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Original Study

Effect of a Group-Based Personal Assistive RObot (PARO) Robot Intervention on Cognitive Function, Autonomic Nervous System Function, and Mental Well-being in Older Adults with Mild Dementia: A Randomized Controlled Trial

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A B S T R A C T

Objectives: Personal Assistive RObot (PARO) interventions have been used to treat agitation and mood symptoms of dementia effectively. However, the effects of a PARO intervention on physiological and cognitive function are unclear. To examine the effects of a group-based PARO intervention for older adults with mild dementia.
Design: Using a group-based PARO intervention randomized controlled trial with 2-arm parallel groups.
Setting and Participants: Older adults with mild dementia aged 65 years or older from 4 dementia day care centers were recruited.
Methods: Physiological parameters were assessed using the finger tapping test (FTT) and heart rate variability (HRV). The Mini-Mental State Examination (MMSE), Geriatric Depression Scale—Short Form (GDS-SF), University of California Los Angeles loneliness scale—version 3 (UCLA-3), and Warwick-Edinburgh Mental Well-being Scale (WEMWBS) were assessed before the intervention, end of the intervention, and 1-month after the intervention.
Results: Using a repeated-measures generalized linear model, significant time × group interactions were found in the MMSE [$F(2, 115) = 19.54$, $P < .001$], FTT [$F(2, 115) = 4.87$, $P = .01$], HRV high-frequency [$F(2, 115) = 3.57$, $P = .03$], and high-frequency/low-frequency ratio [$F(2, 115) = 0.96$, $P = .01$], UCLA-3 [$F(2, 115) = 54.7$, $P < .001$], GDS-SF [$F(2, 115) = 3.36$, $P = .04$], and WEMWBS [$F(2, 115) = 5.93$, $P < .001$]. Furthermore, psychological parameters improved significantly and continuously even 1 month after the PARO intervention was finished. Physiological parameters significantly improved at week 6, but the effects had diminished by week 10.
Conclusions and Implications: A PARO intervention may effectively improve the physiological and psychological responses of people with mild dementia.
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Dementia is a growing global epidemic, and the number of people with dementia is predicted to reach 139 million by 2050.[1] More than 90% of people with dementia are affected by at least 1 behavioral and psychological symptom, and this can have physical or psychological and social impacts on patients and their caregivers.[1] Currently, there is

no cure for dementia. Although nonpharmacologic interventions are important tools for managing dementia symptoms, their benefits are poorly understood.[2]

In recent years, the robotic seal Personal Assistive RObot (PARO) has been used as a nonpharmacologic treatment. Evidence has shown that PARO can improve agitation and reduce anxiety in people with dementia.[3,4] However, the outcomes of human-robot interactions have been inconsistent because of the small sample sizes and lack of control groups.[5] Additionally, objective neurobiological evidence of PARO interventions is lacking, and the underlying mechanisms remain unclear.

Biologically, dopamine is a crucial neurotransmitter involved in multiple physiological functions, including motor control, modulation of affective and emotional states, reinforcement of behavior, and selected higher cognitive functions.[6] Dysfunction of dopaminergic transmission plays a key role in several devastating neurologic and psychiatric disorders.[6] Furthermore, cognitive abilities (nonmotor) such as attention and short-term memory are associated with finger-tapping performance in internal tempo and time reproduction paradigms.[7] These functions are impaired in people with dementia.[7] A previous study demonstrated that finger-tapping was correlated with dopaminergic function,[8] and another showed that finger-tapping was correlated with cognitive function in older adults.[7]

Heart rate variability (HRV) is an index of autonomic nervous system (ANS) function, and it has been associated with several risk factors for adverse health outcomes and psychological stress evaluations.[9,10] For example, high-frequency (HF) HRV has been shown to predict depressive symptoms in adolescents and mentally perceived stress has been negatively correlated with the HF component of HRV.[9,10] Interactions with social robots have been shown to reduce saliva cortisol and improve galvanic skin response.[4,11] Although many studies have focused on the psychosocial outcomes of PARO interventions, the associated intrinsic neurobiologic changes still need to be determined, as demonstrated in the studies above. Furthermore, few studies have investigated changes in cognitive and ANS functions using PARO, and no study has examined the relationship between dopamine and cognition in older adults who interact with social robots such as PARO. Given the workforce shortage, facilities may provide group format activities rather than individualized activities to promote older adults' psychosocial health.[12] We based our study on Liang et al,[13] who used a 30-minute group PARO intervention for 6 weeks. We conducted our 6-week, randomized controlled trial (RCT) of a group-based PARO intervention (GPI) to explore the effects on (1) cognitive function, (2) ANS function, and (3) mental well-being in older adults with mild dementia. Furthermore, we also examined changes within and between groups at different time points.

Methods

Study Design

This 6-week GPI RCT, with 2-arm parallel groups, was conducted using a single-blind and repeated measures design at 4 dementia day care centers in southern Taiwan. All procedures involving human subjects/patients were approved by the National Cheng Kung University Human Research Ethics Committee (approval number: NCKU HREC-F-110-156-2) and registered on the ClinicalTrials.gov database (NCT05102201). All participants signed informed written consent.

Sample Size

The sample size was calculated based on a prior study that explored the effect of a PARO intervention on depression and loneliness using an RCT design.[13,14] A sample size of 108 was determined based on analysis of variance repeated measures to achieve a power of 0.8, effect size of 0.25, and alpha level of 0.05 (G Power v.3.1.5). Based on an estimated 10% dropout rate, the required sample size was 120.

Participants

Participants were recruited from January 2022 to December 2022. The inclusion criteria were (1) aged 65 years or older, (2) mild dementia diagnosed by professional clinicians, (3) an ability to communicate in Mandarin or Taiwanese, and (4) attending a dementia day care center for at least 3 months. The exclusion criteria were (1) severe difficulty in communication; (2) total dependence on carers for all daily activities; and (3) a diagnosed infectious disease, moderate or severe dementia, and severe mental illness such as delusional disorder.

Intervention

Participants in the intervention group received a group (6 people as a group) 30-minute weekly session of the GPI for 6 weeks. There were 4 parts at each session. First, participants introduced her/himself to the group members. Second, the researcher introduced the PARO to participants using a short script according to the protocol and (as the researcher passed PARO around the group she) encouraged them to (briefly) make contact and interact with it both verbally and by touch. Third, the researcher encouraged participants to use PARO to communicate and interact with the participants seated beside them (for a maximum of 3 minutes each). Finally, participants were encouraged by the researcher to discuss with the group what they felt when interacting with PARO. The researcher ensured that all the participants had reasonably equal time to interact with the PARO. The PARO group received the PARO intervention, which was a substitute for the usual arts activity.The control group received usual care with group-based activities (GUA), such as crafts, which each day care center provided.

PARO

PARO (version 9) was developed by Dr Takanori Shibata in Japan. It looks like a baby harp seal and is covered with an array of tactile sensors that monitor sound, light, temperature and touch via artificial intelligence software. PARO can show humanlike emotional reactions when it feels surprised, happy, or angry.

Randomization and Blinding

Using computer-generated sampling, 60 participants were allocated to the intervention or control group at a 1:1 ratio (Figure 1).

Measures

A mixed between- and within-subjects analysis of variance design was used to assess the immediate and sustained effects of the 6-week GPI on outcomes of interest at 3 time points: before the intervention (T1), at the end of the intervention (week 6, T2), and 1 month (week 10) after the intervention (T3). The following evaluations were performed.

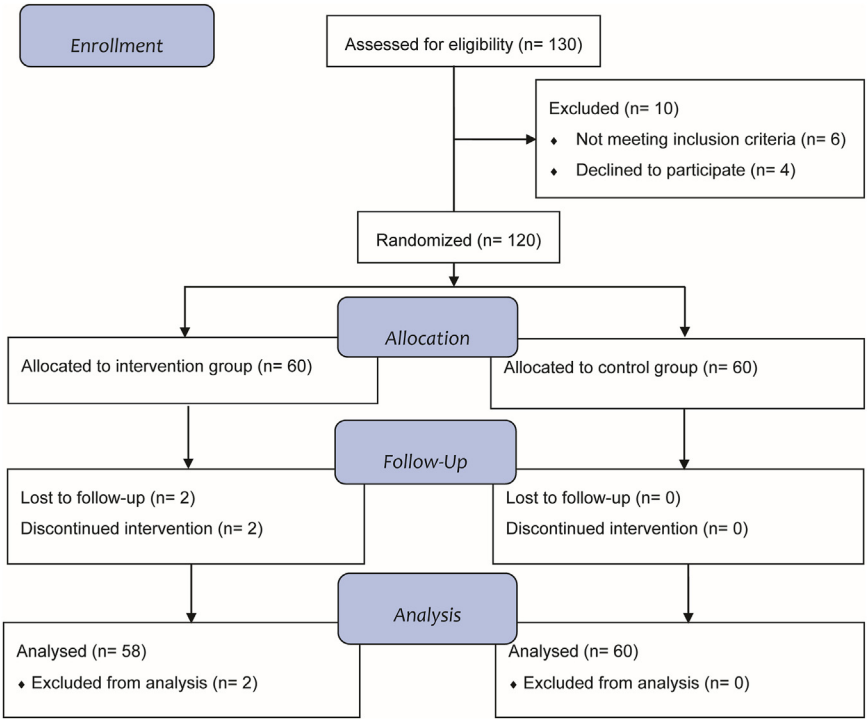

Fig. 1. Flow diagram of the PARO study.

Mini-Mental State Examination

The Mini-Mental State Examination (MMSE) is widely used to assess the level of cognitive impairment based on the concepts of orientation, registration, attention and calculation, recall, and language.[15] The MMSE score ranges from 0 to 30. Generally, a cut-off above 24 indicates normal cognition, 20 to 23 mild cognitive impairment, 10 to 19 moderate cognitive impairment, and 0 to 9 severe cognitive impairment.[16]

Finger Tapping Test

Dopamine activity can be assessed using the finger tapping test (FTT) in older adults.[7] In this study, participants were asked to tap a touchpad continuously for 15 seconds using their predominant index finger, and the total number of taps was recorded. The participants were asked to repeat this procedure 3 consecutive times, and the average number of taps was used for analysis. A higher number of taps indicated better attention and short-term memory of the response.[7]

HRV

A 300-second HRV assessment was conducted immediately after resting using a battery-operated portable HRV device [CheckMyHeart (CMH) PlusTM R30 V4, Daily Care Biomedical, Taiwan]. This device recorded a single-lead ECG at the right sternal edge and cardiac apex using 2 surface ECG electrodes at a sampling rate of 250 Hz. All saved recordings were exported for offline data analysis.

Post-Acute and Long-Term Care Medical AssociationPower spectral density analysis of HRV was performed using fast Fourier transformation.[17] Several spectral components were defined as follows: low frequency (LF) (0.04-0.15 Hz), HF (0.15-0.40 Hz), and total power ($\leq$0.4 Hz). Very-low-frequency data were excluded, as short-term recordings have been reported to be unreliable indicators of HRV.[18] Total power represents total autonomic activity. The HF power of HRV represents an index of cardiac parasympathetic (vagal) activity, whereas the LF power represents an index of vasomotor sympathetic activity or both sympathetic and vagal activities.[17] The LF/HF ratio has been proposed as an index of the relative balance of sympathovagal influences on the heart, with a higher LH/HF ratio reflecting increased sympathetic activity or decreased parasympathetic modulation.[18] These indexes were ln-transformed to correct for skewness.

University of California Los Angeles Loneliness Scale—Version 3

The University of California Los Angeles Loneliness Scale—version 3 (UCLA-3) is a 20-item scale that measures a person's subjective feelings of loneliness and isolation.[19] Each item on the scale is rated from 1 (never) to 4 (often), with a total score ranging from 20 to 80. The higher the score, the more severe a person's feelings of loneliness. In this study, the reliability with a Cronbach alpha of internal consistency was 0.77.

Geriatric Depression Scale—Short Form

The Geriatric Depression Scale—Short Form (GDS-SF) consists of 10 positive and 5 negative items and is a useful tool for detecting depressive symptoms in older populations.[20] The total score ranges from 0 to 21, and a cut-off point of 6 or higher indicates the presence of depression. The study's reliability with a Cronbach α of internal consistency was 0.81.

Warwick-Edinburgh Mental Well-being Scale

The Warwick-Edinburgh Mental Well-being Scale (WEMWBS) scale includes 14 items of mental well-being covering subjective well-being and psychological functioning.[21] The scale is scored by summing responses to each item answered on a 5-point Likert-type scale, and the total score ranges from 14 to 70. The higher the score, the better the mental well-being. The scale has good reliability, with a Cronbach alpha of 0.97 in the study.

Data Analysis

Data were analyzed using SPSS for Windows, version 26. As there was a large sample where power was not an issue, case deletion was used to handle the missing data.[22] Descriptive statistics were used to analyze demographic data. Frequencies and percentages were used to summarize categorical variables, and mean, and standard deviations were used to present continuous variables. A mixed-design generalized linear model was applied, and repeated measurements were used to compare the outcome measures between the control and intervention groups. For significant interactions, a simple main effect with post hoc analysis for the mixed effects model at each time point was conducted with the least significant difference (LSD) correction to adjust for multiple comparisons. To compare the efficacy of the PARO intervention, a series of planned contrasts were conducted to compare changes (T2-T1, as an immediate effect, and T3-T1, T3-T2, as a sustained effect). An alpha value of <.05 was considered statistically significant, and 95% confidence intervals were calculated.

Results

Baseline Characteristics of the Participants

Figure 1 shows the CONSORT flow diagram. One hundred twenty participants from 4 day care centers were randomly allocated to the GPI (n = 60) and GUA (n = 60) groups. The attrition rate of participants was low (2/120, 0.02%), and both cases were due to discharge from the day care center. All participants completed the 6 sessions. Participants were facilitated by the researcher and they could stroke, cuddle, and talk to PARO at each session. The participants were between 65 and 95 years, with a mean age of 81.1 (SD = 7.2). Most participants were female (66.9%) and widowed (62.7%). Most participants were Daoist (82.2%), and 43.2% had completed primary school. There were no significant differences in measurements between the GPI and GUA groups at baseline. The baseline characteristics are summarized in Table 1.

Table 1
Characteristics of the Study Participants (N = 118)

Variable	PARO Group (n = 58)	Control Group (n = 60)	t/χ^2	*P*
Gender				
Male	23 (39.7)	16 (26.7)	0.13	.17
Female	35 (60.3)	44 (42.3)		
Education level				
Illiterate	19 (32.8)	11 (18.3)	5.02	.17
Primary	24 (41.4)	27 (45)		
Secondary and above	15 (25.8)	22 (36.7)		
Marital status				
Married	26 (44.8)	18 (30)	2.77	.09
Single/widow/divorced	32 (55.2)	42 (70)		
Religion				
Taoism	49 (84.5)	48 (80)	4.04	.26
Buddhism	8 (13.8)	7 (11.7)		
Christian	1 (1.7)	4 (6.7)		
Mobility				
Independent walking	27 (46.6)	42 (70)	6.68	.10
Walking assistant	31 (53.4)	18 (30)		
Age, y	81.78 ± 7.39	82.12 ± 7.12	−0.26	.79
Year of admission in day care	2.55 ± 0.75	2.69 ± 0.78	−1.02	.31
MMSE score (T1)	20.22 ± 4.91	21.17 ± 4.16	−1.13	.26
FTT (T1)	32.05 ± 13.01	29.63 ± 14.47	−0.95	.34
HRV-LF (T1)	28.57 ± 15.88	27.89 ± 13.77	−0.24	.81
HRV-HF (T1)	34.05 ± 20.01	38.71 ± 21.73	1.19	.24
HRV-LF/HF (T1)	2.25 ± 0.93	1.03 ± 0.92	−0.7	.48
UCLA-3 (T1)	42.72 ± 7.01	40.72 ± 7.67	1.59	.11
GDS-SF (T1)	6.76 ± 1.97	6.57 ± 1.97	0.53	.11
WEMWBS (T1)	46.38 ± 9.56	49.75 ± 9.71	−1.89	.06

FTT, finger tapping test; GDS-SF, Geriatric Depression Scale- Short Form; HF, high frequency; HRV, heart rate variability; LF, low frequency; MMSE, Mini-Mental State Examination; T1, before the intervention; UCLA-3, the UCLA Loneliness Scale version 3; WEMWBS, Warwick-Edinburgh Mental Well-being Scale.
Data are presented as n (%) or mean ± SD.

Effect of the PARO Intervention on Cognition

Using the repeated measures generalized linear model, the MMSE exhibited significant differences in time × group interaction [$F(2, 115) = 19.54$, $P < .001$], time effect [$F(2, 115) = 13.15$, $P < .001$], and group effect over time [$F(2, 115) = 23.55$, $P < .001$] (Table 2). Post hoc analysis determined the differences over the 3 time points (Table 3). There was an increase in MMSE score from T1 to T3, although the difference was not significant ($F = 0.58$, $P = .56$; Table 3). Compared to the GUA group, the MMSE score increased from T1 to T2 in the GPI group, but the score decreased from T2 to T3 ($F = 11.11$, $P < .001$; Table 3). Planned contrast analysis confirmed the significant group difference from T3-T1, as shown in Table 4. Compared to the GUA group, the changes in MMSE scores in the GPI group were significantly different at T3-T1 and T3-T2 but not at T2-T1.

There was also a significant interaction effect on FTT [$F(2, 115) = 4.87$, $P = .01$] between the GPI and GUA groups (Table 2). Post-hoc analysis showed significant differences over the 3 time points in the GPI group ($F = 3, 32$, $P = .04$; Table 3). Hence, the effect diminished after discontinuing the PARO intervention (T1 < T2 > T3). Compared to the GUA group, the FTT scores significantly decreased from T1 to T2 to T3; inverse effects were found (T1 > T2 > T3). The group difference in the immediate effect (T2-T1) was confirmed, as shown in Table 4. In addition, a difference in the change at T3 (T3-T1) was also observed.

Effect of the PARO Intervention on HRV

There were significant differences in time × group interaction effects between the 2 groups (Table 2) in the domains of HF [$F(2, 115) = 3.57$, $P = .03$] and LF/HF [$F(2, 115) = 4.43$, $P = .01$]. Similarly, in a post hoc analysis to identify possible changes over the 3 time periods, the

Table 2
Mixed Between- and Within-Subject Results for the Impact of the PARO Intervention (N = 118)

Variable	Effect	Wilk Lambda Value	*F*	*P*	Partial η^2
MMSE	Group		23.55	<.01	0.32
	Time	0.55	13.15	<.01	0.45
	Group × Time	0.45	19.54	<.01	0.55
FTT	Group		2.67	.11	0.02
	Time	0.94	3.34	.04	0.06
	Group × Time	0.92	4.87	.01	0.08
HRV-LF	Group		0.71	.40	0.01
	Time	0.99	0.17	.85	0.00
	Group × Time	0.98	0.89	.41	0.02
HRV-HF	Group		0.33	.86	0.79
	Time	1.00	0.02	.09	0.00
	Group × Time	0.94	3.57	.03	0.65
HRV-LF/HF	Group		1.66	.20	0.25
	Time	0.96	1.91	.15	0.33
	Time × Group	0.96	4.43	.01	0.08
UCLA-3	Group		12.99	<.01	0.10
	Time	0.92	5.26	<.01	0.08
	Group × Time	0.51	54.70	<.01	0.49
GDS-SF	Group		2.87	.09	0.02
	Time	0.43	76.40	<.01	0.57
	Group × Time	0.95	3.36	.04	0.06
WEMWBS	Group		0.23	.63	0.01
	Time	0.88	7.66	<.01	0.83
	Group × Time	0.91	5.93	<.01	0.09

Table 3
Post Hoc Analysis for the Impact of the PARO Intervention Over Time Using Generalized Linear Model Repeated Measures (N = 118)

Post Hoc Pairwise Comparisons								
Variable	PARO group				Control group			
	Time Main Effect F	*P*	Partial η^2	Pairwise Comparisons	Time Main Effect F	*P*	Partial η^2	Pairwise comparisons
MMSE	0.58	.56	0.01	Time 1 < Time 2 Time 1 < Time 3 Time 2 < Time 3	11.11	<.001	0.16	Time 1 < Time 2 Time 1 > Time 3* Time 2 > Time 3*
FTT	3.13	.048	0.05	Time 1 < Time 2* Time 1 < Time 3 Time 2 > Time 3	5.19	.008	0.09	Time 1 > Time 2 Time 1 > Time 3* Time 2 > Time 3*
HRV-LF	1.55	.22	0.03	Time 1 > Time 2* Time 1 > Time 3* Time 2 < Time 3	0.40	.67	0.01	Time 1 < Time 2* Time 1 > Time 3* Time 2 > Time 3†
HRV-HF	3.48	.03	0.07	Time 1 < Time 2*,† Time 1 < Time 3 Time 2 > Time 3†	3.07	.05	0.05	Time 1 > Time 2† Time 1 > Time 3 Time 2 < Time 3
HRV-LF/HF	2.24	.11	0.05	Time 1 > Time 2 Time 1 < Time 3 Time 2 < Time 3	0.77	.46	0.14	Time 1 < Time 2* Time 1 < Time 3 Time 2 < Time 3
UCLA-3	12.15	<.001	0.18	Time 1 > Time 2* Time 1 > Time 3 Time 2 < Time 3*	47.76	<.001	0.45	Time 1 < Time 2* Time 1 < Time 3 Time 2 > Time 3*
GDS	66.84	<.001	0.54	Time 1 > Time 2* Time 1 > Time 3* Time 2 > Time 3*	21.59	<.001	0.27	Time 1> Time 2* Time 1 > Time 3* Time 2 >Time 3*
WEMWBS	23.61	<.001	0.29	Time 1 < Time 2* Time 1 < Time 3* Time 2 > Time 3*	0.98	.37	0.02	Time 1 < Time 2 Time 1 < Time 3 Time 2 < Time 3

*$P < .05$.
†$P < .10$.

GPI effects on ANS functions in both domains revealed that there was only an immediate effect on HRV during the intervention ($F = 3.48$, $P = .03$; Table 3), but that the effect diminished during follow-up (week 10). The planned contrast analysis confirmed the immediate effects on HF and LF/HF (Table 4).

Table 4
Comparisons of Outcomes for the Impact of the PARO Intervention Using the Independent *t* Test (N = 118)

Difference	PARO, Mean ± SD	Control, Mean ± SD	*t*	*P*
MMSE				
T2-T1	0.26 ± 3.16	0.56 ± 4.21	−0.45	.66
T3-T1	0.56 ± 4.62	−1.95 ± 4.32	3.04	.003
T3-T2	0.30 ± 3.79	−2.51 ± 4.49	3.67	<.001
FTT				
T2-T1	3.04 ± 9.55	−0.84 ± 9.96	−2.12	.036
T3-T1	1.98 ± 9.96	−3.70 ± 9.40	−3.13	.002
T3-T2	−1.05 ± 8.32	−2.86 ± 7.79	−1.19	.23
HRV-LF				
T2-T1	−3.68 ± 20.15	1.73 ± 21.46	1.33	.42
T3-T1	−0.17 ± 5.86	−0.16 ± 1.03	0.01	.024
T3-T2	3.51 ± 19.49	−1.89 ± 21.42	−1.35	.26
HRV-HF				
T2-T1	6.26 ± 22.57	−6.66 ± 26.42	−2.67	.009
T3-T1	0.45 ± 10.55	−0.79 ± 4.17	−0.81	.42
T3-T2	−5.80 ± 20.42	5.88 ± 27.11	2.47	.015
HRV-LF/HF				
T2-T1	−0.18 ± 0.89	0.77 ± 2.35	2.68	.009
T3-T1	0.02 ± 0.26	0.89 ± 6.68	0.92	.36
T3-T2	0.20 ± 0.87	0.12 ± 7.23	−0.08	.93
UCLA-3				
T2-T1	−5.36 ± 8.35	9.18 ± 8.58	−9.33	<.001
T3-T1	−1.52 ± 8.21	1.23 ± 8.53	−1.78	.07
T3-T2	3.85 ± 9.04	−7.95 ± 6.38	8.21	<.001
GDS				
T2-T1	−2.64 ± 1.94	−1.52 ± 2.88	−2.47	.015
T3-T1	−3.31 ± 2.42	−2.40 ± 2.88	−1.86	.06
T3-T2	−0.67 ± 2.51	−0.88 ± 2.83	0.43	.66
WEMWBS				
T2-T1	9.72 ± 11.68	0.18 ± 18.46	3.34	.001
T3-T1	5.14 ± 10.25	2.58 ± 13.52	1.15	.25
T3-T2	−4.59 ± 10.36	2.40 ± 15.44	−2.88	.005

Effect of the PARO Intervention on Mental Well-being

To investigate the effect of the PARO intervention on psychological changes, the UCLA-3, GDS-SF, and WEMWBS were used to represent mental well-being (Figure 2). The results showed significant time × group interaction effects in the UCLA-3 [$F(2, 115) = 54.7$, $P < .001$], GDS-SF [$F(2, 115) = 76.4$, $P < .001$], and WEMWBS [$F(2, 115) = 5.93$, $P = .04$] between the 2 groups over time (Table 2). Post hoc analysis showed significant differences in the UCLA-3 ($F = 12.15$, $P < .001$), GDS-SF ($F = 66.84$, $P < .001$), and WEMWBS ($F = 23.61$, $P < .001$) over the 3 time points in the GPI group (Table 3). The planned contrast analysis confirmed the immediate and sustained effects in the UCLA-3 and WEMWBS, whereas an immediate effect was found in GDS-SF (Table 4).

Discussion

The current study showed that a PARO intervention may improve cognitive function, autonomic stability, and mental well-being in people with mild dementia. Our analysis included comparisons between the intervention and control groups with an adequate number of cases, thereby enhancing the reliability of the results and minimizing bias and confounding factors.

Older adults with mild dementia face issues maintaining cognitive and mental well-being as their cognition deteriorates. In this study, we used the MMSE and FTT to measure cognitive function, and the results showed increased MMSE scores in the participants who received the GPI, indicating that the intervention may have improved cognition. Our results are inconsistent with previous studies in which individual-based PARO interventions were reported to worsen cognition in people with dementia.[23] A possible reason is that participation in our GPI

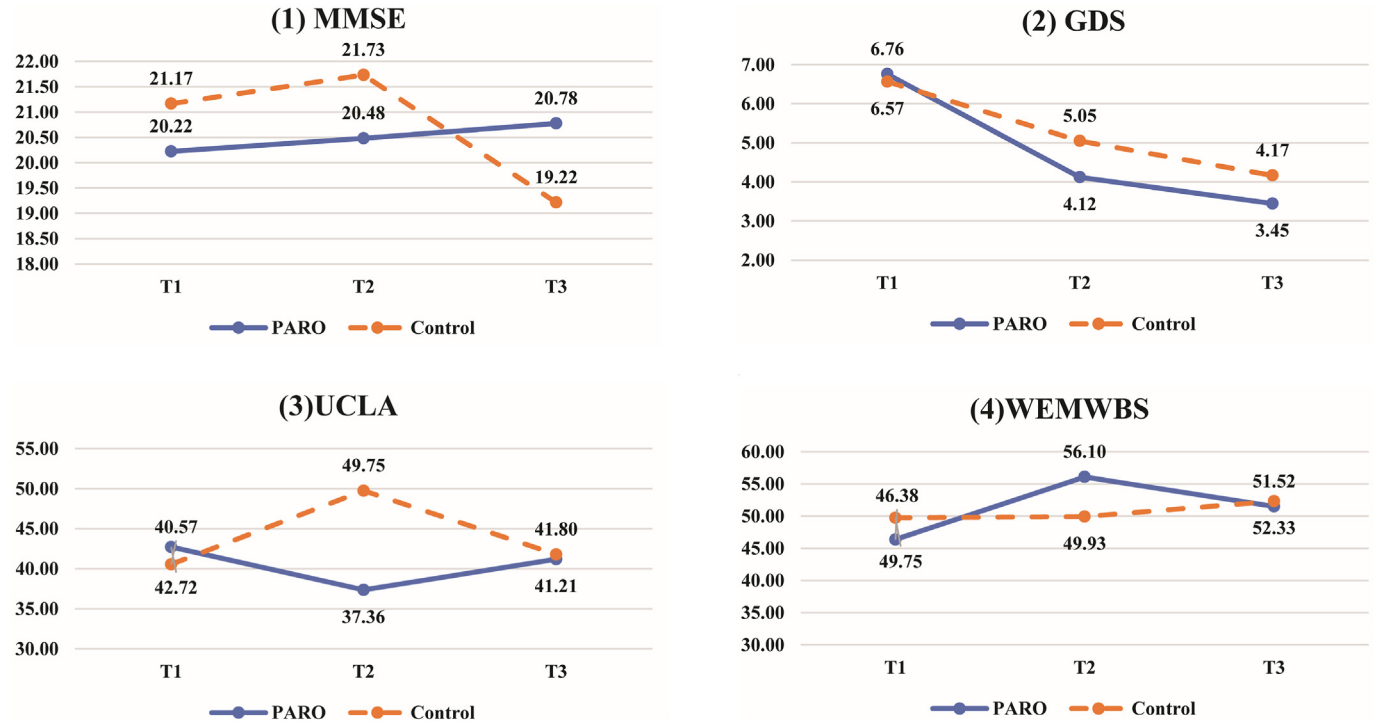

Fig. 2. Mean scores by group over time for the primary outcome (N = 118).

may receive more stimulation from peers while discussing the PARO, consequently leading to an improvement in cognition after the end of the intervention. Furthermore, our results showed that although there were no significant differences in MMSE scores between time points in the GPI group, the planned contrasts showed significant differences compared with the GUA group. This may indicate that the PARO intervention maintained cognitive function.

This is the first study to use the FTT to evaluate the effects of a PARO intervention on cognition in older people with mild dementia. Significantly more finger-taps were recorded in the intervention group. In this study, as the PARO intervention had a time limit, the participants may have lacked sufficient time to limber up their fingers, which may have reduced time spent stroking PARO. In addition, our results showed an immediate but not sustained effect of the PARO intervention on FTT. Neuroplasticity changes in older adults may take a longer time,[24] and prolonged use of PARO in older people with dementia could be beneficial to maintain their dopaminergic function. Another possible reason is that neuroplasticity in people with dementia is also impaired,[25] and a short external stimulation may only temporarily improve dopaminergic function.

Low HRV is related to impaired regulatory and homoeostatic autonomic nervous function, which could reduce the ability to cope with both internal and external stressors.[10] Our results showed a significantly higher HRV LF/HF ratio after the GPI but no difference on follow-up, indicating that the intervention only had an immediate but not sustained effect on HRV. Regarding the theoretical basis of the group dynamic, older adults may have felt safe and confident when they interacted with PARO in a group, which may have improved their mood. Positive moods such as calm and cheerful have been correlated with HRV-HF,[26] as HRV can detect stress levels.[10] This finding, although preliminary, suggests that the GPI may have regulated a balance of sympathetic activity and parasympathetic modulation and that the GPI might temporarily have modulative effects on ANS activities, including cognitive functions, as well as on loneliness and quality of life. However, further research is required to confirm and validate these findings. Furthermore, because HRV varies greatly depending on times and the participants' physical condition, it is recommended that future studies include midpoint measurements to avoid bias.

Our results also revealed that the GPI could alleviate depression and loneliness and improve mental well-being in older people with mild dementia. These results are consistent with those of previous studies.[13,14] Liang et al reported improvements in depression symptoms in people with dementia after interacting with PARO at day care centers.[13] In addition, Robinson et al reported that a 12-week PARO intervention significantly decreased loneliness but had no effect on depression.[14] Furthermore, Chen et al conducted a qualitative study and found that interacting with PARO could help older adults build interpersonal relationships and relieve emotional stress.[27] Compared with other nonpharmacologic therapy for dementia, for example, art therapy or aromatherapy,[28,29] these were not group-based interventions and were difficult to be compared. However, previous studies revealed that cognitive stimulation therapy may have similar effects when given as a group-based intervention.[30] A small-group format seems imperative in delivering cognitive stimulation therapy, as it encourages people to share their thoughts and contribute, positively reinforcing questioning, thinking, and interaction within the group.[31,32]

Although the possible mechanism of PARO action is still unknown, oxytocin is one of the possible candidates for altering changes. Oxytocin is well known for the effects of social attachment, feelings of trust, depressed mood, anxiety relief, and even cognitive function improvement and when oxytocin is stimulated, this can increase meaningful social interaction activities.[33] Notably, oxytocin also proved to have mitigation effects for dementia progression.[34] Previous studies also revealed the possible interaction between dopamine and oxytocin, which may alter anxiety symptoms in different genotypes.[35] Loneliness, which was improved by the PARO intervention, was also correlated with oxytocin found in further studies.[36] Additional studies could be designed to measure oxytocin during PARO interventions, and this may further differentiate whether different genotypes may have different effects as a result of the PARO intervention.

Combined with our HRV findings, interacting with PARO might alter physiological and mental well-being in older people with mild

dementia in a short period. Notably, our results showed positive effects on loneliness, mental well-being, and depression after the GPI. The effects diminished and were nonsignificant after discontinuing the PARO intervention. A persistent PARO rehabilitation program design may be helpful to older adults and further demonstrate the efficacies of PARO on older adults in long-term intervention studies.

Strengths and Limitations

The strengths of this study include a robust sample, physiological and psychological outcomes assessments, and a randomized design. Prior research has lacked rigor concerning the sample size, design, and control for extraneous measurements. Thus, this study provides strong evidence of the effects of the GPI on physiological and psychological changes in older people with mild dementia. However, there are also some limitations to this study. First, participants who needed more motivation to participate in the GPI were excluded, which may restrict the findings' external validity. Second, participants in the control group participated in usual care activities, which may have confounded the findings. These activities also had a training effect, improving finger-tapping. Third, physical illnesses, such as cardiovascular disease, may influence the measurement of ANS function in older adults. Although we carefully reviewed medical records when screening, this may have affected the HRV results.

Conclusion and Implications

The results demonstrated that the GPI improved cognition and HRV and alleviated loneliness and depression in older adults with mild dementia at day care centers. PARO acted as a social agent to facilitate interpersonal relationships, and the intervention was noninvasive, positively received, and convenient to implement. A GPI can be considered a nonpharmacologic intervention for older adults with mild dementia in day care centers to improve their psychological and mental well-being.

Disclosure

The authors declare no conflicts of interest.

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