247 hearing devices, all data of the OHAT, the self- and proxy-assessed oral health, the proxy-
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20 248 assessed availability and use of dentures as well as the result of the Oral Health Impact Profile
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22 249 (OHIP).[24] Moreover, the case reports include the results of the instruments applied for
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24 250 assessing the health-related quality of life,[25] depression,[26-28] functional and cognitive
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26 251 status,[29,30] nutrition,[31-34] as well as all comments made by the trained study nurses
27
28 252 during the assessment. Based on the case reports (in printed form), a geriatrician and a GP
29
30 253 jointly determine case by case whether or not medical care needs in the areas of vision,
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32 254 hearing, oral health and Parkinson's disease are met, i.e. whether or not the provision of
33
34 255 medical care is appropriate. In cases of uncertainties or discrepancies, geriatricians and GPs
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36 256 may access all assessed data (in digital form) and decide to consult a medical specialist of the
37
38 257 corresponding field (i.e. an ophthalmologist, an ear, nose and throat (ENT) specialist, a dentist
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40 258 or a neurologist) who independently determines whether or not medical care needs in the
41
42 259 respective area are met. Based on these data, the prevalence of met and unmet medical care
43
44 260 needs is quantified for each area. The process of evaluating met and unmet medical care needs
45
46 261 is based on standardized guidelines and is tested and adjusted before final application. All
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48 262 physicians are trained on how to evaluate met and unmet medical care needs. Intercoder
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50 263 reliability is assessed for a subsample of 50 nursing home residents.

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265 **Step 3: Expert interviews and case conferences**

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3 266 Semi-structured expert interviews and case conferences are used to identify structural and
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5 267 case-specific explanations of inappropriate medical care provision in nursing homes. Expert
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7 268 interviews are conducted with nursing home staff, physicians, people in need for long-term
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10 269 care and informal caregivers who provide informed consent. The number of interviews is
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12 270 determined by the principal of theoretical saturation. All interviews are recorded on tape,
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14 271 transcribed and analyzed using content analysis.[35] The results provide a framework for the
15
16 272 subsequent case conferences, which are conducted for a selected subsample of nursing home
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18 273 residents assessed in step 2.

21 274 The case conferences are held with the consenting nurses and, where necessary, the
22
23 275 consenting physicians and other health professionals involved in the provision of nursing and
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25 276 medical care of the respective resident. Twenty residents with appropriate medical care and
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27 277 twenty residents with inappropriate medical care are randomly selected for each field of
28
29 278 medical care (i.e. vision, hearing, oral health and Parkinson's disease). The case conferences
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31 279 are based on a summarized presentation of the health status and medical care provision of the
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33 280 respective resident. Using problem-centered group interviews,[36] the conference members
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35 281 then discuss, case by case, factors that foster or inhibit the provision of needs-based medical
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37 282 care.

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44 284 **Step 4: Analysis of linked data, non-response analysis and extrapolation**

46 285 In step 4, primary data of the 500 nursing home residents assessed in step 2 and SHI claims
47
48 286 data covering the years 2014-2018 are linked at the individual level. The linked data are
49
50 287 analyzed to identify generalizable factors that impact the provision of medical care:
51
52 288 First, retrospective and prospective regression analyses are conducted. Retrospective analyses
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54 289 are used to identify factors in the utilization of medical care that impact the quantified met
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56 290 and unmet medical care needs of nursing home residents. Prospective analyses are used to
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3 291 investigate the impact of the standardized assessment conducted in step 2 on the utilization of
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5 292 medical care.

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7 293 Next, a non-response analysis is conducted. SHI claims data of 500 responders and 1,300 non-
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10 294 responders are analyzed to identify systematic differences between responders and non-
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12 295 responders. Chi-square tests are used to identify differences in the distribution of age groups,
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14 296 sex, morbidity and long-term care levels. Differences in the mean duration of stays in long-
15
16 297 term care and nursing homes are identified using t-tests for normally distributed variables and
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18 298 Wilcoxon-Mann-Whitney tests for non-normal distributions.

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21 299 Third, prevalence of met and unmet medical care needs determined in step 2 is extrapolated.
22
23 300 Controlling for systematic differences between responders and non-responders identified in
24
25 301 the non-response analysis, prevalence of met and unmet medical care needs in the areas of
26
27 302 vision, hearing, oral health and Parkinson's disease is projected to all nursing home residents
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29 303 insured by the AOK Bremen/Bremerhaven. Using official statistics, systematic differences in
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31 304 the distribution of age groups, sex and long-term care levels between nursing home residents
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33 305 insured by the AOK Bremen/Bremerhaven and the total population of nursing home residents
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35 306 in the federal state of Bremen are identified. Taking into account identified differences, the
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37 307 prevalence of met and unmet medical care needs is then projected to all nursing home
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39 308 residents of Bremen. Finally, the prevalence is projected to all nursing home residents of
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41 309 Germany controlling for identifiable differences in the distribution of age groups, sex and
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43 310 long-term care levels between nursing home residents in Bremen and Germany.

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51 312 **Step 5: Modified Delphi study and pilot projects**
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53 313 Based on the factors identified that may explain inappropriate medical care in steps 3 and 4, a
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55 314 modified Delphi study is then carried out. The technique is used with stakeholders from the
56
57 315 fields of nursing and medical care and comprises three rounds. The first round is based on
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59 316 face-to-face focus group discussions, while the second and third rounds each consist of a

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3 317 semi-structured online survey. Each survey takes about 20 minutes to complete and is online
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5 318 for up to 2 weeks.

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7 319 In the first round, a convenience sample of at least two homogeneous and two heterogeneous
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10 320 focus groups of four to six participating stakeholders (i.e., nursing home staff, GPs, medical
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12 321 specialist, SHI employees, nursing home residents and relatives) generate ideas on how
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14 322 medical care provision to nursing home residents can be improved. The focus groups are led
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17 323 by two experienced project researchers, who feed the results of steps 3 and 4 into the
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19 324 discussions. All focus group discussions are recorded, summarized and discussed within the
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21 325 research team. Based on the results, the project researchers draft at least two potential pilot
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23 326 projects.

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26 327 In round two, the experts of the first round are given descriptions of the potential pilot
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28 328 projects. They rate and comment on the proposed pilot projects with respect to their feasibility
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30 329 and effectiveness for improving medical care of nursing home residents. These ratings are
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32 330 narratively and visually summarized.

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35 331 In the third round, the same experts re-rate the projects based on the summarized ratings from
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37 332 the previous round. The re-ratings are summarized using the same method as in round two.
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39 333 Taking the results of this last round into account, the concept of the pilot projects is revised.
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42 334 This is expected to result in a more consensual decision. At least two pilot projects are
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44 335 implemented simultaneously in one nursing home to test for practicability. To minimize the
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46 336 risk of contamination effects, the pilot projects are implemented in different areas of the
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48 337 nursing home. A systematic evaluation of the pilot projects is planned in a follow-up study.

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52 53 339 **Patient and public involvement**

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56 340 Nursing home residents and the public were not involved in the development of the research
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58 341 questions and outcome measures as well as in the design of and the recruitment to the study.
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60 342 Nursing home residents are involved in the standardized assessments of vision, hearing, oral

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3 343 health, health-related quality of life, depression as well as functional and cognitive status
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5 344 (self-assessments). Furthermore, nursing home residents and relatives are involved in the
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7 345 expert interviews, the modified Delphi study and the development of pilot projects. The
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10 346 results of the standardized assessment are summarized and disseminated to the participating
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12 347 nursing homes (i.e. the results are not directly disseminated to the participating residents). The
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14 348 results of the expert interviews, the modified Delphi study and the development of pilot
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16 349 projects are disseminated to the participating nursing home residents and relatives.
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21 351 **Discussion**

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24 352 This mixed-methods study broadens the limited evidence on the needs-based provision of
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26 353 medical care in nursing homes. It systematically assesses, evaluates and explains met and
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28 354 unmet medical care needs in nursing homes and takes first steps toward improvement.
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30 355 Up to now, several studies have described differences in the utilization of medical care
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32 356 between nursing home residents and community-dwelling elderly with and without need for
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34 357 long-term care.[2,37-39] None of these, however, has evaluated whether such differences
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36 358 reflect unmet medical care needs at the individual level. Neither have differences in the
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38 359 utilization of medical care been explained by prevailing structures that may be changed.
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40 360 The present mixed-methods study addresses this evidence gap: Based on longitudinal SHI
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42 361 claims data, cross-sectional data collected in nursing homes as well as transcripts of expert
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44 362 interviews and case conferences, differences in the utilization of medical care are identified,
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46 363 met and unmet medical care needs are quantified, explanations of inappropriate provision of
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48 364 medical care are provided and pilot projects are developed aiming to improve the provision of
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50 365 medical care where it is found to be inappropriate. Participatory approaches involve GPs,
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52 366 medical specialists, nursing home staff, SHI employees, nursing home residents and relatives.
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54 367 This is expected to result in strong acceptance and effective pilot projects which will be
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56 368 systematically evaluated in a follow-up study.
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3 369 There are, however, some limitations to consider. First, in the present study, all nursing homes
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5 370 in the federal state of Bremen are invited to participate and to recruit nursing home residents
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7 371 for study participation. Differences in the willingness to participate among nursing homes and
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9 372 nursing home residents may result in a selective study population. The claims-based non-
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11 373 response analysis, however, permits the identification of structural differences between
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13 374 participants and non-participants. Second, the study focuses on nursing homes located in the
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15 375 federal state of Bremen and members of one local SHI fund. Therefore, the generalizability of
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17 376 research findings may be limited.

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19 377 In conclusion, the findings from this study enhance our knowledge of met and unmet medical
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21 378 care needs in nursing homes. The pilot projects provide a first step towards a sustainable
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23 379 improvement of medical care in German nursing homes. Therefore, it is expected that the
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25 380 findings are highly relevant for many stakeholders from the fields of nursing and medical
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27 381 care.

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34 35 383 **Ethics and dissemination**

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37 384 The Ethics Committee of the University of Bremen approved this study on November 23,
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39 385 2017. All eligible nursing home residents and all nursing home staff are informed in detail
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41 386 about the study. Informed consent is obtained from all included nursing home residents (or
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43 387 their legal guardians where applicable). Informed consent is also obtained from all persons
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45 388 included in the expert interviews, case conferences and Delphi study. Dissemination strategies
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47 389 include presentations at national and international conferences and publications in peer-
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49 390 reviewed scientific journals.

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400

401 **Footnotes**

402 **Contributors:** JC, TK, ASchw, GS, KW-O, AG and HR designed the study. MS, TK, CT,
403 ASchw and HR specified the analysis of longitudinal SHI claims data. MS, FH, DG, ASchm,
404 SK, GS, KW-O, AG and HR specified the collection of cross-sectional primary data. JC, MS,
405 FH, DG, ASchm, CT, ASchw and SK wrote the first draft of the protocol which was critically
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411

412 **Figures**

413 See separate file (Figure_1.jpg)

414 **Figure 1 Conceptual framework of the mixed-methods study**

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3 417 **References**
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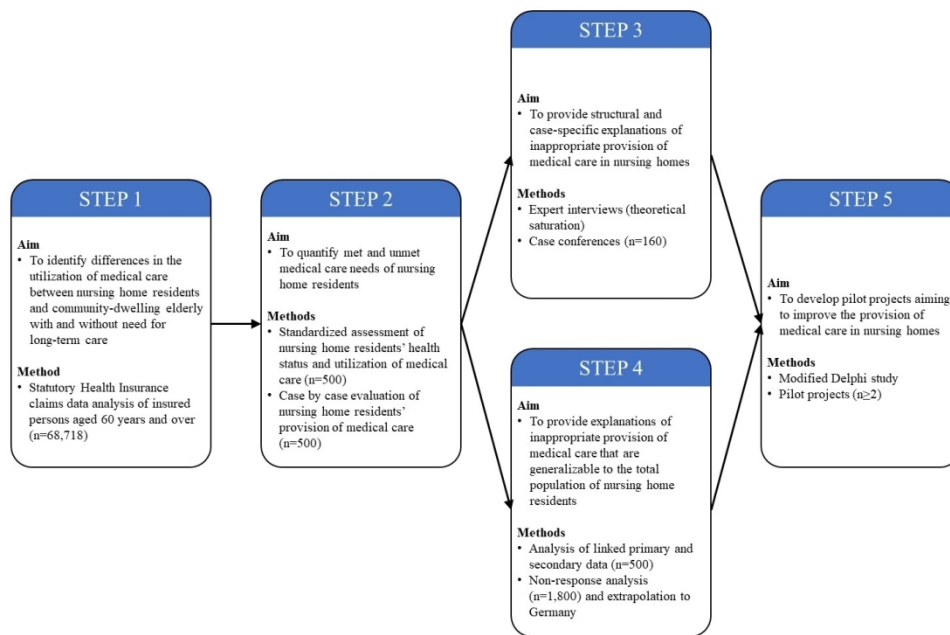


Figure 1 Conceptual framework of the mixed-methods study

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