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# Respectful Caring for the Agitated Elderly (ReCAGE)

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# Respectful Caring for the Agitated Elderly (ReCAGE): A Multicentre, Prospective, Observational Study to Evaluate the Effectiveness of Special Care Units for People with Dementia

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**Abstract.**
**Background:** Behavioral and psychological symptoms of dementia (BPSD) bring complexity in the clinical management of people with dementia; therefore, it is important to evaluate different models of care, such as Special Care Units (SCU-B).
**Objective:** To evaluate the SCU-B effectiveness toward alleviating BPSD and improving the quality of life (QoL) of patients and their caregivers.
**Methods:** ReCAGE was a multicenter, controlled, longitudinal study where 508 patients with BPSD were enrolled in two cohorts: 262 patients from centers endowed with a SCU-B, and 246 from centers without SCU-B. Statistical analyses included factorial ANCOVA for comparison among centers. The primary endpoint was effectiveness of the SCU-B, measured through the Neuropsychiatric Inventory (NPI) changes. Secondary endpoints were change in QoL of patients and caregivers, and the tertiary endpoint was time to nursing home admission.
**Results:** The NPI scores decreased in both arms, with a statistically significant difference from baseline to 36 months ($p < 0.0001$) in both cohorts. Over time, NPI decreased more steeply during the first year in the SCU-B arm, but in the following two years the slope was clearly in favor of the control arm. This different pattern of the two cohorts reached statistical significance at the interaction "cohort by time" ($p < 0.0001$). Conflicting results were found regarding the outcomes of quality of life, while there were no differences in time to institutionalization in both cohorts.
**Conclusions:** The RECage study did not confirm the long-term superiority of the pathway comprising a SCU-B. A *post-hoc* analysis revealed data supporting their acute effectiveness during behavioral crises.

Keywords: Alzheimer's disease, behavioral and psychological symptoms of dementia, caregiver burden, dementia, Neuropsychiatric Inventory, special care unit

## INTRODUCTION

Currently, the number of people with dementia is 55 million around the world, with estimates predicting a striking increase to 139 million by 2050, showing the importance of adapted health models to meet the needs of patients and caregivers [1]. If dementia is characterized by cognitive impairment with significant repercussions on the performance of daily activities, the concomitant presence of non-cognitive symptoms is also a constant feature in the trajectory of persons with dementia (PwD) [2].

The behavioral and psychological symptoms of dementia (BPSD) represent a heterogeneous group of non-cognitive symptoms occurring at some point in the disease trajectory in almost all PwD. They constitute a major component of the dementia syndrome irrespective of the underlying etiology and are not less clinically relevant than cognitive symptoms, as they strongly correlate with the degree of functional impairment, caregiver burden, inappropriate hospital admissions, and institutionalization [3–5]. Worldwide guidelines of good clinical practices recommend a comprehensive assessment of BPSD followed by multicomponent non-pharmacological approaches to be the first line of treatment, but there is lacking evidence of the exact standards of implementation among different settings [6].

However, the use of different classes of drugs such as anticholinesterase inhibitors, memantine, antidepressants, sedatives, and antipsychotics is frequent in the management of BPSD [7]. Up to 60% of persons with moderate or severe dementia PwD receive antipsychotics, although such medications are associated with a poor prognosis, increasing mortality, the risk of accelerated cognitive deterioration, and of stroke [8–10]. This panorama reveals the great challenge that is the management of BPSD in clinical practice [11].

To prevent these undesirable outcomes, Special Care Units (SCU-B) have in some countries been created in both acute and rehabilitation settings, with other special units integrating long-term care and nursing homes [12]. Despite the lack of a common definition of their standards, in this study we defined such units as those present in hospital wards where patients with BPSD are temporarily admitted when their behavioral symptoms are not amenable to being treated at home. The specific role of the SCU-B is to mitigate the challenging symptoms and to allow patients to get back home whenever possible [13].

Our group performed a scoping review of the literature that identified 33 studies that dealt with SCU-B (Pecoraro et al., unpublished). Nine studies provided only descriptive information about the SCU-B structure and organization. Among the studies that

evaluated the impact of SCU-B on patient-centered outcomes, only one was a randomized study and 23 were uncontrolled case series. As to clinical effectiveness, the only randomized clinical trial did not show statistically significant differences versus standard care as regards the primary outcomes, but patients and families were more satisfied [14]. From the uncontrolled studies there is some evidence that a short stay in SCU-Bs can improve BPSD, at least temporarily, and allow return home in approximately 50% of cases. As regards the possible long-term effectiveness, evidence is limited to short-term (1-year) and/or limited cost or health outcomes. In summary, the literature about SCU-B is scant, and the retrieved studies do not allow us to draw confident conclusions about the effectiveness of SCU-B on patient-centered outcomes in the long term.

We hypothesized that patients from regions where SCU-B is available had favorable short- and long-term outcomes in BPSD mitigation than those where such units did not exist. In this context, the main objective of the RECage (REspectful Caring for agitated Elderly) study is to evaluate the effectiveness of BPSD management of PwD in centers with and without SCU-B.

## METHODS

### *Design, setting, and population*

RECAGE was a multicenter, prospective observational study composed of two cohorts of patients with BPSD recruited in centers endowed with SCU-B and in centers lacking this facility. Of the 11 centers that participated in the study, five (Italy, Germany, France, Switzerland, and Norway) and six centers (Italy, Greece, France, and Germany), respectively, composed the two cohorts where there SCU-B were available or not.

Inclusion criteria comprised patients of any age, with a diagnosis of dementia of any etiology according to the DSM-IV, with a Mini-Mental State Examination (MMSE) less than or equal to 24 [15]. In addition, patients presented BPSD, with a Neuropsychiatric Inventory (NPI) score greater than or equal to 32 [16]. The presence of a family member or patient's caregiver during the study committed to the proposed follow-up was mandatory. Exclusion criteria comprised: 1) presence of uncontrolled physical diseases potentially contributing to the cognitive decline and BPSD, 2) concomitant psychiatric disorders or chronic alcoholism, and 3) concomitant diseases severe enough to reduce life expectancy.

The sample size was calculated on the comparison between the two cohorts only at the final time point. So, a difference given by an effect size of about 0.25 at a Student's t test for unpaired data with a power of 0.80 and a significance level of 0.05 (two-sided) could be demonstrated by a sample size of 250 patients in each cohort.

All centers had memory clinics that were the entry point for enrollment in the study. It is important to emphasize that hospitalization in an SCU-B was not mandatory for participation in the study in the centers where it was available. The centers endowed with a SCU-B facility contributed with 266 patients, while the centers without a SCU-B, contributed with 252 patients, for a total of 518 included patients. Ten patients did not perform any assessment after baseline and were therefore excluded from the modified intention to treat population (Fig. 1). The study was conducted according to the ethical principles of the Declaration of Helsinki. All patients, representatives, and caregivers received oral and written information about the study and provided written consent to participate. This study was approved by the local research ethics committees (Comitato Etico di Bergamo, REG.SPERIM. 25/18, 90.02.2018).

### *Study procedures*

Detailed information on the different procedures and the study protocol was the subject of a previous publication [17]. In brief, from the inclusion visit and during the 3-year follow-up of the study, patients and caregivers were extensively assessed by the project team, allowing the collection of clinical data from different domains. The dataset included demographic information, vital signs, active comorbidities and relevant medical history, dementia characteristics (age at diagnosis, etiology, severity of cognitive impairment), clinical examination, functional status, pharmacological treatment, BPSD assessment as well as the quality-of-life parameters of the patient and the caregiver. In addition, we also collected information on the medical-economic dimension, whose in-depth analysis will be the subject of another publication.

### *Follow-up*

The patients and their caregivers attended follow-up visits scheduled every 6 months. This follow-up

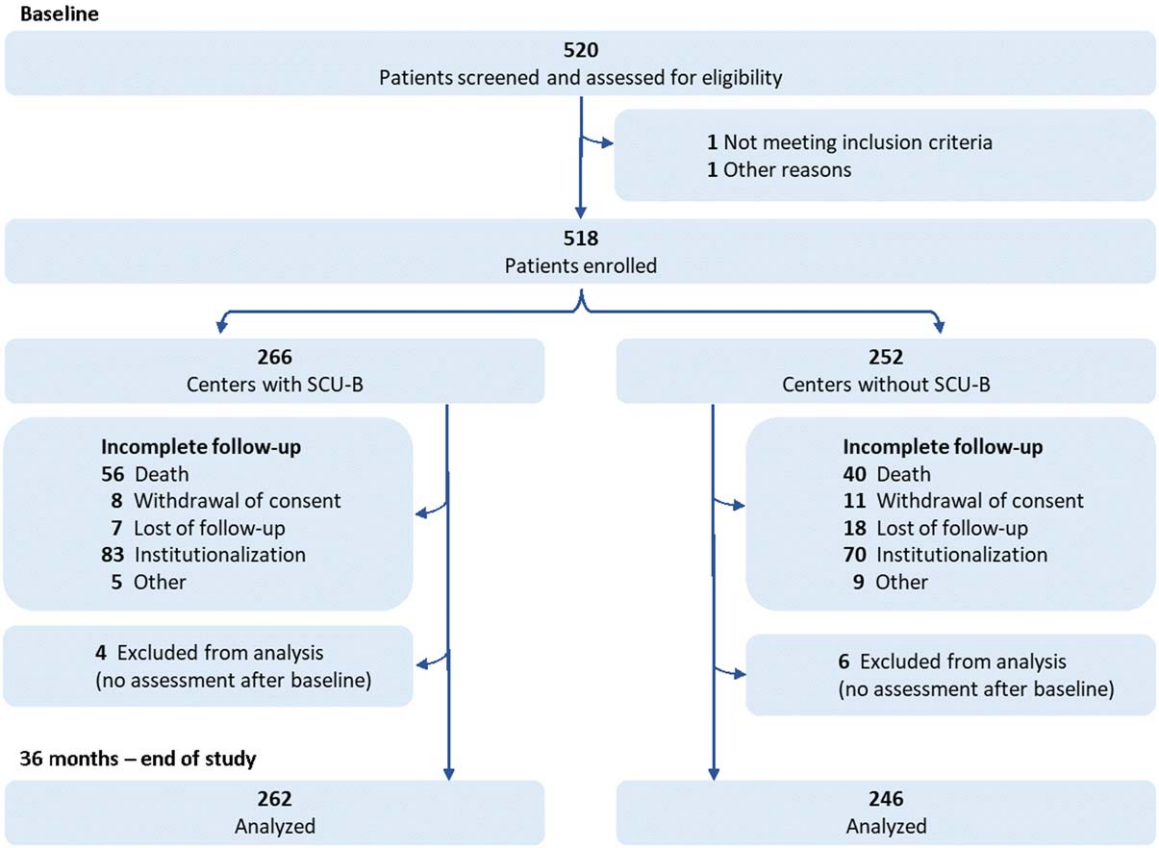


Fig. 1. Flowchart of enrollment and follow-up. SCU-B, special medical care unit for people with behavioral and psychological symptoms of dementia.

duration was chosen to encompass the different short- and long-term outcomes defined in this study. Unscheduled visits were organized if requested by the patient or the caregiver.

*Study outcomes*

The primary outcome referred to the effectiveness in the clinical management of BPSD in centers where SCU-B were available. Such effectiveness was measured through the changes in the total NPI scores from the first visit to the end of the study in both cohorts.

The patient's and caregiver's quality of life throughout the follow-up was established as a secondary outcome. We applied different clinical scales that concern the patient such as the Quality of Life in Alzheimer's Disease questionnaire (QoL-AD; self-rated and proxy-rated) [18] and caregivers such as Adult Carer Quality of life questionnaire (AC-QoL) [19], the Caregiver Burden Inventory (CBI) [20], and the Dementia Attitude Scale (DAS) [21]. It is important to emphasize that in chronic diseases of a progressive nature, as in the case of dementia, the measure of quality of life and caregiver burden will tend to worsen with evolution, even if appropriate interventions are implemented. Although this secondary outcome is not likely to improve in the long term, the differences in the trajectory of the two cohorts were of interest for this analysis. Moreover, the delay in admission to a nursing home was defined as a tertiary outcome.

Several safety-related outcomes were documented throughout the study. They included intercurrent adverse events, such as admission to an emergency room, hospitalization, and mortality. Other serious events anticipated were falls, injury due to falls, accelerated cognitive decline, accelerated functional decline, and parkinsonism. As the COVID-19 pandemic happened during the follow-up of patients and caregivers, the potential repercussions in the study results were also considered in the analysis of adverse events. We highlight the fact that one of the Italian centers with SCU-B, Gazzaniga, was in the Italian region most severely affected by the pandemic.

*Statistical analysis*

Descriptive statistics (mean with standard deviation, minimum and maximum, and 95% confidence interval for the variables with assumed Gaussian distribution; median with the first and third quartile, and interquartile range for the corresponding variables assumed not Gaussian distributed) have been calculated for continuous variables. For categorical variables, patient counts and percentages are provided. The baseline characteristics of the cohorts have been compared for qualitative variables by means of the chi-squared test. Student's *t*-test for unpaired data or its alternative non-parametric Wilcoxon rank sum test has been used for quantitative variables.

To compare the primary outcome, changes over time between the two cohorts and the propensity score was calculated by means of the SAS PROC PSMATCH with the cohort (SCU-B or non SCU-B) as the dependent variable and all the baseline patients' characteristics as the independent variables. Then, the pattern of the different scales over the time has been compared between the two cohorts by means of repeated measures of the ANCOVA model with the propensity score as a covariate. Particularly, the considered models have "Cohorts" at two levels (SCU-B and non-SCU-B) as a fixed "between subjects" factor, "Time" at seven levels (baseline or V0, V6, V12, V18, V24, V30, and V36) as a fixed factor "within subjects", and their interaction "Cohort by time". In addition, "subjects" is a random factor nested into the fixed factor "Cohorts".

The *post hoc* multiple comparison analysis has been carried out by adjusting the significant level according to Šidák [22]. These analyses have been carried out by means of SAS PROC MIXED according to several models (general linear model, heterogeneous general linear model, random coefficients linear model in order to consider the trend for each subject, and heterogeneous random coefficients linear model in considering the trend for each subject and a different pattern of the variance-covariance matrix of the two cohorts). Among the several considered models and patterns of variance-covariance matrices the heterogeneous general linear model with the unstructured matrix pattern has been selected according to a lower value of the Akaike's information criterion for the NPI analysis [23]. Pragmatically, a similar approach was used for the secondary outcomes with the total scores from the QoL-AD self-rated and proxy-rated, AC-QoL, CBI, and DAS scales. SAS PROC MIXED allows to deal with the missing data under the assumption that they are at least "missing at random".

Time to admission to a nursing home has been analyzed by means of the Kaplan-Meier estimate of the cumulative probability of placement to a nursing home and compared between the two cohorts by means of the log-rank test. Also, Cox's proportional hazard regression model to predict time to institutionalization was carried out in order to estimate the hazard ratio between the two cohorts. The statistical significance has been put at $p = 0.05$. All statistical analyses were performed using the SAS® (Statistical Analysis System) version 9.4.

## RESULTS

*Characteristics of the study population*

Overall, in both cohorts, BPSD severity significantly decreased at follow-up (Fig. 2). However, this decrease was more significant in the cohort without specialized units compared to centers with SCU-B (Fig. 3). These results contradict our initial hypothesis.

Of a total of 508 PwD included in the study, 54.9% were female, with a mean age of $78 \pm 7.93$ years, and $8.93 \pm 4.53$ years of formal education. Caregivers were mainly the spouse or the child, 70.2% were female, with a mean age of $61.89 \pm 12.75$ years. The most frequent etiology of dementia was Alzheimer's disease (58.4%), followed by dementia with multiple etiologies (16.4%). The mean MMSE was $15.45 \pm 6.25$ points at baseline. Multimorbidity was frequent in this population (90.6%), with hypertension (52.2%), dyslipidemia (17.5%), diabetes (17.1%), and depression (11.4%) being the most prevalent comorbidities documented. The mean NPI score was of 52.44 points, with the domains of apathy/indifference (85.4%), agitation/aggression (83.1%), depression/dysphoria (81.7%), and irritability/lability (80.9%) being the BPSD most frequently described. The AC-QoL scores of $71.28 \pm 18.09$ indicated a mid-range quality of life of caregivers at baseline. Furthermore, a high burden of caregivers was present with 47.4% presenting a CBI >36 points.

When comparing the characteristics of the centers with and without SCU-B, we highlight a lower proportion of women in those with SCU-B (50.4% versus 59.8%; $p = 0.0338$). Furthermore, caregivers from centers with SCU-B had higher quality of life in baseline according to the AC-QoL ($73.94 \pm 18.44$ versus $68.49 \pm 17.31$; $p = 0.0007$). Similarly, there was a

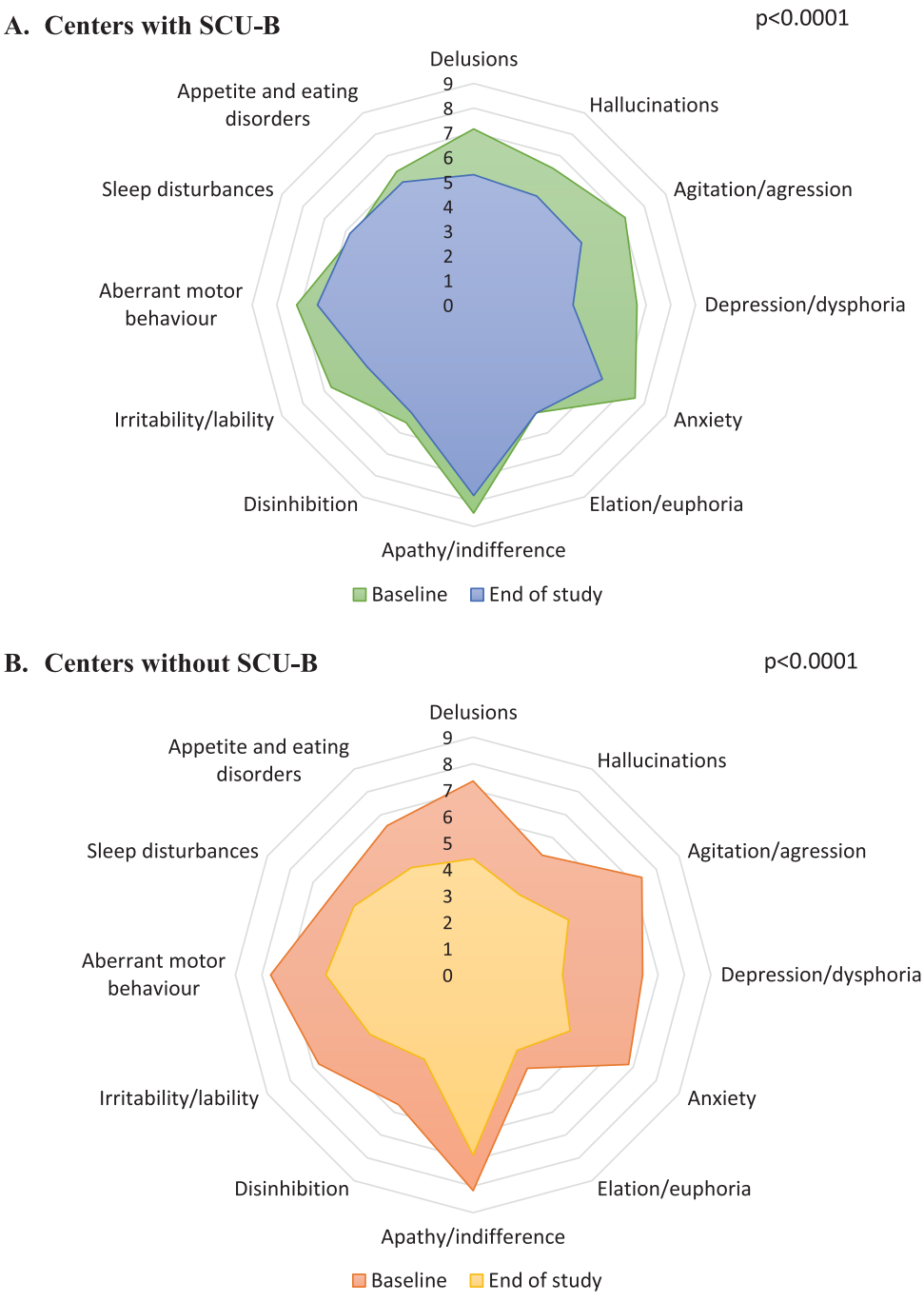


Fig. 2. Mean values of NPI domains at baseline and at the end of the study.

higher burden of caregivers in centers without SCU-B ($32.99 \pm 17.88$ versus $38.07 \pm 16.91$; $p = 0.0006$). Table 1 summarizes the different variables evaluated in both cohorts that finally showed a similar profile in the other parameters of the study.

*Effectiveness*

The Least Squares Means estimates of the total NPI score decreased in both cohorts according to a different pattern (interaction "cohort by time"

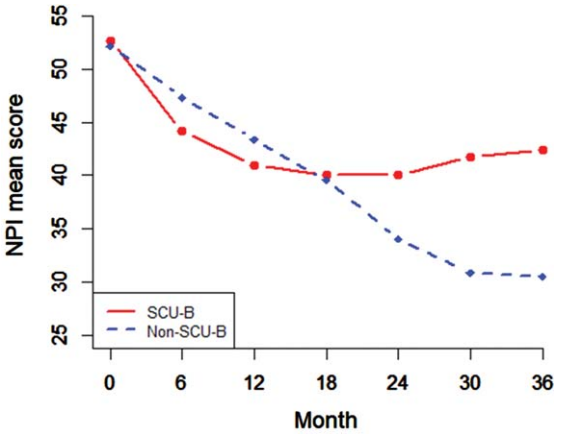


Fig. 3. Least square means of the Neuropsychiatric Inventory in baseline and during follow-up visits in centers with and without SCU-B. *p* value corresponds to the interaction "cohort by time".

was statistically significant: $p < 0.0001$) (Fig. 3). In the centers with SCU-B, the total NPI score decreased from 52.68 (baseline) by 16.21% (at 6 months), 22.21% (at 12 months), 24.0% (at 18 months), 23.95% (at 24 months), 20.73% (at 30 months), and finally, by 19.51% to a score of 42.30 at the 36-month visit. In the centers without SCU-B, the NPI decreased from a baseline of 52.12 by 9.27% (at 6 months), 16.82% (at 12 months), 24.12% (at 18 months), 34.69% (at 24 months), 40.81% (at 30 months), and finally by 41.40% to a score of 30.54 at the 36-month visit. In both cohorts the difference of NPI scores between baseline to the visit performed at the end of study was statistically significant, showing decreased levels of BPSD ($p < 0.0001$) (Fig. 2).

This difference favored the centers without SCU-B, which presented an increased pattern of

Table 1
Baseline characteristics of patients and caregivers included in the study

| Characteristics | Centers with SCU-B N = 262 | Centers without SCU-B N = 246 | *p* | Total N = 508 |
|---|---|---|---|---|
| **Demographics** | | | | |
| Age, y | 78.14 (8.42) | 78.04 (7.40) | 0.8909 | 78.09 (7.93) |
| Female sex | 132 (50.4%) | 147 (59.8%) | 0.0338 | 279 (54.9%) |
| Educational level, y | 9.11 (4.41) | 8.73 (4.65) | 0.1737 | 8.93 (4.53) |
| Primary caregiver | | | 0.8627 | |
| Spouse or child | 245 (93.8%) | 230 (93.5%) | | 475 (93.7%) |
| Other | 17 (6.2%) | 16 (6.5%) | | 33 (6.3%) |
| Caregiver age, y | 62.85 (12.55) | 60.87 (12.90) | 0.0797 | 61.89 (12.75) |
| Caregiver Female sex | 185 (70.9%) | 171 (69.5%) | 0.7362 | 356 (70.2%) |
| Caregiver educational level, y | 11.87 (4.06) | 12.69 (3.89) | 0.0269 | 12.24 (4.00) |
| **Vital signs**[a] | | | | |
| Height, cm | 166.62 (8.88) | 163.14 (9.89) | | 164.97 (9.52) |
| Weight, kg | 69.78 (12.81) | 70.62 (16.50) | | 70.17 (14.64) |
| BMI, kg/m$^2$ | 25.10 (3.56) | 26.39 (4.97) | | 25.71 (4.33) |
| Systolic blood pressure, mmHg | 126.77 (15.70) | 130.79 (17.73) | | 128.75 (16.83) |
| Diastolic blood pressure, mmHg | 77.06 (9.56) | 76.92 (10.14) | | 76.99 (9.84) |
| Heart rate, pulse/min | 72.65 (11.04) | 70.50 (11.65) | | 71.63 (11.37) |
| **Disease characteristics** | | | | |
| Age at diagnosis | 75.35 (8.80) | 75.15 (7.79) | 0.7646 | 75.25 (8.32) |
| Etiology[b] | | | 0.0828 | |
| Alzheimer's disease | 162 (62.1%) | 134 (54.5%) | | 296 (58.4%) |
| Vascular dementia | 28 (10.7%) | 3 (1.2%) | | 31 (6.1%) |
| Lewy body dementia | 13 (5.0%) | 10 (4.1%) | | 23 (4.5%) |
| Parkinson's disease | 1 (0.4%) | 5 (2.0%) | | 6 (1.2%) |
| Frontotemporal dementia | 19 (7.3%) | 19 (7.7%) | | 38 (7.5%) |
| Multiple etiologies | 34 (13.0%) | 49 (19.9%) | | 83(16.4%) |
| Not specified | 5 (1.5%) | 26 (10.6%) | | 31(5.9%) |
| Cognitive impairment | | | | |
| Memory | 252 (96.2%) | 240 (97.6%) | 0.1357 | 492 (96.9%) |
| Executive functioning | 211 (80.5%) | 200 (81.3%) | 0.0553 | 411 (80.9%) |
| Language | 105 (40.1%) | 114 (46.3%) | 0.0939 | 219 (43.1%) |
| Visuospatial | 136 (51.9%) | 127 (51.6%) | 0.3436 | 263 (51.8%) |
| Frontal | 111 (42.4%) | 131 (53.3%) | 0.0007 | 242 (47.6%) |
| Apraxia | 103 (39.3%) | 125 (50.8%) | 0.0014 | 228 (44.9%) |

(*Continued*)

Table 1
(*Continued*)

| Characteristics | Centers with SCU-B N = 262 | Centers without SCU-B N = 246 | *p* | Total N = 508 |
|---|---|---|---|---|
| **Patient status** | | | | |
| MMSE (0–30) | 15.88 (6.08) | 14.99 (6.41) | 0.1102 | 15.45 (6.25) |
| ADCS-ADL (0–78) | 34.59 (18.47) | 35.93 (17.65) | 0.4058 | 35.24 (18.07) |
| Basic activities | 14.77 (5.94) | 13.72 (5.72) | 0.0434 | 14.26 (5.85) |
| Instrumental activities | 19.82 (13.61) | 22.21 (12.85) | 0.0425 | 20.98 (13.29) |
| NPI total score (0–144)[c] | 52.87 (16.45) | 51.98 (21.27) | 0.5963 | 52.44 (18.92) |
| Delusions | 178 (67.9%) | 145 (58.9%) | 0.0352 | 323 (63.6%) |
| Hallucinations | 100 (38.2%) | 80 (32.5%) | 0.1835 | 180 (35.4%) |
| Agitation / aggression | 225 (85.9%) | 197 (80.1%) | 0.0817 | 422 (83.1%) |
| Depression / dysphoria | 221 (84.4%) | 194 (78.9%) | 0.1099 | 415 (81.7%) |
| Anxiety | 211 (80.5%) | 193 (78.5%) | 0.5617 | 404 (79.5%) |
| Elation / euphoria | 52 (19.8%) | 56 (22.8%) | 0.4220 | 108 (21.3%) |
| Apathy / indifference | 226 (86.3%) | 208 (84.6%) | 0.5858 | 434 (85.4%) |
| Disinhibition | 101 (38.5%) | 142 (57.7%) | <0.0001 | 243 (47.8%) |
| Irritability / lability | 220 (84.0%) | 191 (77.6%) | 0.0698 | 411 (80.9%) |
| Aberrant motor behavior | 183 (69.8%) | 162 (65.9%) | 0.3352 | 345 (67.9%) |
| Sleep disturbances | 165 (63.0%) | 149 (60.6%) | 0.5767 | 314 (61.8%) |
| Appetite and eating disorders | 133 (50.8%) | 163 (66.3%) | 0.0004 | 296 (58.3%) |
| **Patient and caregiver quality of life** | | | | |
| Patient QoL-AD; proxy-rated | 28.33 (6.35) | 28.52 (6.39) | 0.7317 | 28.42 (6.36) |
| Patient QoL-AD; self-rated | 34.67 (5.52) | 34.24 (6.62) | 0.4743 | 34.45 (6.09) |
| AC-QoL | 73.94 (18.44) | 68.49 (17.31) | 0.0007 | 71.28 (18.09) |
| CBI | | | 0.0004 | |
| 0–24 | 92 (35.5%) | 51 (20.8%) | | 143 (28.4%) |
| 25–36 | 63 (24.3%) | 59 (24.1%) | | 122 (24.2%) |
| >36 | 104 (40.2%) | 135 (55.1%) | | 239 (47.4%) |
| CBI | 32.99 (17.88) | 38.07 ± 16.91 | 0.0006 | 35.57 (17.67) |
| DAS | 95.24 (15.80) | 95.80 (16.91) | 0.7064 | 95.52 (16.34) |

SCU-B, special medical care unit for people with behavioral and psychological symptoms of dementia; BMI, body mass index; MMSE, Mini-Mental State Examination; ADCS-ADL, Alzheimer's Disease Cooperative Study Activities of Daily Life Scale; NPI, Neuropsychiatric Inventory; QoL-AD, Quality of Life-Alzheimer's Disease; AC-QoL, Adult Carer Quality of Life Questionnaire; CBI, Caregiver's Burden Inventory; DAS, Dementia Attitude Scale. [a]No statistical tests have been carried out, as differences can be statistically significant owing to the sample numbers, without clinical relevance. [b]*p* value refers to the comparison of Alzheimer's disease versus all other etiologies. [c]NPI sub-domains have been calculated only for patients with symptom. *p* values refer to the comparison of the proportion of patients with symptoms versus without symptoms.

Table 2
Effectiveness end-point analysis as NPI least-square means at baseline and during follow-up in centers with and without SCU-B

| NPI | Centers with SCU-B | | Centers without SCU-B | | *p* |
|---|---|---|---|---|---|
| | LSM (SE) | Δ | LSM (SE) | Δ | |
| Baseline | 52.6823 (1.0698) | | 52.1232 (1.3804) | | 1 |
| 6 months | 44.1381 (1.1554) | –8.544 | 47.2894 (1.4358) | –4.834 | 0.9999 |
| 12 months | 40.9805 (1.1991) | –3.158 | 43.3579 (1.4551) | –3.932 | 1 |
| 18 months | 40.0342 (1.4325) | –0.946 | 39.5505 (1.3916) | –3.807 | 1 |
| 24 months | 40.0601 (1.5482) | 0.026 | 34.0424 (1.1632) | –5.508 | 0.1981 |
| 30 months | 41.7625 (1.7699) | 1.702 | 30.8522 (1.3118) | –3.19 | 0.0001 |
| 36 months | 42.4031 (1.8834) | 0.641 | 30.5436 (1.5145) | –0.309 | 0.0001 |

NPI, Neuropsychiatric Inventory; SCU-B, Special medical care unit for people with behavioral and psychological symptoms of dementia; LSM, Least Square Means; SE, Standard Error. *p*-value is the adjusted significance value for the comparison between the two cohorts at each. Δ, Changes are calculated as the difference between the value at the visit and the previous value. A negative change indicates an improvement.

improvement of the NPI total score at the different assessment points, especially after the visit at the 18-month follow-up (Table 2).

*Quality of life*

Although there was no statistically significant difference between the two cohorts at each time point

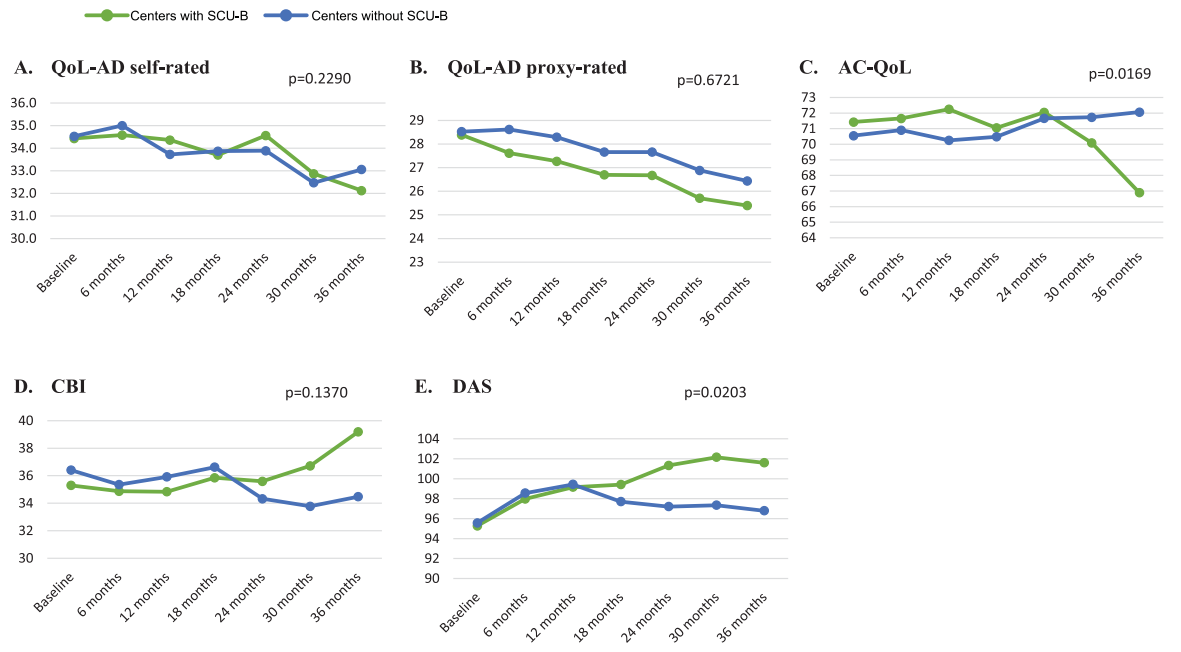


Fig. 4. Least square means of the quality-of-life scales in baseline and during follow-up visits in centers with and without SCU-B. QoL-AD, Quality of Life-Alzheimer's Disease; AC-QoL, Adult Carer Quality of Life Questionnaire; CBI, Caregiver's Burden Inventory; DAS, Dementia Attitude Scale. *p* values correspond to the interaction "cohort by time".

(Supplementary Material), we found a different qualitative pattern between the two cohorts in the AC-QoL scores: caregivers' quality of life of increased in the non-SCU-B centers according to this questionnaire ($p = 0.0169$) (Fig. 4C). On the opposite, DAS total scores significantly improved in centers with SCU-B compared to centers without SCU-B at the end of the study ($p = 0.0203$) (Fig. 4E).

Owing to the statistically significance of the interaction "cohort by time", we specifically considered the differences among the time points within each cohort for both questionnaires. Regarding the AC-QoL, we observed a statistically significant difference between month 24 and month 36 ($p = 0.0094$), as well as between month 30 and month 36 ($p = 0.0177$) of follow-up in centers with SCU-B, both in the direction of a decreased quality of life. No statistically significant difference between any two visits was found in centers without SCU-B for the AC-QoL. All Least squares mean values in both cohorts with their respective differences along follow-up are shown in detail in the Supplementary Material (Tables 1 and 2).

Regarding the DAS, the difference was statistically significant between baseline and month 12 ($p = 0.0032$), month 18 ($p = 0.0067$), month 24 ($p < 0.0001$), month 30 ($p < 0.0001$), and month 36 ($p = 0.0010$) of follow-up, as well as between month 6 and month 30 ($p = 0.0319$). In the centers without SCU-B, the difference between two visits was never statistically significant except for the comparison between baseline and month 12 ($p = 0.0490$).

Neither the QoL-AD nor the CBI scores disclosed a statistically different qualitative/quantitative pattern between the two cohorts, therefore there was no statistically significant interaction (Fig. 4A, B, D). For this reason, we considered only a pooled analysis of both cohorts together. It revealed a statistically significant difference from baseline to the end of the study in the two versions of QoL-AD, patient-rated and proxy-rated ($p < 0.0001$) and in the CBI ($p = 0.0165$). These differences showed a decreased quality of life of PwD and an increased caregiver burden by the end of the study (Supplementary Material).

### *Time to institutionalization*

The evolution of the rate of admission to a nursing home during the 36 months of follow-up is shown in Fig. 5. There was no significant difference between centers with and without SCU-B ($p = 0.3552$). The last probability values in the two curves were: SCU-B: 0.42 (95%CI 0.34; 0.50); non-SCU-B: 0.52 (95% CI 0.45; 0.59). The Cox's proportional-hazard model

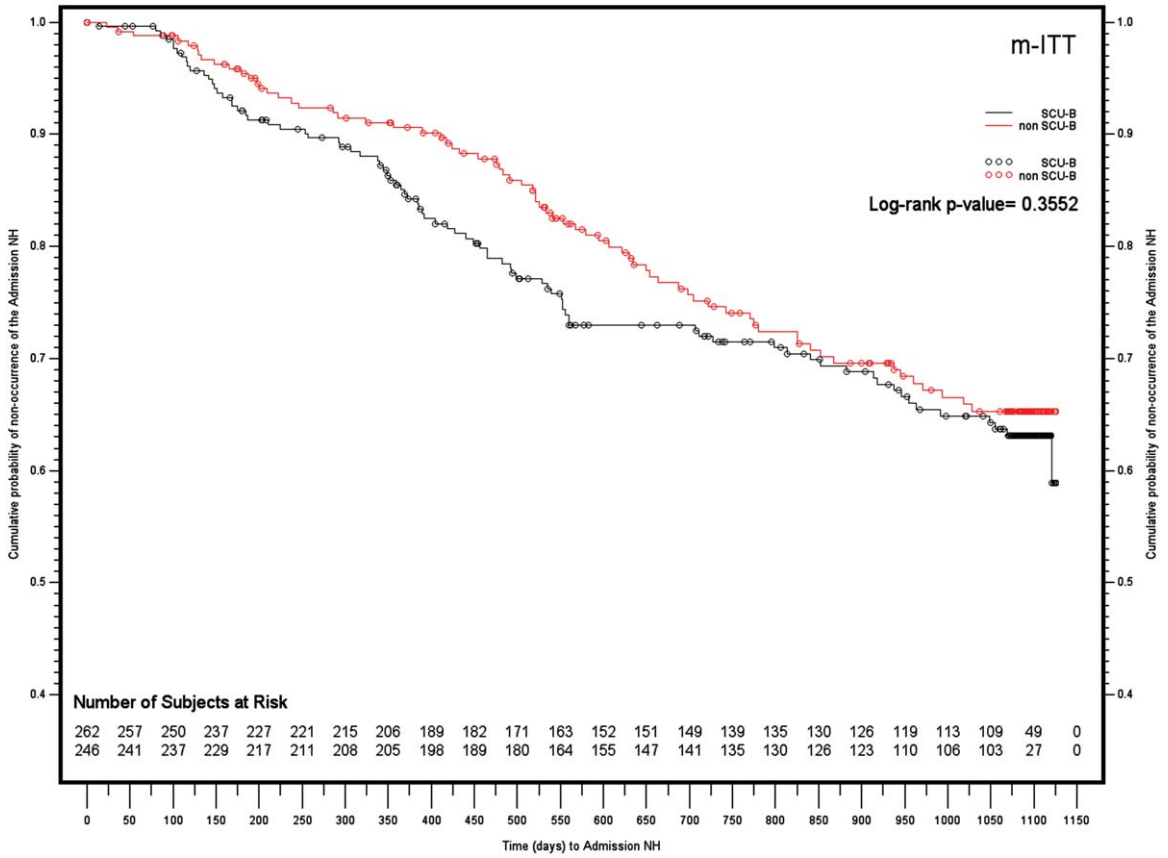


Fig. 5. Kaplan-Meier curves for time to institutionalization in centers with and without SCU-B. SCU-B, Special medical care unit for people with behavioral and psychological symptoms of dementia.

analysis showed a hazard ratio of placement to a nursing home of 1.008 (95%CI: 0.712; 1.429: $p = 0.9626$) for the centers with SCU-B *versus* the centers without SCU-B.

### *Safety*

At least one intercurrent adverse event was reported in 190 (72.5%) and 203 (82.5%) patients in the centers with SCU-B and without SCU-B, respectively. A total of 96 patients died over the course of the study, of whom 15 due to COVID-19. Death due to COVID-19 infection occurred more frequently in the SCU-B cohort, especially in the center severely affected by the pandemic (Gazzaniga). The incidence of falls, injury due to falls, accelerated cognitive decline, accelerated functional decline and parkinsonism was similar between the two cohorts (SCU-B: 18.7%; non-SCU-B: 16.7%). The proportion of patients with at least one admission to a general hospital in the considered time intervals was similar in the two cohorts, with a noticeable increase in the percentage of admissions over time (from 9% at 6 months up to 30% at the end of the study). There were fewer admissions to the emergency room in centers with SCU-B compared to centers without SCU-B (6.11% versus 13.4%; $p = 0.0053$). On the other hand, there was a higher proportion of patients admitted to a general ward in the centers with SCU-B (6.49% versus 2.85%; $p = 0.0531$). At least one psychotropic drug was taken by 79% of patients in the SCU-B cohort and in 86.2% in the non-SCU-B cohort, the difference being statistically significant ($p = 0.0336$).

### *Post-hoc analysis of PwD admitted to the SCU-Bs*

Of the total of 266 patients included in centers where SCU-B were available, only 45 (16.92%) were admitted to such specialized units. As some patients were hospitalized more than once, the total number of admissions in SCU-B was 56 during the

follow-up of the study. We analyzed a sample of 39 patients with available NPI and MMSE values at admission and at discharge from a SCU-B. They had a mean NPI and a mean MMSE of $62.2 \pm 19.02$ and of $14.9 \pm 7.86$, respectively. NPI decreased to $21.4 \pm 12.52$ at discharge, while MMSE slightly increased to $15.08 \pm 7.55$. The decrease between before and after (admission and hospital discharge) was statistically significant for NPI ($p < 0.0001$), whilst the increase of the MMSE ($p = 0.0803$) was not.

## DISCUSSION

When we elaborated the concept of this study, the initial hypothesis was that the care pathways of patients with BPSD in centers with a SCU-B (available for admission in case of behavioral crisis, but not mandatory) were superior to the pathways lacking this facility. This was based on an assumption of better quality of care in centers with SCU-B, translated as efficient mitigation of behavioral crisis in SCU-B, lower prescription of psychotropic drugs, increased delay to nursing home admission, as well as better confidence, knowledge, and support of caregivers. However, the findings of this study do not confirm the initial hypothesis.

As regards the primary outcome of the study, the results did not confirm the research hypothesis of the long-term clinical superiority of the SCU-B arm over the control one. In fact, while a gradual decrease of the score over time in both arms was observed, a trajectory expected from previous evidence [24], the slope was steeper in the SCU-B cohort only until 6 months, but afterward the score continued to decrease only in the control arm, reaching statistical signification at 30 and 36 months of follow-up in favor of the latter. Therefore, in the long term, the outcome improved more in those patients whose behavioral crises were managed without the possibility of being admitted to a SCU-B. Our results do not provide any likely explanation for this (unexpected) difference in favor of the non-SCU-B cohort during the second part of the follow-up, despite several exploratory analyses performed to identify potential confounding/explanatory factors. We carried out several sensitivity analyses by means of ANCOVA, restricting the population to patients with a baseline MMSE within 10 and 20 and including only the first 10 items of NPI. Furthermore, the analysis was repeated excluding centers with the lowest number of enrolled patients; on the patients with all seven visits performed; on the patients with at least the 30-month visit performed; and finally, on the patients with at least the 24-month visit performed. The analyses did not substantially change the results. Other hypotheses could not be tested on the basis of our data: we do not know in depth how the acute crises of patients with BPSD were managed in centers without SCU-B and possibly there were differences not measured by the study variables and responsible, at least in part, for the observed finding. Moreover, differences in primary health care including day care centers, availability of home care, and costs of such interventions could significantly impact on our primary outcome.

Another point to underline is that a much higher number of admissions to SCU-B was expected during the follow-up by the clinicians adhering to the RECage Consortium. The relatively small number of admissions over three years (one admission of 45 pts/508, 56 total number of admissions) was possibly due, at least to some extent, to the pandemic. This means that only 45 pts were exposed, to the SCU-B.

As for the secondary endpoints, a similar result in favor of the centers without SCU-B cohort was found for the quality of life of caregivers (AC-QoL), whereas the caregivers' attitude toward dementia (DAS) improved in the SCU-B cohort, especially concerning the knowledge factor.

Finally, no significant difference between the cohorts was found on time of institutionalization.

To sum up, we must emphasize that RECage was carried out in the European context, where large differences exist as regards the clinical management of patients with BPSD across the participating countries. Outpatient care in centers is probably rather similar across countries, although not superposable, due to the context they operate in, whereas the diffusion of SCU-Bs is very unequal: for instance, Italy does not have a developed network of SCU-B, but only a few, whereas the outpatient clinics for PwD are widespread. In Germany, the treatment of BPSD in severe dementia is provided by the fully sectorized care of the psychiatric hospitals in collaboration with geriatric internal medicine specialists. In Norway, psychiatric wards in all hospital trusts do admit people with dementia, but in their acute ward. Innlandet Hospital trust (Ottestad), which participated in the present study, is the only hospital trust with a SCU-B ward. In France there have for many years been a well-developed network of SCU-Bs called "Unités Cognitivo-Comportementales" and are widespread all over the country. In Switzerland the situation is

variable from a canton to another. In Greece, there are no SCU-B.

Regarding safety-related outcomes, we would like to discuss our findings on psychotropic medication use. Although the prescription was significantly lower in centers with SCU-B, in general, we noticed a high prevalence of psychotropic medications in both cohorts. Although psychotropic medication is not the first-line treatment recommendation, they remain widely prescribed. Several studies showed that a high rate of patients with moderate-severe dementia were under at least one psychotropic medication, including antipsychotics [25]. The main factors associated with the use of pharmacological interventions include persistent neuropsychiatric symptoms, living in nursing homes and prior psychiatric diagnosis [26].

Regarding special units for people with dementia, previous studies showed mixed results, with a few reports of increased psychotropic medication use in people admitted to a SCU-B [27–29]. One explanation is the selection of patients admitted to those units based on the severity of symptoms. They often present criteria of acute crisis that could not be mitigated outside the hospital or symptoms refractory to previous non-pharmacological interventions implemented by the team. Therefore, in certain circumstances, despite the limited efficacy, clinical management in specialized units may culminate in an increase (or absence of decrease) in drug prescription.

*Limitations of the study*

The outbreak of the COVID-19 pandemic, six months after the end of the recruitment period, created many difficulties, especially hindering regular "in presence" visits and compelling the memory clinics to do only or mostly phone visits (NPI is not validated for phone visits), with the obvious consequent loss of data, easing withdrawals from the study, and delayed visits. Moreover, it is important to remark that COVID-19 was specially devastating in Italy, where two SCU-Bs (Gazzaniga and Modena) with a high recruitment rate (150/262) are located, with ensuing mortality (total of 15 COVID-19 related deaths with 14 in SCU-B and only 1 in non-SCU-B arm). Finally, the pandemic may have had other indirect impacts on the study, such as social isolation due to the repeated and prolonged lockdowns (whose effects on cognition and behavior are well known).

The possible COVID-19 impact was evaluated to verify whether the administration of the scales over the phone had any methodological influence and whether there was a country effect due to the different (spatial and temporal) incidence of the pandemic. NPI analysis excluding assessments performed as phone visits and NPI analysis by comparing pattern of scores between non-SCU-B and SCU-B located in Italy versus non-SCU-B and SCU-B in the other countries were carried out. The difference between the SCU-B and non-SCU-B arm persisted after excluding the Gazzaniga and Modena units, the most COVID-stricken centers (and their 150/262 pts). However, all the above analyses confirmed a statistically significant interaction "time by cohorts" in favor of the non-SCU-B.

A variety of factors other than COVID-19 interfered with the trial and possibly led to biased results. Among them is observed discrepancies at baseline, as consequence of the non-randomized study design, which may be relevant despite the use of the propensity score analysis. Most important, the social context of the trial was different across the countries participating in the RECage Consortium.

Many of these units could not carry out usual admissions according to predefined criteria, while other units had to absorb patients with COVID-19 on a temporary basis. In addition, many of the outpatient interventions, such as consultations and therapies, were also suspended or modified to meet the isolation measures imposed in each region and country. Therefore, potential biases regarding the comparison of centers with and without SCU-B were introduced. Supplementary measurements that could help solve this problem would be to accurately incorporate the different interventions and services available at each center, as well as which ones were implemented for each person with dementia and caregiver during the entire follow-up of the study. Such measures would have helped in a deeper understanding of the factors that influenced our results, including during the pandemic period.

*Implications for further research*

Due to the many limitations of the trial, its negative results must be interpreted with caution.

In fact, since literature shows evidence for short-term effect of the SCU-B, albeit mainly from non-controlled studies as well as from our *post-hoc* analysis of the patients admitted to the unit, the RECage results do not invalidate the "acute" clinical effectiveness of the admission to the SCU-B to solve behavioral crises [30–32]. Therefore we think that, where SCU-Bs are available, they should

be supported, at least unless there is an available operational alternative [33]. Despite the potential effectiveness of mitigating behavioral crises, the overall evidence from previous studies shows mixed results, which was also observed in special care units specifically located in long-term care facilities [12].

As to future research, the lack of long-term results puts the discussion of ethical approval for randomization on the table. A randomized clinical trial could be ethically justified, comparing SCU-B admission with another planned alternative, for instance mobile BPSD teams. If studied in a multicenter setting, the participant centers should be stratified for social context of the country or region to minimize biases.

Finally, the definition of a standardized panel of outcomes and measurements to guide future studies is essential, taking into consideration meaningful outcomes for patients, families, staff, and stakeholders.

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## CONFLICT OF INTEREST

The authors have no conflict of interest to report.

## DATA AVAILABILITY

The data supporting the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy and ethical restrictions.

## SUPPLEMENTARY MATERIAL

The supplementary material is available in the electronic version of this article: https://dx.doi.org/10.3233/JAD-230708.

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