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Quality of Life of Patients with Dementia in Acute Hospitals: Comparing a regular ward to a special care ward with dementia care concept. A Bayesian Multilevel Model Analysis.

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Title

Quality of Life of Patients with Dementia in Acute Hospitals: Comparing a regular ward to a special care ward with dementia care concept. A Bayesian Multilevel Model Analysis.

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Keywords

Dementia, Quality of Life, Acute Hospital, Quality of Care, Internal Medicine

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Abstract

Objectives: To identify factors that predict the quality of life (QoL) of patients with dementia in acute hospitals and to analyse if a special care concept can increase the patients' QoL.

Design: A non-randomised case-control-study, including two internal medicine wards from hospitals in Hamburg, Germany.

Setting and Participants: In all, 526 patients with dementia from two hospitals were included in the study (intervention: n=333; control: n=193). Inclusion criteria was an at least mild cognitive impairment or dementia. The intervention group was a hospital with a special care ward for internal medicine focussing on patients with dementia. The control group was from a hospital with a regular care ward without special dementia care concept.

Outcome Measures: Our main outcome was the QoL (range 0-100) from patients with dementia in two different hospitals. A Bayesian multilevel analysis was conducted to identify predictors like age, dementia, agitation, physical and chemical restraints or functional limitations that affect QoL.

Results: QoL differs significantly between the control (40.7) and intervention group (51.2), $p < 0.001$. Regression analysis suggests that physical restraint (estimated effect: -5.0), psychotropic drugs use (-4.4) and agitation (-2.9) are negatively associated with QoL. After controlling for confounders, the positive effect of the special care concept remained (5.7).

Conclusions: A special care ward will improve the quality of care and has a positive impact on the QoL of patients with dementia. Health policies should consider the benefits of special care concepts and develop incentives for hospitals to improve the QoL and quality of care for these patients.

Article Summary

Strengths and Limitations

- This is one of the first studies to investigate quality of life of patients with dementia in acute internal medicine wards in Germany.
- Study results suggest that a special care concept leads to a clinically relevant improvement in quality of life for patients with dementia.
- The statistical method applied in this study explicitly incorporates and accounts for information from previous research.
- The structural differences between the hospitals from the control and intervention may limit the generalizability of the results regarding the benefit of special care concepts for regular internal medicine wards.

Introduction

Acute hospitals face the challenge of an increase in old-age patients, which particularly affects internal medicine wards [1]. The average age of patients in internal medicine wards is above 70 years and may even come close to 80 years [2,3], leading to an increasing prevalence of cognitive impairments [4]. Although data on the occurrence of dementia or cognitive impairments of patients in hospitals is inconsistent, the larger proportion of studies report prevalence rates of about 40% [5–7].

Many hospitals are insufficiently prepared for patients with cognitive impairments, especially in acute care units predominantly focussing on somatic diseases [8]. Patients with cognitive impairments or dementia do not fit into the typical routines and standardised workflows of hospitals as these patients need more resources for care and treatment [9,10]. These patients often become disoriented, anxious, agitated and challenge hospital staff with erratic behaviour when placed in regular care wards. This results in an increased likelihood of falls, complications during the hospital stay and post-operative complications [11,12]. Hence, patients with dementia are a vulnerable group with a higher risk for long-lasting functional impairments [13,14].

To control the challenging behaviour of patients with dementia, a common practice – at least in German acute hospitals, and especially for older patients – is to use physical restraints like side rails to keep patients in bed, or chemical restraints such as the on-demand-use of psychotropic medication or hypnotics and sedatives [15,16]. This practise is not limited to German hospitals; however, there seems to be large variations between countries [17]. Physical and chemical restraints as well as anxiety and challenging behaviour are associated with poorer outcomes in quality of life [QoL] and quality of care of patients with dementia [18,19]. Therefore, hospitals in general, and specifically internal medicine wards with their increasing proportion of patients with

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3 dementia, need to address these issues in order to improve the quality of care for these
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5 patients.
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8 At least in Germany, there were lately no care concepts that fully address the needs of
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10 patients with dementia in internal medicine [20]. The special care ward “DAVID” in the
11
12 Protestant Hospital Alsterdorf in Hamburg was one of the first internal medicine wards
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14 in Germany that implemented a comprehensive care concept for patients with dementia,
15
16 aiming to improve the patients’ QoL during their hospital stay. QoL is an important
17
18 indicator of quality of care and a major dimension when assessing patient reported
19
20 outcomes, particularly in older people as global outcome measure for interventions
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22 [21,22]. The assumption of this care concept is that a special care ward for patients with
23
24 dementia leads to better outcomes in QoL compared to regular internal medicine wards.
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26 A study (“DAVID 2”) was conducted to investigate the impact of such a care concept. This
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28 paper shows the results of this study and addresses two research questions. First, which
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30 factors predict the QoL of patients with dementia in acute hospitals? Second, beyond
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32 these factors, can a special care concept for patients with dementia in acute hospitals
33
34 increase the patients’ QoL?
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43 **Methods**

44 **Study Design and Setting**

45
46 The aim of this study was to compare the quality of care for patients with dementia
47
48 within a specialised dementia care concept as opposed to regular care in acute hospitals.
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50 The present study was designed as a non-randomised case-control-study, including two
51
52 internal medicine wards in two hospitals located in Hamburg, Germany. The
53
54 intervention group was a hospital that implemented a special care ward for internal
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56 medicine focussing on patients with dementia. The control group was from a hospital
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3 with a regular care ward for internal medicine, which had no special dementia care
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5 concept.
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10 **Intervention Group**

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12 The special care ward “DAVID” is an internal medicine ward in the Protestant Hospital
13
14 Alsterdorf and has 14 beds. In the year of data collection (2016), 349 patients were
15
16 treated. The ward employed nine care workers as nursing staff.
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18

19 Key components of the special care concept are a) a specific architectural design,
20
21 including a homelike lounge, a specific colouring of doors and walls, and a light concept
22
23 with minimum 500 lux at eye level; b) doctors, care workers and service staff are trained
24
25 in coping with challenging behaviour and other dementia related issues; c) mobile
26
27 devices for diagnostics, to perform as many treatments as possible in the different
28
29 rooms of the special care ward; d) involvement of relatives into assessment, care and
30
31 discharge planning; and e) regular therapeutic offers like occupational or speech
32
33 therapy, and social offers like music, playing or spending more time than usual to care
34
35 for the patients.
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40 To fulfil these high standards of quality of care, the ward “DAVID” employs more care
41
42 staff in relation to the number of patients as compared to other regular internal
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44 medicine wards.
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50 **Control Group**

51
52 The regular care ward is part of a larger hospital with emergency hospitalisation. It has
53
54 80 beds and in the year of data collection, about 3.500 patients were treated in this
55
56 internal medicine ward. Twenty-six employees worked as care staff in this ward.
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59 Trainees sometimes supported the care team. The regular care ward had no specific care
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3 concept for dementia patients. The care staff was not particularly trained in dementia
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5 topics.
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10 **Data collection and participants**

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12 An assessment questionnaire was developed to obtain data from patients with dementia.
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14 Study nurses were trained in using this assessment questionnaire and then conducted
15
16 the data collection in both hospitals. Two study nurses were responsible for the special
17
18 care ward and one for the regular care ward. A pre-test of two months was conducted to
19
20 test and revise the questionnaire. As a result, some items were removed and instructions
21
22 for study nurses were defined more precisely. After the pre-test, data was collected over
23
24 a period of 12 months. To detect small to medium effect sizes (Cohen's $d \sim 0.1$ to 0.2), a
25
26 power analysis was performed prior to the data collection and yielded a sample size of
27
28 at least 173 subjects per group. Patients were included when they showed at least mild
29
30 cognitive impairments or memory problems. In the special care ward (intervention
31
32 group) all patients were assessed because a diagnosed dementia was a requirement for
33
34 admission to that hospital. Hence, the participation rate for the special care ward was
35
36 about 94% and excluded only a few patients that were not responsive. For the regular
37
38 care ward (control group), a short dementia screening was used to assess the severity of
39
40 dementia, in order to identify patients who qualify for the study [23]. This was necessary
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42 because not all patients have had a clarified dementia diagnosis. The total sample size
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44 for the present analysis consists of $N=526$ patients (special care ward: $n=333$; regular
45
46 care ward: $n=193$).
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55 Prior to the study, a study protocol was developed and submitted to the ethical
56
57 committee of the medical association of Hamburg. The ethical committee approved the
58
59 proposal and attested that the study conforms to ethical and legal requirements
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3 (approval code PV5102). Study participants were not able to give their informed
4
5 consent due to their cognitive impairments. However, as data mostly derived from the
6
7 hospitals' regular documentation and was completely anonymous, the ethics committee
8
9 waived the need of an informed consent.
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14 **Patient and Public involvement**

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17 Patients and the public were not involved in the development of the research question
18
19 nor study design.
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24 **Measures**

25
26 *Outcome:* QoL in patients with dementia was assessed using the QUALIDEM [24,25].
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28 After observing patients for about one week (depending on the length of stay), the study
29
30 nurses rated their QoL. QUALIDEM comprises 37 items reflecting nine different
31
32 subdomains of QoL: "care relationship" (7 items, 0-21 points), "positive affect" (6 items,
33
34 0-18 points), "negative affect" (3 items, 0-9 points), "restless and tense behaviour" (3
35
36 items, 0-9 points), "positive self-image" (3 items, 0-9 points), "social relations" (6 items,
37
38 0-18 points), "social isolation" (3 items, 0-9 points), "feeling at home" (4 items, 0-12
39
40 points) and "have something to do" (2 items, 0-6 points). For patients with very severe
41
42 dementia (Minimental State Examination Test [26] [MMSE] < 7), only six of the nine
43
44 subscales apply, where the dimensions "positive self-image", "feeling at home" and "have
45
46 something to do" were omitted. The recommendation is to report descriptive results of
47
48 the QUALIDEM separately for each subscale. For regression analyses, a QoL index was
49
50 calculated, ranging from 0 to 100 points with a higher score indicating better QoL. The
51
52 QUALIDEM total score applies to all severities of dementia, so all patients' scores are
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54 comparable [27].
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3 *Independent Variables:* Age, gender, main diagnosis for admission to hospital and length
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5 of stay were recorded. A modified version of the Charlson's Comorbidity Index [CCI],
6
7 which included depression and hypertension as new items, was built based upon the
8
9 assessment of comorbidities and chronic diseases [28,29]. If patients had no chronic
10
11 illnesses, the CCI had a score of zero points. Else, higher scores indicated more serious
12
13 comorbid disease. Shortly after admission to hospital, the study nurses measured
14
15 functional limitations and cognitive status of patients. Functional limitations in daily
16
17 living were assessed with the Barthel-Index [30]. This score ranges from 0 (completely
18
19 dependent) to 100 points (no basic functional limitations) and was recoded according to
20
21 the classification of the ICD-10 [31] (German adaption) into a score from 1 to 6 points.
22
23 The Minimental State Examination Test [26] [MMSE] measures the cognitive
24
25 impairments of patients, ranging from 0 (very strong cognitive impairments) to 30 (very
26
27 mild or no cognitive impairments) points. This score was recoded into three categories,
28
29 also based on ICD-10 classification: severe dementia (0-16), moderate dementia (17-23
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31 points) and mild dementia (24-27 points).
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33
34 After about one week of hospital stay, the study nurses rated the patients' agitation and
35
36 challenging behaviour and recorded psychotropic drug use (chemical restraint) and
37
38 physical restraints. Agitation and challenging behaviour of patients was assessed using
39
40 the Pittsburgh Agitation Scale [PAS] [32] ranging from 0 to 16 points (higher scores
41
42 indicate stronger agitation).
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44
45 Physical restraints were defined as the use of one the following measures: Side rails to
46
47 keep a patient in bed, tying a patient to a bed, and use of "therapeutic" chairs that
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49 prevent patients to stand up. The variable was dichotomised, indicating whether
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51 patients (in the course of the hospital stay) were mechanically restrained by at least one
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53 of these measures or not.
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3 Psychotropic drug use was defined as on-demand-use (“as-needed”) of medication for
4 the nervous system by means of the Anatomical Therapeutic Chemical (ATC)
5 classification [33] and comprises antipsychotics, anxiolytics, hypnotics/sedatives and
6 antidepressants (N05A-C, N06A). Indicated use of psychotropic drugs was defined as
7 medications that were prescribed for regular, not on-demand-use and not only given to
8 patients in order to control their challenging behaviour. Such use of psychotropic drugs
9 was excluded from the analysis. The on-demand-use variable was dichotomised and
10 shows whether, during the complete hospital stay, chemical restraints were applied to
11 patients or not.
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24 While these variables already cover many different aspects that have an effect on the
25 QoL, a dummy variable for the hospitals used as proxy for the intervention estimates the
26 impact of the special care concept. This should reflect how much of the change in QoL is
27 attributable to the special care concept.
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36 **Missing Data**

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38 In total, 11% of individual items across all scales were missing (at random). The missing
39 data pattern was analysed and missing data was imputed using the multivariate
40 imputation by chained equations method [34], using 11 imputation steps corresponding
41 to the proportion of missing data [35]. The method for imputing missing values depends
42 on the variable’s nature. For continuous variables, predictive mean matching was
43 applied, while logistic regressions were used for binary variables.
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55 **Statistical Methods**

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57 Descriptive results for the total sample and each hospital are reported. Statistically
58 significant differences of $p < 0.05$ between the two hospital wards were tested using t-
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3 tests, χ^2 -tests or Mann-Whitney-U-tests, depending on the level of measurement and
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5 distribution of variables. Differences between the hospitals in the QUALIDEM subscales
6
7 are presented as boxplots, showing the median value and upper and lower quartiles of
8
9 the value distribution.

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12 As multivariate analysis, a Bayesian linear mixed model was applied to analyse the
13
14 associations between the independent variables and the outcome. Computations were
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16 based on Stan [36], a probabilistic programming language for specifying Bayesian
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18 models, using Markov Chain Monte Carlo sampling (in particular, Hamiltonian Monte
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20 Carlo) [37]. We assume that the patients' main diagnosis is associated with different
21
22 degrees of physical impairments, which affect the QoL. Therefore, the variable 'main
23
24 diagnosis' was used as level-2 unit (*random intercept*) in the multilevel model to control
25
26 for the variation in the outcome. We used informative priors for the predictors age,
27
28 female gender, severe dementia, psychotic drug use and physical restraints, based on
29
30 information from former research [18,38,39]. Weakly informative priors were used for
31
32 the remaining predictors. The prior and posterior distributions of the model are
33
34 summarised in the supplemental material (see Supplementary File 1).

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37 Continuous predictors were centred before entering the model. Age was divided by 10,
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39 so a 1-unit change in the predictor of age reflects a change of 10 years in patients. The
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41 median value of the posterior distribution is used as "Bayesian point estimate", which
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43 minimises the difference of estimates from true values over posterior samples, but there
44
45 are many other plausible values (the "posterior distribution") to describe the association
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47 between predictors and outcome. Hence, 50% and 89% highest density intervals [40]
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49 [HDI] are shown to indicate the range of most credible values and to reflect the (un-
50
51)certainty of the estimates. The intraclass correlation coefficient [41] was calculated to
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53 see how much of the proportion of the variance in the outcome can be explained by the
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3 grouping structure ('main diagnosis'). We developed post-hoc additional regression
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5 models with interaction terms for need predictors (Barthel-Index, physical and chemical
6
7 restraints, PAS-Score) to check if the associations between the complexity of patients'
8
9 needs and QoL differ between hospitals. We found no significant interaction terms and
10
11 decided to present the most parsimonious model here and show further results in the
12
13 appendix (see Supplementary File 2).
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17 All analyses were conducted with the R statistical package [42], including the packages
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19 *mice* [34], *ggplot* [43], *brms* [44] and *sjPlot* [45]. The source code is available in the
20
21 supplemental material (see Supplementary File 3). Data is available online [46].
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26 27 **Results**

28 29 **Sample Characteristics**

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31 Table 1 gives an overview of the sample characteristics. The proportion of female to
32
33 male patients is similar in both groups. The mean age is 4 years higher in the control
34
35 group. There are also significant group differences in the Barthel-Index indicating higher
36
37 functional impairment in the control group, while the dementia severity was the same in
38
39 both hospitals. Comorbid conditions are slightly higher in the control group. Patients
40
41 stayed 9.4 days in hospital on average and nearly one day longer in the intervention
42
43 group as compared to the control group. Large differences between the two hospitals
44
45 can be seen in the use of medical and physical restraints with significantly less use in the
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47 intervention group. Agitation- and QoL-scores also show strong group differences to the
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49 disadvantage of the patients in the control group.
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Table 1: Sample Characteristics

Characteristic	Control Group (Regular Care Ward, n=193)	Intervention Group (Special Care Ward, n=333)	Total (N=526)	p-value of difference
Female, %	59.1	61.6	60.6	.637
Mean Age (SD)	83.1 (7.2)	79.0 (11.9)	80.5 (10.6)	<.001
Mean_Barthel-Index (SD)	29.9 (27.9)	40.7 (30.4)	36.7 (29.9)	<.001
Mild Dementia, %	7.8	9.6	8.9	.580
Moderate Dementia, %	30.0	26.7	27.9	.473
Severe Dementia, %	62.2	63.7	63.2	.805
Mean_Length of Stay (SD)	8.9 (7.5)	9.7 (5.5)	9.4 (6.3)	.002
Physical Restraints (yes), %	54.4	28.2	37.8	<.001
Psychotropic Drug Use (yes, as-needed), %	25.9	14.1	18.4	.001
Mean-Score Pittsburg Agitation Scale (SD)	3.9 (3.1)	3.0 (3.2)	3.3 (3.2)	<.001
Mean Charlson' Comorbidity Index (SD)	3.2 (3.0)	2.5 (2.0)	2.8 (1.6)	<.001
Mean Qualidem Total Score (SD)	40.7 (14.5)	51.2 (17.2)	47.3 (17.0)	<.001

Barthel-Index: 0-100 (higher = better functioning); Dementia (MMSE score): mild: 24-27; moderate: 17-23; severe: <= 16; Pittsburg Agitation Scale: 0-16 (higher = stronger agitation and anxiety); Charlson' Comorbidity Index: 0-9 (higher = more comorbidities); QUALIDEM: 0-100 (higher = better QoL)

Quality of life

Looking at the QoL for patients with severe to mild cognitive impairments (these are the ones, in which all subdomains of the QUALIDEM could be applied), there is a consistent pattern across all QUALIDEM-domains: Patients in the control group have a lower QoL compared to the intervention group. Except for the last subdomain ('having something to do'), all differences are statistically significant (Figure 1).

The same consistent pattern can be found for patients with very severe dementia symptoms (MMSE score < 7). Here, only the second of the six applied subdomains ('positive affect') does not differ significantly between intervention and control (Figure 2).

Predictors of quality of life

Figure 3 shows the results from the Bayesian mixed model. Three predictors are clearly negatively associated with QoL: physical restraint, psychotropic drug use and agitation (PAS-score). Physical restraint is associated with a 4.9-point decrease in QoL. With 50% probability, the QoL decreases by 4.1 to 5.8 points and with a chance of 89% by -7 to -2.8 points respectively. The application of psychotropic drugs as-needed shows similar results, with a posterior median of -4.4. The third clearly negative associated predictor is agitation, which shows a decrease in QoL of about 2.9 points for each additional point in the PAS-score.

Dementia and gender are not clearly associated with QoL. Neither are the length of hospital stay and the CCI.

The age of the patient correlates slightly positive with QoL, where an increase of 10 years means an increase of about 1.2 points in the QoL. The posterior median of the Barthel-Index is 2.0, so for a one-category change in functional impairments the QoL changes by two points. This means that patients with severe functional impairments differ by about 10 points in QoL compared to patients with no functional impairments. Controlling for all other predictors, the intervention (special care ward) shows the strongest association with our outcome of interest, the patients' QoL. The posterior median is 5.7, and with an 89% probability, the credible values describing the effect of the intervention on QoL are within the range from 3.8 to 7.6.

The intraclass correlation coefficient of the model is rather low (0.01). This means, the 'main diagnosis' does not explain much of the variance in the patients' QoL and there is almost no regularization ("shrinkage") of estimated model parameters and no larger differences between hospitals according to the patients' needs, as indicated by their main diagnosis.

Discussion

The study reported in this paper sought to understand those factors that influence the QoL in patients with dementia and whether a special care concept for these patients performs better in this regard as opposed to regular care wards.

One of our main findings is that QoL differs significantly between the control and intervention group. We found substantial differences between the two hospitals in the patients' total QoL score in favour of the special care ward. Beyond the statistical significance, this finding also has a clinical impact. Studies suggest a change in 3 points for the Quality of Life – Alzheimer's Disease Scale [47], which has a range of 40 points, to be clinically relevant [48,49]. Transferred to the range of the QUALIDEM scale, a difference of about 7.5 points would be considered as an important improvement in QoL. Another indicator to evaluate the clinical relevance of a change in QoL is an increase of the score of half a standard deviation [50], which would be about 8.5 points for our data. Taking these reference points as a basis, we found evidence for the clinical relevant improvement in QoL of patients in a special care ward.

A second key finding is the identification of those factors that are clearly associated with QoL. The use of physical and chemical restraints, both happening more frequently in the control group, are associated with lower outcomes in QoL. This finding is in line with other studies that suggest a negative association between physical and chemical restraints and QoL [18,39] and explains why the regular care ward performs less good in this regard than the special care ward. Agitation was also negatively associated with QoL. This is understandable as agitation is an expression of anxiety and indisposition of people with dementia and typically occurs after admission to hospital. Furthermore, agitation is often a reason for psychotropic drug use or physical restraint and, thus, also negatively affects QoL [51,52]. Independent from these factors, the special care ward

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3 itself shows the strongest impact on QoL, indicating that patients with dementia
4 explicitly benefit from specialised care concepts. Other studies also report these
5 benefits, both in a nursing home or hospital setting [53,54]. Since we controlled for
6 patient characteristics like main diagnosis, age, functional limitations, chronic
7 comorbidities, agitation, length of stay etc. in our model, we do not assume that the
8 positive effect of the special care ward is completely a result of a biased sample between
9 intervention and control group. Although the two compared hospitals differ in their
10 structures and size, patients' characteristics are largely comparable between the
11 samples in the control and intervention group. For instance, there is no substantial
12 difference between the two hospitals regarding the relationship between functional
13 impairments and physical restraints. Moreover, to see if the complexity of patients' need
14 affect our findings, we calculated regression models with interaction terms between
15 need factors moderated by hospitals (see Supplementary File 2). The association
16 between complexity of needs and QoL is not significantly different between the
17 intervention and control group. Based on our results we suggest that the special care
18 concept mainly explains the differences in the QoL. Although it is certainly difficult to
19 determine the exact effect of the special care concept on the patients' QoL, our findings
20 seem plausible in the light of the key elements of this intervention. A higher ratio of care
21 staff as to patients, smaller facilities or systematically trained employees can be
22 considered essential for health care provision to patients with dementia and are much
23 better conditions for less physical or chemical restraints, independent of the functional
24 limitations of patients. The special care ward provides a more dementia-friendly interior
25 design, including orientation and navigation aids and the use of light and colours, which
26 are considered as important components to reduce agitation for patients with dementia
27 [55]. These findings and conclusions are in line with other studies on hospital care that
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3 suggest that an increased staff ratio or the implementation of multiple components,
4 which particularly address the needs of patients with dementia, lead to reduced use of
5 physical restraints and psychotropic drug use and improve the quality of care [56,57].
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10 The special care ward benefits from a higher staff ratio, i.e. nurses have to care for fewer
11 patients with dementia compared to the control group. While this is an intentional
12 element of the concept, the downside is higher personnel costs. Only few studies
13 investigated the follow-up costs for patients with dementia in home care settings after
14 hospitalization. Costa et al. predicted additional monthly costs in home care of about
15 445 Euros due to increased agitation of patients with dementia [58]. Thus, if patients
16 with dementia benefit from special care concepts and perceive better outcomes in
17 quality of life and care, the increased costs for more care personnel may be compensated
18 by reducing follow-up costs for the ambulatory care. However, further research is
19 needed to give more exact projections of the increased costs and potential of saving
20 money.
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36 Another finding is that the severity of cognitive impairments, measured with the MMSE,
37 is a rather improper indicator to represent the underlying problems of and with the
38 dementia disease, as these factors were not consistently associated with QoL. Direct
39 measures of the problems associated with dementia, as agitation or challenging
40 behaviour, should be considered as well when it comes to investigate the QoL of patients
41 with dementia.
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50 Our study has several limitations. One concerns the structural differences between the
51 two hospitals. The hospital with the special care ward is much smaller than the hospital
52 that hosted the control group. A second control group or an intervention group in a
53 hospital of a similar size as the hospital with the regular care ward may have permitted
54 a more distinct comparison. However, since we accounted for many different patient
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3 characteristics including functional status, comorbidities and behavioural problems, we
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5 assume that a bias due to patient selection mechanisms is rather low. Another structural
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7 difference between the intervention and control group that certainly affects the results
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9 are the different staff ratios. In the special care ward, nurses have to care for fewer
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11 patients than in the regular care ward. Although we assume that this aspect probably
12
13 has the highest impact on the outcomes in QoL, this is not a “selection bias” but a core
14
15 component of the intervention. A further limitation is possibly the first and thus rather
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17 exploratory use of the QUALIDEM assessment in a hospital setting. Although studies
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19 show reliable results of the QUALIDEM in nursing homes even for a short observation
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21 period of about one week [59], there are no studies that evaluate the reliability and
22
23 validity for use in hospitals. We have done checks of internal consistencies, which
24
25 showed that most subdomains of the QUALIDEM perform well with our data and are
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27 comparable to results from other validation studies [60]. This indicates that the use of
28
29 the QUALIDEM is feasible for hospital research. However, we cannot give evidence on
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31 the interrater reliability apart from the intense training of the study nurses.
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41 **Conclusions**

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43 On the whole, we think that a special care ward will improve the quality of care and is
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45 effective regarding the positive impact on the QoL of patients with dementia. Our study
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47 showed that after controlling for different predictors, the intervention still has a
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49 perceptible effect concerning clinical important differences in our outcome of interest,
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51 the patients’ quality of life. However, such improvements can only be achieved by
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53 implementing a concept with multiple components that address the explicit needs of
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55 patients with dementia. The implementation of a special care concept usually increases
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57 the costs for hospitals because it requires a higher staff-patient-ratio, regular training of
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3 employees or more therapeutic offers. On the other hand, costs that accumulate in
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5 informal care after hospital stay as a result of poorer quality of care in hospitals can be
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7 much higher than additional personnel costs and could probably be reduced [58,61].
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10 Health policies should consider the benefits of special care concepts and develop
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12 incentives for hospitals to improve the QoL and quality of care for patients with
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15 dementia.
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For peer review only

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Author Contributions

DL was involved in conception and design of the study, analysis and interpretation of data and drafting the article. GP was involved in conception and design of the study and interpretation of data. JK was involved in interpretation of data and drafting the article. CK was involved in conception and design of the study, interpretation of data and drafting the article.

Competing interests

The authors have declared that no competing interests exist.

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Ethics approval and consent to participate

Prior to the study, a study protocol was developed and submitted to the ethical committee of the medical association of Hamburg ("Ethik-Kommission der Ärztekammer Hamburg"). The IRB of the ethical committee approved the proposal and attested that the study conforms to ethical and legal requirements (approval code PV5102). Study participants were not able to give their informed consent due to their cognitive impairments. However, as data mostly derived from the hospitals' regular documentation and was completely anonymous, the IRB of the ethics committee waived the need of an informed consent.

Availability of data and material

All data generated or analysed during this study are included are available in the Zenodo repository (DOI: 10.5281/zenodo.1479677) at <https://doi.org/10.5281/zenodo.1479676>.

For peer review only

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Figure Titles and Legends

Figure 1: QUALIDEM subdomain scores by care ward in patients with mild to severe dementia (MMSE score from 7 to 27, n = 400)

Figure 2: QUALIDEM subdomain scores by care ward, patients with very severe dementia (MMSE score < 7, n = 126)

Figure 3: Predictors of Health Related Quality of Life, Regression Coefficients, Bayesian Linear Mixed Model, Posterior Median (+50% and 89% High Density Interval)

Supplementary Files

Supplementary File 1: Methodological comments, Word document (docx-format).

Supplementary File 2: Regression Models with Interaction Terms, Word document (docx-format).

Supplementary File 3: R Souce Code (to use with R statistics, CC BY-NC 4.0 license)

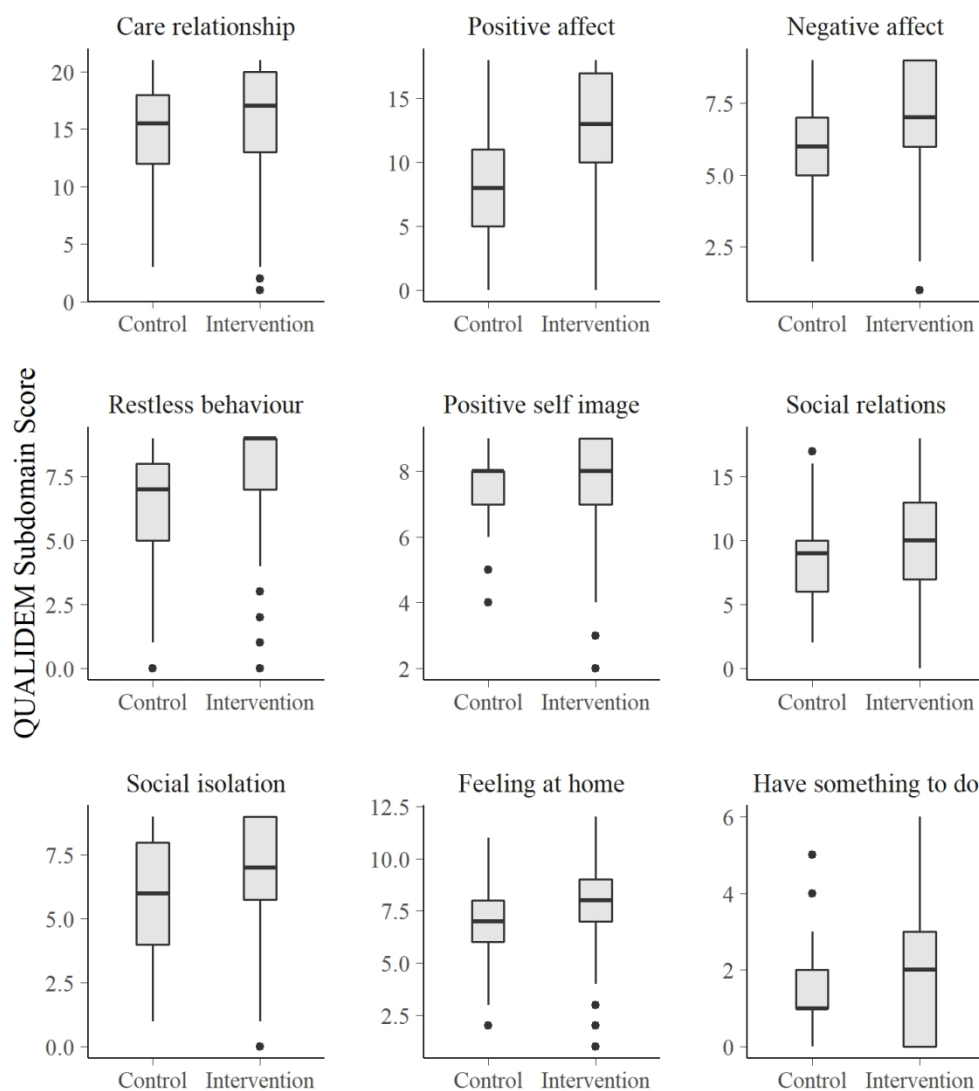


Figure 1: QUALIDEM subdomain scores by care ward in patients with mild to severe dementia (MMSE score from 7 to 27, n = 400)

169x189mm (220 x 220 DPI)

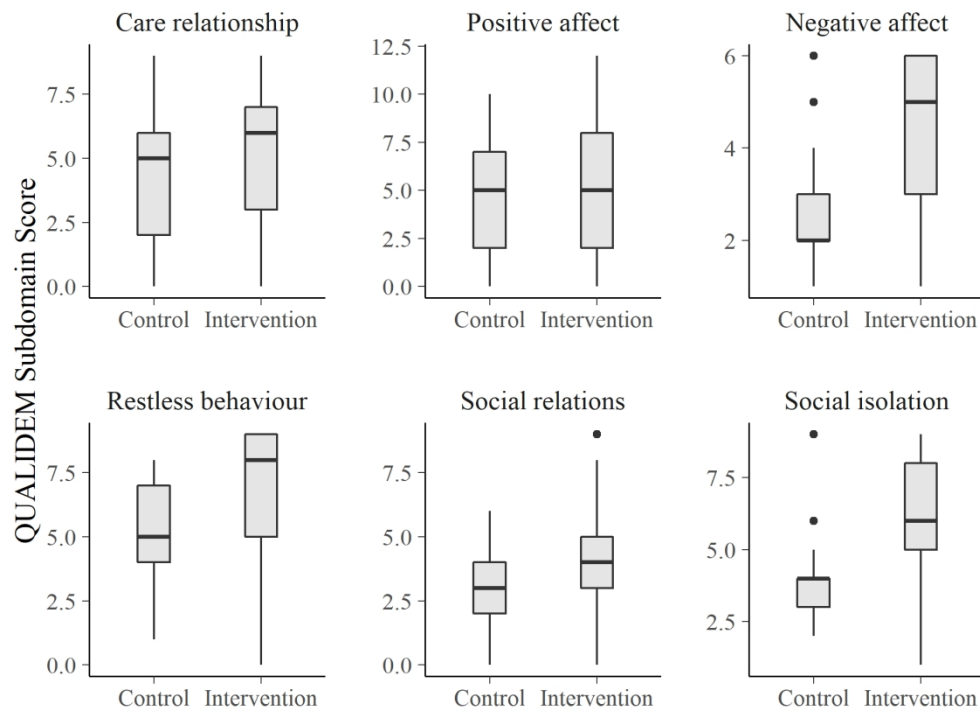


Figure 2: QUALIDEM subdomain scores by care ward, patients with very severe dementia (MMSE score < 7, n = 126)

169x125mm (300 x 300 DPI)

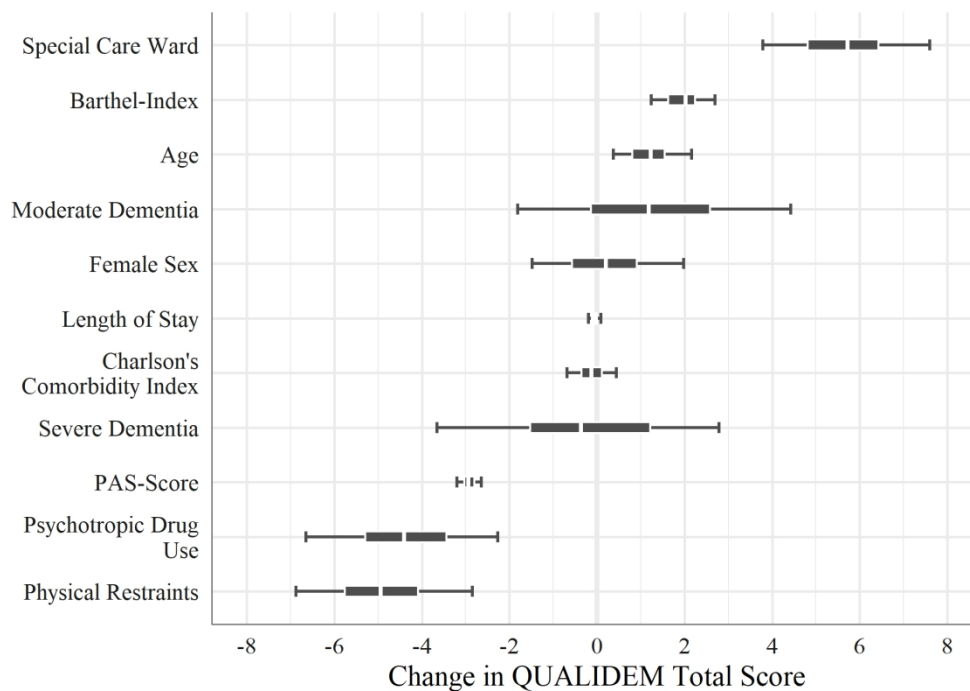


Figure 3: Predictors of Health Related Quality of Life, Regression Coefficients, Bayesian Linear Mixed Model, Posterior Median (+50% and 89% High Density Interval)

169x119mm (300 x 300 DPI)

Supplemental Material 1

Quality of Life of Patients with Dementia in Acute Hospitals: Comparing a regular ward to a special care ward with dementia care concept. A Bayesian Multilevel Model Analysis.

Methodological comments

1. Short note on Bayesian Methods

Bayesian methods are probably not very common, and readers may ask “Why use Bayesian regression models?” Gelman et al.¹ give a well summarized answer to this question: “A pragmatic rationale for the use of Bayesian methods is the inherent flexibility introduced by their incorporation of multiple levels of randomness and the resultant ability to combine information from different sources, while incorporating all reasonable sources of uncertainty in inferential summaries. Such methods naturally lead to smoothed estimates in complicated data structures and consequently have the ability to obtain better real-world answers.”¹. Shortly speaking, advantages of Bayesian methods are, for instance, the ability to derive probability statements for every quantity of interest or explicitly incorporate prior knowledge about parameters into the model.

2. Distribution of Posterior Samples from the Regression Model

Contrary to a frequentist approach, there is no unique point estimate in Bayesian analysis. The posterior median minimises the expected absolute error (i.e. the difference of estimates from true values over posterior samples), but there are many other plausible values to describe the association between predictors and outcome, which is called the *distribution of posterior samples*. Credible or Highest Density Intervals are based on quantiles of this distribution and indicate the probability of an estimate being inside this interval. In terms of inference, this allows us to say that with, e.g. 50% probability, the true effect of a *Special Care Ward* on our outcome lies between 5.1 and 6.6. Figure S1 shows the distribution of posterior samples from our regression model.

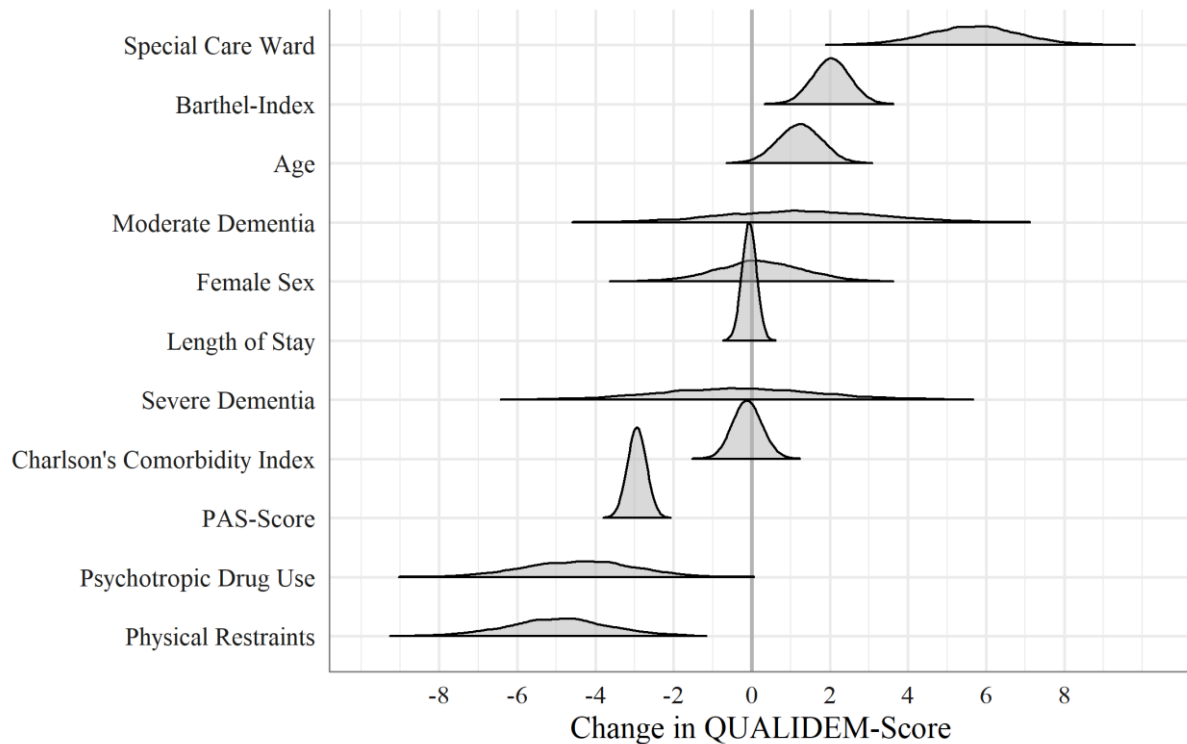
Figure S1: Distribution of Posterior Samples from Regression Model**3. Tabular Summary from the Regression Model**

Table S1 provides a summary of the regression model, including the data for two different Highest Density Intervals as well as the ratio of effective number of samples. The ratio should be 1.0 or close to 1.0 and indicates whether the samples were efficient, which means that the results for the related coefficient are reliable. Furthermore, all R_{hat} values of the models were approximately 1. The R_{hat} statistic² measures the ratio of the average variance of the draws within each chain to the variance of the pooled draws across chains. If the chains have not converged to a common distribution, the R_{hat} statistic will tend to be greater than one, indicating that more iterations may be required for reliable results.

Table S1: Predictors of Quality of Life, Regression Coefficients, Bayesian Linear Mixed Model, Posterior Median (+50% and 89% Highest Density Intervals)

Term	Estimate	SE	50% HDI	89% HDI	Ratio of effective Number of Samples
(Intercept)	46.2	2.2	45.2 – 48.2	42.7 – 49.8	1.00
Length of Stay	-0.1	0.1	-0.1 – 0.0	-0.2 – 0.1	1.00
Age	1.2	0.5	0.8 – 1.5	0.4 – 2.1	1.00
Moderate Dementia	1.2	2.0	-0.1 – 2.7	-1.8 – 4.6	1.00
Severe Dementia	-0.4	2.0	-1.6 – 1.1	-3.6 – 2.7	1.00
Female	0.2	1.1	-0.5 – 1.0	-1.6 – 1.9	1.00
Barthel Score	2.0	0.5	1.8 – 2.4	1.3 – 2.8	1.00
Physical Restraints (yes)	-4.9	1.2	-5.8 – -4.1	-7.0 – -2.8	1.00
Special Care Ward (Intervention)	5.7	1.2	4.9 – 6.5	3.8 – 7.6	1.00
PAS-Score	-2.9	0.2	-3.1 – -2.8	-3.2 – -2.7	1.00
Charlson's Comorbidity Index	-0.1	0.3	-0.4 – 0.1	-0.6 – 0.5	1.00
Psychotropic Drug Use (yes, as-needed)	-4.4	1.4	-5.3 – -3.5	-6.5 – -2.1	1.00
sigma	11.9	0.4	11.5 – 12.0	11.3 – 12.5	1.00

All Rhat values ~ 1, all mcse < 0.05. Results based on 4 chains each 1000 iterations for each chain. LOO-adjusted R²: 0.500

4. Test for Practical Equivalence of Parameters

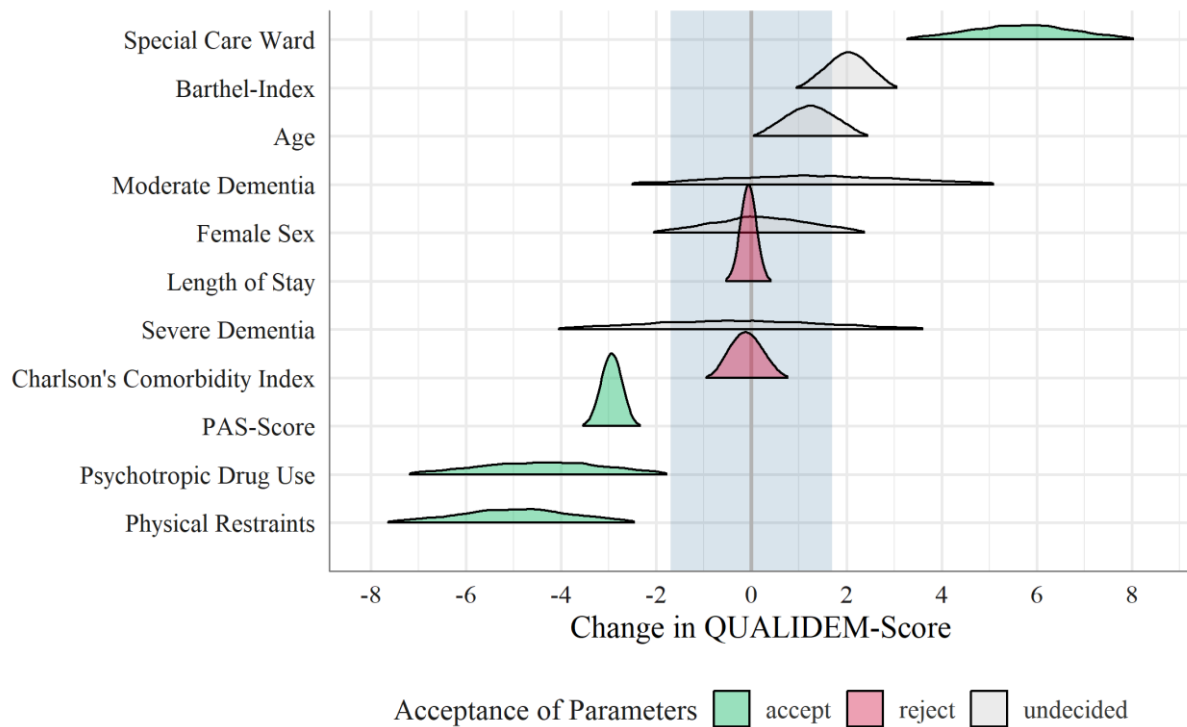
Bayesian methods do not perform classical “null hypothesis significance tests”. Rather, to account for the uncertainty in estimation and the magnitude of parameter values, Kruschke³ suggests checking whether parameter values lie inside a certain range that is considered as “practically no effect”.

Figure S2 shows the distribution of the 95% Highest Density Intervals of posterior samples and indicates whether these lie completely outside, completely inside or partially inside the region of practical equivalence (ROPE). If the HDI is completely outside the ROPE, the “null hypothesis” for this parameter is “rejected”. If the ROPE completely covers the HDI, i.e. all most credible values of a parameter are inside the region of practical equivalence, the null hypothesis is accepted. Else, it is undecided whether to accept or reject the null hypothesis.

The ROPE limits are specified following Kruschke's suggestion, which is defined as $0 \pm SD(\text{dependent variable}) * 0.1$ for linear models.

Physical restraint, psychotropic drug use, agitation (PAS-score) and the intervention (special care ward) are those predictors that can be considered as relevant for our outcome.

Figure S2: 95%-Range of the Distribution of Posterior Samples from Regression Model; Region of Practical Equivalence emphasized in light-blue.



5. Summary of the Distribution of Prior and Posterior Samples

Bayesian regression models can incorporate prior information about the parameters. Informative or weakly informative priors have the advantage of regularization of parameters to rule out large effects. This leads to less biased results and reductions of outliers in situations where the sample size in general, or for certain groups in the data, is small. Where we found information about our parameters, we included it by specifying *informative priors*. For instance, studies suggest that physical restraints are, on average, associated with an about 5-point reduction in quality of life, so the *location* of the prior distribution of our parameter physical restraint is at -5.0 (see Table S2). *Weakly informative priors* simply have a location of zero.

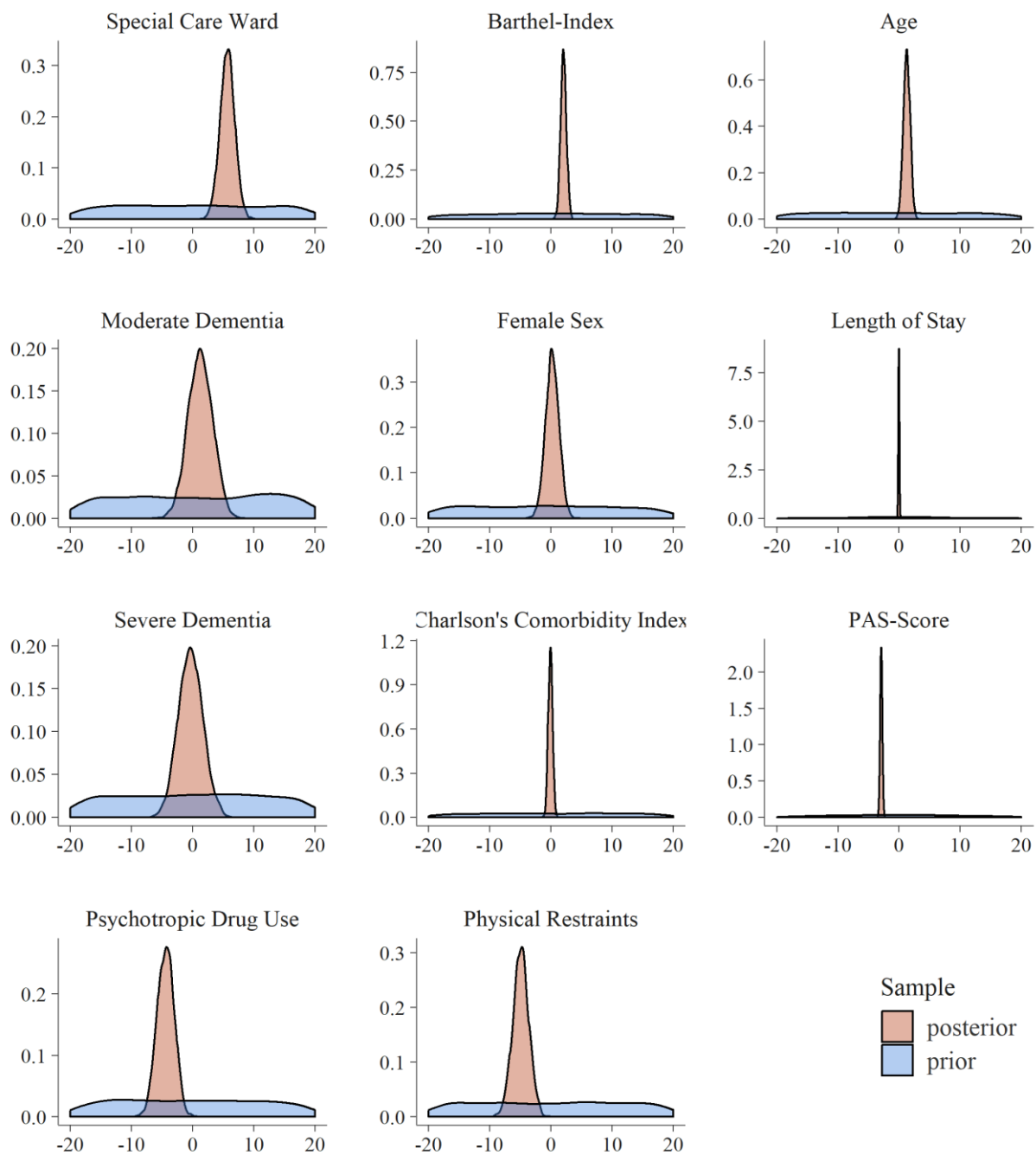
Table S2: Prior Summary

Predictor	Location	Scale
Length of Stay	0.00	6
Age	0.16	40
Moderate dementia	0.00	42
Severe dementia	-0.44	42
Sex, female	-3.22	42
Barthel-Score	0.00	29
Physical restraints	-5.00	42
Special Care Ward	0.00	42
PAS-Score	0.00	13
Charlson's Comorbidity Index	0.00	27
Psychotic Drug Use	0.29	42

To prevent a too strong shrinkage of uncertainty, the *scale* of the prior distribution should be large enough. If no assumptions about the scale of the effect are made, a recommended way (for normally distributed priors) is to use a scale of 2.5 and adjust it by dividing the scale by the standard deviation of the related predictor and multiply it with the standard deviation of the outcome ($2.5 * SD(y) / SD(x)$, see <https://cran.r-project.org/web/packages/rstanarm/vignettes/priors.html>).

When the evidence in the data is *strong*, the impact of the prior information is rather low. On the other hand, if the evidence of the data is *weak*, for instance due to small sample size, the impact of the prior information increases. Figure S3 shows the summary of the prior and posterior sample distributions and suggests that the evidence in the data was rather strong and results were not biased due to unrealistic prior information.

Figure S3: Posterior versus Prior Summary

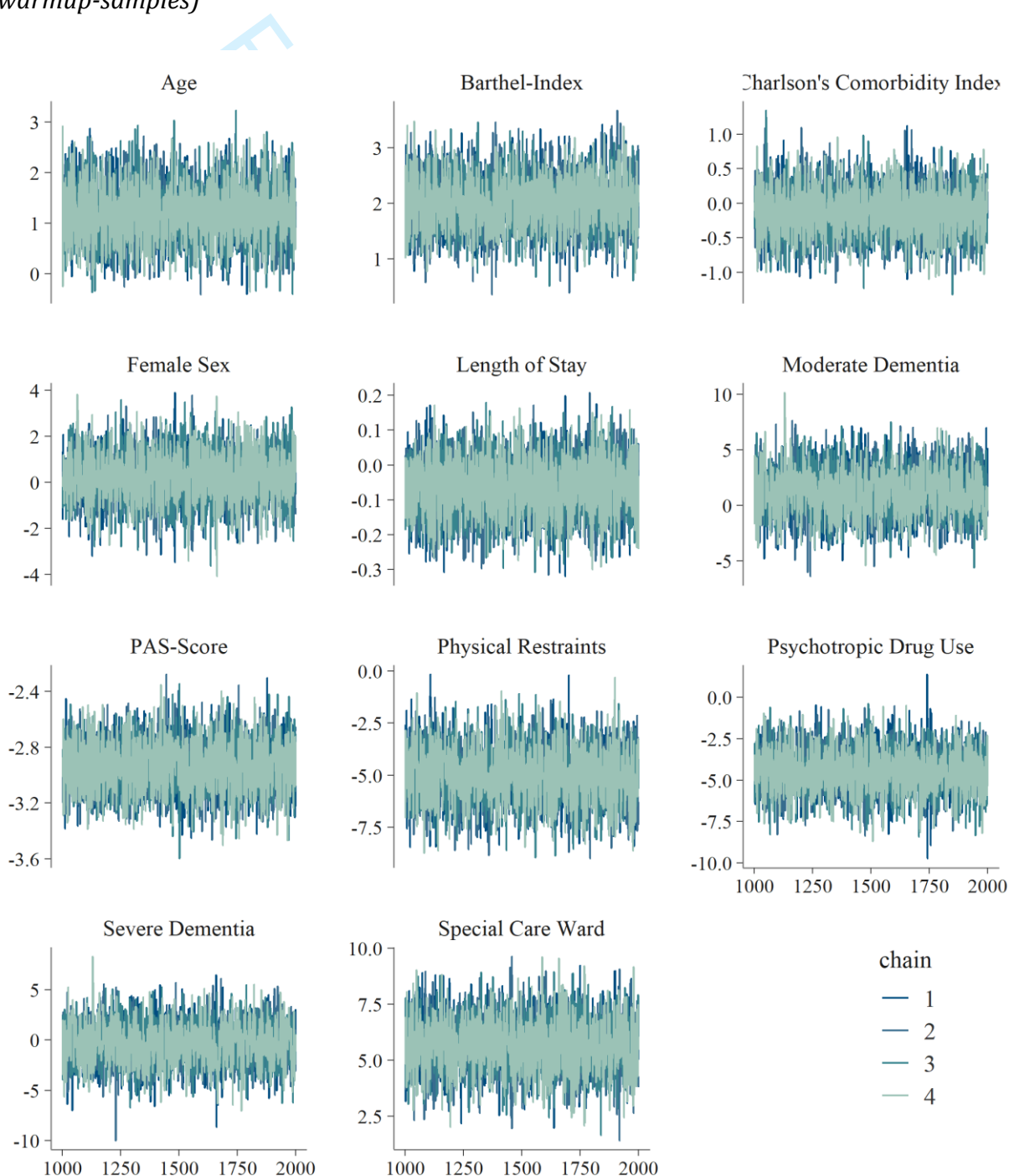


6. Trace plots

A trace plot provides a visual way to inspect sampling the behaviour and can be used, besides the Rhat-statistics, to assess convergence. The desired pattern is a “fat, hairy caterpillar”, which shows no suspicious bends^{4, 5}. If the chains converged to the posterior distribution, we can be confident in our model-based inferences.

The trace plot in Figure S4 indicates that all chains have converged well.

Figure S4: Markov Chain trace plot, 4 chains with 1000 iterations each (excluding warmup-samples)



7. References

1. Gelman A, Carlin JB, Stern HS, Dunson DB, Vehtari A, Rubin DB. Bayesian Data Analysis. Third edition. Boca Raton: CRC Press; 2014: p.24
2. Gelman A, Rubin DB. Inference from Iterative Simulation Using Multiple Sequences. *Statistical Science*. 1992;7(4):457-472. doi:10.1214/ss/1177011136
3. Kruschke JK. Rejecting or Accepting Parameter Values in Bayesian Estimation. *Advances in Methods and Practices in Psychological Science*. 2018; doi: 10.1177/2515245918771304
4. Sorensen T, Hohenstein S, Vasishth S. Bayesian linear mixed models using Stan: A tutorial for psychologists, linguists, and cognitive scientists. *The Quantitative Methods for Psychology*. 2016;12:175–200.
5. Lunn D, Jackson C, Best N, Thomas A, Spiegelhalter D. The BUGS book: a practical introduction to Bayesian analysis. Boca Raton, FL: CRC Press, Taylor & Francis Group; 2013.

Supplemental Material 2

To see if the complexity of patients' needs affect our findings, we calculated regression models with interaction terms between need factors moderated by hospitals. The figures S5 to S8 show the results of the interaction terms. Table S3 shows the coefficients in details. We found no "significant" associations for the interaction terms, concluding that the association between complexity of patients' needs and quality of life is not differing noticeably between the intervention and control group.

Plots were created using the *ggeffects* package in R (Lüdtke D. *ggeffects*: Tidy Data Frames of Marginal Effects from Regression Models. *Journal of Open Source Software*. 2018;3: 772. doi:10.21105/joss.00772).

Figure S5: Interaction between Barthel-Index and Intervention/Control-Group

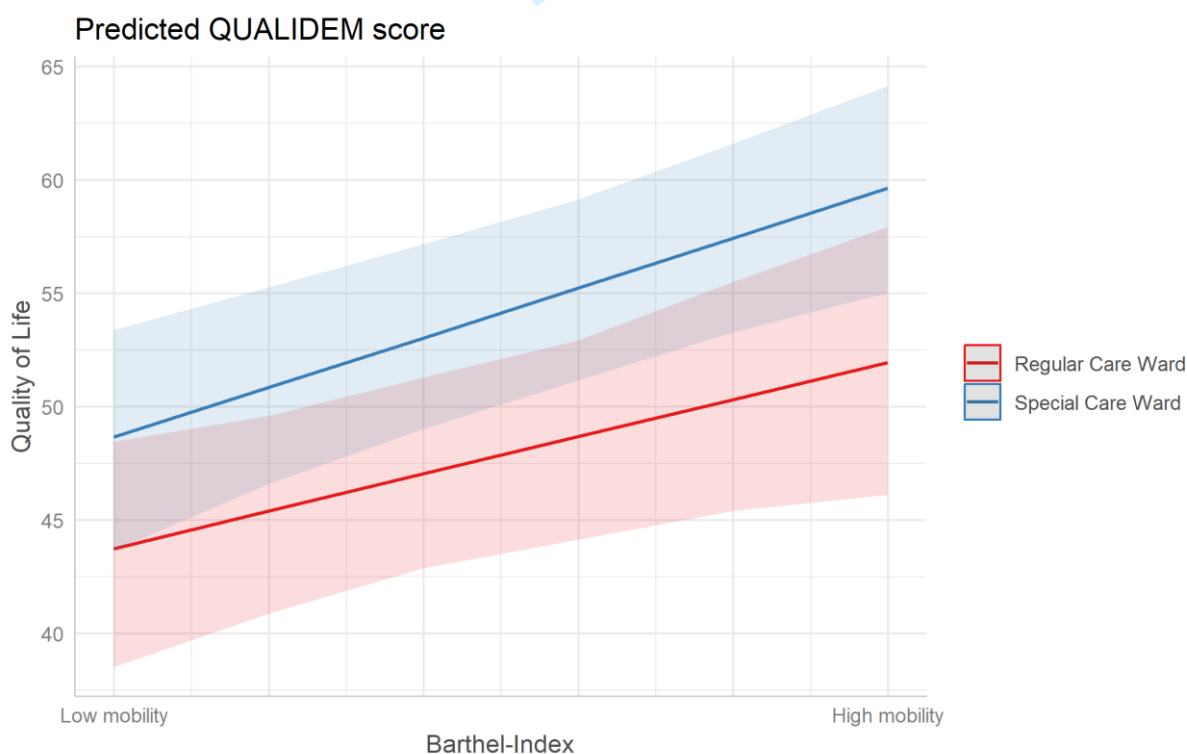


Figure S6: Interaction between Physical Restraints and Intervention/Control-Group

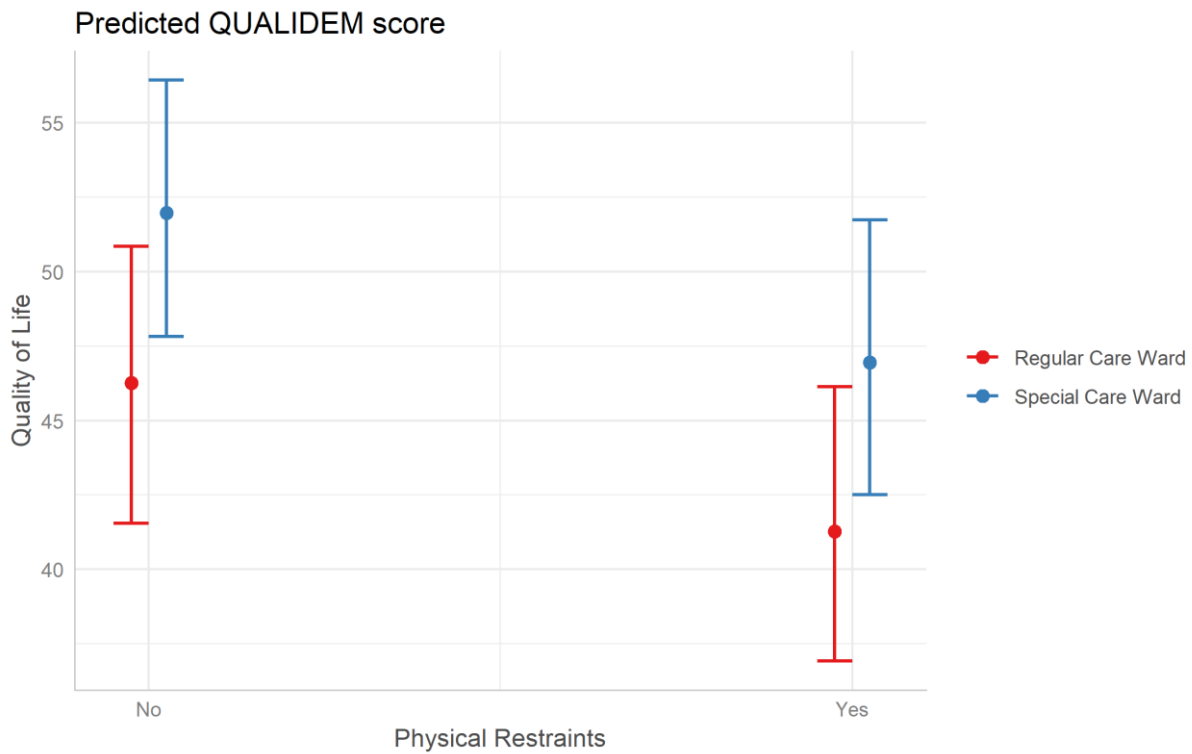


Figure S7: Interaction between PAS and Intervention/Control-Group

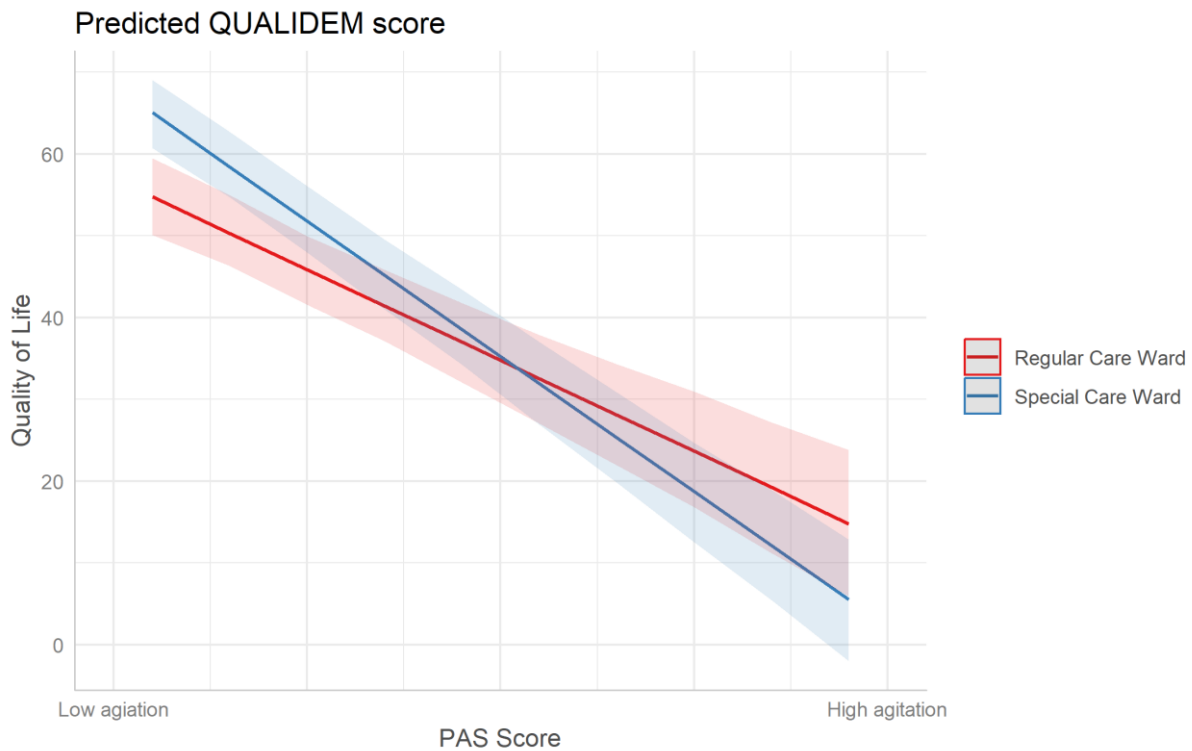
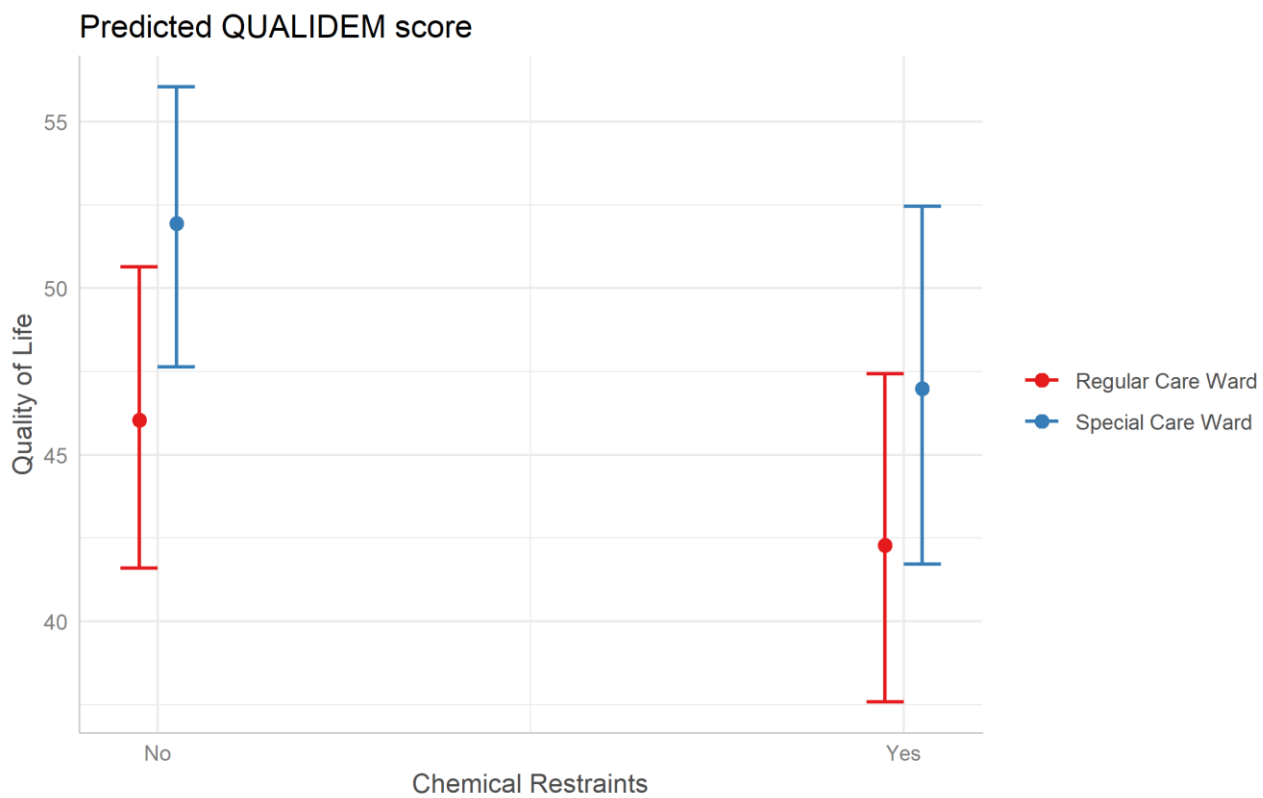


Figure S8: Interaction between Chemical Restraints and Intervention/Control-Group



review only

Table S3: Coefficients for Models with Interaction Terms

Terms	Model: Interaction between Barthel and Hospital		Model: Interaction between Physical Restraints and Hospital		Model: Interaction between PAS and Hospital		Model: Interaction between Chemical Restraints and Hospital	
	Estimates	HDI (95%)	Estimates	HDI (95%)	Estimates	HDI (95%)	Estimates	HDI (95%)
(Intercept)	36.18	26.19 – 45.67	36.31	27.00 – 46.10	36.57	27.11 – 45.71	36.16	26.45 – 45.69
Length of Stay	-0.07	-0.23 – 0.11	-0.06	-0.23 – 0.09	-0.07	-0.23 – 0.10	-0.06	-0.22 – 0.10
Age	0.12	0.01 – 0.23	0.12	0.02 – 0.23	0.12	0.01 – 0.22	0.12	0.02 – 0.23
Moderate Dementia	1.21	-2.79 – 5.13	1.19	-2.72 – 5.24	1.19	-2.83 – 4.72	1.25	-2.95 – 4.89
Severe Dementia	-0.34	-4.30 – 3.70	-0.44	-4.45 – 3.65	-0.74	-4.54 – 3.10	-0.30	-4.45 – 3.59
Female	0.16	-2.06 – 2.29	0.19	-1.98 – 2.29	0.52	-1.53 – 2.70	0.23	-1.76 – 2.53
Charlson's Comorbidity Index	-0.12	-0.81 – 0.59	-0.11	-0.77 – 0.64	-0.11	-0.77 – 0.59	-0.11	-0.82 – 0.59
Barthel Score	1.66	0.27 – 2.99	2.02	1.15 – 2.88	2.07	1.17 – 2.97	2.05	1.13 – 2.98
Physical Restraints (yes)	5.74	3.48 – 7.90	5.76	2.67 – 8.72	5.95	3.64 – 8.18	5.94	3.44 – 8.62
Special Care Ward (Intervention)	-5.02	-7.65 – -2.54	-4.92	-8.57 – -1.11	-4.94	-7.60 – -2.41	-4.96	-7.83 – -2.58
PAS-Score	-2.96	-3.30 – -2.62	-2.94	-3.30 – -2.61	-2.22	-2.77 – -1.66	-2.93	-3.27 – -2.59
Psychotropic Drug Use (yes, as-needed)	-4.43	-7.10 – -1.83	-4.40	-7.08 – -1.87	-4.30	-6.81 – -1.56	-3.76	-7.83 – -0.03
Barthel * Intervention	0.52	-1.00 – 2.06						
Phys. Restr. * Intervention			-0.09	-4.46 – 4.66				
PAS * Intervention					-1.09	-1.76 – -0.42		
Chem. Restr. * Intervention							-1.15	-6.63 – 4.27

Supplemental Material 3 – R Source Code

```

1
2 library(tidyverse)
3 library(gggridges)
4 library(sjmisc)
5 library(sjlabelled)
6 library(sjstats)
7 library(sjPlot)
8 library(brms)
9
10 # Data available at https://doi.org/10.5281/zenodo.1479676
11
12 # load data ----
13 load("Dataset.RData")
14
15 # divide age by 10
16 d$age10 <- d$age / 10
17
18 # Labels for final model ----
19
20 labs <-
21   c(
22     stay_c = "Length of Stay",
23     age = "Age",
24     age10 = "Age",
25     mmse2 = "Moderate Dementia",
26     mmse3 = "Severe Dementia",
27     sex2 = "Female Sex",
28     barthel_code = "Barthel-Index",
29     groupintervention = "Special Care Ward",
30     physres1 = "Physical Restraints",
31     pas_c = "PAS-Score",
32     cci_c = "Charlson's Comorbidity Index",
33     chemicalres1 = "Psychotropic Drug Use", # oder as-needed
34     b_stay_c = "Length of Stay",
35     b_age = "Age",
36     b_age10 = "Age",
37     b_mmse2 = "Moderate Dementia",
38     b_mmse3 = "Severe Dementia",
39     b_sex2 = "Female Sex",
40     b_barthel_code = "Barthel-Index",
41     b_groupintervention = "Special Care Ward",
42     b_physres1 = "Physical Restraints",
43     b_pas_c = "PAS-Score",
44     b_cci_c = "Charlson's Comorbidity Index",
45     b_chemicalres1 = "Psychotropic Drug Use" # oder as-needed
46   )
47
48 # prior-definition in brms ----
49
50 # scale is 2.5 * sd(y) / sd(x)
51
52 bprior <-
53   prior(normal(0, 6), class = "b", coef = "stay_c") +
54   prior(normal(.1554, 40), class = "b", coef = "age10") +
55   prior(normal(0, 42), class = "b", coef = "mmse2") +
56   prior(normal(-.444, 42), class = "b", coef = "mmse3") +
57   prior(normal(-3.219, 42), class = "b", coef = "sex2") +
58   prior(normal(0, 29), class = "b", coef = "barthel_code") +
59   prior(normal(-5, 42), class = "b", coef = "physres1") +
60   prior(normal(0, 42), class = "b", coef = "groupintervention") +
61   prior(normal(0, 13), class = "b", coef = "pas_c") +
62   prior(normal(.2925, 42), class = "b", coef = "chemicalres1") +
63   prior(normal(0, 26.77), class = "b", coef = "cci_c")
64
65 # see:
66 # Beerens HC, Sutcliffe C, Renom-Guiteras A, et al. Quality of Life and
67 # Quality of Care for People With Dementia Receiving Long Term Institutional
68 # Care or Professional Home Care: The European RightTimePlaceCare Study.
69 # Journal of the American Medical Directors Association. 2014;15(1):54-61.
70 # doi:10.1016/j.jamda.2013.09.010

```

```

#
1 # QoL-Scale ranges from 13-52 (40 points). Effects from those study are
2 # multiplied by 2.5 (rescaling 40-points to 100-point-scale of QUALIDEM)
3
4 # see:
5 # Barca, M. L., Engedal, K., Laks, J., & Selbæk, G. (2011). Quality of Life
6 # among Elderly Patients with Dementia in Institutions. Dementia and Geriatric
7 # Cognitive Disorders, 31(6), 435-442. https://doi.org/10.1159/000328969
8
9 # QoL-scale ranges from 11-55 (45 points). Effects from those study are
10 # multiplied by 2.2 (rescaling 45-points to 100-point-scale of QUALIDEM)
11
12 # model formula ----
13 mf <-
14   formula(
15     QoL ~ stay_c + age10 + mmse + sex + cci_c +
16     barthel_code + physres + group + pas_c +
17     chemicalres + (1 | maindiag)
18   )
19
20 # brms-model ----
21 set.seed(1207)
22
23 m2a <- brm(
24   formula = mf,
25   data = d,
26   prior = bprior,
27   sample_prior = TRUE
28 )
29
30 # Figure 3 ----
31 theme_set(theme_sjplot2(base_size = 14, base_family = "serif"))
32
33 p <- plot_model(
34   m2a,
35   title = "",
36   axis.labels = labs,
37   sort.est = T,
38   colors = c("grey30"),
39   axis.title = "Change in QUALIDEM-Score",
40   wrap.title = 100,
41   wrap.labels = 20,
42   width = .2,
43   grid.breaks = 2,
44   size.inner = .1
45 ) +
46   ylab("Change in QUALIDEM Total Score") +
47   theme_sjplot2(base_size = 14, base_family = "serif")
48
49 p_pdf <- p + theme_sjplot2(base_size = 28, base_family = "serif")
50
51 ggsave(
52   filename = "Fig3.tiff", plot = p, width = 170, height = 120, units = "mm",
53   dpi = 300, compression = "lzw"
54 )
55
56 ggsave(
57   filename = "Fig3.pdf", scale = 2, plot = p_pdf, width = 170, height = 120,
58   units = "mm", dpi = 300
59 )
60
61 # Appendix S1: Test for practical equivalence ----
62
63 rope(m2a, rope = c(-6, 6))
64 rope(m2a, rope = c(-7.5, 7.5))
65
66 equi_test(m2a)

```

```

# Appendix S1, Table Regression Coefficients ----
1
2 tab_df(tidy_stan(m2a, prob = c(.5, .89), digits = 1))
3
4 # Appendix S1, Prior Adjustement ----
5
6 ps <- prior_summary(m2a)
7 ps
8
9 # Appendix S1, Figure distribution Posterior Samples ----
10
11 tmp <- m2a %>%
12   as_tibble() %>%
13   select(2:12) %>%
14   gather(key = "predictor", value = "estimate") %>%
15   to_factor(predictor)
16
17 tmp$predictor <- lvl_reorder(tmp$predictor, c(9, 4, 8, 3, 7, 11, 10, 6, 1, 2, 5))
18
19 p2 <- ggplot(tmp, aes(x = estimate, y = predictor)) +
20   geom_vline(xintercept = 0, colour = "grey70", size = .8) +
21   geom_density_ridges2(rel_min_height = 0.001, scale = 2, alpha = .5) +
22   scale_x_continuous(breaks = seq(-8, 8, 2)) +
23   scale_y_discrete(labels = labs) +
24   labs(x = "Change in QUALIDEM-Score", y = NULL) +
25   theme_sjplot2(base_size = 14, base_family = "serif")
26
27 ggsave(filename = "FigS1.tiff", plot = p2, width = 190, height = 120, units = "mm", dpi = 300)
28
29 # Appendix S1, test for practical equivalence ----
30
31 ## Short version
32
33 equi_test(m2a, out = "plot")
34
35 ## More beautiful tweaked version
36
37 tmp.hdi <- hdi(m2a, prob = .95) %>%
38   slice(c(-1, -13))
39
40 tmp2 <- m2a %>%
41   as_tibble() %>%
42   select(2:12) %>%
43   map2_df(tmp.hdi$hdi.low, function(x, y) {
44     x[x < y] <- NA
45     x
46   }) %>%
47   map2_df(tmp.hdi$hdi.high, function(x, y) {
48     x[x > y] <- NA
49     x
50   }) %>%
51   gather(key = "predictor", value = "estimate") %>%
52   to_factor(predictor)
53
54 tmp2$predictor <- lvl_reorder(tmp2$predictor, c(9, 4, 8, 3, 7, 11, 10, 6, 1, 2, 5))
55
56 tmp2$grp <- dplyr::case_when(
57   tmp2$predictor %in% c("b_stay_c", "b_cci_c") ~ "reject",
58   tmp2$predictor %in% c("b_age10", "b_mmse2", "b_mmse3", "b_sex2", "b_barthel_code") ~
59   "undecided",
60   TRUE ~ "accept"
61 )
62
63 p3 <- ggplot(tmp2, aes(x = estimate, y = predictor, fill = grp)) +
64   # rope based on "equi_test(model)".
65   annotate("rect", xmin = -1.7, xmax = 1.7, ymin = 0, ymax = Inf, fill = sjplot_pal(palette =
66   "us")[1], alpha = 0.15) +
67   geom_vline(xintercept = 0, colour = "grey70", size = .8) +
68   geom_density_ridges2(rel_min_height = 0.01, scale = 2, alpha = .4) +
69   scale_x_continuous(breaks = seq(-8, 8, 2)) +
70   scale_y_discrete(labels = labs) +
71   scale_fill_manual(values = sjplot_pal()[c(3, 1, 7)]) +

```

```

1 labs(x = "Change in QUALIDEM-Score", y = NULL, fill = "Acceptance of Parameters") +
2 theme_sjplot2(base_size = 14, base_family = "serif") +
3 theme(
4   legend.title = element_text(size = 13),
5   legend.position = "bottom",
6   axis.line.x = element_line(colour = "grey50"),
7   axis.line.y = element_line(colour = "grey50")
8 )
9
10 ggsave(filename = "FigS2.tiff", plot = p3, width = 190, height = 120, units = "mm", dpi = 300)
11
12 # Appendix S1, Posterior-Prior-Check ----
13 ## Short version
14 plot_model(m2a, type = "diag", axis.lim = c(-20, 20))
15 ## More beautiful tweaked version
16
17 pr_samp <- prior_samples(m2a) %>%
18   select(starts_with("b_")) %>%
19   gather(key = "Term", value = "Estimate") %>%
20   mutate(Sample = "prior")
21
22 ps_samp <- posterior_samples(m2a) %>%
23   select(starts_with("b_"), -b_Intercept) %>%
24   gather(key = "Term", value = "Estimate") %>%
25   mutate(Sample = "posterior")
26
27 m_pp_data <- bind_rows(pr_samp, ps_samp) %>% to_factor(Term)
28 m_pp_data$Term <- lvls_reorder(m_pp_data$Term, rev(c(8, 3, 10, 4, 7, 5, 11, 6, 1, 2, 9)))
29
30 p4 <- ggplot(m_pp_data, aes(x = Estimate, fill = Sample)) +
31   geom_density(alpha = .4) +
32   scale_x_continuous(limits = c(-20, 20)) +
33   facet_wrap(
34     ~ Term,
35     scales = "free",
36     labeller = labeller(Term = labs),
37     nrow = 4
38   ) +
39   labs(x = NULL, y = NULL) +
40   bayesplot::theme_default(base_size = 13) +
41   theme(
42     axis.line.x = element_line(colour = "grey50"),
43     axis.line.y = element_line(colour = "grey50"),
44     axis.text = element_text(colour = "grey10"),
45     axis.title = element_text(colour = "black"),
46     # strip.background = element_rect(colour = "grey50", fill = "grey90"),
47     # strip.text = element_text(colour = "grey20"),
48     legend.title = element_text(colour = "grey10"),
49     legend.text = element_text(colour = "grey20"),
50     legend.position = c(.5, .15),
51     legend.justification = c(-2, 1)
52   ) +
53   scale_fill_manual(values = sjplot_pal("breakfast club")[c(1, 3)])
54
55 ggsave(filename = "FigS3.tiff", plot = p4, width = 190, height = 214, units = "mm", dpi = 300)
56
57 # Appendix S1, Traceplot ----
58
59 p <- rstan::traceplot(m2a$fit, pars = colnames(as.data.frame(m2a))[1:12], inc_warmup = F)
60 p$data$parameter <- as.character(p$data$parameter)
61 tmp <- p$data %>%
62   filter(parameter != "b_Intercept")
63
64 for (i in 1:length(labs)) {
65   if (names(labs)[i] %in% tmp$parameter) {
66     r <- which(tmp$parameter == names(labs)[i])
67     tmp$parameter[r] <- labs[i]
68   }
69 }

```



```
p5 <- ggplot(tmp, aes(x = iteration, y = value, colour = chain)) +
1 geom_line() +
2 facet_wrap(~parameter, scales = "free_y", ncol = 3) +
3 scale_color_manual(values = sjplot_pal("us", n = 4)) +
4 labs(x = NULL, y = NULL) +
5 bayesplot::theme_default(base_size = 13) +
6 theme(
7   axis.line.x       = element_line(colour = "grey50"),
8   axis.line.y       = element_line(colour = "grey50"),
9   axis.text         = element_text(colour = "grey10"),
10  axis.title        = element_text(colour = "black"),
11  # strip.background = element_rect(colour = "grey50", fill = "grey90"),
12  # strip.text       = element_text(colour = "grey20"),
13  legend.title      = element_text(colour = "grey10"),
14  legend.text       = element_text(colour = "grey20"),
15  legend.position   = c(.5, .15),
16  legend.justification = c(-4.2, 0.7)
17 )
18
19 ggsave(filename = "FigS4.tiff", compress = "lzw", plot = p5, width = 190, height = 214, units =
20 "mm", dpi = 300)
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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *case-control studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4-5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	6-7
		(b) For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-10
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10-11
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	10-11
		(b) Describe any methods used to examine subgroups and interactions	10-11
		(c) Explain how missing data were addressed	10
		(d) If applicable, explain how matching of cases and controls was addressed	N/A
		(e) Describe any sensitivity analyses	N/A
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	12
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	12-13
		(b) Indicate number of participants with missing data for each variable of interest	12-13
Outcome data	15*	Report numbers in each exposure category, or summary measures of exposure	12-13
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	13-14
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	15-16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17-18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15-18
Generalisability	21	Discuss the generalisability (external validity) of the study results	18-19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Quality of Life of Patients with Dementia in Acute Hospitals: A non-randomised case-control-study comparing a regular ward to a special care ward with dementia care concept.

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Title

Quality of Life of Patients with Dementia in Acute Hospitals: A non-randomised case-control-study comparing a regular ward to a special care ward with dementia care concept.

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For peer review only

Abstract

Objectives: To identify factors that predict the quality of life (QoL) of patients with dementia in acute hospitals and to analyse if a special care concept can increase the patients' QoL.

Design: A non-randomised case-control-study, including two internal medicine wards from hospitals in Hamburg, Germany.

Setting and Participants: In all, 526 patients with dementia from two hospitals were included in the study (intervention: n=333; control: n=193). Inclusion criteria was an at least mild cognitive impairment or dementia. The intervention group was a hospital with a special care ward for internal medicine focussing on patients with dementia. The control group was from a hospital with a regular care ward without special dementia care concept.

Outcome Measures: Our main outcome was the QoL (range 0-100) from patients with dementia in two different hospitals. A Bayesian multilevel analysis was conducted to identify predictors like age, dementia, agitation, physical and chemical restraints or functional limitations that affect QoL.

Results: QoL differs significantly between the control (40.7) and intervention group (51.2), $p < 0.001$. Regression analysis suggests that physical restraint (estimated effect: -5.0), psychotropic drugs use (-4.4) and agitation (-2.9) are negatively associated with QoL. After controlling for confounders, the positive effect of the special care concept remained (5.7).

Conclusions: A special care ward will improve the quality of care and has a positive impact on the QoL of patients with dementia. Health policies should consider the benefits of special care concepts and develop incentives for hospitals to improve the QoL and quality of care for these patients.

Article Summary

Strengths and Limitations

- This is one of the first studies to investigate quality of life of patients with dementia in acute internal medicine wards in Germany.
- The statistical method applied in this study explicitly incorporates and accounts for information and knowledge from previous research.
- There are no studies which have evaluated the reliability and validity for the use of the assessment instrument for our main outcome (quality of life) in hospitals settings.
- The structural differences between the hospitals from the control and intervention may limit the generalizability of the results regarding the benefit of special care concepts for regular internal medicine wards.

Introduction

Acute hospitals face the challenge of an increase in old-age patients, which particularly affects internal medicine wards [1]. The average age of patients in internal medicine wards is above 70 years and may even come close to 80 years [2,3], leading to an increasing prevalence of cognitive impairments [4]. Although data on the occurrence of dementia or cognitive impairments of patients in hospitals is inconsistent, the larger proportion of studies report prevalence rates of about 40% [5–7].

Many hospitals are insufficiently prepared for patients with cognitive impairments, especially in acute care units predominantly focussing on somatic diseases [8]. Patients with cognitive impairments or dementia do not fit into the typical routines and standardised workflows of hospitals as these patients need more resources for care and treatment [9,10]. These patients often become disoriented, anxious, agitated and challenge hospital staff with erratic behaviour when placed in regular care wards. This results in an increased likelihood of falls, complications during the hospital stay and post-operative complications [11,12]. Hence, patients with dementia are a vulnerable group with a higher risk for long-lasting functional impairments [13,14].

To control the challenging behaviour of patients with dementia, a common practice – at least in German acute hospitals, and especially for older patients – is to use physical restraints like side rails to keep patients in bed, or chemical restraints such as the on-demand-use of psychotropic medication or hypnotics and sedatives [15,16]. This practise is not limited to German hospitals; however, there seems to be large variations between countries [17]. Physical and chemical restraints as well as anxiety and challenging behaviour are associated with poorer outcomes in quality of life [QoL] and quality of care of patients with dementia [18,19]. Therefore, hospitals in general, and specifically internal medicine wards with their increasing proportion of patients with

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3 dementia, need to address these issues in order to improve the quality of care for these
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5 patients.
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8 At least in Germany, there were lately no care concepts that fully address the needs of
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10 patients with dementia in internal medicine [20]. The special care ward “DAVID” in the
11
12 Protestant Hospital Alsterdorf in Hamburg was one of the first internal medicine wards
13
14 in Germany that implemented a comprehensive care concept for patients with dementia,
15
16 aiming to improve the patients’ QoL during their hospital stay. QoL is an important
17
18 indicator of quality of care and a major dimension when assessing patient reported
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20 outcomes, particularly in older people as global outcome measure for interventions
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22 [21,22]. The assumption of this care concept is that a special care ward for patients with
23
24 dementia leads to better outcomes in QoL compared to regular internal medicine wards.
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26 A study (“DAVID 2”) was conducted to investigate the impact of such a care concept. This
27
28 paper shows the results of this study and addresses two research questions. First, which
29
30 factors predict the QoL of patients with dementia in acute hospitals? Second, beyond
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32 these factors, can a special care concept for patients with dementia in acute hospitals
33
34 increase the patients’ QoL?
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43 **Methods**

44 **Study Design and Setting**

45
46 The aim of this study was to compare the quality of care for patients with dementia
47
48 within a specialised dementia care concept as opposed to regular care in acute hospitals.
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50 The present study was designed as a non-randomised case-control-study, including two
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52 internal medicine wards in two hospitals located in Hamburg, Germany. The
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54 intervention group was a hospital that implemented a special care ward for internal
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56 medicine focussing on patients with dementia. The control group was from a hospital
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3 with a regular care ward for internal medicine, which had no special dementia care
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5 concept.
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10 **Intervention Group**

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12 The special care ward “DAVID” is an internal medicine ward in the Protestant Hospital
13 Alsterdorf, a not-for-profit organization, and has 14 beds. In the year of data collection
14 (2016), 349 patients were treated. The ward employed nine care workers as nursing
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16 staff.
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21 Key components of the special care concept are a) a specific architectural design,
22 including a homelike lounge, a specific colouring of doors and walls, and a light concept
23 with minimum 500 lux at eye level; b) doctors, nurses and service staff are trained in
24 coping with challenging behaviour and other dementia related issues, like basal
25 stimulation or validation therapy, but also included case conferences to discuss issues
26 with current patients [23]; duration of training courses and case conferences was about
27 one hour and were provided on a monthly basis by external instructors; additionally,
28 twice per year, an internal training course was offered for employees, lasting for half a
29 day; c) mobile devices for diagnostics, to perform as many treatments as possible in the
30 different rooms of the special care ward; d) involvement of relatives into assessment,
31 care and discharge planning; and e) regular therapeutic offers like occupational or
32 speech therapy, and social offers like music, playing or spending more time than usual to
33 care for the patients.
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52 To fulfil these high standards of quality of care, the ward “DAVID” employs more care
53 staff in relation to the number of patients as compared to other regular internal
54 medicine wards in Germany. With respect to the total number of full-time equivalents
55 [FTE] nurses, the staff-patient-ratio is one FTE nurse per 39 patients.
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3 The Protestant Hospital Alsterdorf has a second ward for internal medicine, however,
4 patients with dementia were usually immediately transferred to the special care ward
5 after admission to hospital. Thus, as almost no patients with dementia were treated in
6 the second internal medicine ward, the control group was taken from another hospital.
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15 **Control Group**

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17 The regular care ward is part of a larger private-company hospital with emergency
18 hospitalisation. It has 80 beds and in the year of data collection, about 3.500 patients
19 were treated in this internal medicine ward. Twenty-six employees worked as care staff
20 in this ward. Trainees sometimes supported the care team. The staff-patient-ratio in the
21 regular care ward is approximately one FTE nurse per 130 patients. However, since the
22 internal medicine ward in this hospital also treats patients from the emergency
23 ambulance, the staff-patient-ratio related to the number of patients who actually stayed
24 longer in hospital (three days and more) is lower. Unfortunately, the hospital
25 management was not willing to provide more detailed information beside the publicly
26 available quality reports, so we cannot quantify the staff-patient-ratio exactly.
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40 The regular care ward had no specific care concept for dementia patients. The care staff
41 was not particularly trained in dementia topics.
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48 **Data collection and participants**

49 An assessment questionnaire was developed to obtain data from patients with dementia.
50 Study nurses were trained in using this assessment questionnaire and then conducted
51 the data collection in both hospitals. Two study nurses were responsible for the special
52 care ward and one for the regular care ward. A pre-test of two months was conducted to
53 test and revise the questionnaire. As a result, some items were removed and instructions
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3 for study nurses were defined more precisely. After the pre-test, data was collected over
4
5 a period of about 12 months (from July 2015 to June 2016 in the special care ward and
6
7 from August 2015 to September 2016 in the regular care ward). To detect small to
8
9 medium effect sizes (Cohen's $d \sim 0.1$ to 0.2), a power analysis was performed prior to
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11 the data collection and yielded a sample size of at least 173 subjects per group. Patients
12
13 were included when they showed at least mild cognitive impairments or memory
14
15 problems. In the special care ward (intervention group) all patients were assessed
16
17 because a diagnosed dementia was a requirement for admission to that hospital. Hence,
18
19 the participation rate for the special care ward was about 94% and excluded only a few
20
21 patients that were not responsive. For the regular care ward (control group), patients
22
23 who already had a diagnosed dementia or cognitive impairments were included in the
24
25 study. A short dementia screening was carried out by the study nurse to assess the
26
27 severity of dementia of patients who had no clarified dementia diagnosis, and to identify
28
29 further patients who qualify for the study [24]. The total sample size for the present
30
31 analysis consists of $N=526$ patients (special care ward: $n=333$; regular care ward:
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33 $n=193$). For both the intervention and control group, patients were excluded from the
34
35 study when they were completely confined to bed due to severe health-related
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37 dependency. As both care wards had no particular selection criteria for patients such as
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39 age, mobility, or the main diagnosis that lead to hospital admission, no further exclusion
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41 criteria for the study were defined.

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43 Prior to the study, a study protocol was developed and submitted to the ethical
44
45 committee of the medical association of Hamburg. The ethical committee approved the
46
47 proposal and attested that the study conforms to ethical and legal requirements
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49 (approval code PV5102). Study participants were not able to give their informed
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51 consent due to their cognitive impairments. However, as data mostly derived from the
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3 hospitals' regular documentation and was completely anonymous, the ethics committee
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5 waived the need of an informed consent.
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10 **Patient and Public involvement**

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12 Patients and the public were not involved in the development of the research question
13
14 nor study design.
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17 **Measures**

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19 *Outcome:* QoL in patients with dementia was assessed using the QUALIDEM [25,26].
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21 After observing patients for about one week (depending on the length of stay), the study
22
23 nurses rated their QoL. QUALIDEM comprises 37 items reflecting nine different
24
25 subdomains of QoL: "care relationship" (7 items, 0-21 points), "positive affect" (6 items,
26
27 0-18 points), "negative affect" (3 items, 0-9 points), "restless and tense behaviour" (3
28
29 items, 0-9 points), "positive self-image" (3 items, 0-9 points), "social relations" (6 items,
30
31 0-18 points), "social isolation" (3 items, 0-9 points), "feeling at home" (4 items, 0-12
32
33 points) and "have something to do" (2 items, 0-6 points). For patients with very severe
34
35 dementia (Minimental State Examination Test [27] [MMSE] < 7), only six of the nine
36
37 subscales apply, where the dimensions "positive self-image", "feeling at home" and "have
38
39 something to do" were omitted. The recommendation is to report descriptive results of
40
41 the QUALIDEM separately for each subscale. For regression analyses, a QoL index was
42
43 calculated by summing up and normalizing the QUALIDEM subscales (six subscales for
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45 patients with very severe dementia, nine subscales for the remaining patients) to a
46
47 range from 0 to 100 points. A higher score indicates better QoL. Due to normalization of
48
49 the QUALIDEM total score for all severities of dementia, all patients' scores are
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51 consistent and comparable [28].
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3 *Independent Variables:* Age, gender, main diagnosis for admission to hospital and length
4 of stay were recorded. Details about the distribution of the main diagnoses among
5 patients and by hospitals are shown in the Supplementary File 1. If a main diagnosis was
6 mentioned no more than one time in both hospital wards, it was recoded into the
7 category “other”. The final variable “main diagnosis” comprised 20 different diagnoses. A
8 modified version of the Charlson’s Comorbidity Index [CCI], which included depression
9 and hypertension as new items, was built based upon the assessment of comorbidities
10 and chronic diseases [29,30]. If patients had no chronic illnesses, the CCI had a score of
11 zero points. Else, higher scores indicated more serious comorbid disease. Shortly after
12 admission to hospital, the study nurses measured functional limitations and cognitive
13 status of patients. Functional limitations in daily living were assessed with the Barthel-
14 Index [31]. This score ranges from 0 (completely dependent) to 100 points (no basic
15 functional limitations) and was recoded according to the classification of the ICD-10 [32]
16 (German adaption) into a score from 1 to 6 points. The Minimental State Examination
17 Test [27] [MMSE] measures the cognitive impairments of patients, ranging from 0 (very
18 strong cognitive impairments) to 30 (very mild or no cognitive impairments) points.
19 This score was recoded into three categories, also based on ICD-10 classification: severe
20 dementia (0-16), moderate dementia (17-23 points) and mild dementia (24-27 points).
21 After about one week of hospital stay, the study nurses rated the patients’ agitation and
22 challenging behaviour and recorded psychotropic drug use (chemical restraint) and
23 physical restraints. Agitation and challenging behaviour of patients was assessed using
24 the Pittsburgh Agitation Scale [PAS] [33] ranging from 0 to 16 points (higher scores
25 indicate stronger agitation).
26 Physical restraints were defined as the use of one the following measures: Side rails to
27 keep a patient in bed, tying a patient to a bed, and use of “therapeutic” chairs that

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3 prevent patients to stand up. The variable was dichotomised, indicating whether
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5 patients (in the course of the hospital stay) were mechanically restrained by at least one
6
7 of these measures or not.
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10 Psychotropic drug use was defined as on-demand-use (“as-needed”) of medication for
11
12 the nervous system by means of the Anatomical Therapeutical Chemical (ATC)
13
14 classification [34] and comprises antipsychotics, anxiolytics, hypnotics/sedatives and
15
16 antidepressants (N05A-C, N06A). Indicated use of psychotropic drugs was defined as
17
18 medications that were prescribed for regular, not on-demand-use and not only given to
19
20 patients in order to control their challenging behaviour. Such use of psychotropic drugs
21
22 was excluded from the analysis. The on-demand-use variable was dichotomised and
23
24 shows whether, during the complete hospital stay, chemical restraints were applied to
25
26 patients or not.
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31 While these variables already cover many different aspects that have an effect on the
32
33 QoL, we decided to add a further predictor as proxy for the intervention to the model.
34
35 Therefore, we included a binary variable with two categories (“control” as reference and
36
37 “intervention”) representing the two hospitals, to estimate the impact of the special care
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39 concept. This should reflect how much of the change in QoL is attributable to the special
40
41 care concept.
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48 **Missing Data**

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50 In total, 11% of individual items across all scales were missing (at random), 6% of
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52 individual items when looking at the QUALIDEM only. The missing data pattern was
53
54 analysed and missing data was imputed using the multivariate imputation by chained
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56 equations method [35], using 11 imputation steps corresponding to the proportion of
57
58 missing data [36]. The method for imputing missing values depends on the variable’s
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3 nature. For continuous variables, predictive mean matching was applied, while logistic
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5 regressions were used for binary variables.
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10 **Statistical Methods**

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12 Descriptive results for the total sample and each hospital are reported. Statistically
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14 significant differences of $p < 0.05$ between the two hospital wards were tested using t-
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16 tests, χ^2 -tests or Mann-Whitney-U-tests, depending on the level of measurement and
17
18 distribution of variables. Differences between the hospitals in the QUALIDEM subscales
19
20 are presented as boxplots, showing the median value and upper and lower quartiles of
21
22 the value distribution.
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24

25
26 As multivariate analysis, a Bayesian linear mixed model was applied to analyse the
27
28 associations between the independent variables and the outcome. Computations were
29
30 based on Stan [37], a probabilistic programming language for specifying Bayesian
31
32 models, using Markov Chain Monte Carlo sampling (in particular, Hamiltonian Monte
33
34 Carlo) [38]. We assume that the patients' main diagnosis is associated with different
35
36 degrees of physical impairments, which affect the QoL. Therefore, the variable 'main
37
38 diagnosis' was used as level-2 unit (*random intercept*) in the multilevel model to control
39
40 for the variation in the outcome. We used informative priors for the predictors age,
41
42 female gender, severe dementia, psychotic drug use and physical restraints, based on
43
44 information from former research [18,39,40]. Weakly informative priors were used for
45
46 the remaining predictors. The prior and posterior distributions of the model are
47
48 summarised in the supplemental material (see Supplementary File 2).
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54 Continuous predictors were centred before entering the model. Age was divided by 10,
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56 so a 1-unit change in the predictor of age reflects a change of 10 years in patients. The
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58 median value of the posterior distribution is used as "Bayesian point estimate", which
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3 minimises the difference of estimates from true values over posterior samples, but there
4 are many other plausible values (the “posterior distribution”) to describe the association
5
6 between predictors and outcome. Hence, 50% and 89% highest density intervals [41]
7
8 [HDI] are shown to indicate the range of most credible values and to reflect the (un-
9
10)certainty of the estimates. The intraclass correlation coefficient [42] was calculated to
11
12 see how much of the proportion of the variance in the outcome can be explained by the
13
14 grouping structure (‘main diagnosis’). We developed post-hoc additional regression
15
16 models with interaction terms for need predictors (Barthel-Index, physical and chemical
17
18 restraints, PAS-Score) to check if the associations between the complexity of patients’
19
20 needs and QoL differ between hospitals. We found no significant interaction terms and
21
22 decided to present the most parsimonious model here and show further results in the
23
24 appendix (see Supplementary File 3).

25
26 All analyses were conducted with the R statistical package [43], including the packages
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28 *mice* [35], *ggplot* [44], *brms* [45] and *sjPlot* [46]. The source code is available in the
29
30 supplemental material (see Supplementary File 4). Data is available online [47].
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41 **Results**

42 **Sample Characteristics**

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44 Table 1 gives an overview of the sample characteristics. The proportion of female to
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46 male patients is similar in both groups. The mean age is 4 years higher in the control
47
48 group. There are also significant group differences in the Barthel-Index indicating higher
49
50 functional impairment in the control group, while the dementia severity was the same in
51
52 both hospitals. Comorbid conditions are slightly higher in the control group. Patients
53
54 stayed 9.4 days in hospital on average and nearly one day longer in the intervention
55
56 group as compared to the control group. Large differences between the two hospitals
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can be seen in the use of medical and physical restraints with significantly less use in the intervention group. Agitation- and QoL-scores also show strong group differences to the disadvantage of the patients in the control group.

In most cases, the distribution of main diagnoses of patients were comparable between the two hospital wards (see Supplemental File 1). Most frequent were pneumonia (13.5% in the intervention group and 11.9% in the control group), a worsening medical condition of patients (8.7% and 7.2%) or exsiccosis (4.8% and 6.7%). Noticeable differences between the two wards were found in urinary tract infections (UTI) (9.9% in the intervention group and 3.1% in the control group) or dyspnoea (1.2% and 7.8%).

Table 1: Sample Characteristics

Characteristic	Control Group (Regular Care Ward, n=193)	Intervention Group (Special Care Ward, n=333)	Total (N=526)	p-value of difference
Female, %	59.1	61.6	60.6	.637
Mean Age (SD)	83.1 (7.2)	79.0 (11.9)	80.5 (10.6)	<.001
Mean Barthel-Index (SD)	29.9 (27.9)	40.7 (30.4)	36.7 (29.9)	<.001
Mild Dementia, %	7.8	9.6	8.9	.580
Moderate Dementia, %	30.0	26.7	27.9	.473
Severe Dementia, %	62.2	63.7	63.2	.805
Mean Length of Stay, in Days (SD)	8.9 (7.5)	9.7 (5.5)	9.4 (6.3)	.002
Physical Restraints (yes), %	54.4	28.2	37.8	<.001
Psychotropic Drug Use (yes, as-needed), %	25.9	14.1	18.4	.001
Mean-Score Pittsburg Agitation Scale (SD)	3.9 (3.1)	3.0 (3.2)	3.3 (3.2)	<.001
Mean Charlson' Comorbidity Index (SD)	3.2 (3.0)	2.5 (2.0)	2.8 (1.6)	<.001
Mean Qualidem Total Score (SD)	40.7 (14.5)	51.2 (17.2)	47.3 (17.0)	<.001

Barthel-Index: 0-100 (higher = better functioning); Dementia (MMSE score): mild: 24-27; moderate: 17-23; severe: <= 16; Pittsburg Agitation Scale: 0-16 (higher = stronger agitation and anxiety); Charlson' Comorbidity Index: 0-9 (higher = more comorbidities); QUALIDEM: 0-100 (higher = better QoL)

Quality of life

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3 Looking at the QoL for patients with severe to mild cognitive impairments (these are the
4 ones, in which all subdomains of the QUALIDEM could be applied), there is a consistent
5 pattern across all QUALIDEM-domains: Patients in the control group have a lower QoL
6 compared to the intervention group. Except for the last subdomain ('having something
7 to do'), all differences are statistically significant (Figure 1).
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17 The same consistent pattern can be found for patients with very severe dementia
18 symptoms (MMSE score < 7). Here, only the second of the six applied subdomains
19 ('positive affect') does not differ significantly between intervention and control (Figure
20 2).
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29 **Predictors of quality of life**

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31 Figure 3 shows the results from the Bayesian mixed model. Three predictors are clearly
32 negatively associated with QoL: physical restraint, psychotropic drug use and agitation
33 (PAS-score). Physical restraint is associated with a 4.9-point decrease in QoL. With 50%
34 probability, the QoL decreases by 4.1 to 5.8 points and with a chance of 89% by -7 to -2.8
35 points respectively. The application of psychotropic drugs as-needed shows similar
36 results, with a posterior median of -4.4. The third clearly negative associated predictor is
37 agitation, which shows a decrease in QoL of about 2.9 points for each additional point in
38 the PAS-score.
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49 Dementia and gender are not clearly associated with QoL. Neither are the length of
50 hospital stay and the CCI.
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54 The age of the patient correlates slightly positive with QoL, where an increase of 10
55 years means an increase of about 1.2 points in the QoL. The posterior median of the
56 Barthel-Index is 2.0, so for a one-category change in functional impairments the QoL
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3 changes by two points. This means that patients with severe functional impairments
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5 differ by about 10 points in QoL compared to patients with no functional impairments.
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7 Controlling for all other predictors, the intervention (special care ward) shows the
8
9 strongest association with our outcome of interest, the patients' QoL. The posterior
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11 median is 5.7, and with an 89% probability, the credible values describing the effect of
12
13 the intervention on QoL are within the range from 3.8 to 7.6.
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16
17 The intraclass correlation coefficient of the model is rather low (0.01). This means, the
18
19 'main diagnosis' does not explain much of the variance in the patients' QoL and there is
20
21 almost no regularization ("shrinkage") of estimated model parameters and no larger
22
23 differences between hospitals according to the patients' needs, as indicated by their
24
25 main diagnosis.
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31 **Discussion**

32
33 The study reported in this paper sought to understand those factors that influence the
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35 QoL in patients with dementia and whether a special care concept for these patients
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37 performs better in this regard as opposed to regular care wards.
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41 One of our main findings is that QoL differs significantly between the control and
42
43 intervention group. We found substantial differences between the two hospitals in the
44
45 patients' total QoL score in favour of the special care ward. Beyond the statistical
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47 significance, this finding also has a clinical impact. Studies suggest a change in 3 points
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49 for the Quality of Life – Alzheimer's Disease Scale [48], which has a range of 40 points, to
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51 be clinically relevant [49,50]. Transferred to the range of the QUALIDEM scale, a
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53 difference of about 7.5 points would be considered as an important improvement in
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55 QoL. Another indicator to evaluate the clinical relevance of a change in QoL is an
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57 increase of the score of half a standard deviation [51], which would be about 8.5 points
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3 for our data. Taking these reference points as a basis, we found evidence for the clinical
4 relevant improvement in QoL of patients in a special care ward.
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8 A second key finding is the identification of those factors that are clearly associated with
9
10 QoL. The use of physical and chemical restraints, both happening more frequently in the
11 control group, are associated with lower outcomes in QoL. This finding is in line with
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13 other studies that suggest a negative association between physical and chemical
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15 restraints and QoL [18,40] and explains why the regular care ward performs less good in
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17 this regard than the special care ward. Agitation was also negatively associated with
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19 QoL. This is understandable as agitation is an expression of anxiety and indisposition of
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21 people with dementia and typically occurs after admission to hospital. Furthermore,
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23 agitation is often a reason for psychotropic drug use or physical restraint and, thus, also
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25 negatively affects QoL [52,53]. Independent from these factors, the special care ward
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27 itself shows the strongest impact on QoL, indicating that patients with dementia
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29 explicitly benefit from specialised care concepts. Other studies also report these
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31 benefits, both in a nursing home or hospital setting [54,55]. Since we controlled for
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33 patient characteristics like main diagnosis, age, functional limitations, chronic
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35 comorbidities, agitation, length of stay etc. in our model, we do not assume that the
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37 positive effect of the special care ward is completely a result of a biased sample between
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39 intervention and control group. Although the two compared hospitals differ in their
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41 structures and size, patients' characteristics are largely comparable between the
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43 samples in the control and intervention group. For instance, there is no substantial
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45 difference between the two hospitals regarding the relationship between functional
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47 impairments and physical restraints. Moreover, to see if the complexity of patients' need
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49 affects our findings, we calculated regression models with interaction terms between
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51 need factors moderated by hospitals (see Supplementary File 3). The association
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3 between complexity of needs and QoL is not significantly different between the
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5 intervention and control group. Based on our results we suggest that the special care
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7 concept mainly explains the differences in the QoL. Although it is certainly difficult to
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9 determine the exact effect of the special care concept on the patients' QoL, our findings
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11 seem plausible in the light of the key elements of this intervention. A higher ratio of care
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13 staff as to patients, smaller facilities or systematically trained employees can be
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15 considered essential for health care provision to patients with dementia and are much
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17 better conditions for less physical or chemical restraints, independent of the functional
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19 limitations of patients. The special care ward provides a more dementia-friendly interior
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21 design, including orientation and navigation aids and the use of light and colours, which
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23 are considered as important components to reduce agitation for patients with dementia
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25 [56]. These findings and conclusions are in line with other studies on hospital care that
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27 suggest that an increased staff ratio or the implementation of multiple components,
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29 which particularly address the needs of patients with dementia, lead to reduced use of
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31 physical restraints and psychotropic drug use and improve the quality of care [57,58].
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33 Furthermore, dementia-specific educational programmes, as implemented in the special
34
35 care ward, have positive effects on nurses regarding their interaction with patients with
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37 dementia. Trained nurses can improve their coping skills in handling challenging
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39 behaviour of these patients, and better attend to the patients' unmet physical and
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41 psychological needs [59]. Studies suggest that the use of both physical and chemical
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43 restraints is reduced for nurses who completed a dementia-specific training as opposed
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45 to nurses who did not complete such an educational programme. Trained nurses had
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47 better skills in providing patient-centred care and thus improving the QoL for patients
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49 with dementia [59–61]. The special care ward benefits from a higher staff ratio, i.e.
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51 nurses have to care for fewer patients with dementia compared to the control group.
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3 While this is an intentional element of the concept, the downside is higher personnel
4 costs. Only few studies investigated the follow-up costs for patients with dementia in
5 home care settings after hospitalization. Costa et al. predicted additional monthly costs
6 in home care of about 445 Euros due to increased agitation of patients with dementia
7 [62]. Thus, if patients with dementia benefit from special care concepts and perceive
8 better outcomes in quality of life and care, the increased costs for more care personnel
9 may be compensated by reducing follow-up costs for the ambulatory care. However,
10 further research is needed to give more exact projections of the increased costs and
11 potential of saving money.
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24 Another finding is that the severity of cognitive impairments, measured with the MMSE,
25 is a rather improper indicator to represent the underlying problems of and with the
26 dementia disease, as these factors were not consistently associated with QoL. Direct
27 measures of the problems associated with dementia, as agitation or challenging
28 behaviour, should be considered as well when it comes to investigate the QoL of patients
29 with dementia.
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38 Our study has several limitations. One concerns the structural differences between the
39 two hospitals. The hospital with the special care ward is much smaller than the hospital
40 that hosted the control group. A second control group or an intervention group in a
41 hospital of a similar size as the hospital with the regular care ward may have permitted
42 a more distinct comparison. We tried to keep the impact of the structural differences as
43 minimal as possible, for instance by accounting for many different patient
44 characteristics including functional status, comorbidities and behavioural problems.
45 Furthermore, the main diagnoses of patients were also considered in the analysis. We
46 assume that we could at least partly adjust our analysis for a bias due to patient
47 selection mechanisms. To validate our assumptions, we investigated to which extent the
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3 association between patient characteristics and QoL is affected by differences between
4 the control and intervention group (details shown in Supplementary File 3). Results
5 suggest that our data provides no strong evidence for noticeably differences between
6 the intervention and control group regarding the association between complexity of
7 patients' needs and QoL. However, although we adjusted our analysis for many patient
8 characteristics, we cannot eliminate a potential bias due to different hospital structures.
9
10 In particular, the higher mean age and stronger functional limitations in the control
11 group may indicate a selection bias in our sample. We suggest that further studies
12 should take a second control group or a more comparable intervention group into
13 account to gain more insight into potential biases due to structural differences of the
14 control and intervention group. Another structural difference between the intervention
15 and control group that certainly affects the results are the different staff-patient-ratios.
16
17 In the special care ward, nurses have to care for fewer patients than in the regular care
18 ward. Although we assume that this aspect probably has the highest impact on the
19 outcomes in QoL, this is not a "selection bias" per se rather than a core component of the
20 intervention. A higher staff-patient-ratio, dementia-specific training programmes, or a
21 specific architectural design are key elements of the special care concept, which, in
22 their entirety, are reflected in the resulting differences between hospitals. A further
23 limitation is possibly the first and thus rather exploratory use of the QUALIDEM
24 assessment in a hospital setting. Although studies show reliable results of the
25 QUALIDEM in nursing homes even for a short observation period of about one week
26 [63], there are no studies that evaluate the reliability and validity for use in hospitals.
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28 We have done checks of internal consistencies, which showed that most subdomains of
29 the QUALIDEM perform well with our data and are comparable to results from other
30 validation studies [64]. This indicates that the use of the QUALIDEM is feasible for
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3 hospital research. However, due to financial and logistic limitations, it was not possible
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5 to monitor the complete data collection and accurate completion of questionnaires.
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7 Hence, we cannot give evidence on the interrater reliability apart from the intense
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9 training of the study nurses. Finally, due to the nature of the study design, it was not
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11 possible that study nurses in the intervention and control group were blinded. This
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13 might affect the results insofar as study nurses may have generated more generous
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15 responses for the assessment scales [65].
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22 **Conclusions**

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24 On the whole, we think that a special care ward will improve the quality of care and is
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26 effective regarding the positive impact on the QoL of patients with dementia. Our study
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28 showed that after controlling for different predictors, the intervention still has a
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30 perceptible effect concerning clinical important differences in our outcome of interest,
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32 the patients' quality of life. However, such improvements can only be achieved by
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34 implementing a concept with multiple components that address the explicit needs of
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36 patients with dementia. The implementation of a special care concept usually increases
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38 the costs for hospitals because it requires a higher staff-patient-ratio, regular training of
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40 employees or more therapeutic offers. On the other hand, costs that accumulate in
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42 informal care after hospital stay as a result of poorer quality of care in hospitals can be
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44 much higher than additional personnel costs and could probably be reduced [62,66].
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50 Health policies should consider the benefits of special care concepts and develop
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52 incentives for hospitals to improve the QoL and quality of care for patients with
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54 dementia.
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For peer review only

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Author Contributions

DL was involved in conception and design of the study, analysis and interpretation of data and drafting the article. GP was involved in conception and design of the study and interpretation of data. JK was involved in interpretation of data and drafting the article. CK was involved in conception and design of the study, interpretation of data and drafting the article.

Competing interests

The authors have declared that no competing interests exist.

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Ethics approval and consent to participate

Prior to the study, a study protocol was developed and submitted to the ethical committee of the medical association of Hamburg ("Ethik-Kommission der Ärztekammer Hamburg"). The IRB of the ethical committee approved the proposal and attested that the study conforms to ethical and legal requirements (approval code PV5102). Study participants were not able to give their informed consent due to their cognitive impairments. However, as data mostly derived from the hospitals' regular documentation and was completely anonymous, the IRB of the ethics committee waived the need of an informed consent.

Availability of data and material

All data generated or analysed during this study are licensed under CC BY-NC 4.0 and available in the Zenodo repository (DOI: 10.5281/zenodo.1479677) at <https://doi.org/10.5281/zenodo.1479676>.

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- 39 66 Leon J, Cheng CK, Neumann PJ. Alzheimer’s disease care: costs and potential savings.
40 *Health Aff Proj Hope* 1998;**17**:206–16.
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Figure Titles and Legends

Figure 1: QUALIDEM subdomain scores by care ward in patients with mild to severe dementia (MMSE score from 7 to 27, n = 400)

Figure 2: QUALIDEM subdomain scores by care ward, patients with very severe dementia (MMSE score < 7, n = 126)

Figure 3: Predictors of Health Related Quality of Life, Regression Coefficients, Bayesian Linear Mixed Model, Posterior Median (+50% and 89% High Density Interval)

Supplementary Files

Supplementary File 1: Figure, Distribution of Patients' Main Diagnosis by Hospital

Supplementary File 2: Methodological comments, Word document (docx-format).

Supplementary File 3: Regression Models with Interaction Terms, Word document (docx-format).

Supplementary File 4: R Source Code (to use with R statistics, CC BY-NC 4.0 license)

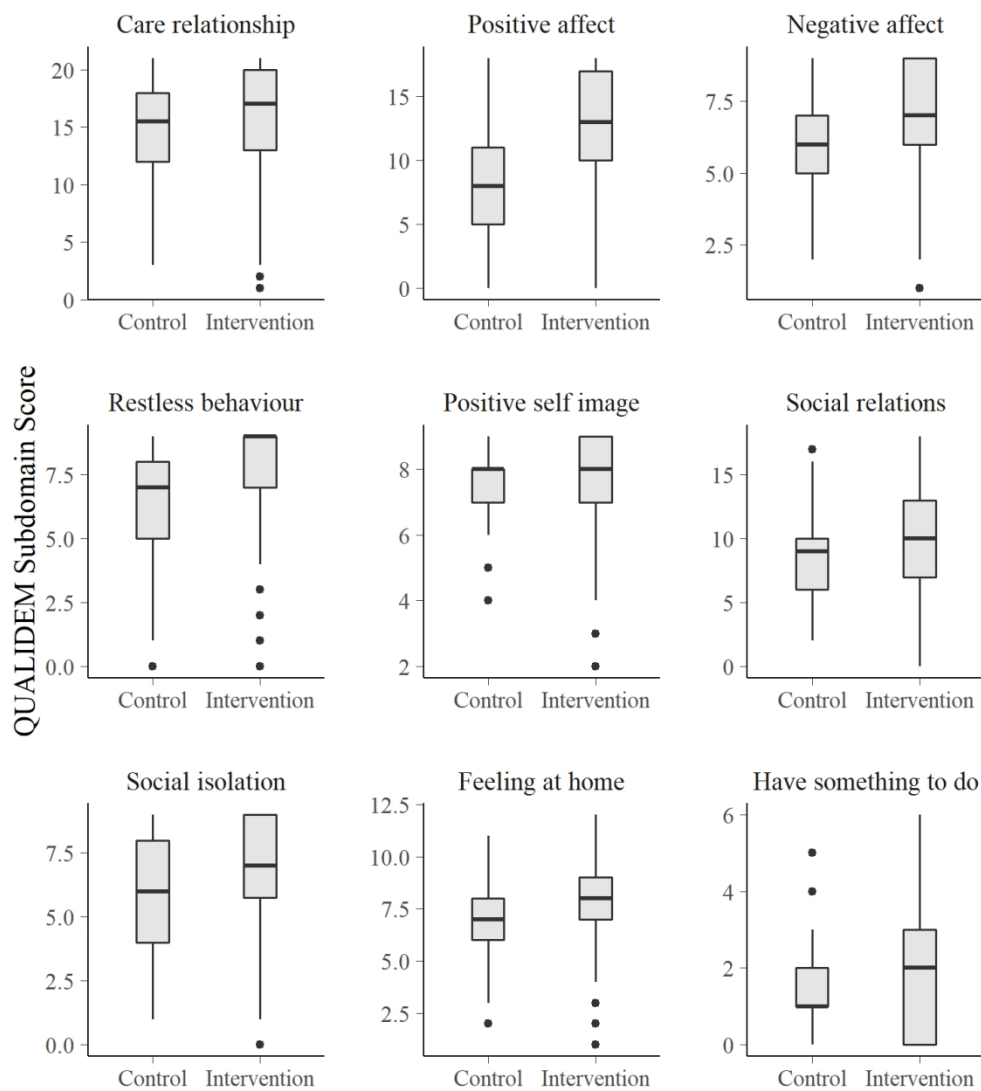


Figure 1: QUALIDEM subdomain scores by care ward in patients with mild to severe dementia (MMSE score from 7 to 27, n = 400)

169x189mm (220 x 220 DPI)

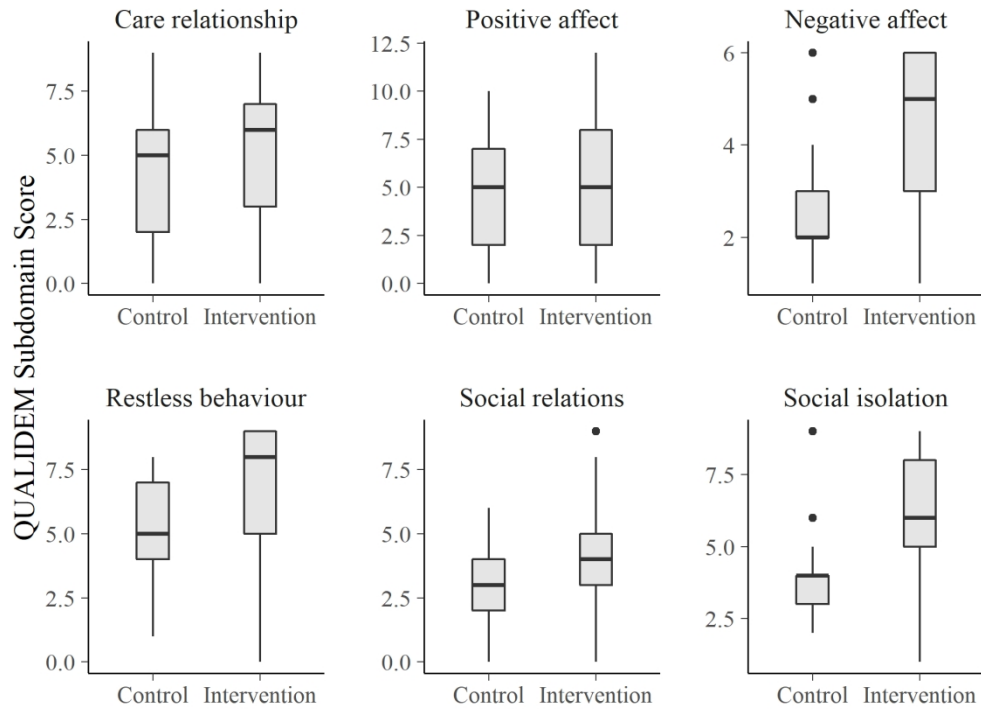


Figure 2: QUALIDEM subdomain scores by care ward, patients with very severe dementia (MMSE score < 7, n = 126)

169x125mm (300 x 300 DPI)

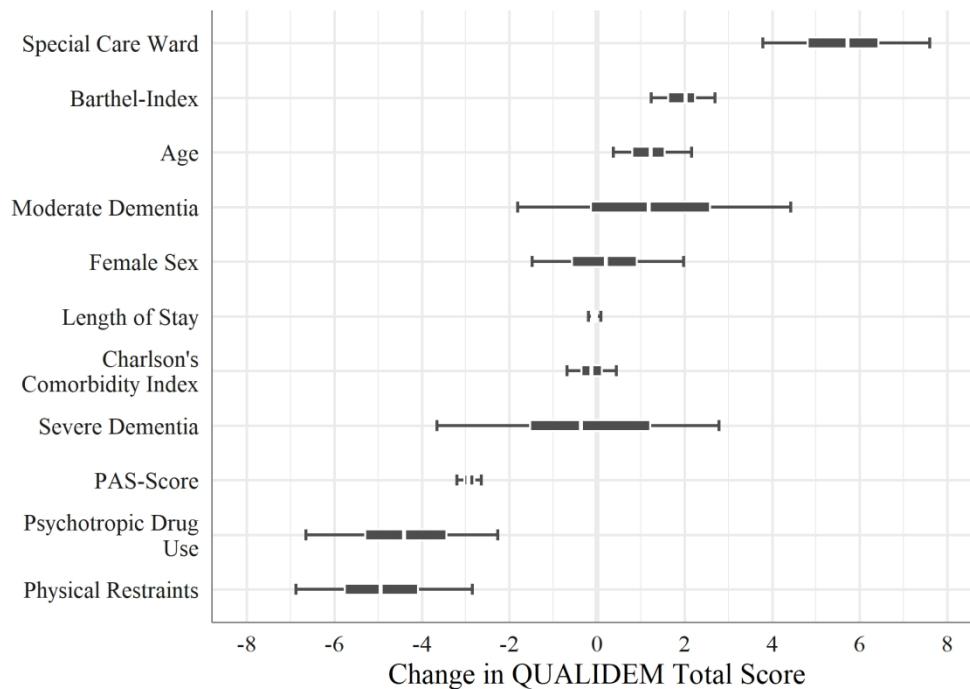
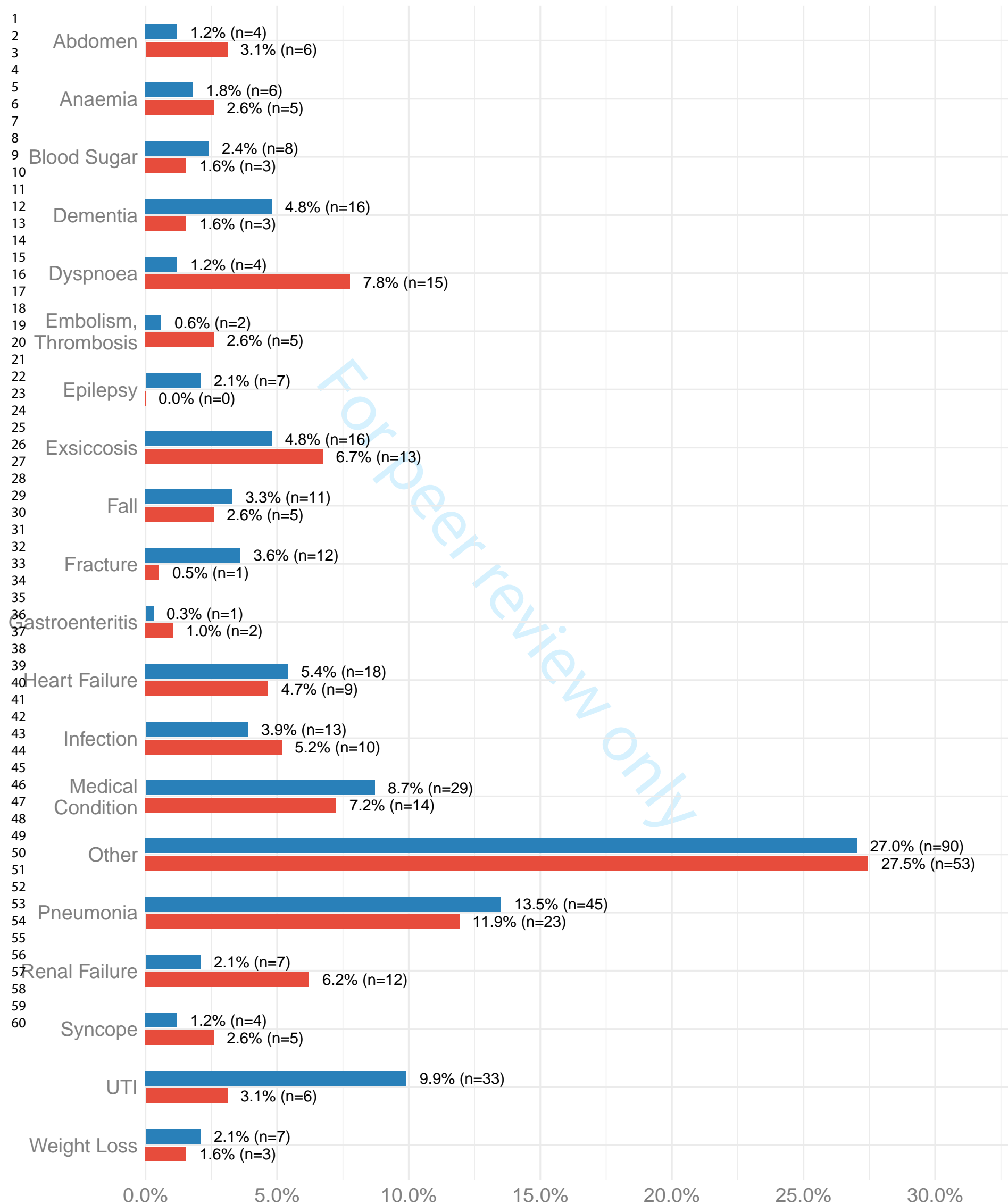


Figure 3: Predictors of Health Related Quality of Life, Regression Coefficients, Bayesian Linear Mixed Model, Posterior Median (+50% and 89% High Density Interval)

169x119mm (300 x 300 DPI)

Main Diagnosis by Hospital Ward



Supplemental Material 2

Quality of Life of Patients with Dementia in Acute Hospitals: Comparing a regular ward to a special care ward with dementia care concept. A Bayesian Multilevel Model Analysis.

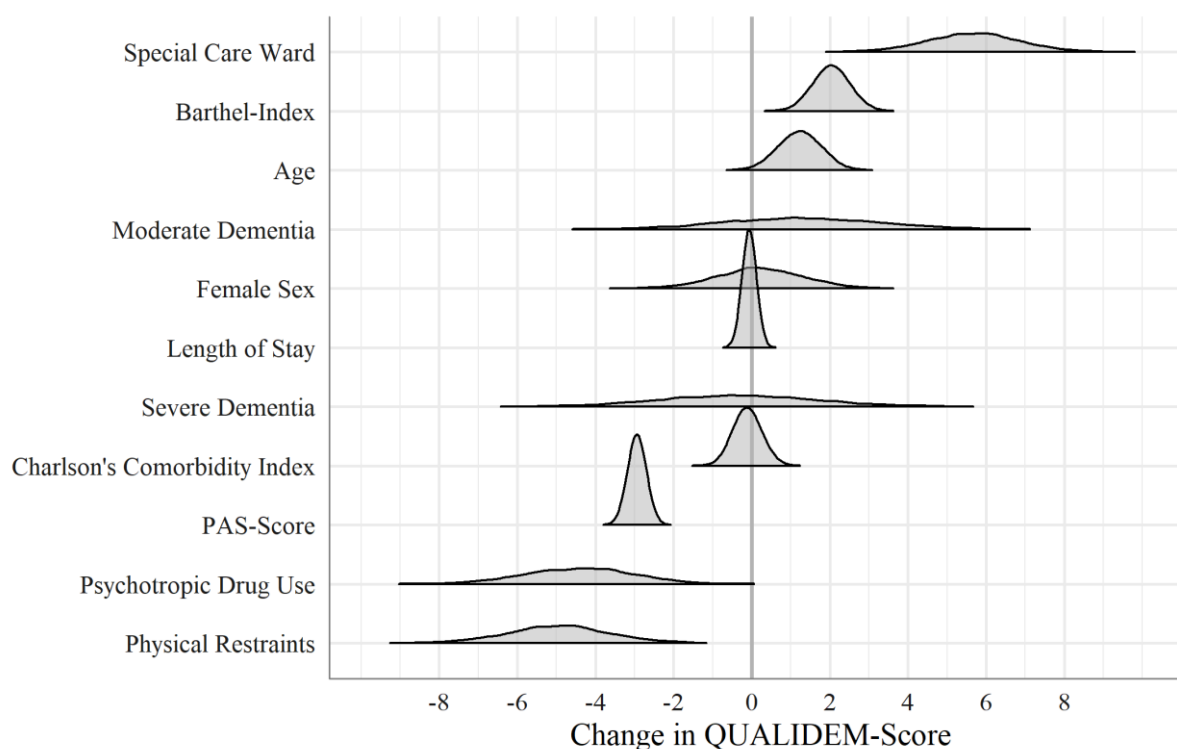
Methodological comments

1. Short note on Bayesian Methods

Bayesian methods are probably not very common, and readers may ask “Why use Bayesian regression models?” Gelman et al.¹ give a well summarized answer to this question: “A pragmatic rationale for the use of Bayesian methods is the inherent flexibility introduced by their incorporation of multiple levels of randomness and the resultant ability to combine information from different sources, while incorporating all reasonable sources of uncertainty in inferential summaries. Such methods naturally lead to smoothed estimates in complicated data structures and consequently have the ability to obtain better real-world answers.”¹. Shortly speaking, advantages of Bayesian methods are, for instance, the ability to derive probability statements for every quantity of interest or explicitly incorporate prior knowledge about parameters into the model.

2. Distribution of Posterior Samples from the Regression Model

Contrary to a frequentist approach, there is no unique point estimate in Bayesian analysis. The posterior median minimises the expected absolute error (i.e. the difference of estimates from true values over posterior samples), but there are many other plausible values to describe the association between predictors and outcome, which is called the *distribution of posterior samples*. Credible or Highest Density Intervals are based on quantiles of this distribution and indicate the probability of an estimate being inside this interval. In terms of inference, this allows us to say that with, e.g. 50% probability, the true effect of a *Special Care Ward* on our outcome lies between 5.1 and 6.6. Figure S1 shows the distribution of posterior samples from our regression model.

Figure S1: Distribution of Posterior Samples from Regression Model

3. Tabular Summary from the Regression Model

Table S1 provides a summary of the regression model, including the data for two different Highest Density Intervals as well as the ratio of effective number of samples. The ratio should be 1.0 or close to 1.0 and indicates whether the samples were efficient, which means that the results for the related coefficient are reliable. Furthermore, all R_{hat} values of the models were approximately 1. The R_{hat} statistic² measures the ratio of the average variance of the draws within each chain to the variance of the pooled draws across chains. If the chains have not converged to a common distribution, the R_{hat} statistic will tend to be greater than one, indicating that more iterations may be required for reliable results.

Table S1: Predictors of Quality of Life, Regression Coefficients, Bayesian Linear Mixed Model, Posterior Median (+50% and 89% Highest Density Intervals)

Term	Estimate	SE	50% HDI	89% HDI	Ratio of effective Number of Samples
(Intercept)	46.2	2.2	45.2 – 48.2	42.7 – 49.8	1.00
Length of Stay	-0.1	0.1	-0.1 – 0.0	-0.2 – 0.1	1.00
Age	1.2	0.5	0.8 – 1.5	0.4 – 2.1	1.00
Moderate Dementia	1.2	2.0	-0.1 – 2.7	-1.8 – 4.6	1.00
Severe Dementia	-0.4	2.0	-1.6 – 1.1	-3.6 – 2.7	1.00
Female	0.2	1.1	-0.5 – 1.0	-1.6 – 1.9	1.00
Barthel Score	2.0	0.5	1.8 – 2.4	1.3 – 2.8	1.00
Physical Restraints (yes)	-4.9	1.2	-5.8 – -4.1	-7.0 – -2.8	1.00
Special Care Ward (Intervention)	5.7	1.2	4.9 – 6.5	3.8 – 7.6	1.00
PAS-Score	-2.9	0.2	-3.1 – -2.8	-3.2 – -2.7	1.00
Charlson's Comorbidity Index	-0.1	0.3	-0.4 – 0.1	-0.6 – 0.5	1.00
Psychotropic Drug Use (yes, as-needed)	-4.4	1.4	-5.3 – -3.5	-6.5 – -2.1	1.00
sigma	11.9	0.4	11.5 – 12.0	11.3 – 12.5	1.00

All Rhat values ~ 1 , all mcse < 0.05 . Results based on 4 chains each 1000 iterations for each chain. LOO-adjusted R^2 : 0.500

4. Test for Practical Equivalence of Parameters

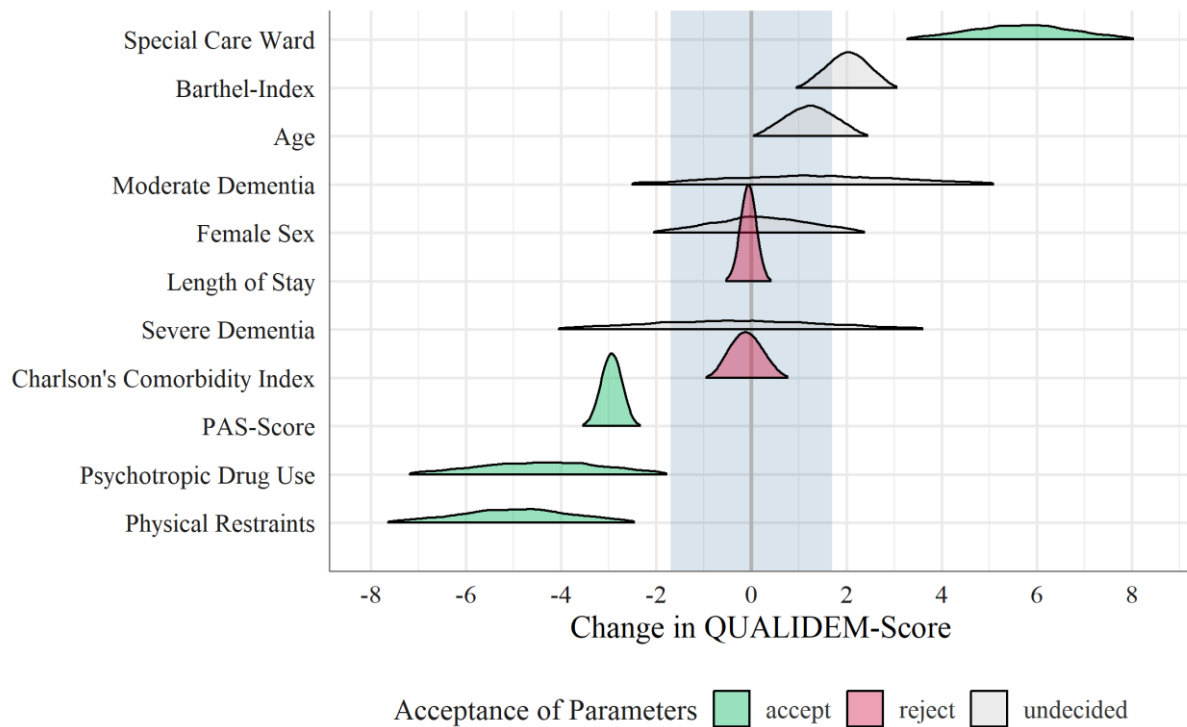
Bayesian methods do not perform classical “null hypothesis significance tests”. Rather, to account for the uncertainty in estimation and the magnitude of parameter values, Kruschke³ suggests checking whether parameter values lie inside a certain range that is considered as “practically no effect”.

Figure S2 shows the distribution of the 95% Highest Density Intervals of posterior samples and indicates whether these lie completely outside, completely inside or partially inside the region of practical equivalence (ROPE). If the HDI is completely outside the ROPE, the “null hypothesis” for this parameter is “rejected”. If the ROPE completely covers the HDI, i.e. all most credible values of a parameter are inside the region of practical equivalence, the null hypothesis is accepted. Else, it is undecided whether to accept or reject the null hypothesis.

The ROPE limits are specified following Kruschke's suggestion, which is defined as $0 \pm SD(\text{dependent variable}) * 0.1$ for linear models.

Physical restraint, psychotropic drug use, agitation (PAS-score) and the intervention (special care ward) are those predictors that can be considered as relevant for our outcome.

Figure S2: 95%-Range of the Distribution of Posterior Samples from Regression Model; Region of Practical Equivalence emphasized in light-blue.



5. Summary of the Distribution of Prior and Posterior Samples

Bayesian regression models can incorporate prior information about the parameters. Informative or weakly informative priors have the advantage of regularization of parameters to rule out large effects. This leads to less biased results and reductions of outliers in situations where the sample size in general, or for certain groups in the data, is small. Where we found information about our parameters, we included it by specifying *informative priors*. For instance, studies suggest that physical restraints are, on average, associated with an about 5-point reduction in quality of life, so the *location* of the prior distribution of our parameter physical restraint is at -5.0 (see Table S2). *Weakly informative priors* simply have a location of zero.

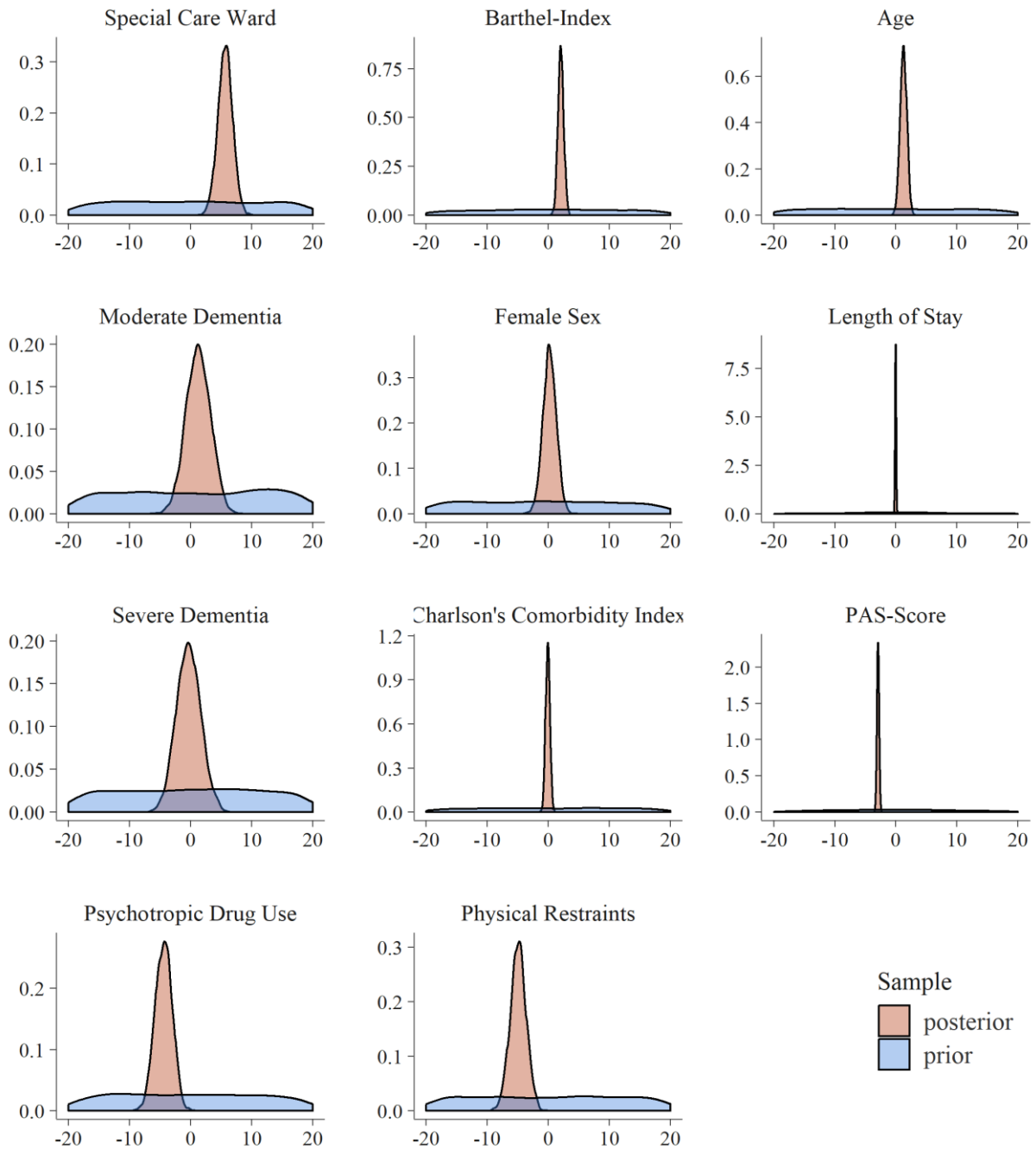
Table S2: Prior Summary

Predictor	Location	Scale
Length of Stay	0.00	6
Age	0.16	40
Moderate dementia	0.00	42
Severe dementia	-0.44	42
Sex, female	-3.22	42
Barthel-Score	0.00	29
Physical restraints	-5.00	42
Special Care Ward	0.00	42
PAS-Score	0.00	13
Charlson's Comorbidity Index	0.00	27
Psychotic Drug Use	0.29	42

To prevent a too strong shrinkage of uncertainty, the *scale* of the prior distribution should be large enough. If no assumptions about the scale of the effect are made, a recommended way (for normally distributed priors) is to use a scale of 2.5 and adjust it by dividing the scale by the standard deviation of the related predictor and multiply it with the standard deviation of the outcome ($2.5 * SD(y) / SD(x)$, see <https://cran.r-project.org/web/packages/rstanarm/vignettes/priors.html>).

When the evidence in the data is *strong*, the impact of the prior information is rather low. On the other hand, if the evidence of the data is *weak*, for instance due to small sample size, the impact of the prior information increases. Figure S3 shows the summary of the prior and posterior sample distributions and suggests that the evidence in the data was rather strong and results were not biased due to unrealistic prior information.

Figure S3: Posterior versus Prior Summary

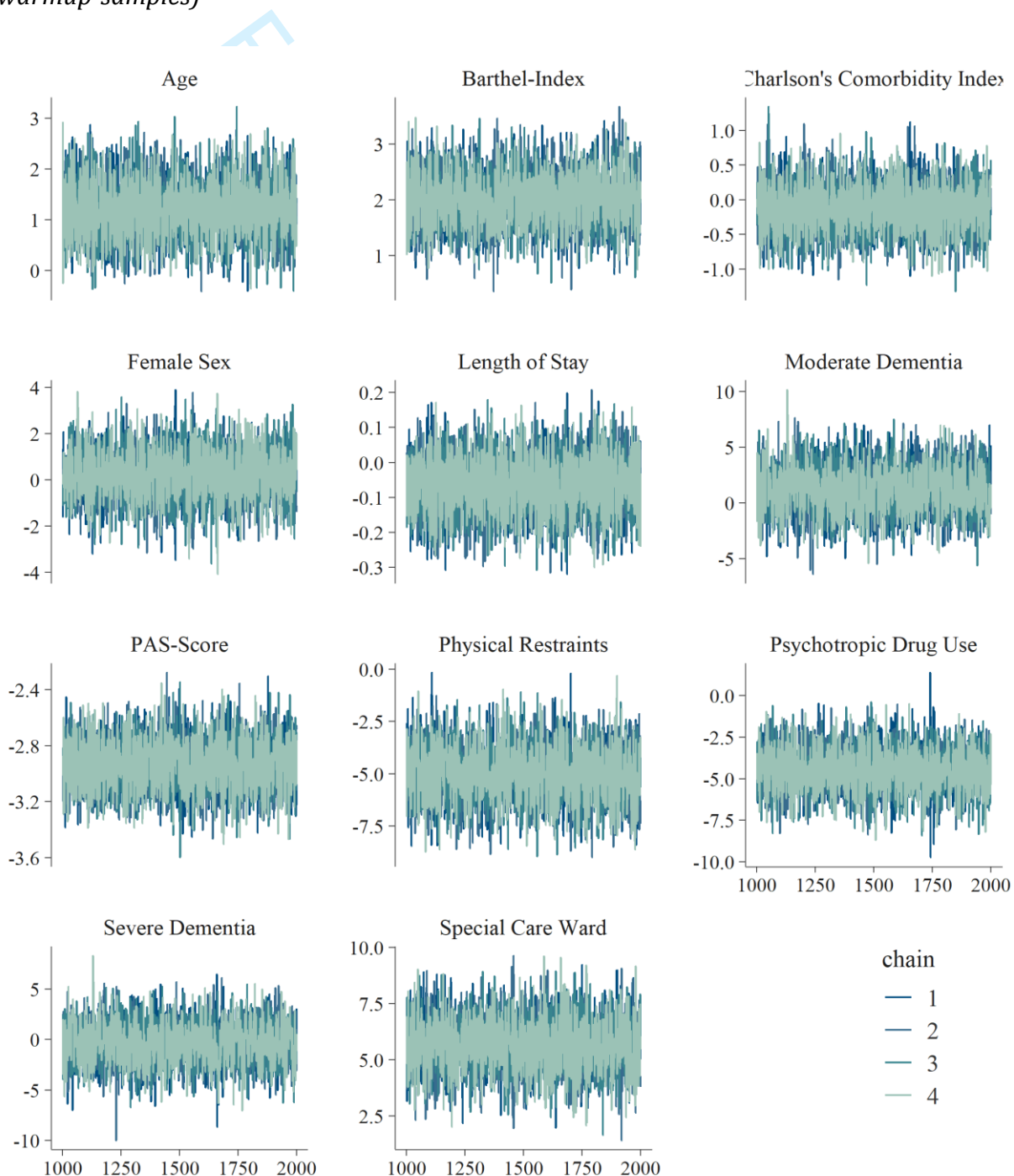


6. Trace plots

A trace plot provides a visual way to inspect sampling the behaviour and can be used, besides the Rhat-statistics, to assess convergence. The desired pattern is a “fat, hairy caterpillar”, which shows no suspicious bends^{4, 5}. If the chains converged to the posterior distribution, we can be confident in our model-based inferences.

The trace plot in Figure S4 indicates that all chains have converged well.

Figure S4: Markov Chain trace plot, 4 chains with 1000 iterations each (excluding warmup-samples)



7. References

1. Gelman A, Carlin JB, Stern HS, Dunson DB, Vehtari A, Rubin DB. Bayesian Data Analysis. Third edition. Boca Raton: CRC Press; 2014: p.24
2. Gelman A, Rubin DB. Inference from Iterative Simulation Using Multiple Sequences. *Statistical Science*. 1992;7(4):457-472. doi:10.1214/ss/1177011136
3. Kruschke JK. Rejecting or Accepting Parameter Values in Bayesian Estimation. *Advances in Methods and Practices in Psychological Science*. 2018; doi: 10.1177/2515245918771304
4. Sorensen T, Hohenstein S, Vasishth S. Bayesian linear mixed models using Stan: A tutorial for psychologists, linguists, and cognitive scientists. *The Quantitative Methods for Psychology*. 2016;12:175–200.
5. Lunn D, Jackson C, Best N, Thomas A, Spiegelhalter D. *The BUGS book: a practical introduction to Bayesian analysis*. Boca Raton, FL: CRC Press, Taylor & Francis Group; 2013.

Supplemental Material 3

To see if the complexity of patients' needs affect our findings, we calculated regression models with interaction terms between need factors moderated by hospitals. The figures S5 to S8 show the results of the interaction terms. Table S3 shows the coefficients in details. We found no "significant" associations for the interaction terms, concluding that the association between complexity of patients' needs and quality of life is not differing noticeably between the intervention and control group.

Plots were created using the *ggeffects* package in R (Lüdtke D. *ggeffects*: Tidy Data Frames of Marginal Effects from Regression Models. *Journal of Open Source Software*. 2018;3: 772. doi:10.21105/joss.00772).

Figure S5: Interaction between Barthel-Index and Intervention/Control-Group

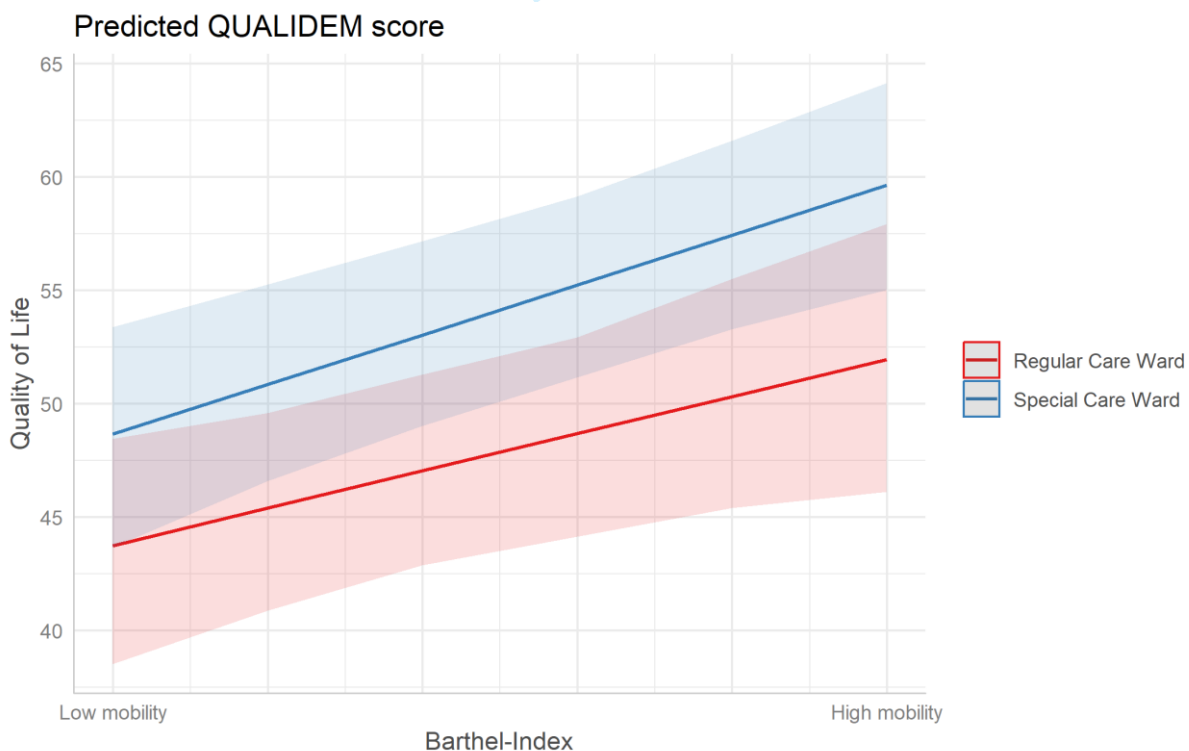


Figure S6: Interaction between Physical Restraints and Intervention/Control-Group

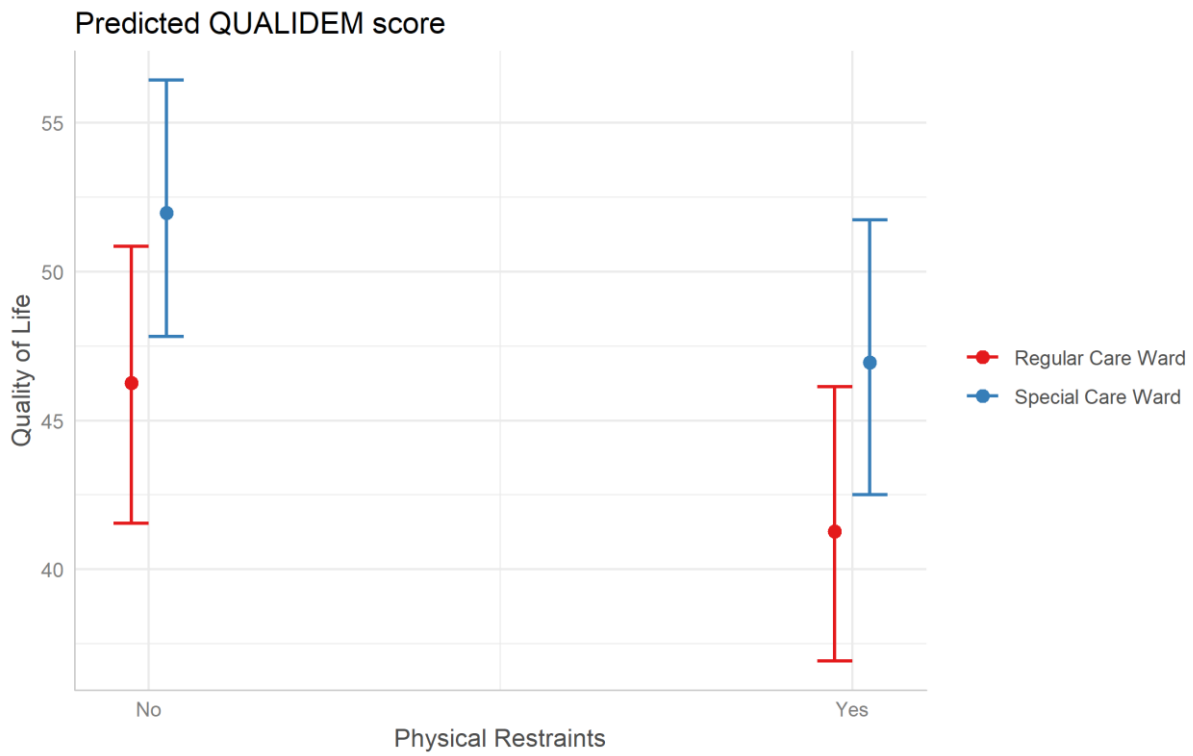


Figure S7: Interaction between PAS and Intervention/Control-Group

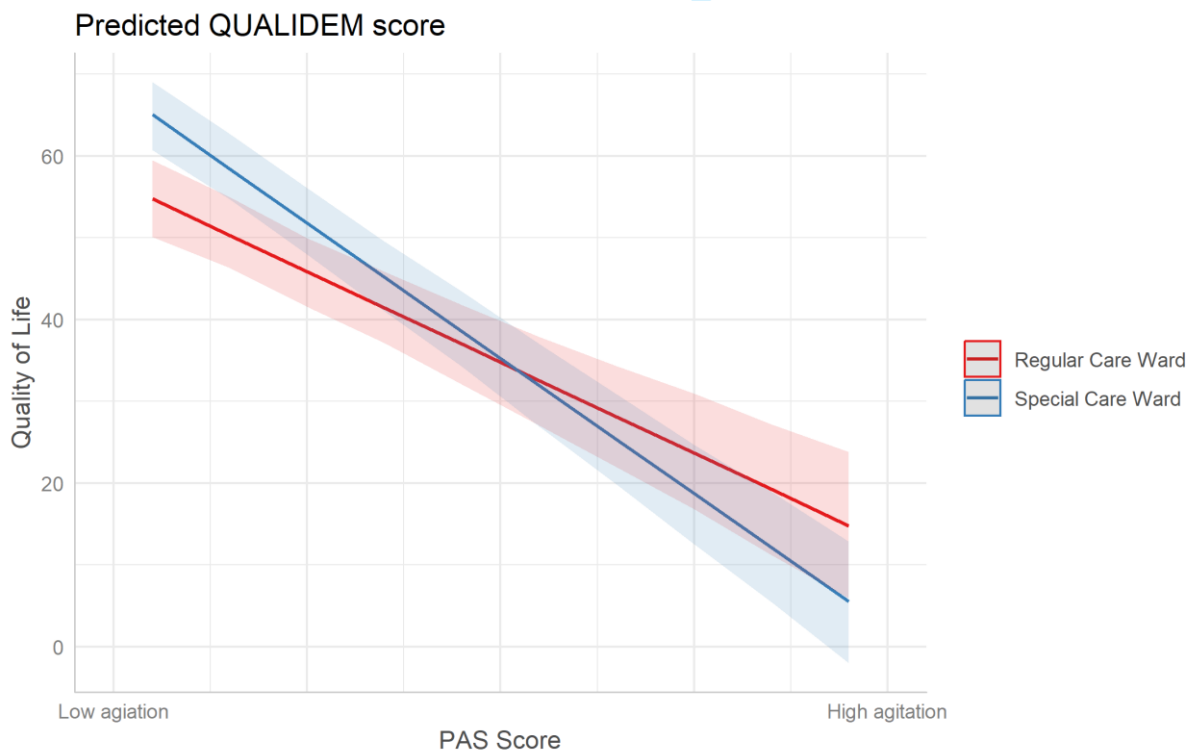
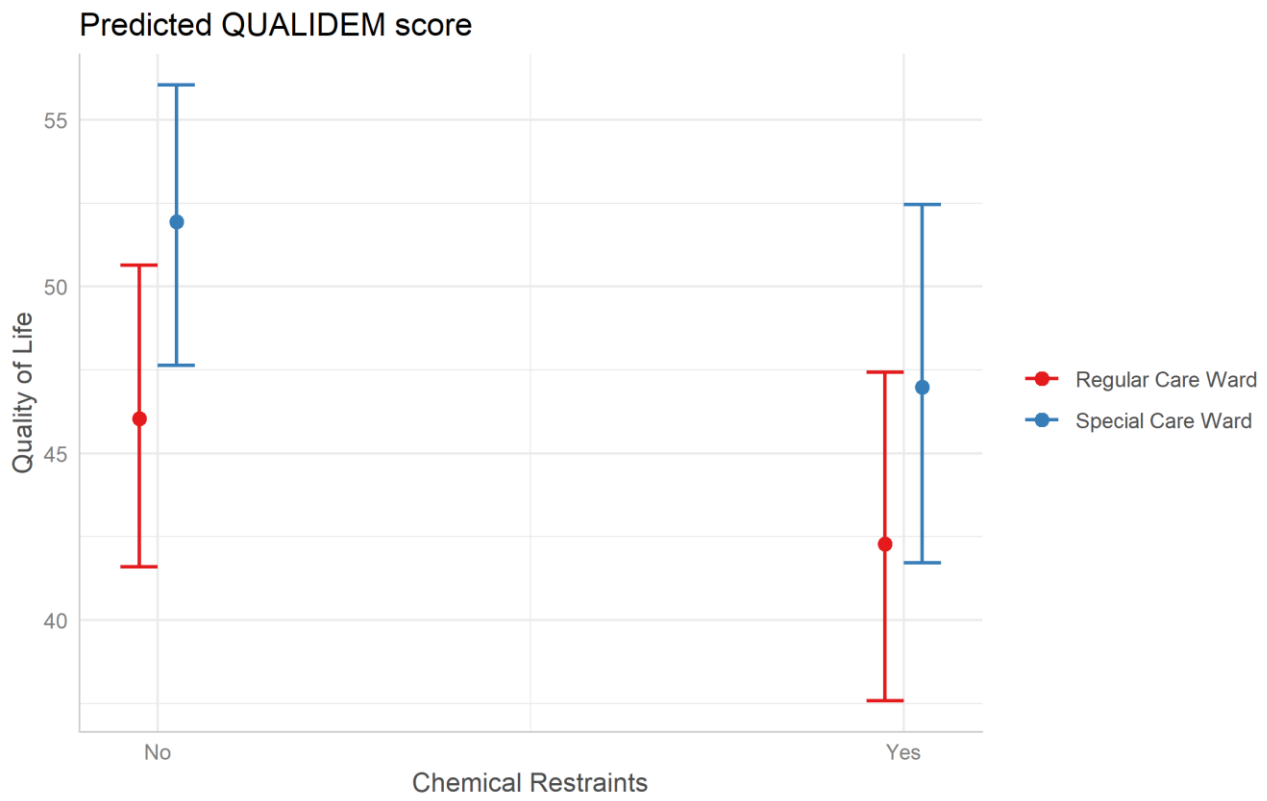


Figure S8: Interaction between Chemical Restraints and Intervention/Control-Group



review only

Table S3: Coefficients for Models with Interaction Terms

Terms	Model: Interaction between Barthel and Hospital		Model: Interaction between Physical Restraints and Hospital		Model: Interaction between PAS and Hospital		Model: Interaction between Chemical Restraints and Hospital	
	Estimates	HDI (95%)	Estimates	HDI (95%)	Estimates	HDI (95%)	Estimates	HDI (95%)
(Intercept)	36.18	26.19 – 45.67	36.31	27.00 – 46.10	36.57	27.11 – 45.71	36.16	26.45 – 45.69
Length of Stay	-0.07	-0.23 – 0.11	-0.06	-0.23 – 0.09	-0.07	-0.23 – 0.10	-0.06	-0.22 – 0.10
Age	0.12	0.01 – 0.23	0.12	0.02 – 0.23	0.12	0.01 – 0.22	0.12	0.02 – 0.23
Moderate Dementia	1.21	-2.79 – 5.13	1.19	-2.72 – 5.24	1.19	-2.83 – 4.72	1.25	-2.95 – 4.89
Severe Dementia	-0.34	-4.30 – 3.70	-0.44	-4.45 – 3.65	-0.74	-4.54 – 3.10	-0.30	-4.45 – 3.59
Female	0.16	-2.06 – 2.29	0.19	-1.98 – 2.29	0.52	-1.53 – 2.70	0.23	-1.76 – 2.53
Charlson's Comorbidity Index	-0.12	-0.81 – 0.59	-0.11	-0.77 – 0.64	-0.11	-0.77 – 0.59	-0.11	-0.82 – 0.59
Barthel Score	1.66	0.27 – 2.99	2.02	1.15 – 2.88	2.07	1.17 – 2.97	2.05	1.13 – 2.98
Physical Restraints (yes)	5.74	3.48 – 7.90	5.76	2.67 – 8.72	5.95	3.64 – 8.18	5.94	3.44 – 8.62
Special Care Ward (Intervention)	-5.02	-7.65 – -2.54	-4.92	-8.57 – -1.11	-4.94	-7.60 – -2.41	-4.96	-7.83 – -2.58
PAS-Score	-2.96	-3.30 – -2.62	-2.94	-3.30 – -2.61	-2.22	-2.77 – -1.66	-2.93	-3.27 – -2.59
Psychotropic Drug Use (yes, as-needed)	-4.43	-7.10 – -1.83	-4.40	-7.08 – -1.87	-4.30	-6.81 – -1.56	-3.76	-7.83 – -0.03
Barthel * Intervention	0.52	-1.00 – 2.06						
Phys. Restr. * Intervention			-0.09	-4.46 – 4.66				
PAS * Intervention					-1.09	-1.76 – -0.42		
Chem. Restr. * Intervention							-1.15	-6.63 – 4.27

Supplemental Material 4 – R Source Code

```

1
2 library(tidyverse)
3 library(gggridges)
4 library(sjmisc)
5 library(sjlabelled)
6 library(sjstats)
7 library(sjPlot)
8 library(insight)
9 library(bayestestR)
10 library(brms)
11
12 # Data available at https://doi.org/10.5281/zenodo.1479676
13
14 # load data ----
15
16 load("Dataset.RData")
17
18 # divide age by 10
19
20 d$age10 <- d$age / 10
21
22 # Labels for final model ----
23
24 labs <-
25   c(
26     stay_c = "Length of Stay",
27     age = "Age",
28     age10 = "Age",
29     mmse2 = "Moderate Dementia",
30     mmse3 = "Severe Dementia",
31     sex2 = "Female Sex",
32     barthel_code = "Barthel-Index",
33     groupintervention = "Special Care Ward",
34     physres1 = "Physical Restraints",
35     pas_c = "PAS-Score",
36     cci_c = "Charlson's Comorbidity Index",
37     chemicalres1 = "Psychotropic Drug Use", # oder as-needed
38     b_stay_c = "Length of Stay",
39     b_age = "Age",
40     b_age10 = "Age",
41     b_mmse2 = "Moderate Dementia",
42     b_mmse3 = "Severe Dementia",
43     b_sex2 = "Female Sex",
44     b_barthel_code = "Barthel-Index",
45     b_groupintervention = "Special Care Ward",
46     b_physres1 = "Physical Restraints",
47     b_pas_c = "PAS-Score",
48     b_cci_c = "Charlson's Comorbidity Index",
49     b_chemicalres1 = "Psychotropic Drug Use" # oder as-needed
50   )
51
52 # prior-definition in brms ----
53
54 # scale is 2.5 * sd(y) / sd(x)
55
56 bprior <-
57   prior(normal(0, 6), class = "b", coef = "stay_c") +
58   prior(normal(.1554, 40), class = "b", coef = "age10") +
59   prior(normal(0, 42), class = "b", coef = "mmse2") +
60   prior(normal(-.444, 42), class = "b", coef = "mmse3") +
61   prior(normal(-3.219, 42), class = "b", coef = "sex2") +
62   prior(normal(0, 29), class = "b", coef = "barthel_code") +
63   prior(normal(-5, 42), class = "b", coef = "physres1") +
64   prior(normal(0, 42), class = "b", coef = "groupintervention") +
65   prior(normal(0, 13), class = "b", coef = "pas_c") +
66   prior(normal(.2925, 42), class = "b", coef = "chemicalres1") +
67   prior(normal(0, 26.77), class = "b", coef = "cci_c")
68
69 # see:
70 # Beerens HC, Sutcliffe C, Renom-Guiteras A, et al. Quality of Life and
71 # Quality of Care for People With Dementia Receiving Long Term Institutional
72 # Care or Professional Home Care: The European RightTimePlaceCare Study.

```

```

1 # Journal of the American Medical Directors Association. 2014;15(1):54-61.
2 # doi:10.1016/j.jamda.2013.09.010
3 #
4 # QoL-Scale ranges from 13-52 (40 points). Effects from those study are
5 # multiplied by 2.5 (rescaling 40-points to 100-point-scale of QUALIDEM)
6 # see:
7 # Barca, M. L., Engedal, K., Laks, J., & Selbæk, G. (2011). Quality of Life
8 # among Elderly Patients with Dementia in Institutions. Dementia and Geriatric
9 # Cognitive Disorders, 31(6), 435-442. https://doi.org/10.1159/000328969
10 # QoL-scale ranges from 11-55 (45 points). Effects from those study are
11 # multiplied by 2.2 (rescaling 45-points to 100-point-scale of QUALIDEM)
12
13 # model formula ----
14 mf <-
15   formula(
16     QoL ~ stay_c + age10 + mmse + sex + cci_c +
17     barthel_code + physres + group + pas_c +
18     chemicalres + (1 | maindiag)
19   )
20
21 # brms-model ----
22
23 set.seed(1207)
24
25 m2a <- brm(
26   formula = mf,
27   data = d,
28   prior = bprior,
29   sample_prior = TRUE
30 )
31
32 # Figure 3 ----
33 theme_set(theme_sjplot2(base_size = 14, base_family = "serif"))
34
35 p <- plot_model(
36   m2a,
37   title = "",
38   axis.labels = labs,
39   sort.est = T,
40   colors = c("grey30"),
41   axis.title = "Change in QUALIDEM-Score",
42   wrap.title = 100,
43   wrap.labels = 20,
44   width = .2,
45   grid.breaks = 2,
46   size.inner = .1
47 ) +
48   ylab("Change in QUALIDEM Total Score") +
49   theme_sjplot2(base_size = 14, base_family = "serif")
50
51 p_pdf <- p +
52   theme_sjplot2(base_size = 28, base_family = "serif") +
53   theme(
54     panel.grid.major = element_line(size = .1),
55     panel.grid.minor = element_line(size = .05),
56     axis.line.x = element_line(size = .15),
57     axis.line.y = element_line(size = .15)
58   )
59
60 ggsave(filename = "Fig3.tiff", plot = p, width = 170, height = 120, units = "mm", dpi = 300,
61 compression = "lzw")
62 ggsave(filename = "Fig3.pdf", scale = 2, plot = p_pdf, width = 170, height = 120, units = "mm",
63 dpi = 300)
64
65 # Appendix S1: Test for practical equivalence ----
66
67 rope(m2a, rope = c(-6, 6))

```

```

1 rope(m2a, rope = c(-7.5, 7.5))
2 equivalence_test(m2a, parameters = "^(?!prior)")
3 equivalence_test(m2a, parameters = "^(?!prior)") %>% plot()
4
5 # Appendix S1, Table Regression Coefficients ----
6
7 tab_df(tidy_stan(m2a, prob = c(.5, .89), digits = 1))
8
9 # Appendix S1, Prior Adjustment ----
10
11 insight::get_priors(m2a)
12
13 # Appendix S1, Figure distribution Posterior Samples ----
14
15 tmp <- m2a %>%
16   as_tibble() %>%
17   select(2:12) %>%
18   gather(key = "predictor", value = "estimate") %>%
19   to_factor(predictor)
20
21 tmp$predictor <- lvl_reorder(tmp$predictor, c(9, 4, 8, 3, 7, 11, 10, 6, 1, 2, 5))
22
23 p2 <- ggplot(tmp, aes(x = estimate, y = predictor)) +
24   geom_vline(xintercept = 0, colour = "grey70", size = .8) +
25   geom_density_ridges2(rel_min_height = 0.001, scale = 2, alpha = .5) +
26   scale_x_continuous(breaks = seq(-8, 8, 2)) +
27   scale_y_discrete(labels = labs) +
28   labs(x = "Change in QUALIDEM-Score", y = NULL) +
29   theme_sjplot2(base_size = 14, base_family = "serif")
30
31 ggsave(filename = "FigS1.tiff", plot = p2, width = 190, height = 120, units = "mm", dpi = 300)
32
33 # Appendix S1, test for practical equivalence ----
34
35 ## Short version
36
37 equivalence_test(m2a, parameters = "^(?!prior)")
38 equivalence_test(m2a, parameters = "^(?!prior)") %>% plot()
39
40 ## More beautiful tweaked version
41
42 tmp.hdi <- hdi(m2a, prob = .95) %>%
43   slice(c(-c(1, 13:23)))
44
45 tmp2 <- m2a %>%
46   as_tibble() %>%
47   select(2:12) %>%
48   map2_df(tmp.hdi$CI_low, function(x, y) {
49     x[x < y] <- NA
50     x
51   }) %>%
52   map2_df(tmp.hdi$CI_high, function(x, y) {
53     x[x > y] <- NA
54     x
55   }) %>%
56   gather(key = "predictor", value = "estimate") %>%
57   to_factor(predictor)
58
59 tmp2$predictor <- lvl_reorder(tmp2$predictor, c(9, 4, 8, 3, 7, 11, 10, 6, 1, 2, 5))
60
61 tmp2$grp <- dplyr::case_when(
62   tmp2$predictor %in% c("b_stay_c", "b_cci_c") ~ "reject",
63   tmp2$predictor %in% c("b_age10", "b_mmse2", "b_mmse3", "b_sex2", "b_barthel_code") ~
64   "undecided",
65   TRUE ~ "accept"
66 )
67
68 p3 <- ggplot(tmp2, aes(x = estimate, y = predictor, fill = grp)) +
69   # rope based on "equi_test(model)".

```

```

1   annotate("rect", xmin = -1.7, xmax = 1.7, ymin = 0, ymax = Inf, fill = sjplot_pal(palette =
2   "us")[1], alpha = 0.15) +
3   geom_vline(xintercept = 0, colour = "grey70", size = .8) +
4   geom_density_ridges2(rel_min_height = 0.01, scale = 2, alpha = .4) +
5   scale_x_continuous(breaks = seq(-8, 8, 2)) +
6   scale_y_discrete(labels = labs) +
7   scale_fill_manual(values = sjplot_pal()[c(3, 1, 7)]) +
8   labs(x = "Change in QUALIDEM-Score", y = NULL, fill = "Acceptance of Parameters") +
9   theme_sjplot2(base_size = 14, base_family = "serif") +
10  theme(
11    legend.title = element_text(size = 13),
12    legend.position = "bottom",
13    axis.line.x = element_line(colour = "grey50"),
14    axis.line.y = element_line(colour = "grey50")
15  )
16  ggsave(filename = "FigS2.tiff", plot = p3, width = 190, height = 120, units = "mm", dpi = 300)
17
18  # Appendix S1, Posterior-Prior-Check ----
19
20  ## Short version
21  plot_model(m2a, type = "diag", axis.lim = c(-20, 20))
22
23  ## More beautiful tweaked version
24  pr_samp <- prior_samples(m2a) %>%
25    select(starts_with("b_")) %>%
26    gather(key = "Term", value = "Estimate") %>%
27    mutate(Sample = "prior")
28
29  ps_samp <- posterior_samples(m2a) %>%
30    select(starts_with("b_"), -b_Intercept) %>%
31    gather(key = "Term", value = "Estimate") %>%
32    mutate(Sample = "posterior")
33
34  m_pp_data <- bind_rows(pr_samp, ps_samp) %>% to_factor(Term)
35  m_pp_data$Term <- lvls_reorder(m_pp_data$Term, rev(c(8, 3, 10, 4, 7, 5, 11, 6, 1, 2, 9)))
36
37  p4 <- ggplot(m_pp_data, aes(x = Estimate, fill = Sample)) +
38    geom_density(alpha = .4) +
39    scale_x_continuous(limits = c(-20, 20)) +
40    facet_wrap(
41      ~ Term,
42      scales = "free",
43      labeller = labeller(Term = labs),
44      nrow = 4
45    ) +
46    labs(x = NULL, y = NULL) +
47    bayesplot::theme_default(base_size = 13) +
48    theme(
49      axis.line.x = element_line(colour = "grey50"),
50      axis.line.y = element_line(colour = "grey50"),
51      axis.text = element_text(colour = "grey10"),
52      axis.title = element_text(colour = "black"),
53      # strip.background = element_rect(colour = "grey50", fill = "grey90"),
54      # strip.text = element_text(colour = "grey20"),
55      legend.title = element_text(colour = "grey10"),
56      legend.text = element_text(colour = "grey20"),
57      legend.position = c(.5, .15),
58      legend.justification = c(-2, 1)
59    ) +
60    scale_fill_manual(values = sjplot_pal("breakfast club")[c(1, 3)])
61
62  ggsave(filename = "FigS3.tiff", plot = p4, width = 190, height = 214, units = "mm", dpi = 300)
63
64  # Appendix S1, Traceplot ----
65
66  p <- rstan::traceplot(m2a$fit, pars = colnames(as.data.frame(m2a))[1:12], inc_warmup = F)
67  p$data$parameter <- as.character(p$data$parameter)
68  tmp <- p$data %>%
69    filter(parameter != "b_Intercept")

```

```
for (i in 1:length(labs)) {
1   if (names(labs)[i] %in% tmp$parameter) {
2     r <- which(tmp$parameter == names(labs)[i])
3     tmp$parameter[r] <- labs[i]
4   }
5 }
6 p5 <- ggplot(tmp, aes(x = iteration, y = value, colour = chain)) +
7   geom_line() +
8   facet_wrap(~parameter, scales = "free_y", ncol = 3) +
9   scale_color_manual(values = sjplot_pal("us", n = 4)) +
10  labs(x = NULL, y = NULL) +
11  bayesplot::theme_default(base_size = 13) +
12  theme(
13    axis.line.x      = element_line(colour = "grey50"),
14    axis.line.y      = element_line(colour = "grey50"),
15    axis.text        = element_text(colour = "grey10"),
16    axis.title       = element_text(colour = "black"),
17    # strip.background = element_rect(colour = "grey50", fill = "grey90"),
18    # strip.text       = element_text(colour = "grey20"),
19    legend.title     = element_text(colour = "grey10"),
20    legend.text      = element_text(colour = "grey20"),
21    legend.position  = c(.5, .15),
22    legend.justification = c(-4.2, 0.7)
23  )
24 ggsave(filename = "FigS4.tiff", compress = "lzw", plot = p5, width = 190, height = 214, units =
25 "mm", dpi = 300)
26
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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of case-control studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4-5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	6-7
		(b) For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-10
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10-11
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	10-11
		(b) Describe any methods used to examine subgroups and interactions	10-11
		(c) Explain how missing data were addressed	10
		(d) If applicable, explain how matching of cases and controls was addressed	N/A
		(e) Describe any sensitivity analyses	N/A
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	12
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	12-13
		(b) Indicate number of participants with missing data for each variable of interest	12-13
Outcome data	15*	Report numbers in each exposure category, or summary measures of exposure	12-13
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	13-14
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	15-16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17-18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15-18
Generalisability	21	Discuss the generalisability (external validity) of the study results	18-19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Quality of Life of Patients with Dementia in Acute Hospitals: A non-randomised case-control-study comparing a regular ward to a special care ward with dementia care concept.

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Title

Quality of Life of Patients with Dementia in Acute Hospitals: A non-randomised case-control-study comparing a regular ward to a special care ward with dementia care concept.

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Keywords

Dementia, Quality of Life, Acute Hospital, Quality of Care, Internal Medicine

1
2
3 **Word Count:** 5.256 (excluding title page, abstract, strength and limitations, references,
4 tables)
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For peer review only

Abstract

Objectives: To identify factors that predict the quality of life (QoL) of patients with dementia in acute hospitals and to analyse if a special care concept can increase the patients' QoL.

Design: A non-randomised case-control-study, including two internal medicine wards from hospitals in Hamburg, Germany.

Setting and Participants: In all, 526 patients with dementia from two hospitals were included in the study (intervention: n=333; control: n=193). Inclusion criteria was an at least mild cognitive impairment or dementia. The intervention group was a hospital with a special care ward for internal medicine focussing on patients with dementia. The control group was from a hospital with a regular care ward without special dementia care concept.

Outcome Measures: Our main outcome was the QoL (range 0-100) from patients with dementia in two different hospitals. A Bayesian multilevel analysis was conducted to identify predictors like age, dementia, agitation, physical and chemical restraints or functional limitations that affect QoL.

Results: QoL differs significantly between the control (40.7) and intervention group (51.2), $p < 0.001$. Regression analysis suggests that physical restraint (estimated effect: -4.9), psychotropic drugs use (-4.4) and agitation (-2.9) are negatively associated with QoL. After controlling for confounders, the positive effect of the special care concept remained (5.7).

Conclusions: A special care ward will improve the quality of care and has a positive impact on the QoL of patients with dementia. Health policies should consider the benefits of special care concepts and develop incentives for hospitals to improve the QoL and quality of care for these patients.

Article Summary

Strengths and Limitations

- This is one of the first studies to investigate quality of life of patients with dementia in acute internal medicine wards in Germany.
- The statistical method applied in this study explicitly incorporates and accounts for information and knowledge from previous research.
- There are no studies which have evaluated the reliability and validity for the use of the assessment instrument for our main outcome (quality of life) in hospitals settings.
- The structural differences between the hospitals from the control and intervention may limit the generalizability of the results regarding the benefit of special care concepts for regular internal medicine wards.

Introduction

Acute hospitals face the challenge of an increase in old-age patients, which particularly affects internal medicine wards [1]. The average age of patients in internal medicine wards is above 70 years and may even come close to 80 years [2,3], leading to an increasing prevalence of cognitive impairments [4]. Although data on the occurrence of dementia or cognitive impairments of patients in hospitals is inconsistent, the larger proportion of studies report prevalence rates of about 40% [5–7].

Many hospitals are insufficiently prepared for patients with cognitive impairments, especially in acute care units predominantly focussing on somatic diseases [8]. Patients with cognitive impairments or dementia do not fit into the typical routines and standardised workflows of hospitals as these patients need more resources for care and treatment [9,10]. These patients often become disoriented, anxious, agitated and challenge hospital staff with erratic behaviour when placed in regular care wards. This results in an increased likelihood of falls, complications during the hospital stay and post-operative complications [11,12]. Hence, patients with dementia are a vulnerable group with a higher risk for long-lasting functional impairments [13,14].

To control the challenging behaviour of patients with dementia, a common practice – at least in German acute hospitals, and especially for older patients – is to use physical restraints like side rails to keep patients in bed, or chemical restraints such as the on-demand-use of psychotropic medication or hypnotics and sedatives [15,16]. This practise is not limited to German hospitals; however, there seems to be large variations between countries [17]. Physical and chemical restraints as well as anxiety and challenging behaviour are associated with poorer outcomes in quality of life [QoL] and quality of care of patients with dementia [18,19]. Therefore, hospitals in general, and specifically internal medicine wards with their increasing proportion of patients with

dementia, need to address these issues in order to improve the quality of care for these patients.

At least in Germany, there were lately no care concepts that fully address the needs of patients with dementia in internal medicine [20]. The special care ward “DAVID” in the Protestant Hospital Alsterdorf in Hamburg was one of the first internal medicine wards in Germany that implemented a comprehensive care concept for patients with dementia, aiming to improve the patients’ QoL during their hospital stay. QoL is an important indicator of quality of care and a major dimension when assessing patient reported outcomes, particularly in older people as global outcome measure for interventions [21,22]. The assumption of this care concept is that a special care ward for patients with dementia leads to better outcomes in QoL compared to regular internal medicine wards. A study (“DAVID 2”) was conducted to investigate the impact of such a care concept. This paper shows the results of this study and addresses two research questions. First, which factors predict the QoL of patients with dementia in acute hospitals? Second, beyond these factors, can a special care concept for patients with dementia in acute hospitals increase the patients’ QoL?

Methods

Study Design and Setting

The aim of this study was to compare the quality of care for patients with dementia within a specialised dementia care concept as opposed to regular care in acute hospitals. The present study was designed as a non-randomised case-control-study, including two internal medicine wards in two hospitals located in Hamburg, Germany. The intervention group was a hospital that implemented a special care ward for internal medicine focussing on patients with dementia. The control group was from a hospital

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3 with a regular care ward for internal medicine, which had no special dementia care
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5 concept.
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10 **Intervention Group**

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12 The special care ward “DAVID” is an internal medicine ward in the Protestant Hospital
13 Alsterdorf, a not-for-profit organization, and has 14 beds. In the year of data collection
14 (2016), 349 patients were treated. The ward employed nine care workers as nursing
15 staff.
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21 Key components of the special care concept are a) a specific architectural design,
22 including a homelike lounge, a specific colouring of doors and walls, and a light concept
23 with minimum 500 lux at eye level; b) doctors, nurses and service staff are trained in
24 coping with challenging behaviour and other dementia related issues, like basal
25 stimulation or validation therapy, but also included case conferences to discuss issues
26 with current patients [23]; duration of training courses and case conferences was about
27 one hour and were provided on a monthly basis by external instructors; additionally,
28 twice per year, an internal training course was offered for employees, lasting for half a
29 day; c) mobile devices for diagnostics, to perform as many treatments as possible in the
30 different rooms of the special care ward; d) involvement of relatives into assessment,
31 care and discharge planning; and e) regular therapeutic offers like occupational or
32 speech therapy, and social offers like music, playing or spending more time than usual to
33 care for the patients.
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51 To fulfil these high standards of quality of care, the ward “DAVID” employs more care
52 staff in relation to the number of patients as compared to other regular internal
53 medicine wards in Germany. With respect to the total number of full-time equivalents
54 [FTE] nurses, the staff-patient-ratio is one FTE nurse per 39 patients.
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3 The Protestant Hospital Alsterdorf has a second ward for internal medicine, however,
4 patients with dementia were usually immediately transferred to the special care ward
5 after admission to hospital. Thus, as almost no patients with dementia were treated in
6 the second internal medicine ward, the control group was taken from another hospital.
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15 **Control Group**

16
17 The regular care ward is part of a larger private-company hospital with emergency
18 hospitalisation. It has 80 beds and in the year of data collection, about 3.500 patients
19 were treated in this internal medicine ward. Twenty-six employees worked as care staff
20 in this ward. Trainees sometimes supported the care team. The staff-patient-ratio in the
21 regular care ward is approximately one FTE nurse per 130 patients. However, since the
22 internal medicine ward in this hospital also treats patients from the emergency
23 ambulance, the staff-patient-ratio related to the number of patients who actually stayed
24 longer in hospital (three days and more) is lower. Unfortunately, the hospital
25 management was not willing to provide more detailed information beside the publicly
26 available quality reports, so we cannot quantify the staff-patient-ratio exactly.
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40 The regular care ward had no specific care concept for dementia patients. The care staff
41 was not particularly trained in dementia topics.
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48 **Data collection and participants**

49 An assessment questionnaire was developed to obtain data from patients with dementia.
50 Study nurses were trained in using this assessment questionnaire and then conducted
51 the data collection in both hospitals. Two study nurses were responsible for the special
52 care ward and one for the regular care ward. A pre-test of two months was conducted to
53 test and revise the questionnaire. As a result, some items were removed and instructions
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3 for study nurses were defined more precisely. After the pre-test, data was collected over
4
5 a period of about 12 months (from July 2015 to June 2016 in the special care ward and
6
7 from August 2015 to September 2016 in the regular care ward). To detect small to
8
9 medium effect sizes (Cohen's $d \sim 0.1$ to 0.2), a power analysis was performed prior to
10
11 the data collection and yielded a sample size of at least 173 subjects per group. Patients
12
13 were included when they showed at least mild cognitive impairments or memory
14
15 problems. In the special care ward (intervention group) all patients were assessed
16
17 because a diagnosed dementia was a requirement for admission to that hospital. Hence,
18
19 the participation rate for the special care ward was about 94% and excluded only a few
20
21 patients that were not responsive. For the regular care ward (control group), patients
22
23 who already had a diagnosed dementia or cognitive impairments were included in the
24
25 study. A short dementia screening was carried out by the study nurse to assess the
26
27 severity of dementia of patients who had no clarified dementia diagnosis, and to identify
28
29 further patients who qualify for the study [24]. The total sample size for the present
30
31 analysis consists of $N=526$ patients (special care ward: $n=333$; regular care ward:
32
33 $n=193$). For both the intervention and control group, patients were excluded from the
34
35 study when they were completely confined to bed due to severe health-related
36
37 dependency. As both care wards had no particular selection criteria for patients such as
38
39 age, mobility, or the main diagnosis that lead to hospital admission, no further exclusion
40
41 criteria for the study were defined.

42
43 Prior to the study, a study protocol was developed and submitted to the ethical
44
45 committee of the medical association of Hamburg. The ethical committee approved the
46
47 proposal and attested that the study conforms to ethical and legal requirements
48
49 (approval code PV5102). Study participants were not able to give their informed
50
51 consent due to their cognitive impairments. However, as data mostly derived from the
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3 hospitals' regular documentation and was completely anonymous, the ethics committee
4
5 waived the need of an informed consent.
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10 **Patient and Public involvement**

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12 Patients and the public were not involved in the development of the research question
13
14 nor study design.
15
16

17 **Measures**

18
19 *Outcome:* QoL in patients with dementia was assessed using the QUALIDEM [25,26].

20
21 After observing patients for about one week (depending on the length of stay), the study
22
23 nurses rated their QoL. QUALIDEM comprises 37 items reflecting nine different
24
25 subdomains of QoL: "care relationship" (7 items, 0-21 points), "positive affect" (6 items,
26
27 0-18 points), "negative affect" (3 items, 0-9 points), "restless and tense behaviour" (3
28
29 items, 0-9 points), "positive self-image" (3 items, 0-9 points), "social relations" (6 items,
30
31 0-18 points), "social isolation" (3 items, 0-9 points), "feeling at home" (4 items, 0-12
32
33 points) and "have something to do" (2 items, 0-6 points). For patients with very severe
34
35 dementia (Minimental State Examination Test [27] [MMSE] < 7), only six of the nine
36
37 subscales apply, where the dimensions "positive self-image", "feeling at home" and "have
38
39 something to do" were omitted. The recommendation is to report descriptive results of
40
41 the QUALIDEM separately for each subscale. For regression analyses, a QoL index was
42
43 calculated by summing up and normalizing the QUALIDEM subscales (six subscales for
44
45 patients with very severe dementia, nine subscales for the remaining patients) to a
46
47 range from 0 to 100 points. A higher score indicates better QoL. Due to normalization of
48
49 the QUALIDEM total score for all severities of dementia, all patients' scores are
50
51 consistent and comparable [28].
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3 *Independent Variables:* Age, gender, main diagnosis for admission to hospital and length
4 of stay were recorded. Details about the distribution of the main diagnoses among
5 patients and by hospitals are shown in the Supplementary File 1. If a main diagnosis was
6 mentioned no more than one time in both hospital wards, it was recoded into the
7 category “other”. The final variable “main diagnosis” comprised 20 different diagnoses. A
8 modified version of the Charlson’s Comorbidity Index [CCI], which included depression
9 and hypertension as new items, was built based upon the assessment of comorbidities
10 and chronic diseases [29,30]. If patients had no chronic illnesses, the CCI had a score of
11 zero points. Else, higher scores indicated more serious comorbid disease. Shortly after
12 admission to hospital, the study nurses measured functional limitations and cognitive
13 status of patients. Functional limitations in daily living were assessed with the Barthel-
14 Index [31]. This score ranges from 0 (completely dependent) to 100 points (no basic
15 functional limitations) and was recoded according to the classification of the ICD-10 [32]
16 (German adaption) into a score from 1 to 6 points. The Minimental State Examination
17 Test [27] [MMSE] measures the cognitive impairments of patients, ranging from 0 (very
18 strong cognitive impairments) to 30 (very mild or no cognitive impairments) points.
19 This score was recoded into three categories, also based on ICD-10 classification: severe
20 dementia (0-16), moderate dementia (17-23 points) and mild dementia (24-27 points).
21 After about one week of hospital stay, the study nurses rated the patients’ agitation and
22 challenging behaviour and recorded psychotropic drug use (chemical restraint) and
23 physical restraints. Agitation and challenging behaviour of patients was assessed using
24 the Pittsburgh Agitation Scale [PAS] [33] ranging from 0 to 16 points (higher scores
25 indicate stronger agitation).
26 Physical restraints were defined as the use of one the following measures: Side rails to
27 keep a patient in bed, tying a patient to a bed, and use of “therapeutic” chairs that

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2
3 prevent patients to stand up. The variable was dichotomised, indicating whether
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5 patients (in the course of the hospital stay) were mechanically restrained by at least one
6
7 of these measures or not.
8
9

10 Psychotropic drug use was defined as on-demand-use (“as-needed”) of medication for
11
12 the nervous system by means of the Anatomical Therapeutical Chemical (ATC)
13
14 classification [34] and comprises antipsychotics, anxiolytics, hypnotics/sedatives and
15
16 antidepressants (N05A-C, N06A). Indicated use of psychotropic drugs was defined as
17
18 medications that were prescribed for regular, not on-demand-use and not only given to
19
20 patients in order to control their challenging behaviour. Such use of psychotropic drugs
21
22 was excluded from the analysis. The on-demand-use variable was dichotomised and
23
24 shows whether, during the complete hospital stay, chemical restraints were applied to
25
26 patients or not.
27
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30
31 While these variables already cover many different aspects that have an effect on the
32
33 QoL, we decided to add a further predictor as proxy for the intervention to the model.
34
35 Therefore, we included a binary variable with two categories (“control” as reference and
36
37 “intervention”) representing the two hospitals, to estimate the impact of the special care
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39 concept. This should reflect how much of the change in QoL is attributable to the special
40
41 care concept.
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48 **Missing Data**

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50 In total, 11% of individual items across all scales were missing (at random), 6% of
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52 individual items when looking at the QUALIDEM only. The missing data pattern was
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54 analysed and missing data was imputed using the multivariate imputation by chained
55
56 equations method [35], using 11 imputation steps corresponding to the proportion of
57
58 missing data [36]. The method for imputing missing values depends on the variable’s
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3 nature. For continuous variables, predictive mean matching was applied, while logistic
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5 regressions were used for binary variables.
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10 **Statistical Methods**

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12 Descriptive results for the total sample and each hospital are reported. Statistically
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14 significant differences of $p < 0.05$ between the two hospital wards were tested using t-
15
16 tests, χ^2 -tests or Mann-Whitney-U-tests, depending on the level of measurement and
17
18 distribution of variables. Differences between the hospitals in the QUALIDEM subscales
19
20 are presented as boxplots, showing the median value and upper and lower quartiles of
21
22 the value distribution.
23
24

25
26 As multivariate analysis, a Bayesian linear mixed model was applied to analyse the
27
28 associations between the independent variables and the outcome. Computations were
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30 based on Stan [37], a probabilistic programming language for specifying Bayesian
31
32 models, using Markov Chain Monte Carlo sampling (in particular, Hamiltonian Monte
33
34 Carlo) [38]. We assume that the patients' main diagnosis is associated with different
35
36 degrees of physical impairments, which affect the QoL. Therefore, the variable 'main
37
38 diagnosis' was used as level-2 unit (*random intercept*) in the multilevel model to control
39
40 for the variation in the outcome. We used informative priors for the predictors age,
41
42 female gender, severe dementia, psychotic drug use and physical restraints, based on
43
44 information from former research [18,39,40]. Weakly informative priors were used for
45
46 the remaining predictors. The prior and posterior distributions of the model are
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48 summarised in the supplemental material (see Supplementary File 2).
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54 Continuous predictors were centred before entering the model. Age was divided by 10,
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56 so a 1-unit change in the predictor of age reflects a change of 10 years in patients. The
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58 median value of the posterior distribution is used as "Bayesian point estimate", which
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3 minimises the difference of estimates from true values over posterior samples, but there
4 are many other plausible values (the “posterior distribution”) to describe the association
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6 between predictors and outcome. Hence, 50% and 89% highest density intervals [41]
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8 [HDI] are shown to indicate the range of most credible values and to reflect the (un-
9
10)certainty of the estimates. The intraclass correlation coefficient [42] was calculated to
11
12 see how much of the proportion of the variance in the outcome can be explained by the
13
14 grouping structure (‘main diagnosis’). We developed post-hoc additional regression
15
16 models with interaction terms for need predictors (Barthel-Index, physical and chemical
17
18 restraints, PAS-Score) to check if the associations between the complexity of patients’
19
20 needs and QoL differ between hospitals. We found no significant interaction terms and
21
22 decided to present the most parsimonious model here and show further results in the
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24 appendix (see Supplementary File 3).
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31 All analyses were conducted with the R statistical package [43], including the packages
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33 *mice* [35], *ggplot* [44], *brms* [45] and *sjPlot* [46]. The source code is available in the
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35 supplemental material (see Supplementary File 4). Data is available online [47].
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40 41 **Results**

42 43 **Sample Characteristics**

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45 Table 1 gives an overview of the sample characteristics. The proportion of female to
46
47 male patients is similar in both groups. The mean age is 4 years higher in the control
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49 group. There are also significant group differences in the Barthel-Index indicating higher
50
51 functional impairment in the control group, while the dementia severity was the same in
52
53 both hospitals. Comorbid conditions are slightly higher in the control group. Patients
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55 stayed 9.4 days in hospital on average and nearly one day longer in the intervention
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57 group as compared to the control group. Large differences between the two hospitals
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can be seen in the use of medical and physical restraints with significantly less use in the intervention group. Agitation- and QoL-scores also show strong group differences to the disadvantage of the patients in the control group.

In most cases, the distribution of main diagnoses of patients were comparable between the two hospital wards (see Supplemental File 1). Most frequent were pneumonia (13.5% in the intervention group and 11.9% in the control group), a worsening medical condition of patients (8.7% and 7.2%) or exsiccosis (4.8% and 6.7%). Noticeable differences between the two wards were found in urinary tract infections (UTI) (9.9% in the intervention group and 3.1% in the control group) or dyspnoea (1.2% and 7.8%).

Table 1: Sample Characteristics

Characteristic	Control Group (Regular Care Ward, n=193)	Intervention Group (Special Care Ward, n=333)	Total (N=526)	p-value of difference
Female, %	59.1	61.6	60.6	.637
Mean Age (SD)	83.1 (7.2)	79.0 (11.9)	80.5 (10.6)	<.001
Mean Barthel-Index (SD)	29.9 (27.9)	40.7 (30.4)	36.7 (29.9)	<.001
Mild Dementia, %	7.8	9.6	8.9	.580
Moderate Dementia, %	30.0	26.7	27.9	.473
Severe Dementia, %	62.2	63.7	63.2	.805
Mean Length of Stay, in Days (SD)	8.9 (7.5)	9.7 (5.5)	9.4 (6.3)	.002
Physical Restraints (yes), %	54.4	28.2	37.8	<.001
Psychotropic Drug Use (yes, as-needed), %	25.9	14.1	18.4	.001
Mean-Score Pittsburg Agitation Scale (SD)	3.9 (3.1)	3.0 (3.2)	3.3 (3.2)	<.001
Mean Charlson' Comorbidity Index (SD)	3.2 (3.0)	2.5 (2.0)	2.8 (1.6)	<.001
Mean QUALIDEM Total Score (SD)	40.7 (14.5)	51.2 (17.2)	47.3 (17.0)	<.001

Barthel-Index: 0-100 (higher = better functioning); Dementia (MMSE score): mild: 24-27; moderate: 17-23; severe: <= 16; Pittsburg Agitation Scale: 0-16 (higher = stronger agitation and anxiety); Charlson' Comorbidity Index: 0-9 (higher = more comorbidities); QUALIDEM: 0-100 (higher = better QoL)

Quality of life

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3 Looking at the QoL for patients with severe to mild cognitive impairments (these are the
4 ones, in which all subdomains of the QUALIDEM could be applied), there is a consistent
5 pattern across all QUALIDEM-domains: Patients in the control group have a lower QoL
6 compared to the intervention group. Except for the last subdomain ('having something
7 to do'), all differences are statistically significant (Figure 1).
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17 The same consistent pattern can be found for patients with very severe dementia
18 symptoms (MMSE score < 7). Here, only the second of the six applied subdomains
19 ('positive affect') does not differ significantly between intervention and control (Figure
20 2).
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29 **Predictors of quality of life**

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31 Figure 3 shows the results from the Bayesian mixed model. Three predictors are clearly
32 negatively associated with QoL: physical restraint, psychotropic drug use and agitation
33 (PAS-score). Physical restraint is associated with a 4.9-point decrease in QoL. With 50%
34 probability, the QoL decreases by 4.1 to 5.8 points and with a chance of 89% by -7 to -2.8
35 points respectively. The application of psychotropic drugs as-needed shows similar
36 results, with a posterior median of -4.4. The third clearly negative associated predictor is
37 agitation, which shows a decrease in QoL of about 2.9 points for each additional point in
38 the PAS-score.
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49 Dementia and gender are not clearly associated with QoL. Neither are the length of
50 hospital stay and the CCI.
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54 The age of the patient correlates slightly positive with QoL, where an increase of 10
55 years means an increase of about 1.2 points in the QoL. The posterior median of the
56 Barthel-Index is 2.0, so for a one-category change in functional impairments the QoL
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3 changes by two points. This means that patients with severe functional impairments
4
5 differ by about 10 points in QoL compared to patients with no functional impairments.
6
7 Controlling for all other predictors, the intervention (special care ward) shows the
8
9 strongest association with our outcome of interest, the patients' QoL. The posterior
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11 median is 5.7, and with an 89% probability, the credible values describing the effect of
12
13 the intervention on QoL are within the range from 3.8 to 7.6.
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17 The intraclass correlation coefficient of the model is rather low (0.01). This means, the
18
19 'main diagnosis' does not explain much of the variance in the patients' QoL and there is
20
21 almost no regularization ("shrinkage") of estimated model parameters and no larger
22
23 differences between hospitals according to the patients' needs, as indicated by their
24
25 main diagnosis.
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31 Discussion

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33 The study reported in this paper sought to understand those factors that influence the
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35 QoL in patients with dementia and whether a special care concept for these patients
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37 performs better in this regard as opposed to regular care wards.
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41 One of our main findings is that QoL differs significantly between the control and
42
43 intervention group. We found substantial differences between the two hospitals in the
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45 patients' total QoL score in favour of the special care ward. Beyond the statistical
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47 significance, this finding also has a clinical impact. Studies suggest a change in 3 points
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49 for the Quality of Life – Alzheimer's Disease Scale [48], which has a range of 40 points, to
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51 be clinically relevant [49,50]. Transferred to the range of the QUALIDEM scale, a
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53 difference of about 7.5 points would be considered as an important improvement in
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55 QoL. Another indicator to evaluate the clinical relevance of a change in QoL is an
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57 increase of the score of half a standard deviation [51], which would be about 8.5 points
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3 for our data. Taking these reference points as a basis, we found evidence for the clinical
4 relevant improvement in QoL of patients in a special care ward.
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8 A second key finding is the identification of those factors that are clearly associated with
9
10 QoL. The use of physical and chemical restraints, both happening more frequently in the
11 control group, are associated with lower outcomes in QoL. This finding is in line with
12
13 other studies that suggest a negative association between physical and chemical
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15 restraints and QoL [18,40] and explains why the regular care ward performs less good in
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17 this regard than the special care ward. Agitation was also negatively associated with
18
19 QoL. This is understandable as agitation is an expression of anxiety and indisposition of
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21 people with dementia and typically occurs after admission to hospital. Furthermore,
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23 agitation is often a reason for psychotropic drug use or physical restraint and, thus, also
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25 negatively affects QoL [52,53].
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31 Independent from these factors, the special care ward itself shows the strongest impact
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33 on QoL, indicating that patients with dementia explicitly benefit from specialised care
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35 concepts. Other studies also report these benefits, both in a nursing home or hospital
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37 setting [54,55]. Since we controlled for patient characteristics like main diagnosis, age,
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39 functional limitations, chronic comorbidities, agitation, length of stay etc. in our model,
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41 we do not assume that the positive effect of the special care ward is completely a result
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43 of a biased sample between intervention and control group. Although the two compared
44
45 hospitals differ in their structures and size, patients' characteristics are largely
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47 comparable between the samples in the control and intervention group. For instance,
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49 there is no substantial difference between the two hospitals regarding the relationship
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51 between functional impairments and physical restraints. Moreover, to see if the
52
53 complexity of patients' need affects our findings, we calculated regression models with
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3 interaction terms between need factors moderated by hospitals (see Supplementary File
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5 3).

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8 The association between complexity of needs and QoL is not significantly different
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10 between the intervention and control group. Based on our results we suggest that the
11
12 special care concept mainly explains the differences in the QoL. Although it is certainly
13
14 difficult to determine the exact effect of the special care concept on the patients' QoL,
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16 our findings seem plausible in the light of the key elements of this intervention. A higher
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18 ratio of care staff as to patients, smaller facilities or systematically trained employees
19
20 can be considered essential for health care provision to patients with dementia and are
21
22 much better conditions for less physical or chemical restraints, independent of the
23
24 functional limitations of patients. The special care ward provides a more dementia-
25
26 friendly interior design, including orientation and navigation aids and the use of light
27
28 and colours, which are considered as important components to reduce agitation for
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30 patients with dementia [56].

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33 These findings and conclusions are in line with other studies on hospital care that
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35 suggest that an increased staff ratio or the implementation of multiple components,
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37 which particularly address the needs of patients with dementia, lead to reduced use of
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39 physical restraints and psychotropic drug use and improve the quality of care [57,58].
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41 Furthermore, dementia-specific educational programmes, as implemented in the special
42
43 care ward, have positive effects on nurses regarding their interaction with patients with
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45 dementia. Trained nurses can improve their coping skills in handling challenging
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47 behaviour of these patients, and better attend to the patients' unmet physical and
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49 psychological needs [59].

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52 Studies suggest that the use of both physical and chemical restraints is reduced for
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54 nurses who completed a dementia-specific training as opposed to nurses who did not
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3 complete such an educational programme. Trained nurses had better skills in providing
4 patient-centred care and thus improving the QoL for patients with dementia [59–61].
5

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7 The special care ward benefits from a higher staff ratio, i.e. nurses have to care for fewer
8 patients with dementia compared to the control group. While this is an intentional
9 element of the concept, the downside is higher personnel costs. Only few studies
10 investigated the follow-up costs for patients with dementia in home care settings after
11 hospitalization. Costa et al. predicted additional monthly costs in home care of about
12 445 Euros due to increased agitation of patients with dementia [62]. Thus, if patients
13 with dementia benefit from special care concepts and perceive better outcomes in
14 quality of life and care, the increased costs for more care personnel may be compensated
15 by reducing follow-up costs for the ambulatory care. However, further research is
16 needed to give more exact projections of the increased costs and potential of saving
17 money.
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33 Another finding is that the severity of cognitive impairments, measured with the MMSE,
34 is a rather improper indicator to represent the underlying problems of and with the
35 dementia disease, as these factors were not consistently associated with QoL. Direct
36 measures of the problems associated with dementia, as agitation or challenging
37 behaviour, should be considered as well when it comes to investigate the QoL of patients
38 with dementia.
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47 Our study has several limitations. One concerns the structural differences between the
48 two hospitals. The hospital with the special care ward is much smaller than the hospital
49 that hosted the control group. A second control group or an intervention group in a
50 hospital of a similar size as the hospital with the regular care ward may have permitted
51 a more distinct comparison. We tried to keep the impact of the structural differences as
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3 minimal as possible, for instance by accounting for many different patient
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5 characteristics including functional status, comorbidities and behavioural problems.
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7 Furthermore, the main diagnoses of patients were also considered in the analysis. We
8
9 assume that we could at least partly adjust our analysis for a bias due to patient
10
11 selection mechanisms. To validate our assumptions, we investigated to which extent the
12
13 association between patient characteristics and QoL is affected by differences between
14
15 the control and intervention group (details shown in Supplementary File 3). Results
16
17 suggest that our data provides no strong evidence for noticeably differences between
18
19 the intervention and control group regarding the association between complexity of
20
21 patients' needs and QoL. However, although we adjusted our analysis for many patient
22
23 characteristics, we cannot eliminate a potential bias due to different hospital structures.
24
25 In particular, the higher mean age and stronger functional limitations in the control
26
27 group may indicate a selection bias in our sample. We suggest that further studies
28
29 should take a second control group or a more comparable intervention group into
30
31 account to gain more insight into potential biases due to structural differences of the
32
33 control and intervention group.
34
35 Another structural difference between the intervention and control group that certainly
36
37 affects the results are the different staff-patient-ratios. In the special care ward, nurses
38
39 have to care for fewer patients than in the regular care ward. Although we assume that
40
41 this aspect probably has the highest impact on the outcomes in QoL, this is not a
42
43 "selection bias" per se rather than a core component of the intervention. A higher staff-
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45 patient-ratio, dementia-specific training programmes, or a specific architectural
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47 design are key elements of the special care concept, which, in their entirety, are reflected
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49 in the resulting differences between hospitals.
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3 A further limitation is possibly the first and thus rather exploratory use of the
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5 QUALIDEM assessment in a hospital setting. Although studies show reliable results of
6
7 the QUALIDEM in nursing homes even for a short observation period of about one week
8
9 [63], there are no studies that evaluate the reliability and validity for use in hospitals.
10
11 We have done checks of internal consistencies, which showed that most subdomains of
12
13 the QUALIDEM perform well with our data and are comparable to results from other
14
15 validation studies [64]. This indicates that the use of the QUALIDEM is feasible for
16
17 hospital research. However, due to financial and logistic limitations, it was not possible
18
19 to monitor the complete data collection and accurate completion of questionnaires.
20
21 Hence, we cannot give evidence on the interrater reliability apart from the intense
22
23 training of the study nurses.
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27
28 Another debatable issue regarding the QUALIDEM concerns the computation concept of
29
30 the total score for patients with very severe dementia. We followed the QUALIDEM
31
32 authors' instruction to use only six of the nine subscales to calculate the total score for
33
34 this group [65]. Technically, this is similar to mean value imputation for the missing
35
36 scores of the three omitted subscales. This, however, may result in biased and/or
37
38 underestimated measurement error variance for this group. Therefore, we also
39
40 calculated a regression model with a QUALIDEM total score based on imputation for
41
42 missing values for all nine subscales for patients with very severe dementia (see
43
44 Supplementary File 5). In the results section, we have provided the analyses as
45
46 suggested by the QUALIDEM authors for comparability reasons. In order to meet
47
48 different views on the computation concept, we also provide the results of the
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50 alternative analysis in the Supplementary File 5. These are very similar to the first
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52 analysis and do not differ significantly.
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3 Finally, due to the nature of the study design, it was not possible that study nurses in the
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5 intervention and control group were blinded. This might affect the results insofar as
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7 study nurses may have generated more generous responses for the assessment scales
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9 [66].
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15 **Conclusions**

16
17 On the whole, we think that a special care ward will improve the quality of care and is
18
19 effective regarding the positive impact on the QoL of patients with dementia. Our study
20
21 showed that after controlling for different predictors, the intervention still has a
22
23 perceptible effect concerning clinical important differences in our outcome of interest,
24
25 the patients' quality of life. However, such improvements can only be achieved by
26
27 implementing a concept with multiple components that address the explicit needs of
28
29 patients with dementia. The implementation of a special care concept usually increases
30
31 the costs for hospitals because it requires a higher staff-patient-ratio, regular training of
32
33 employees or more therapeutic offers. On the other hand, costs that accumulate in
34
35 informal care after hospital stay as a result of poorer quality of care in hospitals can be
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37 much higher than additional personnel costs and could probably be reduced [62,67].
38
39 Health policies should consider the benefits of special care concepts and develop
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41 incentives for hospitals to improve the QoL and quality of care for patients with
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43 dementia.
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Author Contributions

DL was involved in conception and design of the study, analysis and interpretation of data and drafting the article. GP was involved in conception and design of the study and interpretation of data. JK was involved in interpretation of data and drafting the article. CK was involved in conception and design of the study, interpretation of data and drafting the article.

Competing interests

The authors have declared that no competing interests exist.

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Ethics approval and consent to participate

Prior to the study, a study protocol was developed and submitted to the ethical committee of the medical association of Hamburg ("Ethik-Kommission der Ärztekammer Hamburg"). The IRB of the ethical committee approved the proposal and attested that the study conforms to ethical and legal requirements (approval code PV5102). Study participants were not able to give their informed consent due to their cognitive impairments. However, as data mostly derived from the hospitals' regular documentation and was completely anonymous, the IRB of the ethics committee waived the need of an informed consent.

Availability of data and material

All data generated or analysed during this study are licensed under CC BY-NC 4.0 and available in the Zenodo repository (DOI: 10.5281/zenodo.3351450) at <https://doi.org/10.5281/zenodo.3351450>.

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Figure Titles and Legends

Figure 1: QUALIDEM subdomain scores by care ward in patients with mild to severe dementia (MMSE score from 7 to 27, n = 400)

Figure 2: QUALIDEM subdomain scores by care ward, patients with very severe dementia (MMSE score < 7, n = 126)

Figure 3: Predictors of Health Related Quality of Life, Regression Coefficients, Bayesian Linear Mixed Model, Posterior Median (+50% and 89% High Density Interval)

Supplementary Files

Supplementary File 1: Figure, Distribution of Patients' Main Diagnosis by Hospital

Supplementary File 2: Methodological comments

Supplementary File 3: Regression Models with Interaction Terms

Supplementary File 4: R Source Code (to use with R statistics, CC BY-NC 4.0 license)

Supplementary File 5: Regression Model with Alternative QUALIDEM-Score

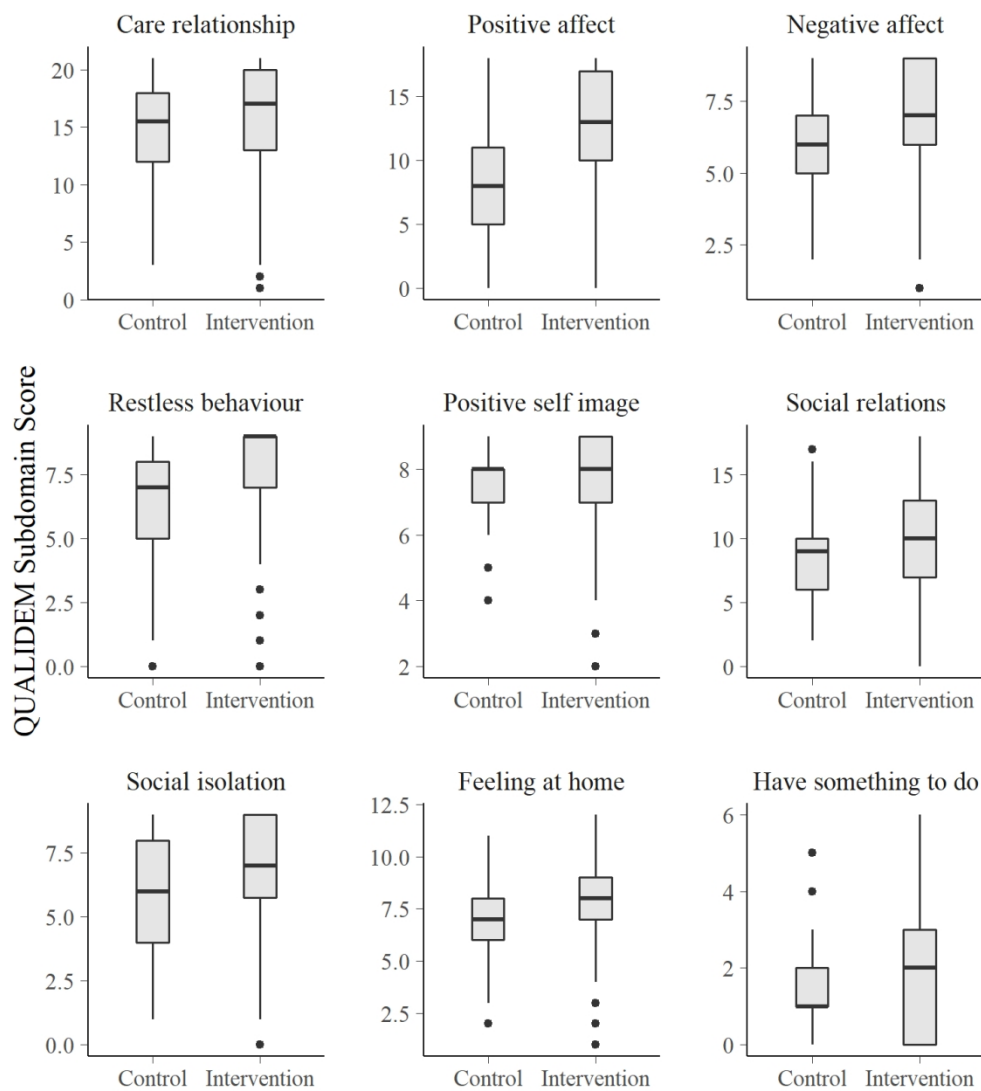


Figure 1: QUALIDEM subdomain scores by care ward in patients with mild to severe dementia (MMSE score from 7 to 27, n = 400)

169x189mm (220 x 220 DPI)

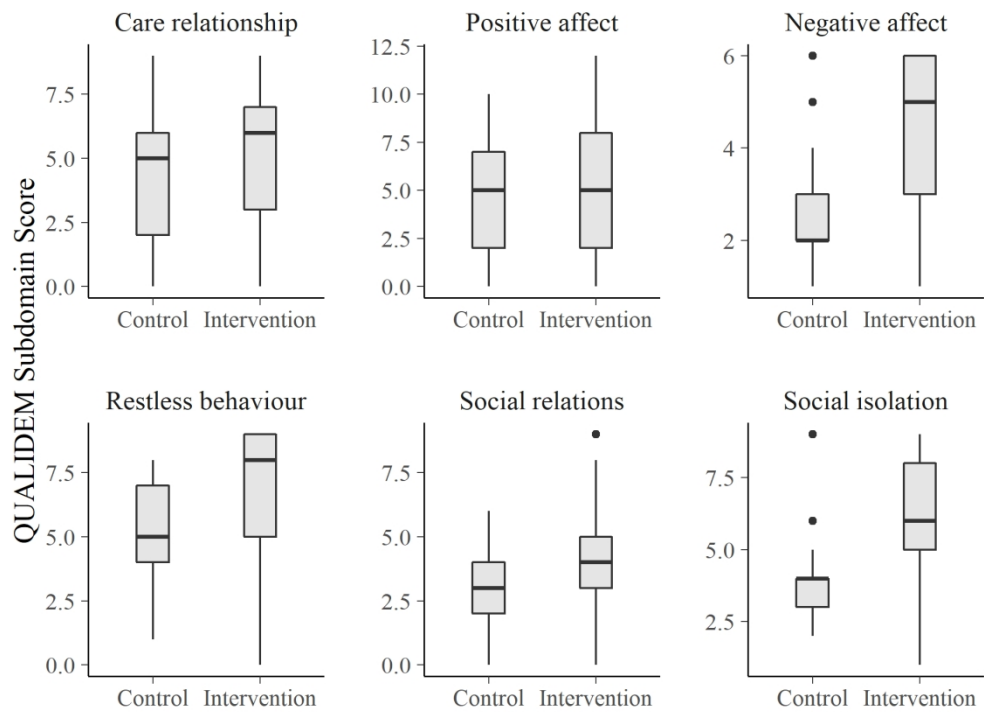


Figure 2: QUALIDEM subdomain scores by care ward, patients with very severe dementia (MMSE score < 7, n = 126)

169x125mm (300 x 300 DPI)

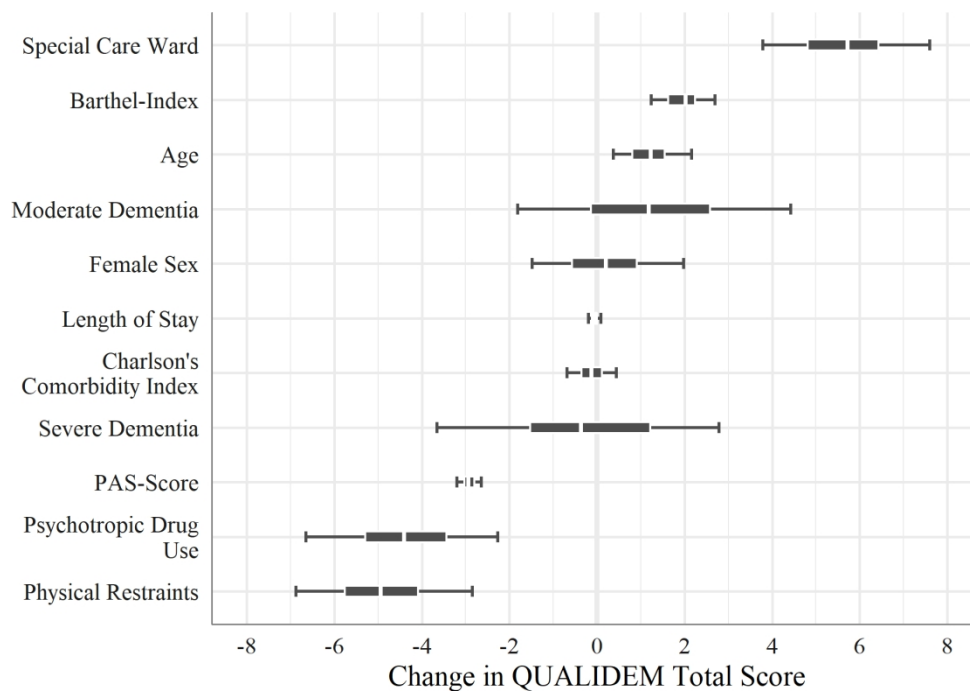
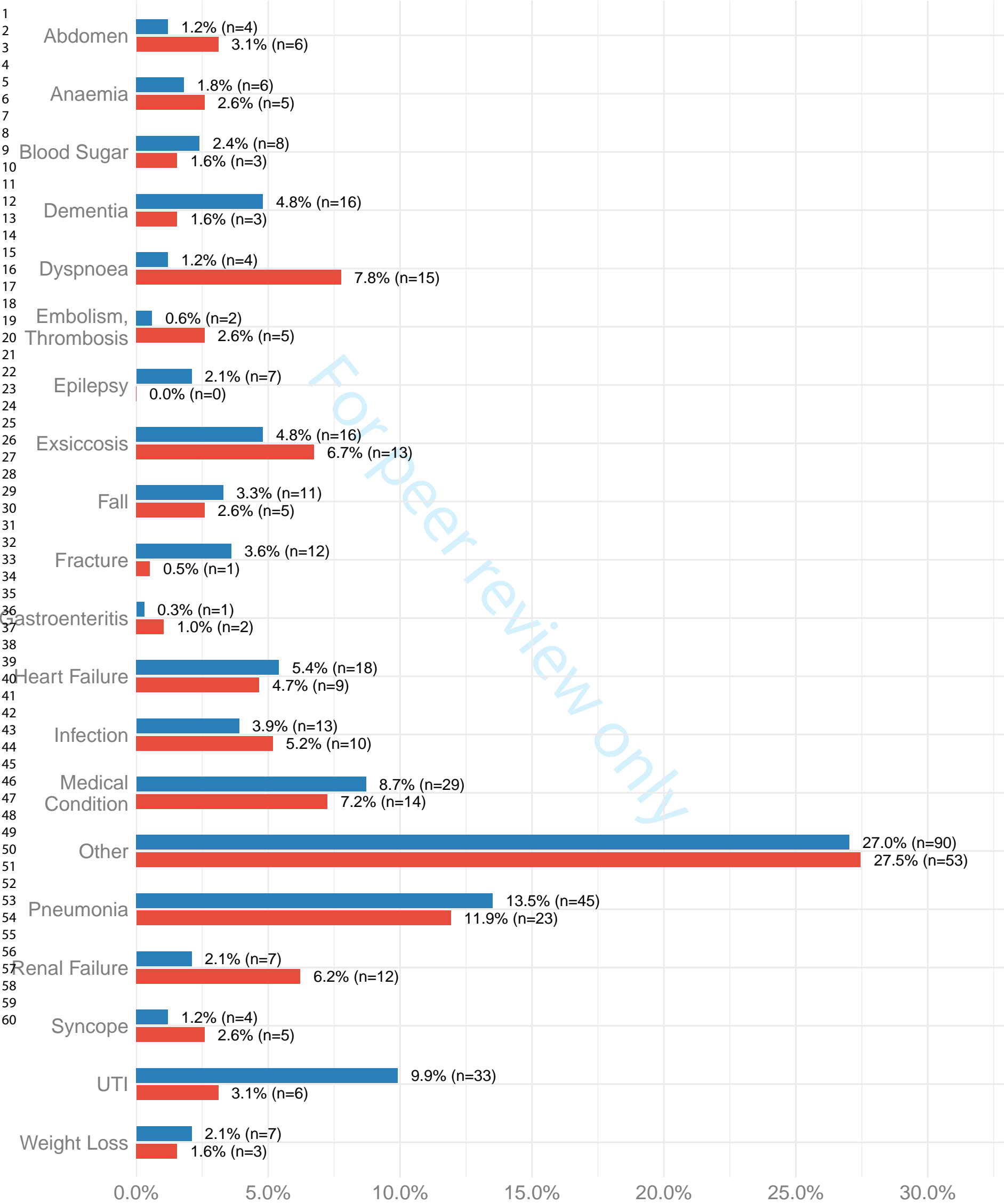


Figure 3: Predictors of Health Related Quality of Life, Regression Coefficients, Bayesian Linear Mixed Model, Posterior Median (+50% and 89% High Density Interval)

169x119mm (300 x 300 DPI)

Main Diagnosis by Hospital Ward



Supplemental Material 2

Quality of Life of Patients with Dementia in Acute Hospitals: Comparing a regular ward to a special care ward with dementia care concept. A Bayesian Multilevel Model Analysis.

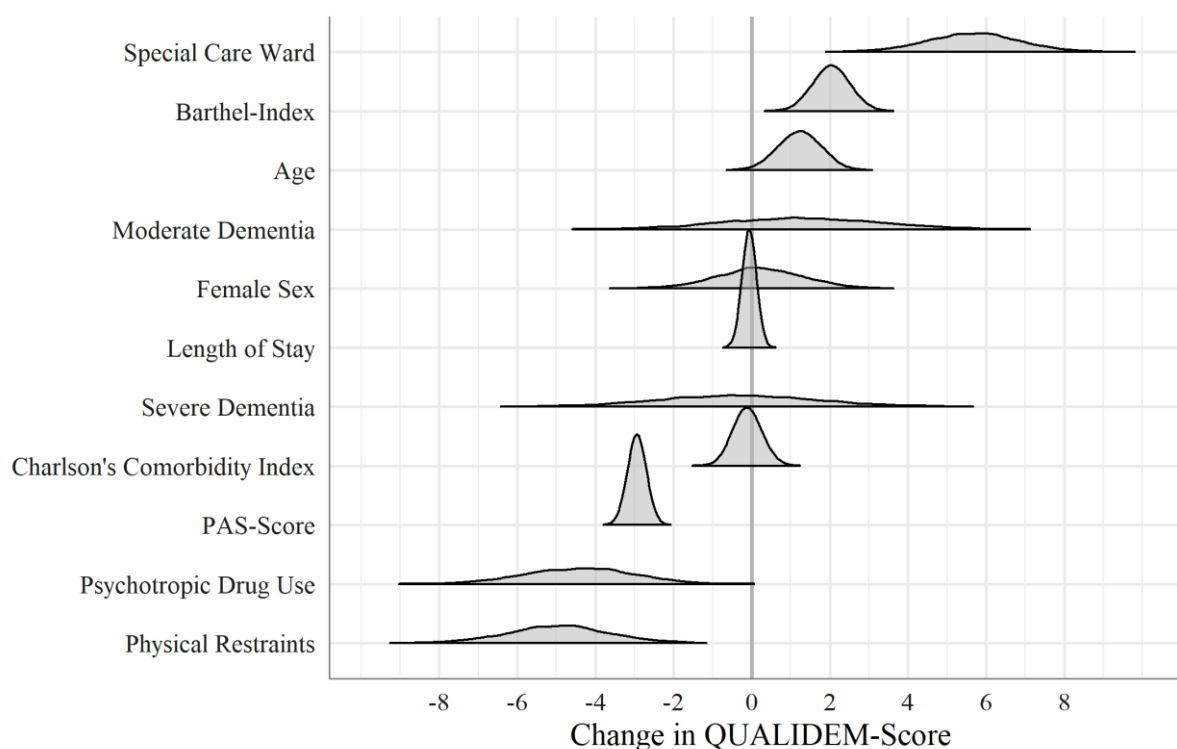
Methodological comments

1. Short note on Bayesian Methods

Bayesian methods are probably not very common, and readers may ask “Why use Bayesian regression models?” Gelman et al.¹ give a well summarized answer to this question: “A pragmatic rationale for the use of Bayesian methods is the inherent flexibility introduced by their incorporation of multiple levels of randomness and the resultant ability to combine information from different sources, while incorporating all reasonable sources of uncertainty in inferential summaries. Such methods naturally lead to smoothed estimates in complicated data structures and consequently have the ability to obtain better real-world answers.”¹. Shortly speaking, advantages of Bayesian methods are, for instance, the ability to derive probability statements for every quantity of interest or explicitly incorporate prior knowledge about parameters into the model.

2. Distribution of Posterior Samples from the Regression Model

Contrary to a frequentist approach, there is no unique point estimate in Bayesian analysis. The posterior median minimises the expected absolute error (i.e. the difference of estimates from true values over posterior samples), but there are many other plausible values to describe the association between predictors and outcome, which is called the *distribution of posterior samples*. Credible or Highest Density Intervals are based on quantiles of this distribution and indicate the probability of an estimate being inside this interval. In terms of inference, this allows us to say that with, e.g. 50% probability, the true effect of a *Special Care Ward* on our outcome lies between 5.1 and 6.6. Figure S1 shows the distribution of posterior samples from our regression model.

Figure S1: Distribution of Posterior Samples from Regression Model

3. Tabular Summary from the Regression Model

Table S1 provides a summary of the regression model, including the data for two different Highest Density Intervals as well as the ratio of effective number of samples. The ratio should be 1.0 or close to 1.0 and indicates whether the samples were efficient, which means that the results for the related coefficient are reliable. Furthermore, all R_{hat} values of the models were approximately 1. The R_{hat} statistic² measures the ratio of the average variance of the draws within each chain to the variance of the pooled draws across chains. If the chains have not converged to a common distribution, the R_{hat} statistic will tend to be greater than one, indicating that more iterations may be required for reliable results.

Table S1: Predictors of Quality of Life, Regression Coefficients, Bayesian Linear Mixed Model, Posterior Median (+50% and 89% Highest Density Intervals)

Term	Estimate	SE	50% HDI	89% HDI	Ratio of effective Number of Samples
(Intercept)	46.2	2.2	45.2 – 48.2	42.7 – 49.8	1.00
Length of Stay	-0.1	0.1	-0.1 – 0.0	-0.2 – 0.1	1.00
Age	1.2	0.5	0.8 – 1.5	0.4 – 2.1	1.00
Moderate Dementia	1.2	2.0	-0.1 – 2.7	-1.8 – 4.6	1.00
Severe Dementia	-0.4	2.0	-1.6 – 1.1	-3.6 – 2.7	1.00
Female	0.2	1.1	-0.5 – 1.0	-1.6 – 1.9	1.00
Barthel Score	2.0	0.5	1.8 – 2.4	1.3 – 2.8	1.00
Physical Restraints (yes)	-4.9	1.2	-5.8 – -4.1	-7.0 – -2.8	1.00
Special Care Ward (Intervention)	5.7	1.2	4.9 – 6.5	3.8 – 7.6	1.00
PAS-Score	-2.9	0.2	-3.1 – -2.8	-3.2 – -2.7	1.00
Charlson's Comorbidity Index	-0.1	0.3	-0.4 – 0.1	-0.6 – 0.5	1.00
Psychotropic Drug Use (yes, as-needed)	-4.4	1.4	-5.3 – -3.5	-6.5 – -2.1	1.00
sigma	11.9	0.4	11.5 – 12.0	11.3 – 12.5	1.00

All Rhat values ~ 1, all mcse < 0.05. Results based on 4 chains each 1000 iterations for each chain. LOO-adjusted R²: 0.500

4. Test for Practical Equivalence of Parameters

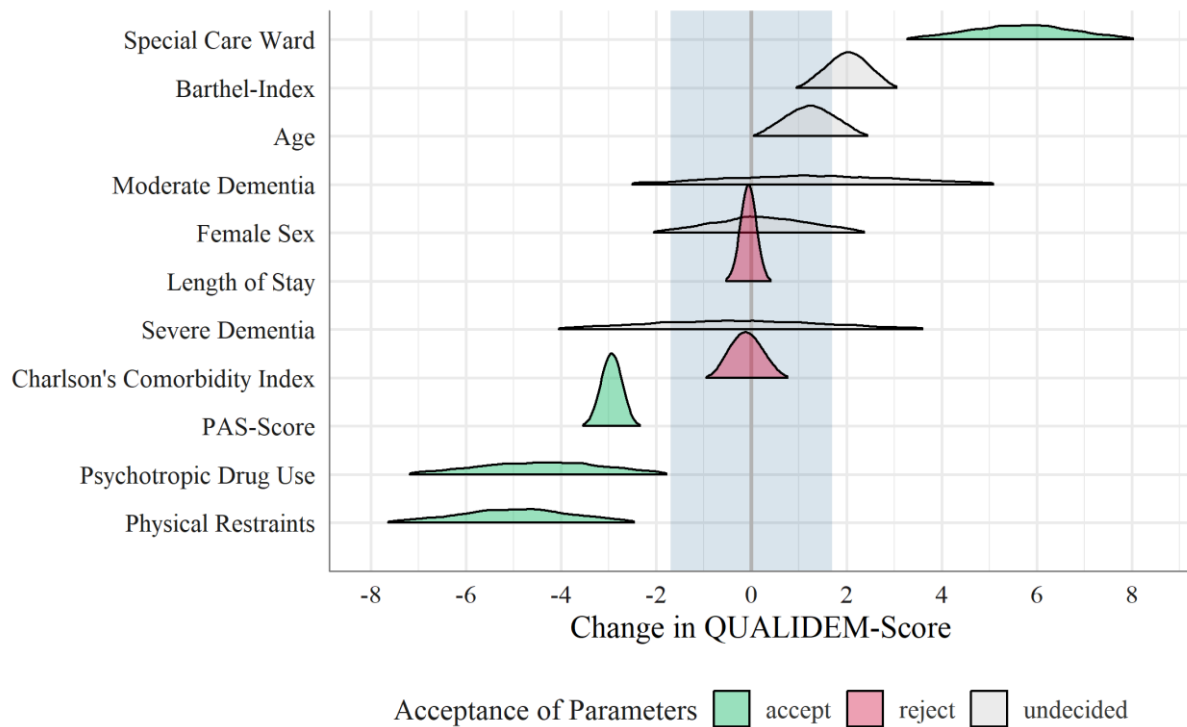
Bayesian methods do not perform classical “null hypothesis significance tests”. Rather, to account for the uncertainty in estimation and the magnitude of parameter values, Kruschke³ suggests checking whether parameter values lie inside a certain range that is considered as “practically no effect”.

Figure S2 shows the distribution of the 95% Highest Density Intervals of posterior samples and indicates whether these lie completely outside, completely inside or partially inside the region of practical equivalence (ROPE). If the HDI is completely outside the ROPE, the “null hypothesis” for this parameter is “rejected”. If the ROPE completely covers the HDI, i.e. all most credible values of a parameter are inside the region of practical equivalence, the null hypothesis is accepted. Else, it is undecided whether to accept or reject the null hypothesis.

The ROPE limits are specified following Kruschke's suggestion, which is defined as $0 \pm SD(\text{dependent variable}) * 0.1$ for linear models.

Physical restraint, psychotropic drug use, agitation (PAS-score) and the intervention (special care ward) are those predictors that can be considered as relevant for our outcome.

Figure S2: 95%-Range of the Distribution of Posterior Samples from Regression Model; Region of Practical Equivalence emphasized in light-blue.



5. Summary of the Distribution of Prior and Posterior Samples

Bayesian regression models can incorporate prior information about the parameters. Informative or weakly informative priors have the advantage of regularization of parameters to rule out large effects. This leads to less biased results and reductions of outliers in situations where the sample size in general, or for certain groups in the data, is small. Where we found information about our parameters, we included it by specifying *informative priors*. For instance, studies suggest that physical restraints are, on average, associated with an about 5-point reduction in quality of life, so the *location* of the prior distribution of our parameter physical restraint is at -5.0 (see Table S2). *Weakly informative priors* simply have a location of zero.

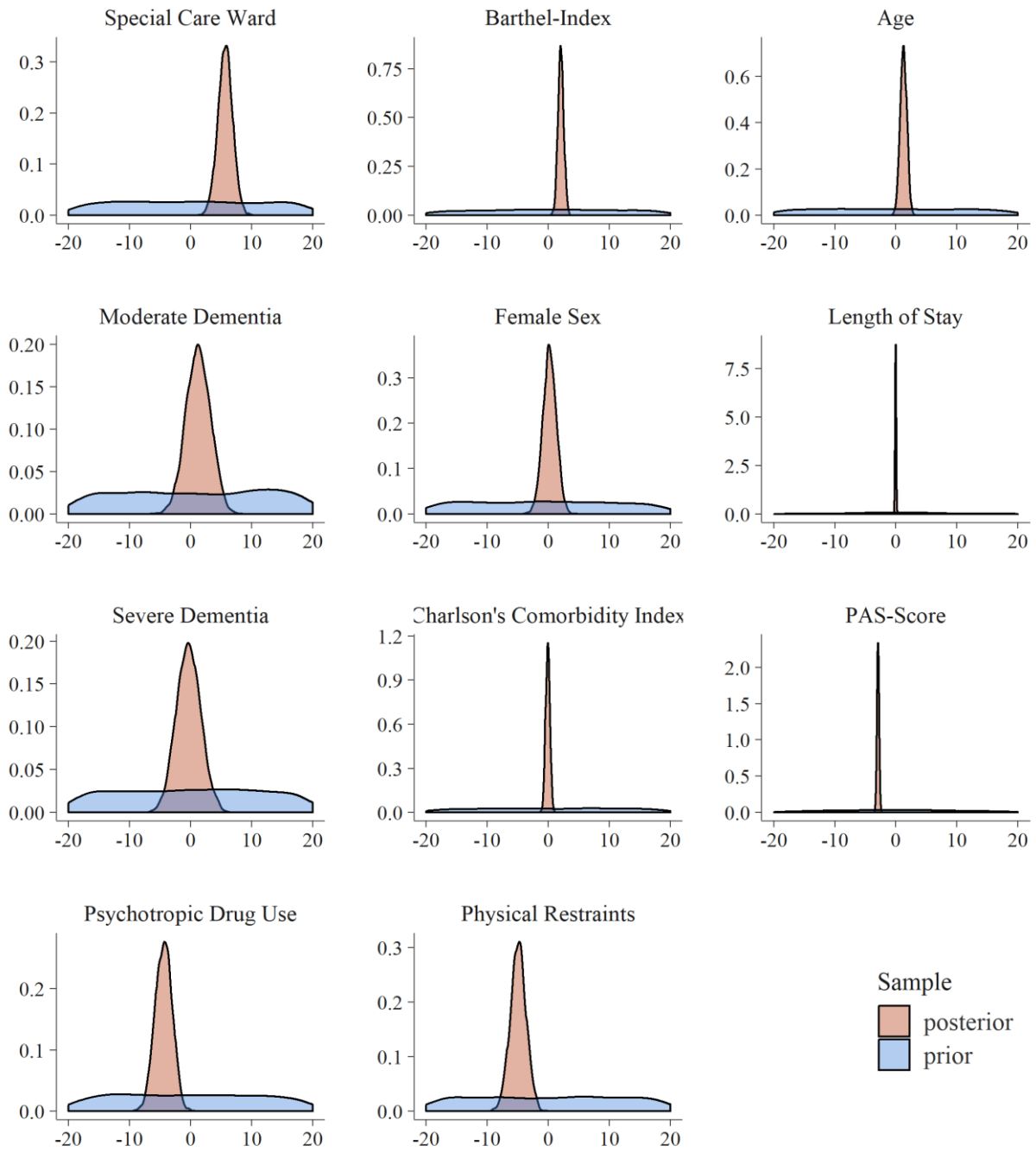
Table S2: Prior Summary

Predictor	Location	Scale
Length of Stay	0.00	6
Age	0.16	40
Moderate dementia	0.00	42
Severe dementia	-0.44	42
Sex, female	-3.22	42
Barthel-Score	0.00	29
Physical restraints	-5.00	42
Special Care Ward	0.00	42
PAS-Score	0.00	13
Charlson's Comorbidity Index	0.00	27
Psychotic Drug Use	0.29	42

To prevent a too strong shrinkage of uncertainty, the *scale* of the prior distribution should be large enough. If no assumptions about the scale of the effect are made, a recommended way (for normally distributed priors) is to use a scale of 2.5 and adjust it by dividing the scale by the standard deviation of the related predictor and multiply it with the standard deviation of the outcome ($2.5 * SD(y) / SD(x)$, see <https://cran.r-project.org/web/packages/rstanarm/vignettes/priors.html>).

When the evidence in the data is *strong*, the impact of the prior information is rather low. On the other hand, if the evidence of the data is *weak*, for instance due to small sample size, the impact of the prior information increases. Figure S3 shows the summary of the prior and posterior sample distributions and suggests that the evidence in the data was rather strong and results were not biased due to unrealistic prior information.

Figure S3: Posterior versus Prior Summary

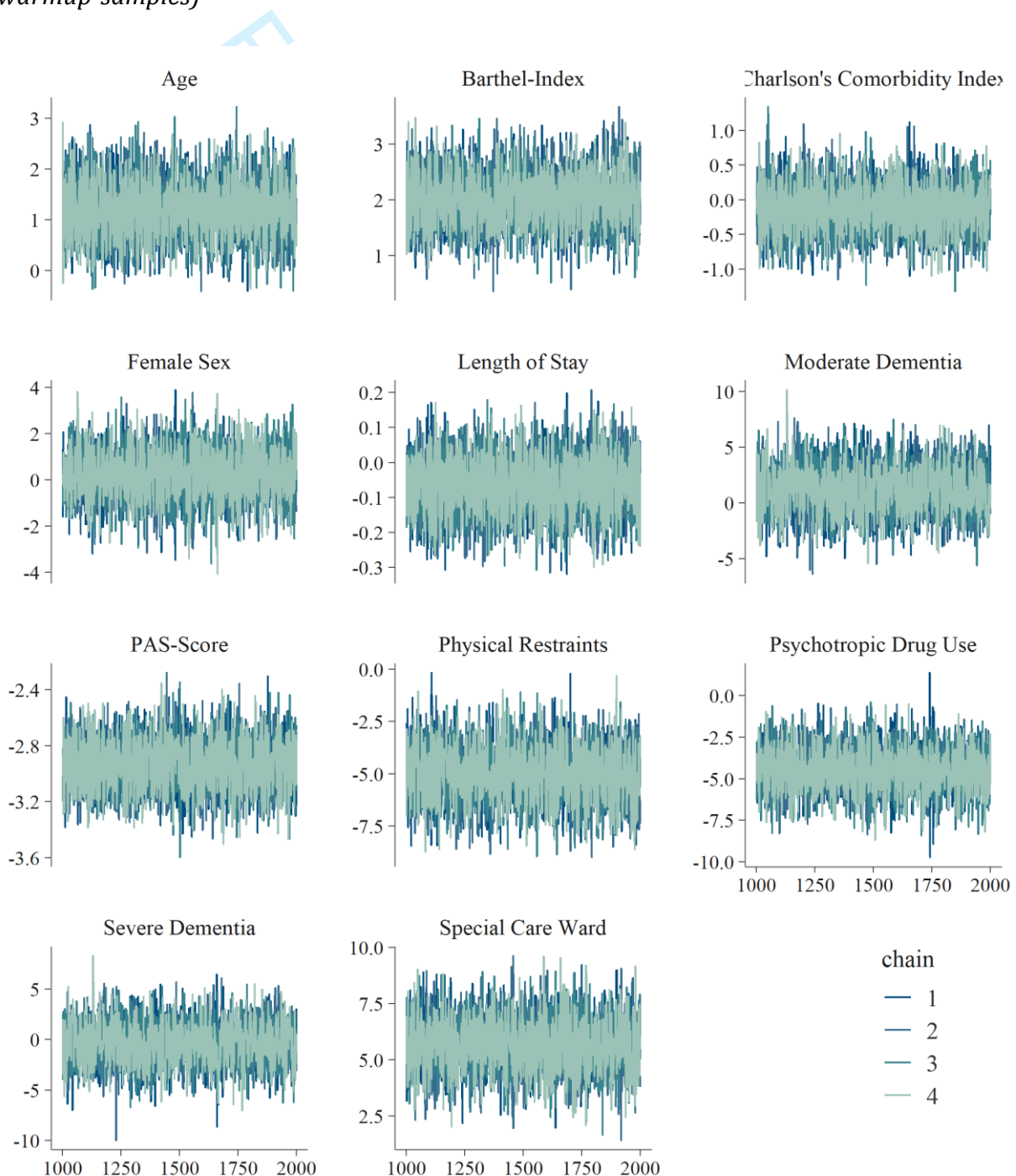


6. Trace plots

A trace plot provides a visual way to inspect sampling the behaviour and can be used, besides the Rhat-statistics, to assess convergence. The desired pattern is a “fat, hairy caterpillar”, which shows no suspicious bends^{4, 5}. If the chains converged to the posterior distribution, we can be confident in our model-based inferences.

The trace plot in Figure S4 indicates that all chains have converged well.

Figure S4: Markov Chain trace plot, 4 chains with 1000 iterations each (excluding warmup-samples)



7. References

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Supplemental Material 3

To see if the complexity of patients' needs affect our findings, we calculated regression models with interaction terms between need factors moderated by hospitals. The figures S5 to S8 show the results of the interaction terms. Table S3 shows the coefficients in details. We found no "significant" associations for the interaction terms, concluding that the association between complexity of patients' needs and quality of life is not differing noticeably between the intervention and control group.

Plots were created using the *ggeffects* package in R (Lüdtke D. *ggeffects*: Tidy Data Frames of Marginal Effects from Regression Models. *Journal of Open Source Software*. 2018;3: 772. doi:10.21105/joss.00772).

Figure S5: Interaction between Barthel-Index and Intervention/Control-Group

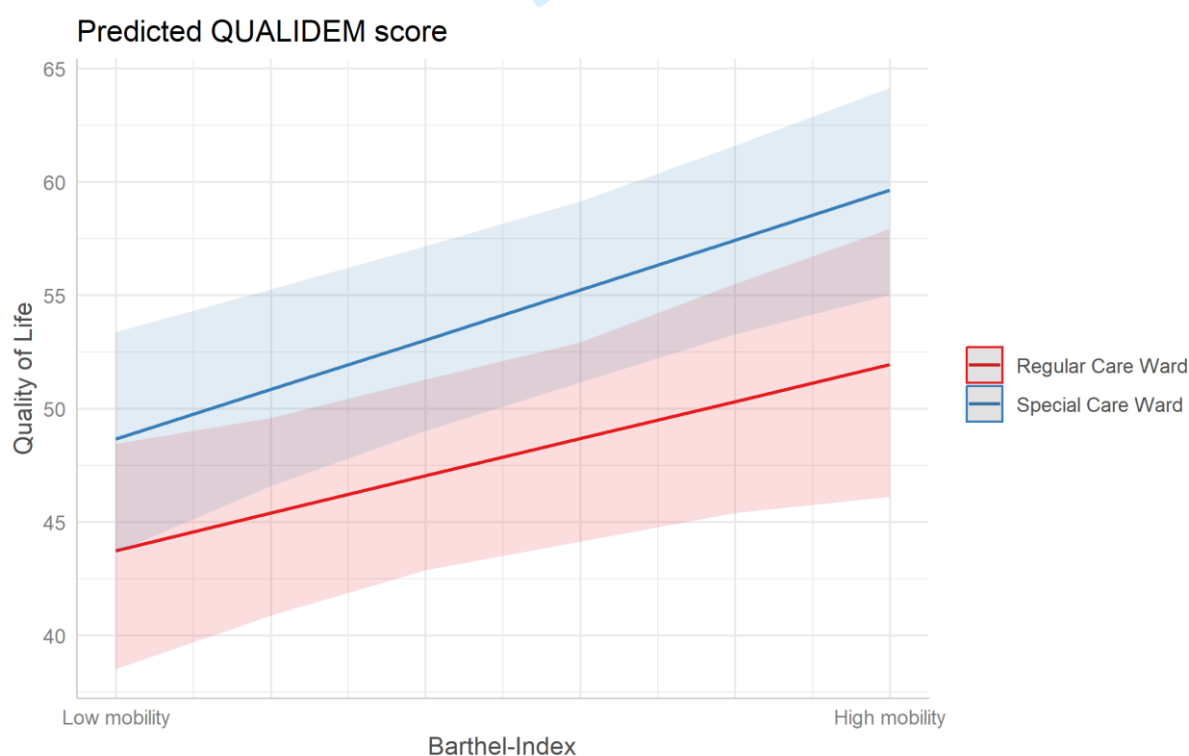


Figure S6: Interaction between Physical Restraints and Intervention/Control-Group

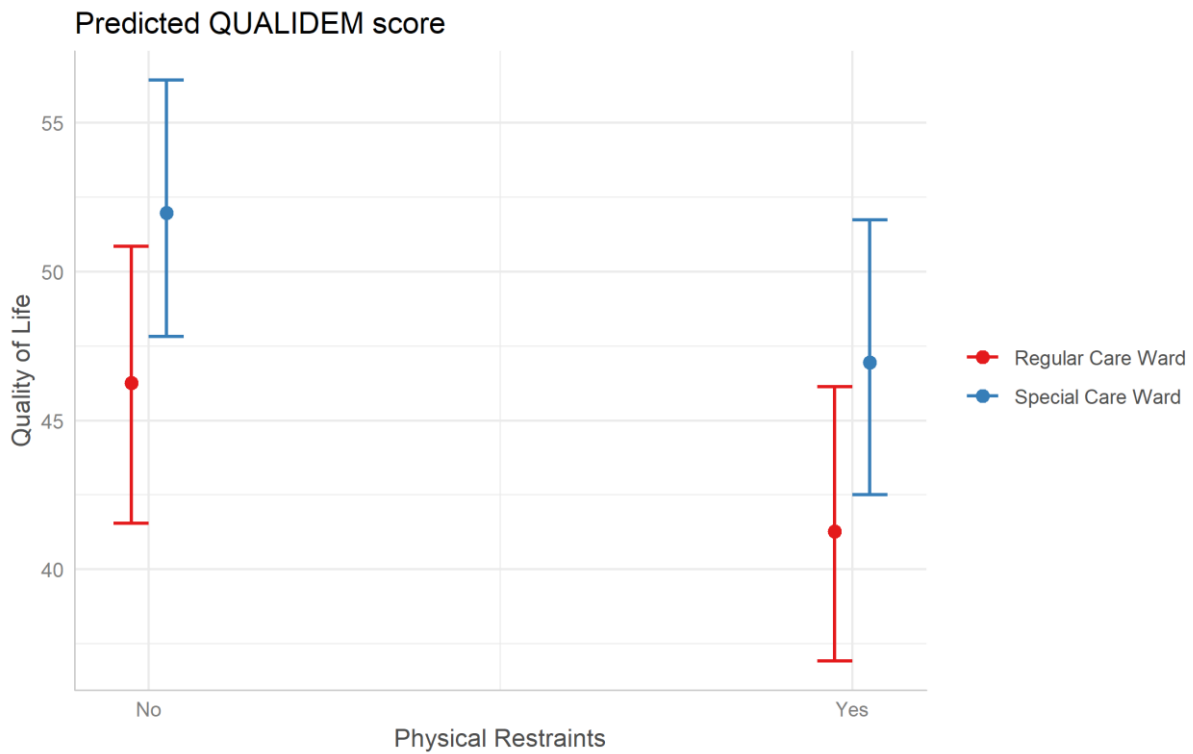


Figure S7: Interaction between PAS and Intervention/Control-Group

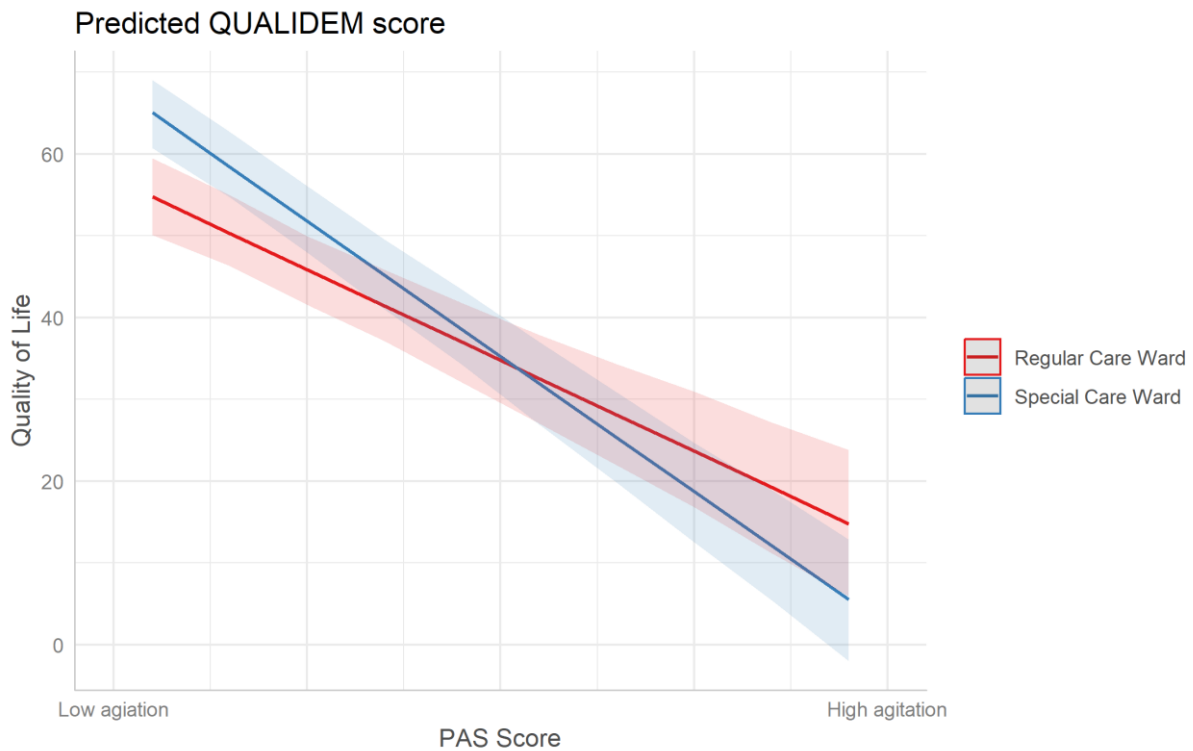
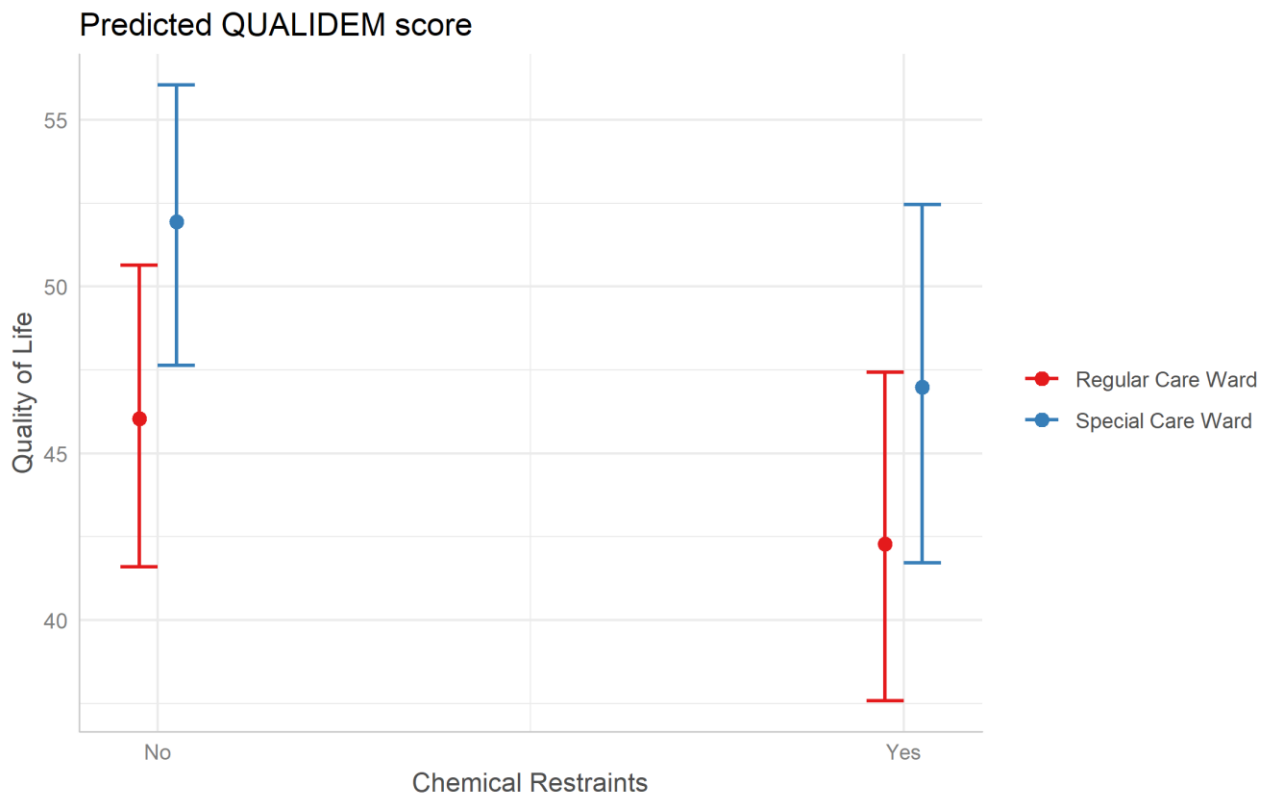


Figure S8: Interaction between Chemical Restraints and Intervention/Control-Group



review only

Table S3: Coefficients for Models with Interaction Terms

Terms	Model: Interaction between Barthel and Hospital		Model: Interaction between Physical Restraints and Hospital		Model: Interaction between PAS and Hospital		Model: Interaction between Chemical Restraints and Hospital	
	Estimates	HDI (95%)	Estimates	HDI (95%)	Estimates	HDI (95%)	Estimates	HDI (95%)
(Intercept)	36.18	26.19 – 45.67	36.31	27.00 – 46.10	36.57	27.11 – 45.71	36.16	26.45 – 45.69
Length of Stay	-0.07	-0.23 – 0.11	-0.06	-0.23 – 0.09	-0.07	-0.23 – 0.10	-0.06	-0.22 – 0.10
Age	0.12	0.01 – 0.23	0.12	0.02 – 0.23	0.12	0.01 – 0.22	0.12	0.02 – 0.23
Moderate Dementia	1.21	-2.79 – 5.13	1.19	-2.72 – 5.24	1.19	-2.83 – 4.72	1.25	-2.95 – 4.89
Severe Dementia	-0.34	-4.30 – 3.70	-0.44	-4.45 – 3.65	-0.74	-4.54 – 3.10	-0.30	-4.45 – 3.59
Female	0.16	-2.06 – 2.29	0.19	-1.98 – 2.29	0.52	-1.53 – 2.70	0.23	-1.76 – 2.53
Charlson's Comorbidity Index	-0.12	-0.81 – 0.59	-0.11	-0.77 – 0.64	-0.11	-0.77 – 0.59	-0.11	-0.82 – 0.59
Barthel Score	1.66	0.27 – 2.99	2.02	1.15 – 2.88	2.07	1.17 – 2.97	2.05	1.13 – 2.98
Physical Restraints (yes)	5.74	3.48 – 7.90	5.76	2.67 – 8.72	5.95	3.64 – 8.18	5.94	3.44 – 8.62
Special Care Ward (Intervention)	-5.02	-7.65 – -2.54	-4.92	-8.57 – -1.11	-4.94	-7.60 – -2.41	-4.96	-7.83 – -2.58
PAS-Score	-2.96	-3.30 – -2.62	-2.94	-3.30 – -2.61	-2.22	-2.77 – -1.66	-2.93	-3.27 – -2.59
Psychotropic Drug Use (yes, as-needed)	-4.43	-7.10 – -1.83	-4.40	-7.08 – -1.87	-4.30	-6.81 – -1.56	-3.76	-7.83 – -0.03
Barthel * Intervention	0.52	-1.00 – 2.06						
Phys. Restr. * Intervention			-0.09	-4.46 – 4.66				
PAS * Intervention					-1.09	-1.76 – -0.42		
Chem. Restr. * Intervention							-1.15	-6.63 – 4.27

Supplemental Material 4 – R Source Code

```

1
2 library(tidyverse)
3 library(gggridges)
4 library(sjmisc)
5 library(sjlabelled)
6 library(sjstats)
7 library(sjPlot)
8 library(insight)
9 library(bayestestR)
10 library(brms)
11
12 # Data available at https://doi.org/10.5281/zenodo.1479676
13
14 # load data ----
15 load("Dataset.RData")
16
17 # divide age by 10
18 d$age10 <- d$age / 10
19
20 # Labels for final model ----
21
22 labs <-
23   c(
24     stay_c = "Length of Stay",
25     age = "Age",
26     age10 = "Age",
27     mmse2 = "Moderate Dementia",
28     mmse3 = "Severe Dementia",
29     sex2 = "Female Sex",
30     barthel_code = "Barthel-Index",
31     groupintervention = "Special Care Ward",
32     physres1 = "Physical Restraints",
33     pas_c = "PAS-Score",
34     cci_c = "Charlson's Comorbidity Index",
35     chemicalres1 = "Psychotropic Drug Use", # oder as-needed
36     b_stay_c = "Length of Stay",
37     b_age = "Age",
38     b_age10 = "Age",
39     b_mmse2 = "Moderate Dementia",
40     b_mmse3 = "Severe Dementia",
41     b_sex2 = "Female Sex",
42     b_barthel_code = "Barthel-Index",
43     b_groupintervention = "Special Care Ward",
44     b_physres1 = "Physical Restraints",
45     b_pas_c = "PAS-Score",
46     b_cci_c = "Charlson's Comorbidity Index",
47     b_chemicalres1 = "Psychotropic Drug Use" # oder as-needed
48   )
49
50 # prior-definition in brms ----
51
52 # scale is 2.5 * sd(y) / sd(x)
53
54 bprior <-
55   prior(normal(0, 6), class = "b", coef = "stay_c") +
56   prior(normal(.1554, 40), class = "b", coef = "age10") +
57   prior(normal(0, 42), class = "b", coef = "mmse2") +
58   prior(normal(-.444, 42), class = "b", coef = "mmse3") +
59   prior(normal(-3.219, 42), class = "b", coef = "sex2") +
60   prior(normal(0, 29), class = "b", coef = "barthel_code") +
61   prior(normal(-5, 42), class = "b", coef = "physres1") +
62   prior(normal(0, 42), class = "b", coef = "groupintervention") +
63   prior(normal(0, 13), class = "b", coef = "pas_c") +
64   prior(normal(.2925, 42), class = "b", coef = "chemicalres1") +
65   prior(normal(0, 26.77), class = "b", coef = "cci_c")
66
67 # see:
68 # Beerens HC, Sutcliffe C, Renom-Guiteras A, et al. Quality of Life and
69 # Quality of Care for People With Dementia Receiving Long Term Institutional
70 # Care or Professional Home Care: The European RightTimePlaceCare Study.

```

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# Journal of the American Medical Directors Association. 2014;15(1):54-61.
1 # doi:10.1016/j.jamda.2013.09.010
2 #
3 # QoL-Scale ranges from 13-52 (40 points). Effects from those study are
4 # multiplied by 2.5 (rescaling 40-points to 100-point-scale of QUALIDEM)
5 # see:
6 # Barca, M. L., Engedal, K., Laks, J., & Selbæk, G. (2011). Quality of Life
7 # among Elderly Patients with Dementia in Institutions. Dementia and Geriatric
8 # Cognitive Disorders, 31(6), 435-442. https://doi.org/10.1159/000328969
9 # QoL-scale ranges from 11-55 (45 points). Effects from those study are
10 # multiplied by 2.2 (rescaling 45-points to 100-point-scale of QUALIDEM)
11
12
13 # model formula ----
14 mf <-
15   formula(
16     QoL ~ stay_c + age10 + mmse + sex + cci_c +
17     barthel_code + physres + group + pas_c +
18     chemicalres + (1 | maindiag)
19   )
20
21 # brms-model ----
22
23 set.seed(1207)
24
25 m2a <- brm(
26   formula = mf,
27   data = d,
28   prior = bprior,
29   sample_prior = TRUE
30 )
31
32 # Figure 3 ----
33 theme_set(theme_sjplot2(base_size = 14, base_family = "serif"))
34
35 p <- plot_model(
36   m2a,
37   title = "",
38   axis.labels = labs,
39   sort.est = T,
40   colors = c("grey30"),
41   axis.title = "Change in QUALIDEM-Score",
42   wrap.title = 100,
43   wrap.labels = 20,
44   width = .2,
45   grid.breaks = 2,
46   size.inner = .1
47 ) +
48   ylab("Change in QUALIDEM Total Score") +
49   theme_sjplot2(base_size = 14, base_family = "serif")
50
51 p_pdf <- p +
52   theme_sjplot2(base_size = 28, base_family = "serif") +
53   theme(
54     panel.grid.major = element_line(size = .1),
55     panel.grid.minor = element_line(size = .05),
56     axis.line.x = element_line(size = .15),
57     axis.line.y = element_line(size = .15)
58   )
59
60 ggsave(filename = "Fig3.tiff", plot = p, width = 170, height = 120, units = "mm", dpi = 300,
61 compression = "lzw")
62 ggsave(filename = "Fig3.pdf", scale = 2, plot = p_pdf, width = 170, height = 120, units = "mm",
63 dpi = 300)
64
65 # Appendix S1: Test for practical equivalence ----
66
67 rope(m2a, rope = c(-6, 6))

```

```

1 rope(m2a, rope = c(-7.5, 7.5))
2 equivalence_test(m2a, parameters = "^(?!prior)")
3 equivalence_test(m2a, parameters = "^(?!prior)") %>% plot()
4
5 # Appendix S1, Table Regression Coefficients ----
6
7 tab_df(tidy_stan(m2a, prob = c(.5, .89), digits = 1))
8
9 # Appendix S1, Prior Adjustment ----
10 insight::get_priors(m2a)
11
12
13 # Appendix S1, Figure distribution Posterior Samples ----
14
15 tmp <- m2a %>%
16   as_tibble() %>%
17   select(2:12) %>%
18   gather(key = "predictor", value = "estimate") %>%
19   to_factor(predictor)
20
21 tmp$predictor <- lvl_reorder(tmp$predictor, c(9, 4, 8, 3, 7, 11, 10, 6, 1, 2, 5))
22
23 p2 <- ggplot(tmp, aes(x = estimate, y = predictor)) +
24   geom_vline(xintercept = 0, colour = "grey70", size = .8) +
25   geom_density_ridges2(rel_min_height = 0.001, scale = 2, alpha = .5) +
26   scale_x_continuous(breaks = seq(-8, 8, 2)) +
27   scale_y_discrete(labels = labs) +
28   labs(x = "Change in QUALIDEM-Score", y = NULL) +
29   theme_sjplot2(base_size = 14, base_family = "serif")
30
31 ggsave(filename = "FigS1.tiff", plot = p2, width = 190, height = 120, units = "mm", dpi = 300)
32
33 # Appendix S1, test for practical equivalence ----
34 ## Short version
35 equivalence_test(m2a, parameters = "^(?!prior)")
36 equivalence_test(m2a, parameters = "^(?!prior)") %>% plot()
37
38 ## More beautiful tweaked version
39
40 tmp.hdi <- hdi(m2a, prob = .95) %>%
41   slice(c(-c(1, 13:23)))
42
43 tmp2 <- m2a %>%
44   as_tibble() %>%
45   select(2:12) %>%
46   map2_df(tmp.hdi$CI_low, function(x, y) {
47     x[x < y] <- NA
48     x
49   }) %>%
50   map2_df(tmp.hdi$CI_high, function(x, y) {
51     x[x > y] <- NA
52     x
53   }) %>%
54   gather(key = "predictor", value = "estimate") %>%
55   to_factor(predictor)
56
57 tmp2$predictor <- lvl_reorder(tmp2$predictor, c(9, 4, 8, 3, 7, 11, 10, 6, 1, 2, 5))
58
59 tmp2$grp <- dplyr::case_when(
60   tmp2$predictor %in% c("b_stay_c", "b_cci_c") ~ "reject",
61   tmp2$predictor %in% c("b_age10", "b_mmse2", "b_mmse3", "b_sex2", "b_barthel_code") ~
62   "undecided",
63   TRUE ~ "accept"
64 )
65
66 p3 <- ggplot(tmp2, aes(x = estimate, y = predictor, fill = grp)) +
67   # rope based on "equi_test(model)".

```

```

1   annotate("rect", xmin = -1.7, xmax = 1.7, ymin = 0, ymax = Inf, fill = sjplot_pal(palette =
2   "us")[1], alpha = 0.15) +
3   geom_vline(xintercept = 0, colour = "grey70", size = .8) +
4   geom_density_ridges2(rel_min_height = 0.01, scale = 2, alpha = .4) +
5   scale_x_continuous(breaks = seq(-8, 8, 2)) +
6   scale_y_discrete(labels = labs) +
7   scale_fill_manual(values = sjplot_pal()[c(3, 1, 7)]) +
8   labs(x = "Change in QUALIDEM-Score", y = NULL, fill = "Acceptance of Parameters") +
9   theme_sjplot2(base_size = 14, base_family = "serif") +
10  theme(
11    legend.title = element_text(size = 13),
12    legend.position = "bottom",
13    axis.line.x = element_line(colour = "grey50"),
14    axis.line.y = element_line(colour = "grey50")
15  )
16  ggsave(filename = "FigS2.tiff", plot = p3, width = 190, height = 120, units = "mm", dpi = 300)
17
18  # Appendix S1, Posterior-Prior-Check ----
19
20  ## Short version
21  plot_model(m2a, type = "diag", axis.lim = c(-20, 20))
22
23  ## More beautiful tweaked version
24
25  pr_samp <- prior_samples(m2a) %>%
26    select(starts_with("b_")) %>%
27    gather(key = "Term", value = "Estimate") %>%
28    mutate(Sample = "prior")
29
30  ps_samp <- posterior_samples(m2a) %>%
31    select(starts_with("b_"), -b_Intercept) %>%
32    gather(key = "Term", value = "Estimate") %>%
33    mutate(Sample = "posterior")
34
35  m_pp_data <- bind_rows(pr_samp, ps_samp) %>% to_factor(Term)
36  m_pp_data$Term <- lvls_reorder(m_pp_data$Term, rev(c(8, 3, 10, 4, 7, 5, 11, 6, 1, 2, 9)))
37
38  p4 <- ggplot(m_pp_data, aes(x = Estimate, fill = Sample)) +
39    geom_density(alpha = .4) +
40    scale_x_continuous(limits = c(-20, 20)) +
41    facet_wrap(
42      ~ Term,
43      scales = "free",
44      labeller = labeller(Term = labs),
45      nrow = 4
46    ) +
47    labs(x = NULL, y = NULL) +
48    bayesplot::theme_default(base_size = 13) +
49    theme(
50      axis.line.x = element_line(colour = "grey50"),
51      axis.line.y = element_line(colour = "grey50"),
52      axis.text = element_text(colour = "grey10"),
53      axis.title = element_text(colour = "black"),
54      # strip.background = element_rect(colour = "grey50", fill = "grey90"),
55      # strip.text = element_text(colour = "grey20"),
56      legend.title = element_text(colour = "grey10"),
57      legend.text = element_text(colour = "grey20"),
58      legend.position = c(.5, .15),
59      legend.justification = c(-2, 1)
60    ) +
61    scale_fill_manual(values = sjplot_pal("breakfast club")[c(1, 3)])
62
63  ggsave(filename = "FigS3.tiff", plot = p4, width = 190, height = 214, units = "mm", dpi = 300)
64
65  # Appendix S1, Traceplot ----
66
67  p <- rstan::traceplot(m2a$fit, pars = colnames(as.data.frame(m2a))[1:12], inc_warmup = F)
68  p$data$parameter <- as.character(p$data$parameter)
69  tmp <- p$data %>%
70    filter(parameter != "b_Intercept")

```

```
for (i in 1:length(labs)) {
1   if (names(labs)[i] %in% tmp$parameter) {
2     r <- which(tmp$parameter == names(labs)[i])
3     tmp$parameter[r] <- labs[i]
4   }
5 }
6 p5 <- ggplot(tmp, aes(x = iteration, y = value, colour = chain)) +
7   geom_line() +
8   facet_wrap(~parameter, scales = "free_y", ncol = 3) +
9   scale_color_manual(values = sjplot_pal("us", n = 4)) +
10  labs(x = NULL, y = NULL) +
11  bayesplot::theme_default(base_size = 13) +
12  theme(
13    axis.line.x      = element_line(colour = "grey50"),
14    axis.line.y      = element_line(colour = "grey50"),
15    axis.text        = element_text(colour = "grey10"),
16    axis.title       = element_text(colour = "black"),
17    # strip.background = element_rect(colour = "grey50", fill = "grey90"),
18    # strip.text       = element_text(colour = "grey20"),
19    legend.title     = element_text(colour = "grey10"),
20    legend.text      = element_text(colour = "grey20"),
21    legend.position  = c(.5, .15),
22    legend.justification = c(-4.2, 0.7)
23  )
24 ggsave(filename = "FigS4.tiff", compress = "lzw", plot = p5, width = 190, height = 214, units =
25 "mm", dpi = 300)
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Supplemental Material 5

Regression Model with Alternative QUALIDEM-Score

A limitation of the QUALIDEM total score is how it is calculated for patients with very severe dementia. As recommended by the authors of QUALIDEM, only six of the nine subscales are used to calculate the total score [1]. Technically speaking, this is similar to simple mean value imputation of the missing scores for the three omitted subscales, resulting in biased and underestimated measurement error variance for this group. In order to see to which extent an alternative computation of the QUALIDEM total score might be more appropriate than the recommended approach, we calculated another regression model (called “New Model”, see *Table S4*). This model used a QUALIDEM total score based on full imputation of missing values for *all nine* subscales for patients with very severe dementia (instead of only using six subscales).

Table S4 shows the result of the new model in comparison to the main model presented in the manuscript. Both results for the estimates as well as standard error and HDI are very similar. This suggests that in our particular case we found no improvement in the estimation accuracy after imputing the missing values for the originally omitted three subscales for people with very severe dementia. Still it might be statistically more sound to either have the same amount of subscales for all groups of dementia severity or to consider appropriate missing data imputation algorithms for the group with very severe dementia. Thus, future research in QoL for patients with dementia should also focus on the reliability and validity of the QUALIDEM.

Table S4: Comparison of Models for two different QoL-Scores

Term	New Model with full imputed QoL-Score for very severe dementia			Main Model		
	Estimate	SE	89% HDI	Estimate	SE	89% HDI
Length of Stay	-0.0	0.1	-0.2 – 0.1	-0.1	0.1	-0.2 – 0.1
Age	0.8	0.5	-0.0 – 1.6	1.2	0.5	0.4 – 2.1
Moderate Dementia	1.1	1.9	-1.8 – 4.1	1.2	2.0	-1.8 – 4.6
Severe Dementia	-0.3	1.9	-3.2 – 2.7	-0.4	2.0	-3.6 – 2.7
Female	0.6	1.0	-1.0 – 2.2	0.2	1.1	-1.6 – 1.9
Barthel Score	2.0	0.4	1.3 – 2.7	2.0	0.5	1.3 – 2.8
Physical Restraints (yes)	-4.1	1.3	-6.1 – -2.1	-4.9	1.2	-7.0 – -2.8
Special Care Ward (Intervention)	5.2	1.1	3.4 – 6.9	5.7	1.2	3.8 – 7.6
PAS-Score	-2.7	0.2	-3.0 – -2.4	-2.9	0.2	-3.2 – -2.7
Charlson's Comorbidity Index	0.0	0.3	-0.5 – 0.5	-0.1	0.3	-0.6 – 0.5
Psychotropic Drug Use (yes, as-needed)	-4.3	1.3	-6.3 – -2.3	-4.4	1.4	-6.5 – -2.1

All Rhat values ~ 1, all mcse < 0.05. Results based on 4 chains each 1000 iterations for each chain.

1 Dichter MN, Quasdorf T, Schwab CGG, et al. Dementia care mapping: effects on residents' quality of life and challenging behavior in German nursing homes. A quasi-experimental trial. *International Psychogeriatrics* 2015;27:1875–92.
doi:10.1017/S1041610215000927

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of case-control studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4-5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	6-7
		(b) For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-10
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10-11
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	10-11
		(b) Describe any methods used to examine subgroups and interactions	10-11
		(c) Explain how missing data were addressed	10
		(d) If applicable, explain how matching of cases and controls was addressed	N/A
		(e) Describe any sensitivity analyses	N/A
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	12
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	12-13
		(b) Indicate number of participants with missing data for each variable of interest	12-13
Outcome data	15*	Report numbers in each exposure category, or summary measures of exposure	12-13
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	13-14
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	15-16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17-18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15-18
Generalisability	21	Discuss the generalisability (external validity) of the study results	18-19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.