Excess Mortality Among Assisted Living Residents With Dementia During the COVID-19 Pandemic

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A B S T R A C T

Objective: To evaluate whether assisted living (AL) residents with Alzheimer's disease and related dementias (ADRD) experienced a greater rate of excess all-cause mortality during the first several months of the COVID-19 pandemic compared to residents without ADRD, and to compare excess all-cause mortality rates in memory care vs general AL among residents with ADRD.
Design: Retrospective cohort study.
Setting and Participants: Two cohorts of AL residents enrolled in Medicare Fee-For-Service who resided in 9-digit ZIP codes corresponding to US AL communities of $\geq$25 beds during calendar year 2019 or 2020.
Method: By linking Medicare claims and Vital Statistics data, we examined the weekly excess all-cause mortality rate, comparing the rate from March 12, 2020, to December 31, 2020, to the rate from January 1, 2019, to March 11, 2020. We adjusted for demographics, chronic conditions, AL community size, and county fixed effects.
Results: Of the 286,350 residents in 2019 and the 273,601 in 2020 identified in these cohorts, approximately 31% had a diagnosis of ADRD. Among all AL residents, the excess weekly mortality rate in 2020 was 49.1 per 100,000 overall during the pandemic. Compared to residents without ADRD, residents with ADRD experienced 33.4 more excess deaths per 100,000 during the pandemic. Among residents with ADRD, those who resided in memory care communities did not experience a statistically significant different mortality rate than residents who lived in general AL.
Conclusions and Implications: AL residents with ADRD were more vulnerable to mortality during COVID-19 than residents without ADRD, a finding similar to those reported in other settings such as nursing homes. Additionally, the study provides important new information that residents with ADRD in memory care communities may not have been at differential risk of COVID-19 mortality when compared to residents with ADRD in general AL, despite prior research suggesting they have more advanced dementia.

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Older adults diagnosed with Alzheimer's disease and related dementias (ADRD) have a higher risk of mortality from COVID-19 than older adults without ADRD.[1,2] Long-term care residents with ADRD may be at particular risk of mortality during the COVID-19 pandemic when compared to residents without ADRD even after accounting for their age and comorbidities because they reside in a congregate setting and are less able to adhere to preventive practices such as use of masks and social distancing.[2–4] Additionally, residents with ADRD require hands-on assistance from staff, potentially increasing their exposure to the virus.[2]

Much of the literature on COVID-19 in long-term care has focused on nursing homes; much less is known about the experiences of assisted living residents.[5–7] Assisted living (AL) communities warrant focused attention because of the size and vulnerability of the population: more than 63% of the over 800,000 individuals who live in AL have trouble getting out of bed and 48% have trouble dressing.[8] Additionally, AL communities have variable infection control policies across states and a limited presence of licensed nursing staff.[9,10] AL communities provide assistance with daily activities, at least 2 meals a day, and supervision for older adults who have some personal care needs but do not need daily nursing care.[6] AL residents experienced increased rates of mortality during the COVID-19 pandemic compared to their rates of mortality prior to the pandemic.[7] However, to our knowledge, it is not known whether the rate of all-cause mortality during the COVID-19 pandemic was different for residents of AL communities with ADRD than for residents without ADRD.

Additionally, no studies of which we are aware have examined rates of all-cause mortality during the COVID-19 pandemic comparing memory care communities to general AL. Although regulations for memory care vary by state, most states require that administrators and direct care staff receive dementia-specific training and that buildings contain features such as locked doors to prevent egress.[11,12] Providers in memory-care AL communities may be better able to attend to the needs of residents with dementia than providers in general AL, helping to prevent the spread of infection to other residents. However, there is controversy as to whether memory care communities provide better care overall,[10] which is important to understand given they cost 29% more on average than general AL.[13] In fact, there is reason to hypothesize that outcomes in memory care are worse than those in general AL given that these residents tend to have more advanced dementia.[14]

Objectives

This study compared the weekly rate of excess all-cause mortality during the first several months of the COVID-19 pandemic among a US cohort of AL residents with ADRD to residents without ADRD. It also explored whether the weekly rate of excess all-cause mortality among residents with ADRD varied by whether the residents with ADRD lived in memory care AL or in general AL.

Methods

Data

Information on AL communities came from a 2019 national directory we compiled from websites of state licensing agencies. Vital Statistics data were used to capture the date of death. The Medicare Beneficiary Summary file was used to obtain the demographic characteristics of the AL residents; the Chronic Conditions Data Warehouse subsection was used to identify residents with an ADRD diagnosis. Using Medicare enrollment data, we implemented a previously published methodology using 9-digit ZIP codes to create a finder file that identified residents in AL communities from the contiguous United States that had at least 25 beds.[15]

Participants

Residents were included in the sample if they lived in AL on January 1 of either 2019 or 2020; their mortality was tracked for the entire year. We excluded Minnesota and Connecticut because those states license AL agencies rather than physical locations. We excluded residents with Medicare Advantage enrollment or without Medicare enrollment during the prior years (2018 and 2019) because the diagnosis data were incomplete for these residents. A subanalysis cohort was created to examine whether residing in memory care was associated with all-cause mortality during the first year of the COVID-19 pandemic among AL residents with dementia. Consistent with previous literature, we define a memory care community as an AL community with a state license, certification, or designation to provide care for residents with ADRD.[11] For this analysis, we excluded AL residents who did not reside in the 30 states for which we had information on memory care licensure (see Supplementary Table 1). We also excluded AL residents who did not have ADRD. For a figure depicting our sample selection process, see Supplementary Figures 1 and 2.

Measures

Our outcome was the weekly rate of mortality per 100,000 AL residents per week. We identified whether an individual had ADRD by the Chronic Conditions Data Warehouse flag. We used our directory of licensed AL communities to identify communities that had a license, certification, or designation to provide care for residents with ADRD. For our adjusted analysis, we included demographic characteristics from the Medicare Beneficiary Summary File as covariates; these included age (<65, 65-74, 75-84, 85-94, ≥95), sex, race or ethnicity (non-Hispanic White, non-Hispanic Black, Hispanic, and other), and dual enrollment in Medicaid. We also included chronic conditions associated with COVID-19 mortality[16] [ie, asthma, cancer, chronic kidney disease, chronic obstructive pulmonary disease, diabetes, heart conditions (acute myocardial infarction, atrial fibrillation, congestive heart failure, or ischemic heart disease), hypertension, obesity, stroke, and number of chronic conditions (<2, 2-3, 4-5, ≥6) of those listed]. In addition, we incorporated a measure of AL bed size derived from our national directory.

Statistical Methods

We did not expect mortality in 2020 to differ from 2019 prior to March 12, before many outbreaks were reported in the United States. Therefore, we confirmed this by plotting weekly rates of mortality, comparing the entire year of 2020 to the entire year of 2019. We estimated a linear probability model of the probability of death of individual i in week w and year y to examine weekly fluctuations in mortality comparing 2020 to 2019 using the following equation:

$$M_{iwy} = (Year2020_y \times Week_w)\alpha + \varepsilon_{iwy} \text{ (Model 1)}$$

The outcome M_{iwy} is the number of deaths per 100,000 AL residents per week. The vector α represents the differences in all-cause mortality for 2020 vs 2019 for each week w (1-52).

We then created an indicator for weeks that occurred on or after March 12 (March 12—December 31), the day before COVID-19 was declared a national emergency in the United States,[17] and interacted it with our year variable (model 2):

$$M_{ipy} = (Year2020_y \times Pandemic_p) + \in_{ipy} \text{ (Model 2)}$$

We used this interaction as a way to measure excess all-cause mortality related to COVID-19.

We stratified model 1 by diagnosis of ADRD to visualize how the weekly unadjusted rates of excess mortality differed for residents with and without ADRD for the entire year of 2020. We then used the pandemic period and year interaction model (model 2) to examine excess mortality during the pandemic comparing residents with ADRD to residents without ADRD. We calculated unadjusted models and models adjusting for age, sex, race, dual enrollment in Medicaid, and chronic conditions previously described. Given that bed size and local COVID-19 prevalence are the strongest predictors of COVID-19

mortality in nursing homes,[18] we controlled for AL bed size and county fixed effects.

The next analysis estimated similar sets of models among a subgroup of residents with ADRD. We included data only from residents in the 30 states where information was available regarding whether each community was licensed, certified, or designated to provide memory care. We adjusted for the same covariates as the first set of models; instead of an indicator for ADRD, we included an indicator for memory care licensure.

All analyses were conducted with Stata, version 16.0 (StataCorp LLC). The Brown University institutional review board provided a waiver of informed consent for this observational study. This study follows the relevant portions of the REporting of studies Conducted using Observational Routinely-collected Data (RECORD) guideline. The completed RECORD checklist can be found in Supplementary Table 2. Additional information about the data and methods used for these analyses can be found in the Brown Digital Repository (https://doi.org/10.26300/zmq1-5136).

Results

Descriptive Data

We identified 286,350 individuals living in a larger (≥25-bed) AL community on January 1, 2019, and 273,601 individuals on January 1, 2020; approximately 31% of residents in both years had an ADRD diagnosis. The characteristics of residents with ADRD compared to residents without ADRD in both years are shown in Table 1. For our subanalysis, we identified 65,469 Medicare beneficiaries on January 1, 2019, and 61,964 individuals on January 1, 2020, residing in the 30 states. This subsample consisted of the 34% of residents in memory care licensed AL communities who had ADRD (reflecting the fact that some memory care licensed communities also provided care to residents who did not have ADRD). The characteristics of residents with ADRD in memory care communities compared to those in general AL during both years are shown in Table 2. In both tables, we observed consistency in the characteristics of AL resident populations between the 2 years. For example, in both years, approximately 6% of AL residents with ADRD had 6 or more chronic conditions compared with 3% of AL residents without ADRD. During both years, 61%-62% of AL residents with ADRD who lived in memory care AL communities were aged ≥85 years.

Main Results

The average weekly all-cause mortality rate among AL residents in 2019 was 217.6 per 100,000 AL residents. Unadjusted excess weekly mortality in 2020 during the pandemic (after March 12) was 47.9 per 100,000 AL residents; adjusted weekly excess mortality was 49.1 per 100,000 (Table 3).

Figure 1 displays the unadjusted change in the rate of all-cause mortality each week per 100,000 AL residents in 2020 vs 2019, comparing AL residents with ADRD to residents without ADRD. The figure shows that residents with ADRD experienced higher excess mortality throughout the time period studied; these differences were greatest in April and December. As shown in Table 3, unadjusted rates of weekly excess all-cause mortality were 34.3 deaths per 100,000 higher among residents with ADRD compared to residents without

Table 1
Characteristics of Assisted Living Residents With Alzheimer's Disease and Related Dementias (ADRD) Compared to Residents Without ADRD, by Year

Characteristic	2019		2020	
	ADRD Diagnosis (n = 88,520)	No ADRD Diagnosis (n = 197,830)	ADRD Diagnosis (n = 83,824)	No ADRD Diagnosis (n = 189,777)
Age group, %				
<65 y	3.6	8.8	3.4	8.6
65-74 y	9.9	20.9	10.1	21.4
75-84 y	25.8	27.5	26.3	27.9
85-94 y	48.9	35.9	47.9	35.0
≥95 y	11.8	7.0	12.3	7.1
Sex, %				
Male	31.0	35.9	31.2	36.2
Female	69.0	64.1	68.8	63.8
Race, %				
White	91.6	91.1	91.4	90.9
Black	4.1	3.7	4.2	37
Hispanic	2.2	2.0	2.3	2.0
Other	2.0	3.2	2.2	3.4
Dually enrolled in Medicare and Medicaid, %	20.5	16.2	20.5	16.0
Chronic conditions, %				
Asthma	6.3	5.7	6.5	5.7
Cancer	10.8	10.4	10.9	10.5
Chronic kidney disease	43.1	28.8	44.5	29.9
Chronic obstructive pulmonary disease	21.4	13.9	21.0	13.8
Diabetes	31.3	25.4	32.0	25.5
Heart disease	60.6	43.2	60.6	43.2
Hypertension	81.8	67.2	81.5	67.2
Obesity	14.5	16.7	15.1	17.4
Stroke	10.3	5.0	10.1	5.0
<2 chronic conditions[*,†]	23.2	39.0	22.8	38.5
2-3 chronic conditions[*,†]	44.3	39.5	44.0	39.5
4-5 chronic conditions[*,†]	26.7	18.3	27.3	18.7
≥6 chronic conditions[*,†]	5.8	3.3	6.0	3.4
No. of chronic conditions, mean (SD)[*,†]	2.8 (1.6)	2.2 (1.7)	2.8 (1.6)	2.2 (1.7)

Residents were enrolled in Medicare Fee-for-Service during the entire year prior and lived in assisted living on December 31, 2018, or December 31, 2019. Data were obtained from the 2018 and 2019 Medicare Master Beneficiary Summary file and chronic conditions files.

[*]As of December 31, the year prior.

[†]Of the conditions listed above.

Table 2
Characteristics of Residents With Alzheimer's Disease and Related Dementias in Memory Care Communities Compared to Residents With Alzheimer's Disease and Related Dementias in General Assisted Living Communities

Characteristics	2019		2020	
	Memory Care Community Residents (n = 24,152)	General Assisted Living Residents (n = 41,317)	Memory Care Community Residents (n = 23,229)	General Assisted Living Residents (n = 38,735)
Age group, %				
<65 y	2.8	4.8	2.8	4.5
65-74 y	8.6	11.3	9.0	11.6
75-84 y	27.0	25.1	26.8	25.8
85 -94 y	50.4	47.2	49.5	46.1
≥95 y	11.2	11.6	12.0	12.0
Sex, %				
Male	30.0	31.7	30.7	31.7
Female	70.0	68.3	69.3	68.3
Race, %				
White	93.1	91.1	93.1	90.7
Black	4.1	4.9	4.0	5.1
Hispanic	1.5	2.4	1.6	2.5
Other	1.3	1.6	1.4	1.8
Dually enrolled in Medicare and Medicaid, %	16.9	26.3	17.0	26.6
Chronic conditions (%)*				
Asthma	5.8	6.4	6.2	6.6
Cancer	10.8	10.8	10.8	10.8
Chronic kidney disease	43.4	43.1	44.6	44.4
Chronic obstructive pulmonary disease	20.8	22.6	20.3	22.4
Diabetes	29.8	33.7	31.0	34.6
Heart disease	60.1	61.4	60.8	61.0
Hypertension	82.4	82.2	82.3	82.1
Stroke	10.8	10.4	10.5	10.2
Obesity	13.8	15.8	14.3	16.5
<2 chronic conditions*,†	23.3	22.3	22.6	21.8
2-3 chronic conditions*,†	45.3	43.5	44.8	43.3
4-5 chronic conditions*,†	25.9	27.8	26.9	28.3
≥6 chronic conditions*,†	5.5	6.4	5.8	6.6
No. of chronic conditions, mean (SD)*,†	2.8 (1.6)	2.9 (1.7)	2.8 (1.6)	2.9 (1.7)

Residents were enrolled in Medicare Fee-for-Service during the entire year prior. Residents lived in assisted living on January 1, 2019, or January 1, 2020. We define memory care as AL communities with a state license, designation, or certification specific to dementia care. Data came from the 2018 and 2019 Medicare Master Beneficiary Summary file and chronic conditions.

*As of December 31, the year prior.

†Of the conditions listed above.

ADRD. Adjusted rates of excess weekly all-cause mortality were 33.4 excess deaths per week per 100,000 AL residents ($P < .001$) among residents with ADRD.

Figure 2 shows the unadjusted excess mortality rate each week comparing residents in memory care AL communities to general AL communities. Residents in memory care had slightly lower excess mortality rates in April and May compared with the rest of the year, but higher excess mortality in other months such as June and July. CIs overlapped throughout the study period.

Table 3 displays the unadjusted and adjusted rates of excess all-cause mortality during the COVID-19 pandemic. On average, residents with ADRD who resided in memory care communities experienced 3.1 per 100,000 fewer excess deaths than residents with ADRD who did not reside in memory care communities during the 2020 pandemic period. However, this difference was not statistically significant ($P = .761$). Adjusted rates were also not statistically significant (5.0 per 100,000 fewer excess deaths; $P = .625$).

Discussion

Consistent with pandemic mortality in nursing homes and in the community, AL residents with ADRD experienced substantially higher

Table 3
Excess Weekly Mortality per 100,000 Assisted Living Residents: Results From Linear Probability Models Examining Differences in Rates of Excess All-Cause Mortality Between Populations of Assisted Living Residents During the COVID-19 Pandemic

	Excess Mortality for 2020 vs 2019, β (95% CI)	*P* Value	Excess Mortality ADRD vs Non-ADRD, β (95% CI)	*P* Value	Excess Mortality in Memory Care Communities vs General AL Among Residents With ADRD, β (95% CI)	*P* Value
Unadjusted rates of excess all-cause mortality for the pandemic period (3/12/2020–12/31/2020)	47.9 (44.2, 51.7)	<.001	34.3 (26.8, 41.8)	<.001	−3.1 (−2.3, 16.8)	.761
Adjusted rates of excess all-cause mortality for the pandemic period (3/12/2020–12/31/2020)*	49.1 (45.3, 52.8)	<.001	33.4 (25.9, 40.9)	<.001	−5.0 (−2.5, 14.9)	.625

We assigned the week beginning March 12, 2020, as the first week of the pandemic because COVID-19 was declared a national emergency on March 13, 2020.[12]

*Rates were adjusted for age, race, sex, dual eligibility, the presence and number of chronic conditions, AL community size, and county fixed effects.

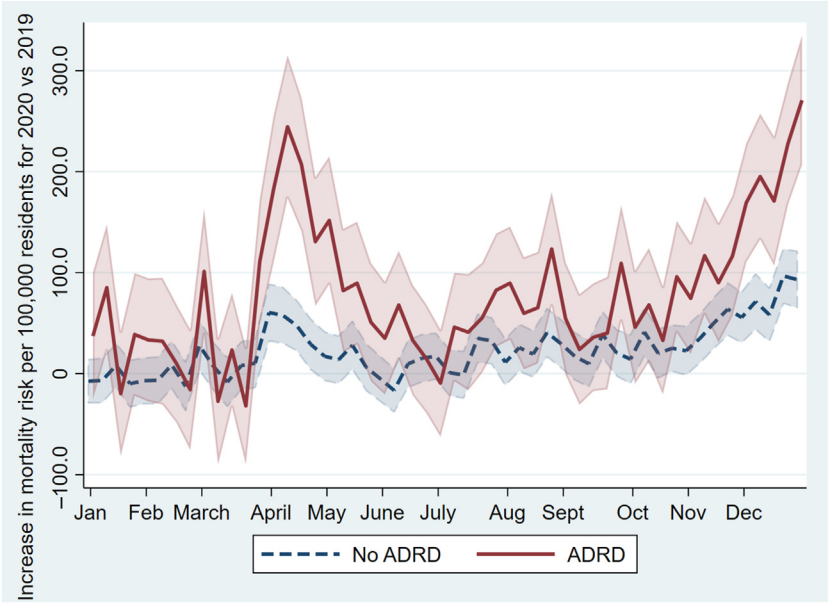

Fig. 1. The unadjusted weekly rate of excess all-cause mortality per 100,000 assisted living residents during COVID-19 comparing assisted living residents with diagnoses of ADRD to those without ADRD. Weekly unadjusted excess all-cause mortality was calculated using the Centers for Medicare & Medicaid Services Vital Status file. The calendar week began on January 1 of each year. Assisted living residents with Medicare Advantage and residents in small assisted living communities (<25 beds) were excluded. Minnesota and Connecticut were excluded because of their different licensing structures. Shaded areas represent CIs.

rates of excess all-cause mortality during the COVID-19 pandemic than residents without ADRD.[1,2] This difference was robust to adjustment for other risk factors for mortality that are common among individuals with ADRD such as advanced age and chronic conditions. Although additional research is needed to explore mechanisms for this finding, it could be posited that individuals with ADRD may have more exposure to the virus because they are less likely to be able to follow social distancing guidelines or to wear a face covering; they also require more hands-on assistance from staff.[2,19] Also, individuals with ADRD are less able to verbally express their symptoms, likely leading to delayed detection of COVID-19.[20] Further, residents with ADRD are at risk of dysphasia, which heightens the likelihood of aspiration and thus pneumonia[2]; in addition, pneumonia complicates the course of COVID-19, increasing the risk of mortality.[2] As another potential risk factor—and although the US Food and Drug Administration discourages the practice—long-term care residents with ADRD

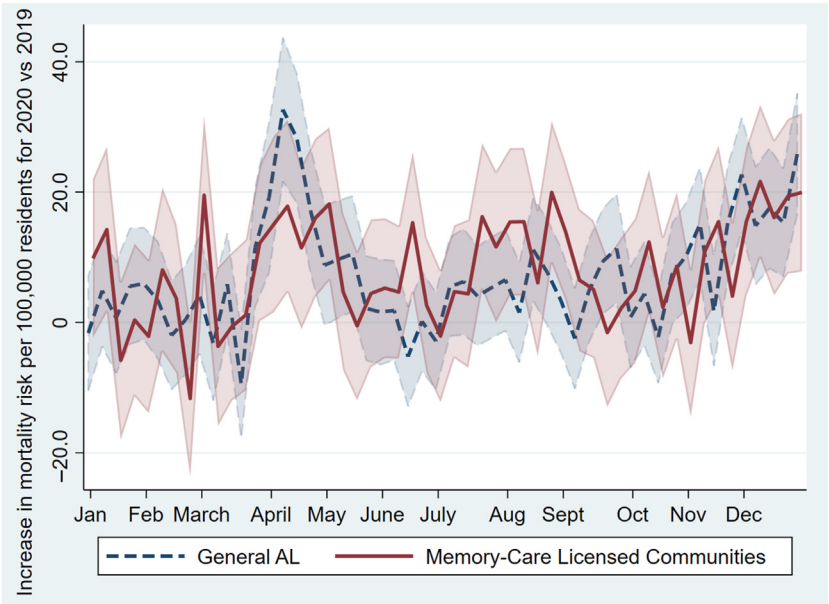

Fig. 2. The unadjusted weekly rate of excess mortality per 100,000 assisted living residents during COVID-19 comparing assisted living residents with ADRD in memory care and general assisted living communities. Weekly unadjusted excess all-cause mortality was calculated using the Centers for Medicare & Medicaid Services Vital Status file. The calendar week began on January 1 of each year. Assisted living residents with Medicare Advantage and residents in small assisted living communities (<25 beds) were excluded. The subsample includes 30 states in which we have information regarding whether they provide memory care. We define memory care as AL communities with a state license, designation, or certification specific to dementia care (Supplementary Table 1). Shaded areas represent CIs.

are often prescribed antipsychotics to manage behavioral expressions.[21] Taking antipsychotics is associated with increased risk of thromboembolism among individuals with dementia, which may be exacerbated by a COVID-19 infection.[22,23]

We did not find that memory care AL communities experienced differential rates of excess all-cause mortality during COVID-19 when compared to general AL communities, despite the fact that prior research suggests residents in these communities have more advanced dementia than residents in communities that do not provide memory care.[14] The fact that residents in memory care did not fare worse (which could be expected given that residents who have more advanced dementia are at higher risk for COVID-19 and COVID-19–related mortality) suggests that memory care communities have structures and processes of care that are advantageous in the context of infection prevention such as more consistent staff assignment.[24] Additionally, memory care communities often have higher staffing levels,[25] which may confer more risk, as having a higher number of staff members is associated with increased risk of COVID-19.[26] On the other hand, more nurse staff hours is associated with decreased COVID-19 mortality in nursing homes once 1 case of COVID-19 has been detected.[27] Of course, challenges faced during the pandemic affected dementia care communities and general AL communities alike, which may explain our null findings. Across both types, administrators expressed difficulties maintaining staffing levels, managing staff burnout, and keeping abreast of rapidly changing policy decisions,[28] and communities often did not have adequate personal protective equipment, as nursing homes were the first to receive these resources.[29]

Although the number of memory care AL communities has increased in recent years, there is much we do not know about this setting. A systematic review of studies about dementia care in nursing facilities and residential care settings found very limited evidence that these specialized settings improved resident outcomes,[19] but they do tend to relate to reduced nursing home admissions for residents with dementia.[11] Variation in how states regulate "memory care," such as requirements for staffing levels and building design features[12] or different licensing standards,[30] likely contribute to the mixed study findings. There is need for additional research to examine how states' regulatory approaches and variable models of care relate to resident health and well-being.

Limitations

Importantly, we identified AL communities providing memory care as those with a state license, designation, or certification specific to dementia care. In some states, this designation applies to only a unit or a wing within an AL community, meaning that in such cases, we surely identified some residents with ADRD who resided in a portion of the AL community that was *not* licensed as memory care, but attributed them to memory care because of this lack of differentiation; this underidentification would again bias our findings toward the null. In addition, administrative data are not collected for research purposes and the validity of diagnostic codes to identify medical conditions is variable.[31] Further, underdiagnosis of ADRD in the Medicare population, most especially within the general AL population,[32] suggests that there are more residents with ADRD than reported, affecting the accuracy of the estimates overall and perhaps the association with memory care.

Additional limitations are that we did not include individuals residing in smaller (<25-bed) AL communities, and that because of our reliance on Medicare claims for identifying dementia status and comorbidities, we did not include AL residents who were enrolled in Medicare Advantage. We also did not have information on memory care licensure for 18 states; thus, caution should be used when extrapolating results to residents in these states. In addition, although we controlled for county fixed effects, there may have been additional variation in COVID-19 prevalence at smaller geographies that could have influenced our findings.

Conclusions and Implications

This study found that AL residents with ADRD were particularly vulnerable to excess all-cause mortality during the COVID-19 pandemic, regardless of whether they resided in memory care or general AL. Our findings illustrate the importance of infection prevention and treatment strategies for residents with ADRD who reside in AL communities. Memory care AL likely faced the same burdens (lack of access to PPE, staffing shortage) as general AL, and the fact that their residents did not fare worse—despite previous research suggesting that they have more advanced dementia[14]—suggests potential benefits to infection control in these settings. More information is needed about memory care AL, including whether and how they can best protect vulnerable residents from infectious diseases as well as other emergencies and disasters (eg, fires, climate change).

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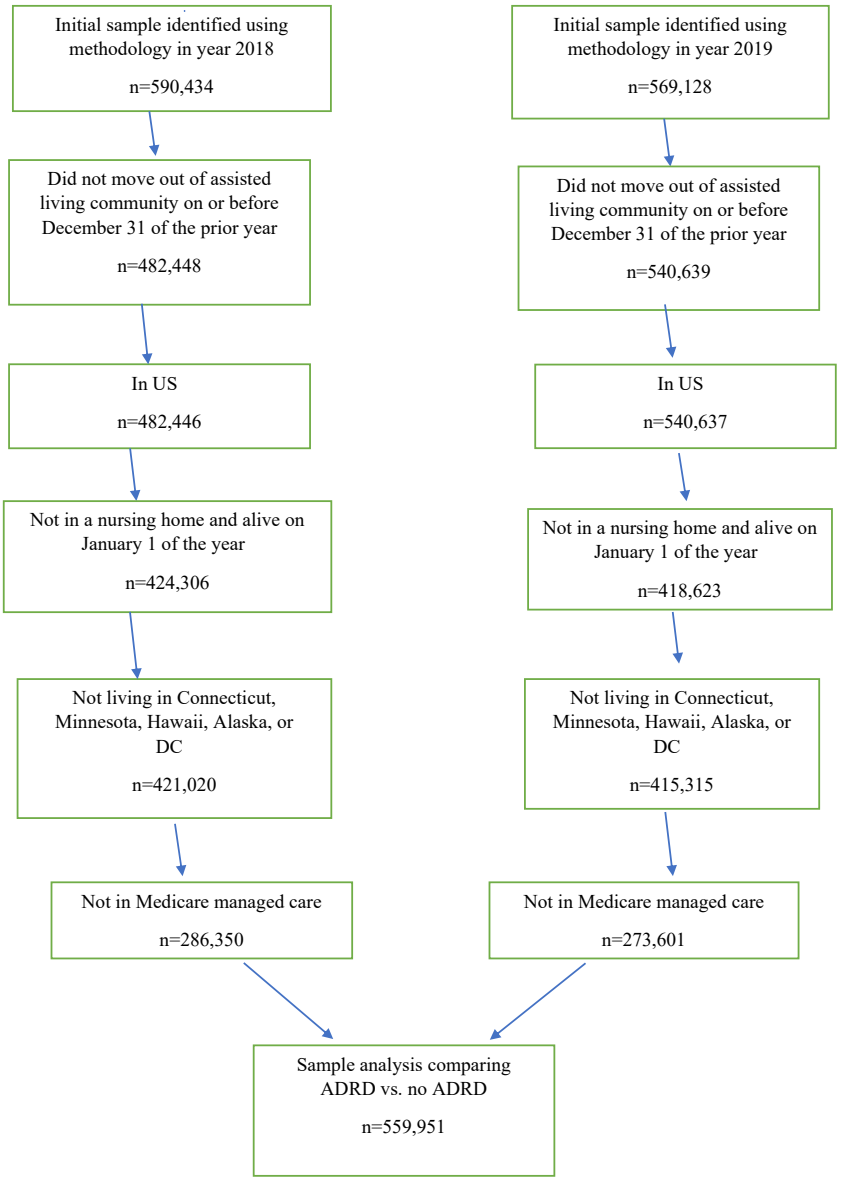
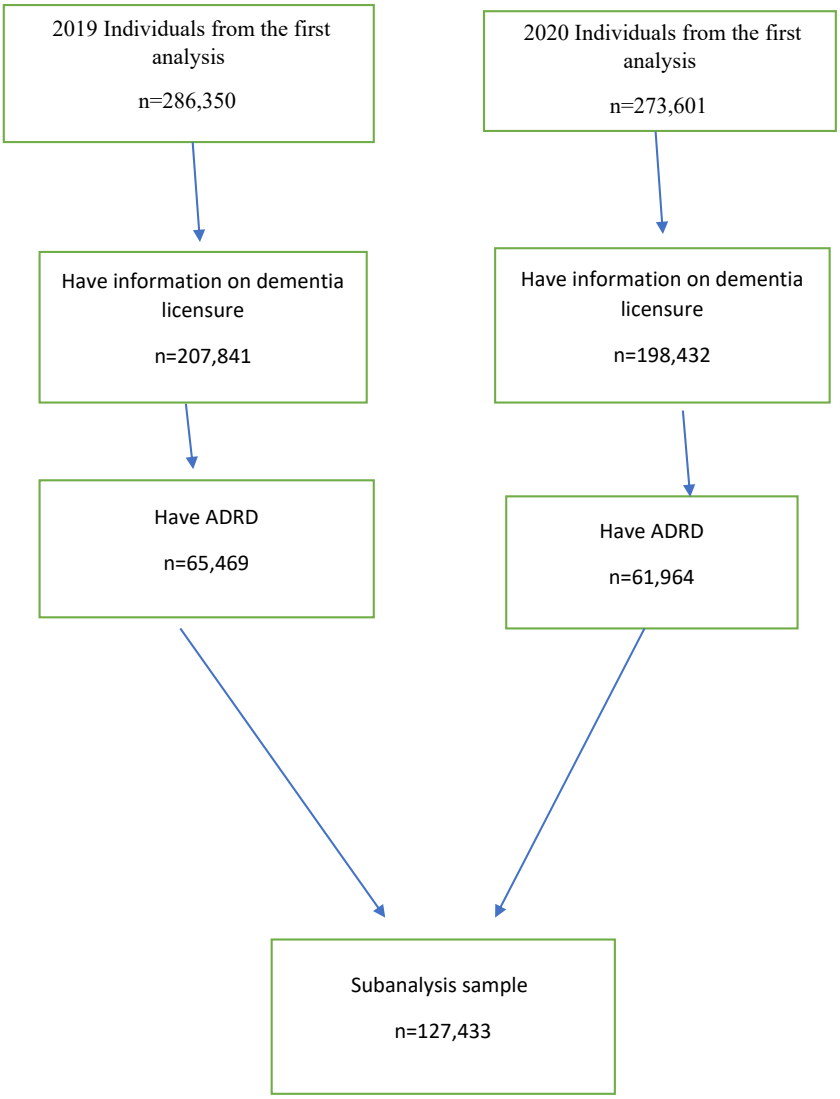


Supplementary Fig. 1. Sample selection flowchart for the analysis comparing residents with ADRD to residents without ADRD. (ADRD, Alzheimer's disease and related dementias.)



Supplementary Fig. 2. Sample selection flowchart for subanalysis comparing residents with ADRD in memory care to residents with ADRD in general AL. (ADRD, Alzheimer's disease and related dementias; AL, assisted living.)

Supplementary Table 1
States Where Memory Care Licensure Data Were Available in 2019

Alabama
Arizona
Colorado
Florida
Iowa
Idaho
Illinois
Indiana
Maine
Michigan
Missouri
Mississippi
Montana
North Carolina
Nebraska
New Jersey
Nevada
New York
Ohio
Oklahoma
Oregon
Pennsylvania
Rhode Island
South Carolina
Texas
Virginia
Vermont
Washington
Wisconsin
Wyoming

Supplementary Table 2
The RECORD Statement—Checklist of Items, Extended From the STROBE Statement, That Should Be Reported in Observational Studies Using Routinely Collected Health Data

STROBE Items	RECORD Items	Location in Manuscript where Items are Reported
(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included. RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract. RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract.	Abstract p. 1 (methods) Abstract p. 1 (setting and participants) Abstract p. 1 (methods)
Explain the scientific background and rationale for the investigation being reported		Introduction pp. 3 and 4.
State specific objectives, including any prespecified hypotheses		Introduction p. 4.
Present key elements of study design early in the paper		Introduction pp. 4 and 5
Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection		Introduction pp. 4 and 5
(a) *Cohort study* - Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study* - 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 *Cross-sectional study* - Give the eligibility criteria, and the sources and methods of selection of participants (b) *Cohort study* - For matched studies, give matching criteria and number of exposed and unexposed *Case-control study* - For matched studies, give matching criteria and the number of controls per case	RECORD 6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided. RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided. RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage.	Supplementary Figure 1 (referenced on page 5); Brown Digital Repository (referenced on p. 7)
Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided.	Brown Digital Repository (referenced on p. 7)
For each variable of interest, give sources of data and details of methods of assessment (measurement).		Brown Digital Repository (referenced on p. 7)
Describe comparability of assessment methods if there is more than one group		
Describe any efforts to address potential sources of bias		
Explain how the study size was arrived at		Supplementary Figure 1 (referenced on p. 5)
Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why		Brown Digital Repository (referenced on p. 7)

(*continued on next page*)

Supplementary Table 2 (*continued*)

STROBE Items	RECORD Items	Location in Manuscript where Items are Reported
(a) Describe all statistical methods, including those used to control for confounding		pp. 5 and 6
(b) Describe any methods used to examine subgroups and interactions		
(c) Explain how missing data were addressed		
(d) *Cohort study* - If applicable, explain how loss to follow-up was addressed		
Case-control study - If applicable, explain how matching of cases and controls was addressed		
Cross-sectional study - If applicable, describe analytical methods taking account of sampling strategy		
(e) Describe any sensitivity analyses		
	RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population.	Brown Digital Repository (referenced on p. 7)
	RECORD 12.2: Authors should provide information on the data cleaning methods used in the study.	
..	RECORD 12.3: State whether the study included person-level, institutional-level, or other data linkage across 2 or more databases. The methods of linkage and methods of linkage quality evaluation should be provided.	Brown Digital Repository (referenced on p. 7)
(a) Report the numbers of individuals at each stage of the study (*e.g.*, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed)	RECORD 13.1: Describe in detail the selection of the persons included in the study (*i.e.,* study population selection) including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram.	Supplementary Figure 1 (referenced on page 5)
(b) Give reasons for non-participation at each stage.		
(c) Consider use of a flow diagram		
(a) Give characteristics of study participants (*e.g.*, demographic, clinical, social) and information on exposures and potential confounders		Tables 1 and 2
(b) Indicate the number of participants with missing data for each variable of interest		
(c) *Cohort study* - summarise follow-up time (*e.g.*, average and total amount)		
Cohort study - Report numbers of outcome events or summary measures over time		Figures 1 and 2
Case-control study - Report numbers in each exposure category, or summary measures of exposure		
Cross-sectional study - Report numbers of outcome events or summary measures		
(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included		Figures 1 and 2, Table 3
(b) Report category boundaries when continuous variables were categorized		
(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period		
Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses		Table 3
Summarise key results with reference to study objectives		pp. 9 and 10

Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported.	p. 11
Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence		p. 12
Discuss the generalisability (external validity) of the study results		p. 11, described as part of limitations
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		Title page
..	RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code.	Brown Digital Repository (referenced on p. 7)

Notes: Reference: Benchimol EI, Smeeth L, Guttmann A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM, the RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. *PLoS Med.* 2015; in press.