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## Original Study

# Person Profile Dementia Intervention in Long-Term Care: A Stepped-Wedge Cluster-Randomized Trial

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## A B S T R A C T

## Keywords:

Person-centered  
dementia  
long-term care  
nursing home  
quality of life  
randomized clinical trial

**Objectives:** We aimed to assess the efficacy of a person-centered care intervention in improving quality of life (QoL) for people with dementia in long-term care facilities.

**Design:** This study was a stepped-wedge cluster-randomized clinical trial of monthly person-centered outcome measurements, followed by collaborative nurse-led person profile interventions involving nursing staff and family members, compared with monthly person-centered outcome measurements alone.

**Setting and Participants:** We included people with a medical diagnosis of Alzheimer's disease or vascular dementia or with clinical symptoms of dementia from 23 long-term care facilities in the German-speaking part of Switzerland.

**Methods:** The primary outcome was QoL, as assessed using the QUALIDEM. Secondary outcomes were the QUALIDEM subscales and the Integrated Palliative Care Outcome Scale for People with Dementia subscales. The study duration was 15 months, and linear mixed-effect models were used for the analysis.

**Results:** We recruited 240 people with dementia from 23 long-term care facilities. Modeling 1143 observations, we found a statistically significant positive intervention effect of 2.6 points according to the QUALIDEM (95% CI, 1.34–3.86;  $P < .001$ ; total QUALIDEM intervention: 67; 95% CI, 64.8–69.1 vs 64.4; 95% CI, 62.3–66.4 for the control). We also found positive effects of the intervention on all secondary outcomes.

**Conclusions and Implications:** Once-a-month person profile interventions based on person-centered outcome measurements provided a small but significant improvement in QoL. Thus, our findings suggest a potential benefit to the broader implementation of person profiles involving nursing staff and family members in long-term care facilities.

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F.S and A.L.K these authors are co–first authors.

This work was supported by the Swiss Academy of Medical Sciences, the Gottlieb and Julia Bangerter-Rhyner Foundation (grant number PC 20/17), HES-SO University of Applied Science, Arts Western Switzerland Bureau d'appui et de coordination de la formation doctorale, and the Swiss Academy for Socratic Care. The funders had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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<https://doi.org/10.1016/j.jamda.2024.105351>

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People with dementia frequently require care in long-term care facilities (LTCFs),<sup>1,2</sup> and according to current care models,<sup>3,4</sup> dementia care in LTCFs should be coordinated collaboratively on an ongoing basis. However, in clinical practice, coordination sometimes occurs infrequently and in an unstructured way.<sup>5-7</sup> Furthermore, family input on the care process may go overlooked,<sup>8</sup> despite its potential impact on quality of care and quality of life (QoL).<sup>9,10</sup>

Patient-centered outcomes are measurable health outcomes that are important to patients; they are often collected from patients themselves

using patient-reported outcome measures (PROMs) or patient-reported experience measures (PREMs). PROMs and PREMs can increase symptom recognition and facilitate communication between families and LTCF staff.<sup>11-13</sup> However, collecting PROMs or PREMs alone appears insufficient to comprehensively reshape care to address both emotional and functional aspects.<sup>13</sup> Point-of-care coaching and personalized, context-sensitive interventions grounded in frequent and detailed observations are emerging as more promising strategies to modify care toward peer learning, knowledge exchange, and person-centered practices for people with dementia.<sup>14,15</sup>

To improve care coordination between staff, facilitate communication with families, and promote person-centered care, we define an intervention called the person profile (Supplementary Material 1), which consists of a multiprofessional discussion (involving family members) following a 5-step process (outlined in Figure 1). Measurements of the Integrated Palliative Care Outcome Scale for People with Dementia (IPOS-Dem),<sup>16-18</sup> a proxy PREM designed for dementia care, provide the basis for the discussion, and the actionable outcomes of the person profile discussions are integrated into the care plan. Person profiles thus combine PREMs with case-based reflection and the collaborative development of personalized interventions.

In this study, we aimed to investigate the efficacy of person profile discussions to improve the QoL of people with dementia living in LTCFs. This study was a cohort-type stepped-wedge cluster-randomized intervention trial (SW-CRT) and is reported according to the Consolidated Standards of Reporting Trials guideline.<sup>19</sup> An SW-CRT design was chosen based on ethical considerations (ie, to enable all clusters and participants to receive the intervention for at least 6 months).

## Methods

### Ethical Considerations and Trial Registration

We obtained approval for this trial from the ethics committee of the Canton of Zürich (clearance certification number BASEC 2019-01847). The trial and the secondary analysis were registered in the German Clinical Trials Register (DRKS00022339).

### Study Design

The trial was conducted across 23 LTCFs in Switzerland from 2020 to 2023. The study protocol was previously published.<sup>20</sup> The trial duration was 15 months (5 periods of 3 months each), and LTCFs were allocated by one author (F.S.) using a random number generator to 1 of 3 cluster groups and moved from the control to the intervention condition 3, 6, or 9 months after baseline, respectively (Figure 2). The specific time periods and total duration of the trial were guided by our power calculations.<sup>20</sup> Crossover between control and intervention conditions occurred without transition periods. The intervention nurse and the LTCFs were unblinded by one author (F.S.) regarding sequence allocation after collecting the baseline data.

### Sample Size and Recruitment

Based on our previously published sample size calculation,<sup>20</sup> we aimed to include 23 LTCF clusters, with an average of 10 people with dementia per cluster. LTCFs were excluded from the trial if they did not agree to our request for study participation or provided ongoing care to <8 people with dementia. The chief nursing officer of each

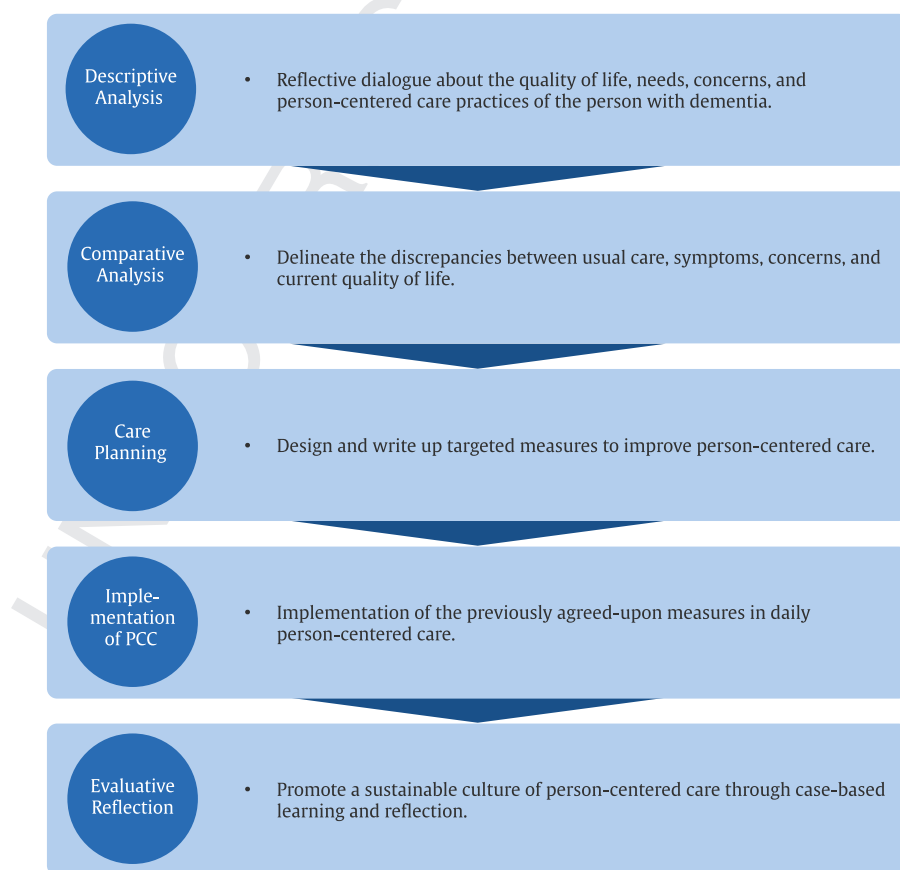


Fig. 1. Step-by-step overview of the person profile intervention.

participating LTCF appointed a local clinical champion, who screened patients for eligibility, coordinated introductory training with the research team, and facilitated consent procedures with the research team. For the inclusion and exclusion criteria adopted for people with dementia, family members, and LTCF staff, see [Table 1](#).

### Study Intervention

The intervention consisted of monthly IPOS-Dem measurements, followed by person profile discussions with LTCF staff and family members guided by an intervention nurse. The person profile follows a structured, iterative 5-step process, detailed in [Supplementary Material 1](#), that focuses on managing needs and concerns and improving the person-centeredness of care. Person profile discussions were held for 6–12 months, depending on the cluster group allocation. A report of the intervention according to the Template for Intervention Description and Reporting<sup>21</sup> is available from [Supplementary Material 3](#). In the context of the ongoing COVID-19 public health measures, the attendance of LTCF staff and family members varied according to local conditions and regulations. As a control condition, monthly IPOS-Dem assessments were implemented for the study, in addition to usual care.

### Outcomes

The primary outcome, QoL, was assessed by LTCF staff every 3 months using the German QUALIDEM for people with mild to advanced dementia.<sup>22,23</sup> No minimal clinically important difference has yet been published for QUALIDEM. Secondary outcomes were the subscales of the QUALIDEM and the subscales of the Swiss easy-read IPOS-Dem instrument,<sup>16,17</sup> which was translated and validated using the same population and dataset. The IPOS-Dem covers the symptoms and concerns of people with dementia and was assessed monthly by LTCF staff. IPOS-Dem provided the intervention nurse, LTCF staff, and family members with information on the symptom burden of the person with dementia. Outcome assessment was restricted to these 2 instruments to minimize the research effort required by LTCF staff. No data on safety or adverse outcomes were collected.

### Data Management and Analysis

The study database was maintained in REDCap.<sup>24,25</sup> Data analysis was performed according to a prespecified statistical analysis plan,<sup>20</sup> and patient-level outcomes were analyzed per protocol (PP). Furthermore, an intention-to-treat (ITT) dataset was generated, with the last observations carried forward for sensitivity analysis.

We used linear mixed-effects models with random intercepts to assess the intervention effect on primary and secondary outcomes. The random effects allow adjustment of cohort SW-CRT clustering

(observations within patients, patients within clusters). As fixed effects, we incorporated intervention, calendar, and exposure time, which characterize SW-CRT. Therefore, our modeling strategy involves the integration of different combinations of interventions, times, and interaction effects in the fixed part of the model, as previously described,<sup>20</sup> followed by model selection based on fit and parsimony indices. We used the same model selection process to arrive at a model for the 2 IPOS-Dem subscales that incorporated time effects. We present effect estimates with 95% CIs and *P* values. To validate the results, the same model selection process was undertaken with the ITT data, and the model assumptions were assessed by residual analysis.

Missing data were excluded from the PP analysis, and where more than one-half of the symptoms and concerns in the IPOS-Dem were completed (including cannot assess), a subscale score ranging between 0 (no impact) and 4 (very severe impact) was generated by calculating the mean of the remaining items. For the QUALIDEM, the sum scores were scaled to a percentage score ranging from 0% (low QoL) to 100% (high QoL), according to its guidance.<sup>26</sup> Data analysis was performed using R 4.3.2 with multiple packages (available with the dataset).

## Results

### Recruitment and Sample Characteristics

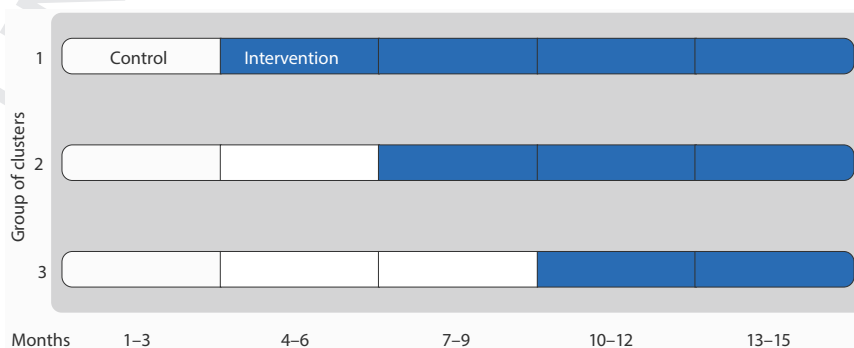
We approached 387 Swiss German LTCFs to reach our recruitment target of 23 clusters. LTCFs were randomly allocated to 1 of 3 cluster groups. For details on recruitment, see [Figure 3](#). The first cluster started at baseline in November 2020, and the last follow-up was completed in February 2023.

We screened 1044 people with dementia for participation, of whom 240 met the inclusion criteria and consented to participate. Due to impaired decision-making capacity, consent by proxy was provided by the legal representative in almost all cases. Furthermore, we recruited 118 family members for inclusion in the person profile discussions, and 307 LTCF staff members, who were trained in the study assessments.

Despite randomization, our final sample of people with dementia was imbalanced in terms of attrition and sex across the cluster groups ([Table 2](#) and [Supplementary Material 2](#)). Attrition overall was higher than anticipated, with only 52% of people with dementia (125 of 240) finishing the trial.

### Outcomes

The person-centered intervention was delivered in 401 structured person profile sessions, and feasibility and procedural adherence were documented by the intervention nurse regularly to verify that the person profile discussions were conducted in collaboration with LTCF



**Fig. 2.** Trial design schematic. Cluster group 1 contained 5 LTCFs, group 2 contained 10 LTCFs, and group 3 contained 8 LTCFs. Each block corresponds to a period of 3 months.

staff and family members according to the intended framework (Supplementary Material 1).

Residual analysis showed no evidence contradicting the model assumptions, but the optimal linear mixed-effects model included no time or interaction effects in the fixed part. Based on this model, including 1143 QUALIDEM observations in the PP population, the primary outcome, the QUALIDEM total score, demonstrated a significant time-averaged increase of 2.6 points (95% CI, 1.34–3.85,  $P = .0001$ ), attributable to the intervention. The QUALIDEM total score for the intervention improved to 67 (95% CI, 64.8–69.1) from 64.4 (95% CI, 62.3–66.4) for the control, and subscale analyses further delineated the intervention's effect across the 6 QUALIDEM subscales as secondary end points (Table 3). Models fitted to the ITT data provided similar effect estimates, but adjusting for potentially confounding factors (eg, age, sex) did not significantly affect the effect estimates.

For the secondary end point IPOS-Dem, we fitted our model to 3176 observations. We estimated a significant time-averaged intervention effect ( $P = .048$ ) on the dementia physical and interaction impact subscale, with  $-0.03$  (95% CI,  $-0.06$  to  $-0.01$ ). Thus, the estimated mean physical and interaction impact decreased from 1.01 (95% CI, 0.91–1.12) to 0.98 (95% CI, 0.87–1.09) under the intervention condition. A significant effect of calendar time was estimated for the dementia emotional and behavioral impact subscale. Regarding the dementia emotional and behavioral impact subscale, a more complex model adjusting the effect of calendar time was selected, represented by an intervention effect of 0.01 (95% CI,  $-0.05$  to 0.08;  $P = .68$ ) multiplied by the number of days spent in the trial plus the calendar time, by  $-0.001$  (95% CI, 0.00–1.25;  $P < .001$ ).

The model presented for QUALIDEM estimates the intervention effect, which did not adjust for time effects or time-intervention interaction. This simple model resulted in the significant main effect estimate previously described for the total score and QUALIDEM subscales. However, we tested and compared models for time in study, time in intervention, and time in study  $\times$  time in intervention interaction effects and sociodemographic variables like sex and age as fixed effects. In our second model, the intervention effect was represented in the same terms as the first model, with an effect estimate of 0.894 (95% CI,  $-1.394$  to 3.182;  $P = .444$ ) in the total QUALIDEM score. Model 3, in turn, incorporated the intervention effect with 2 terms: the sum of intervention and time in the study. In model 3, the intervention effect results from  $-0.489$  (95% CI,  $-3.753$  to 2.775) plus 0.009 (95% CI,  $-0.006$  to 0.025) multiplied by the number of days in the study.

Our fourth model allowed for a step effect and incorporated both time effects. This means the intervention's effect estimate was represented in the intervention term of model 4 with 1.179 (95% CI,  $-1.213$  to 3.570). This step effect of the intervention term is removed in model 5's equation; the intervention effect was represented only by the term exposure time with 0.004 (95% CI,  $-0.011$  to 0.019).

We compared the first 3 models using the  $\chi^2$  statistic and AIC. Models 2 ( $\chi^2_1 = 3.022$ ) and 3 ( $\chi^2_1 = 1.374$ ) did not significantly differ

from the first model. However, although the Akaike information criterion coefficient was lowest in model 2, with 8909.8, it lies within 2 points of the other models. With the additional consideration of the Bayesian information criterion, our model selection criteria indicated the first model. Models applied to the ITT data demonstrated similar effect estimates for the 2 secondary outcomes. Fidelity and adherence findings are detailed in Supplementary Material 3.

## Discussion

We conducted an SW-CRT in 23 Swiss LTCFs, including 240 people with dementia and 118 family members, with the aim of evaluating the effect of a nurse-led person profile intervention on QoL. Our main finding is that the person profile intervention has a positive—albeit small—effect on QoL; however, we can demonstrate further beneficial effects of the intervention on all secondary end points.

Our findings contribute to the limited but growing evidence base concerning the efficacy of complex, person-centered care interventions in long-term care.<sup>3,28,29</sup> Our study supports the notion that measuring patient-centered outcomes alone may not improve the QoL or care for various populations,<sup>11,13</sup> because the estimated effect of our intervention was independent of time. Instead, as suggested by Bolt et al,<sup>14</sup> care improvements may be achieved via on-site, practical, and goal-oriented case-based reflection and discussion, representing the core of our person profile intervention. Our person profile intervention can be framed as a complex intervention<sup>30</sup> and a behavior change intervention directed at the whole LTCF staff team level.<sup>31</sup> Due to the skewed skill/grade mix,<sup>32</sup> an on-site iterative approach (subsequently discussed) can be considered more effective but requires a longer duration and sustainable intervention implementation.<sup>31</sup>

We think the effectiveness of our intervention relies (at least) on the following 3 aspects: (1) systematic reflection on the needs and concerns derived from proxy-PREMs,<sup>33</sup> which may be more concordant with a patient's overall health status and may enable earlier communication of symptom occurrence and severity than clinician reports, which tend to underestimate these experiences<sup>33–35</sup>; (2) collaborative development of individualized care interventions<sup>36–38</sup> necessitates that the multimorbidity common among LTCF populations, which drives complex needs and concerns, be assessed, treated, and supported by a team that includes family members offering differing viewpoints<sup>4,36</sup>; and (3) an iterative approach<sup>14,33</sup> that involves observing change over time was described as a factor enabling the implementation of complex interventions in LTCFs.<sup>39</sup>

A comparable SW-CRT in The Netherlands<sup>40</sup> tested the effect of a custom intervention (STA OP!) based on the serial trial intervention<sup>41</sup> for reducing reactive behavior in dementia. The authors observed an increase of 0.95 percentage points in the restless tense behavior subscale of the QUALIDEM in the first 3 months of their trial, an effect that, unfortunately, seemed to wane over the remainder of the study.

**Table 1**  
Criteria for Trial Participation

Participant Category	Inclusion Criteria	Exclusion Criteria
Person with dementia	<ul style="list-style-type: none"> <li>- Resident of an LTCF cluster</li> <li>- Diagnosis of Alzheimer's disease or vascular dementia, or presenting with clinical symptoms of dementia</li> <li>- Informed consent (by proxy)</li> </ul>	<ul style="list-style-type: none"> <li>- Absent during baseline (eg, due to hospitalization)</li> </ul>
Family member LTCF staff	<ul style="list-style-type: none"> <li>- Informed consent</li> <li>- Works <math>\geq 0.2</math> FTEs</li> <li>- Employed in LTCF for <math>\geq 3</math> months</li> <li>- Age <math>\geq 18</math> years</li> <li>- Informed consent</li> </ul>	<ul style="list-style-type: none"> <li>None</li> <li>- Unable to communicate in German or follow the study procedures</li> <li>- Does not provide continuing care to people with dementia</li> </ul>

FTE, full-time equivalent.



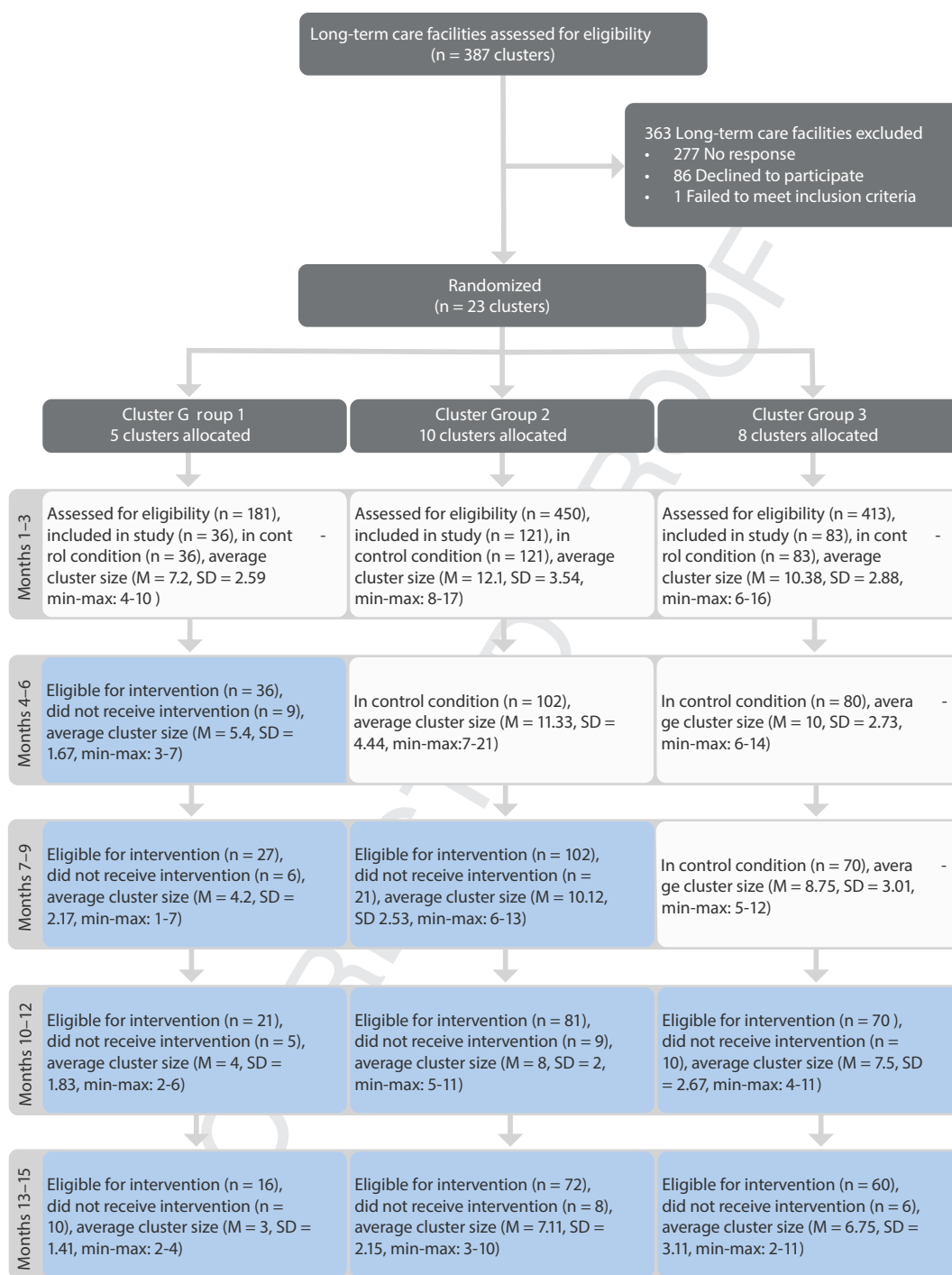


Fig. 3. Long-term care facilities' randomization and participant flow in the trial. M, mean; max, maximum; min, minimum.

Compared with this Dutch study, the effect of our person profile intervention was broader, not only extending to all QUALIDEM subscales, but also maintaining no decreases over time. Family involvement—omitted in the Dutch trial—may have contributed to the higher and more sustained effect in our trial. The latter is noteworthy because QoL and dementia symptoms are expected to stagnate or worsen over time due to the progressive nature of the syndrome. As such, any improvements at all could thus be considered a positive outcome.<sup>4,42</sup>

In a Norwegian trial of monthly geriatric case conferences based on a comprehensive geriatric assessment of people with dementia living in LTCFs,<sup>43</sup> no significant effect on neuropsychiatric symptoms was found in the 3-month follow-up period.<sup>43</sup> Compared with our person profile intervention, the case conferences did not include an evaluative reflection component based on context. This additional step (Supplementary Material 1) may have driven team adherence to the care plan and, consequently, QoL improvement over the longer follow-up period of our study.

**Table 2**  
Demographic Characteristics of the ITT Cohort by Cluster Group

Demographic	Cluster Group 1	Cluster Group 2	Cluster Group 3	Total
People with dementia	36	121	83	240
Female	19 (52.8)	96 (79.3)	60 (72.3)	175 (72.9)
Age, y	87.7 ± 8.4	86.1 ± 7.8	85.2 ± 7.6	86 ± 7.8
Dementia diagnosis*				
Alzheimer's disease	13 (36.1)	37 (30.6)	29 (34.9)	79 (32.9)
Vascular	3 (8.3)	16 (13.2)	2 (2.4)	21 (8.75)
Other	11 (30.6)	48 (39.7)	41 (49.4)	100 (41.7)
Not diagnosed	9 (25)	20 (16.5)	11 (13.3)	40 (16.7)
Dementia severity				
Mild	2 (5.6)	3 (2.5)	2 (2.4)	7 (2.9)
Severe	8 (22.2)	48 (39.7)	18 (21.7)	75 (31.2)
Very severe	10 (27.8)	37 (30.6)	29 (34.9)	76 (31.7)
Missing	15 (41.7)	33 (27.3)	34 (41)	82 (34.2)
Care dependency*,†				
Supervision (1)	0 (0)	2 (1.7)	2 (2.4)	4 (1.7)
Limited (2)	9 (25)	20 (16.5)	13 (15.7)	42 (17.5)
Extensive (3)	14 (38.9)	73 (60.3)	44 (53)	131 (54.6)
Maximal (4)	12 (33.3)	21 (17.4)	13 (15.7)	46 (19.2)
Dependent (5)	1 (2.8)	5 (4.1)	11 (13.3)	17 (7.1)
Family members engaged <sup>27</sup>	14 (39)	77 (63.6)	34 (41)	125 (52.1)

Values are n, mean ± SD, or n (%).

\*Based on the administrative files accessible by LTCF staff.

†Based on the ADL Hierarchy Scale.

During a 19-month SW-CRT of German LTCFs that compared 2 types of case conferences—with and without a prior assessment focusing on behavior that challenges—QUALIDEM was used as a secondary outcome.<sup>44</sup> In one case conference type, the study found small positive changes in the care relationship, positive affect, and social isolation in a population comparable with ours. In the second intervention cohort, the only increase observed was in positive affect. According to the authors, contextual factors (eg, inadequate staffing, qualification levels) may have contributed to the limited effects observed in the trial. In contrast, our case conference was highly receptive to the context of each participating LTCF, which we think contributed to its effectiveness.

### Strengths and Limitations

Our study has several strengths. First, we used a robust methodology to test a nonpharmacologic intervention in LTCFs, using a large sample size and including participants from multiple centers and a follow-up period of 15 months. We used purposefully broad inclusion criteria for dementia, thus accounting for underdiagnosis and potentially enhancing generalizability to the wider population of LTCF residents with dementia. Finally, our analysis was based on an evidence-based model selection process adjusting for calendar time, exposure time, and clustering effects.

The study also has several limitations. Due to the nature of the intervention, there was no possibility of blinding during the intervention periods, and there was no active control condition besides the IPOS-Dem assessment. Because our primary and secondary outcomes

were proxy measures completed by unblinded LTCF staff, our trial is prone to performance bias; future studies should consider using multiple, disparate outcomes that are triangulated between different sources, optimally the people with dementia themselves. Our trial is also susceptible to selection bias; this may be driven by the limited number of people with dementia recruited from each cluster and the high attrition rate. Due to the intensity of the overall data capture efforts for the clinical sites and resource constraints, we did not undertake initial dementia staging. Instead, we relied on administrative data accessible to frontline staff to determine the dementia diagnosis and its severity, if staged. Recent literature implies that stratified analysis based on dementia severity and type should be undertaken to avoid generalizing specific results to an unselected all-cause dementia population. Furthermore, attrition in our trial was higher than anticipated, which may be explained at least partially by the ongoing COVID-19 pandemic. However, a sensitivity analysis of the ITT population supports our findings. Regardless, it is unclear whether the effect we found amounts to a clinically meaningful difference because a QUALIDEM difference has not yet been identified.

Further refinement of the intervention (eg, by enhancing family involvement) may increase its efficacy. Likewise, conducting a person profile more frequently than monthly could produce a stronger effect. Despite our detailed reporting of the intervention procedures, a person-centered and nonpharmacologic intervention remains challenging to replicate. Conducting person profiles truly is a complex intervention, ticking all the boxes of the MRC definition.<sup>30</sup> Person profiles result in rather broad targeted measures to improve person-centered care (ie, the person profiles are designed to be individualized, which makes them highly dependent on individual scenarios for residents). Finally, usual care and available resources may differ considerably between LTCFs,<sup>2,45</sup> potentially limiting the generalizability to other language regions or countries.

### Impact

Our findings demonstrate the benefit of a person-centered, nonpharmacologic, nurse-led intervention on the QoL of people with dementia in LTCFs. With its compact format and person-centered symptom assessment in combination with person profiles, it can be adapted to fit many LTCF contexts, facilitating its widespread

**Table 3**  
Effect Estimates on Total QUALIDEM Scores and QUALIDEM Subscales

QUALIDEM Score	Effect Estimate	95% CI	P Value
Total score	2.60	1.34–3.85	<.001
Social relations	3.21	1.41–5.0	<.001
Restless tense behavior	3.15	1.09–5.2	.003
Negative affect	2.67	0.82–4.51	.005
Care relationship	2.53	0.76–4.3	.005
Positive affect	2.50	0.75–4.26	.005
Social isolation	1.96	0.08–3.84	.041

implementation. Consequently, people with dementia living in LTCFs may be directly impacted, experiencing improved QoL and care due to the person profile intervention. Our results also support health care providers and policymakers in advocating for validated person-centered approaches involving family members to improve dementia care. Future research should clarify how and why the effect of the person profile intervention is realized, particularly, for example, if it depends on team functioning or family involvement, and how its effect can be maximized.

## Conclusions and Implications

We demonstrated that a systematic person-centered approach in the form of a monthly person profile intervention improved QoL in people with dementia in LTCFs. Based on a structured and easy-to-use assessment instrument, care and caring narratives were shared, and highly individualized interventions were developed that had a measurably positive impact on QoL.

## Disclosure

The authors declare no conflicts of interest.

## Acknowledgments

We want to thank the people with dementia, their family members, and the LTCF staff for their participation in this study. Furthermore, we wish to thank the following clinical champions: A. Beqiri, R. Benz, M. Bonaconsa, A. Brunner, A. Conti, M. Deflorin, D. Deubelbeiss, L. Ebener, S. Egger, E. Eichinger, D. Elmer, A. Ermler, M. Fuhrer, C. Grichting, M. Havarneanu, H. Hettich, E. Hoffmann, E. Imgrueth, R. Juchli, I. Juric, K. Knöpfli, S. Kuonen, F. Laich, H. Meiser, N. Mergime, B. Michel, C. Ming, F. Müller, C. Niederer, G. Parkes, P. Piguët, A. Repesa, C. Ritz, B. Santer, A. Schallenberg, C. Schweiger, M. Spitz, and R. Strunck, all of whom supported the study in each LTCF.

## Supplementary Data

Supplementary data related to this article can be found online at <https://doi.org/10.1016/j.jamda.2024.105351>.

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