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RESEARCH ARTICLE

Livestream, group movement program for people living with cognitive impairment and care partners: A randomized clinical trial

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Abstract

INTRODUCTION: There are few widely-available, evidence-based options to support quality of life (QOL) for people living with Alzheimer's disease and related dementias.

METHODS: We performed a randomized, controlled trial with a Waitlist control group to determine whether an online, livestream, mind-body, group movement program (Moving Together, 1 hour, 2 days/week, 12 weeks) improves QOL in people with cognitive impairment (PWCI) or care partners (CPs) and explore mechanisms of action. The primary outcome for both participants was self-reported QOL. Secondary outcomes and potential mediators included mobility, isolation, well-being, cognitive function, and sleep in PWCI and burden, positive emotions, caregiver self-efficacy, stress management, and sleep in CPs. Blinded assessors collected outcome data at baseline, 12, and 24 weeks. We assessed adverse events including falls through monthly check-in surveys and collected qualitative data through evaluation surveys. Intention-to-treat analyses used linear mixed models to compare mean change over time between groups and calculated standardized effect sizes (ESs).

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RESULTS: Ninety-seven dyads enrolled (PWCI: age 76 ± 11 years, 43% female, 80% non-Hispanic White; CPs: age 66 ± 12 years, 78% female, 71% non-Hispanic White); 15% withdrew before 12 weeks and 22% before 24 weeks. PWCI self-reported significantly better QOL from baseline to 12 weeks in the Moving Together group compared to the Waitlist group (ES = 0.474, $p = 0.048$) and CPs self-reported improved ability to manage stress (ES = 0.484, $p = 0.021$). Improvements in participant self-reported QOL were mediated by improvements in their self-reported well-being and CP-reported ability to manage stress. Results were similar when the Waitlist group participated in the program (QOL ES = 0.663, $p = 0.006$; stress management ES = 0.742, $p = 0.002$) and were supported by qualitative data. Exploratory analyses suggested possible fall reduction in PWCI. There were no study-related serious adverse events.

DISCUSSION: Online programs such as Moving Together offer a scalable strategy for supporting high QOL for PWCI and helping CPs manage stress.

TRIAL REGISTRATION: ClinicalTrials.gov NCT04621448

KEYWORDS

caregivers, cognitive dysfunction, dementia, movement, online, quality of life

Highlights

- The approval of new medications that slow cognitive decline in people living with Alzheimer's disease and related disorders (ADRD) has raised hope and excitement. However, these medications do not appear to impact quality of life, which is often considered by patients and care partners to be the most important outcome.
- In this randomized clinical trial, we found that an evidence-based, online, livestream, mind-body, group movement program significantly and meaningfully improves self-rated quality of life in people with ADRD and helps care partners manage stress. Mediation analyses revealed that the key drivers of improvements in participants' quality of life were improvements in their feelings of well-being and care partners' ability to manage stress. Exploratory analyses also suggested a 30% reduction in falls.
- These results are important because they suggest that an online program, which is available now and can be performed by people from the comfort of home or other location of choice, could be recommended as a complement or alternative to new therapies to help maximize quality of life for people living with ADRD and their care partners.

1 | BACKGROUND

Nearly 7 million people in the U.S. are living with Alzheimer's disease and related dementias with more than 16 million unpaid caregivers, and dementia prevalence is expected to nearly triple by 2060.¹ New dementia medications may delay cognitive decline by 6 months but do not appear to improve quality of life (QOL) and are often costly, contraindicated, or discontinued due to significant side effects.²⁻⁴ Several non-pharmacologic interventions have been found to improve QOL for

people with cognitive impairment (PWCI) or dementia⁵⁻⁹; however, they are typically delivered in-person, which makes them difficult to scale due to the need for physical space and local instructors. Online programs could potentially address these barriers, but their efficacy is unknown.

We have previously developed and tested Preventing Loss of Independence through Exercise (PLIÉ)—an in-person, mind-body, group movement program that improves QOL in PWCI and has a wide range of physical, social, emotional, and cognitive benefits.¹⁰⁻¹⁵ In addition,

we recently adapted and piloted an online version of PLIÉ called Moving Together.¹⁶ PWCI and care partners (CPs) joined the online classes together and reported benefits similar to the in-person program. The primary goals of this randomized, controlled trial (RCT) were to determine whether Moving Together significantly improves QOL in PWCI or CPs and explore the mechanisms of action.

2 | METHODS

2.1 | Study design

Detailed study procedures are provided in the Trial Protocol in Appendix A). Participants were enrolled in cohorts and randomized to Moving Together (intervention) or Waitlist (control) groups with a goal of 16 dyads/cohort. The Moving Together group participated together in the online, group movement program (1 hour, 2 days/week, 12 weeks) while the Waitlist group engaged in usual activities. After 12 weeks, the Moving Together group was invited to join continuing classes (1 or 2 days/week, initially free, later paid), and the Waitlist group participated together in the online, group movement program (1 hour, 2 days/week, 12 weeks). Outcomes were assessed in both groups at baseline, 12, and 24 weeks. The study is registered on ClinicalTrials.gov (NCT04621448).

2.2 | Study participants

Study participants were recruited through University of California, San Francisco (UCSF) patient lists, posting and advertising online, presentations and webinars, sending flyers to support groups, and hiring a recruitment firm. Eligibility criteria included English-language proficiency, U.S. residency, and having a device with a video camera that enabled participation in two-way, livestreaming video classes. CPs reported the type of dementia/cognitive impairment and symptom severity for PWCI. We restricted enrollment to those with mild symptom severity (defined as Quick Dementia Rating System score, 2.5 to 12.5)¹⁷ to reduce heterogeneity within groups. CPs were willing to participate in online classes with PWCI from the same physical location and answer study questionnaires.

2.3 | Consent statement

All study procedures were approved by the Institutional Review Board at UCSF. All participants provided consent or assent.

2.4 | Data management, randomization, and blinding

Study data were collected and managed using REDCap electronic data capture tools hosted at UCSF.^{18,19} The randomization sequence was generated in advance by the database manager and was not accessible

RESEARCH IN CONTEXT

- 1. Systematic Review:** The authors reviewed the literature for interventions (pharmacologic or non-pharmacologic) that have been found in clinical trials to improve self-rated quality of life (QOL) for people living with Alzheimer's disease and related dementias (ADRD) using traditional sources (eg, PubMed, article references). Those identified (eg, reminiscence therapy, cognitive/social stimulation, caregiver coping + tailored activities) are typically delivered in-person, which makes them difficult to scale.
- 2. Interpretation:** Moving Together—an online, livestreaming, mind-body, group movement program that people living with ADRD and care partners can do from home—is a scalable program that significantly improves QOL in people living with ADRD and helps care partners manage stress.
- 3. Future Directions:** Our study population was primarily non-Hispanic White and well-educated. Additional studies are needed to determine whether these results generalize to more diverse groups with lower education levels.

to research team members. Team members who enrolled study participants and collected outcome data were blinded to participant group assignments.

2.5 | Outcomes

The primary outcome was self-reported QOL, which was measured in PWCI using the Quality of Life in Alzheimer's Disease scale²⁰ and in CPs using the 12-item Short Form Health Survey (SF-12) Physical and Mental Component Summary scores.²¹ Secondary outcomes were selected to explore potential mechanisms of action based on our conceptual model (Trial Protocol in Appendix A). This included PWCI well-being (self-reported, Neuro-QOL Positive Affect and Well-Being),²² PWCI and CP isolation (self-reported, PROMIS Social Isolation Scale),²³ PWCI mobility (self- and CP-reported, Neuro-QOL Mobility),²² and PWCI cognitive function (direct assessment: Telephone Montreal Cognitive Assessment).²⁴ The following CP-reported items were also included: PWCI cognitive function (Cognitive Function Instrument–modified),²⁵ CP ability to manage stress (Multidimensional Assessment of Interoceptive Awareness-2, Self-Regulation Scale),²⁶ CP healthy days (Healthy Days),²⁷ CP caregiving self-efficacy (GAIN in Alzheimer Care Instrument),²⁸ CP burden (Zarit Burden Interview),²⁹ CP positive affect (Positive States of Mind),³⁰ and CP and PWCI sleep difficulty (Sleep Problems).³¹

2.6 | Other measures

CPs reported demographic data for themselves and PWCI. CPs completed monthly surveys regarding adverse events (AEs) for themselves and PWCI including falls, hospitalizations, emergency visits, and other changes in health status. All AEs reported in monthly surveys or spontaneously by study participants were documented in an AE log. PWCI and CPs independently answered survey questions about their experience with Moving Together at the beginning, middle, and end of the 12-week class series. After program completion or withdrawal, PWCI and CPs independently completed an evaluation survey that included overall program rating (poor, fair, good, excellent) and open-ended questions (changes observed in themselves, their study partners, and others in the class; what they liked most; suggestions for improvement). In addition, PWCI and CPs rated their likelihood of recommending the program to others (Likert scale, 0 to 10 points), and we calculated Net Promoter Scores (NPS) as the proportion of promoters (9 or 10) minus the proportion of detractors (0 to 6).

2.7 | Intervention

2.7.1 | Orientation and instructor meeting

Before the first Moving Together class, participant dyads met by video-conference with research team members who provided technology support, ensured a safe home environment, and learned about their background and interests, musical preferences, physical challenges, and motivators to help tailor the classes.

2.7.2 | Moving together classes

The Moving Together class principles are based on the in-person PLIÉ programs,^{11,14} which target abilities and neural mechanisms that are relatively well-preserved in PWCI. This includes (1) training procedural (“muscle”) memory for movements to support daily function; (2) increasing awareness of in-the-moment physical sensations; and (3) supporting social connection and positive emotions through group movement, gratitude, and music. Dyadic movements and weekly themes are incorporated to support PWCI and CPs participating together.^{12,14} Each Moving Together class began with seated, full body awareness through touch, and deep breathing movements with vocalization. Next, instructors led participants through seated, standing, and/or paired movement sequences that focused on increasing capacity to perform movements needed for daily function, such as reaching, turning, transitioning smoothly between sitting and standing, and balancing while standing and walking. Movement sequences built slowly in complexity over the 12-week program and were tailored to the functional ability levels of each group. Instructors supported participation and experiences of success for all participants by using step-by-step instructions (to minimize cognitive demands) and a non-judgmental, “errorless” learning process (no right or wrong). Personally

meaningful music was incorporated to enhance positive emotions. Each class ended with repetition of the body awareness and breathing movements, and participants were invited to share what makes them feel happy or grateful.

2.8 | Sample size and power

To be conservative, our original power calculations were based on an unpaired *t*-test analysis with two-sided alpha = 0.05. A target sample size of 224 dyads (112/group) was selected to provide 80% power to detect a clinically meaningful standardized effect size of 0.375. Due to recruitment challenges, our Safety Officer (SO) requested that we perform a futility analysis after completion of data collection for the first three cohorts ($n = 43$ dyads). The SO determined that there was evidence of potential efficacy and no evidence of harm and recommended that the study continue with a modified target sample size of 112 dyads (56/group), which would provide 80% power with two-sided alpha = 0.05 to detect a moderate effect size of 0.53. We did not penalize the alpha for this unplanned interim analysis.

2.9 | Analysis

We assessed balance between the Moving Together and Waitlist groups by comparing baseline characteristics using descriptive statistics. Our primary analytic approach was intention-to-treat using linear mixed models (LMMs) with terms for group, time, and group \times time interaction and random intercepts. LMMs enable inclusion of all participants randomized and provide unbiased estimates when data are missing at random. We used the estimated effect from the group \times time interaction to represent the estimated mean between-group differences, which were then used to compare changes from baseline to 12 weeks and 12 to 24 weeks. In post hoc analyses, we used participants as their own controls and compared change “on treatment” (Moving Together: baseline-12 weeks; Waitlist: 12 to 24 weeks) to change “off treatment” (Moving Together: 12 to 24 weeks; Waitlist: baseline to 12 weeks) using paired *t*-tests in those who completed all assessments. We also calculated the raw Cohen’s *d* effect size (ES) by dividing the difference in mean change between groups by the pooled standard deviation (SD).

We performed pre-specified, exploratory mediation analyses to identify direct and indirect effects of Moving Together on QOL. To maximize statistical power, we decided post hoc to combine data from both groups to compare change “on” versus “off” treatment. We first performed single mediation analyses in which change in each secondary outcome was considered as a mediator in the pathway between Moving Together and change in QOL. We then performed multiple mediation analyses that included all variables that were associated with QOL change ($p < 0.05$) in the single mediation analysis. The effect of each path was estimated from the linear mixed effect model, where we considered data from the same subject to share the same random effect. Confidence intervals for the direct and indirect effects were estimated

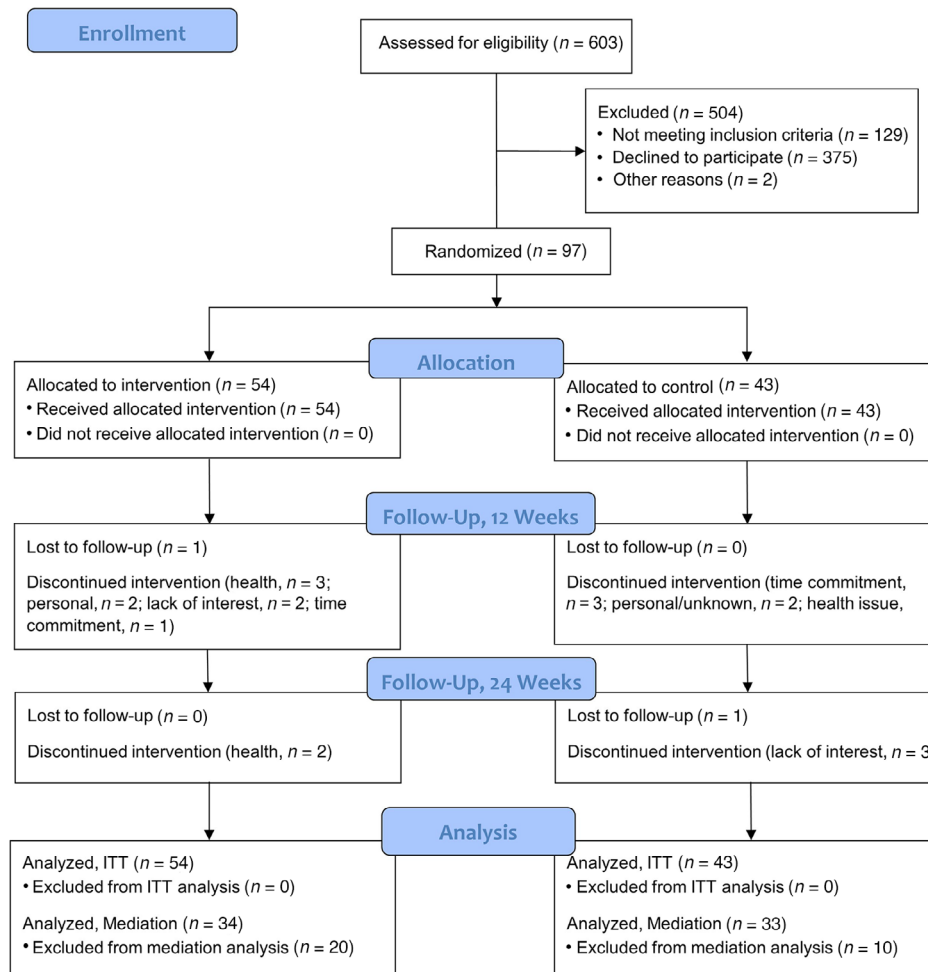


FIGURE 1 CONSORT flow diagram. ITT, intention-to-treat.

using bootstrap resampling with 97 replications, which was the total sample size for the mediation analysis. We assessed for collinearity by evaluating the largest condition index in the covariance matrix. This index was 1.70, which is below the threshold of 10 for collinearity.³² All analyses were performed using R.³³

Finally, we performed post hoc exploratory analyses to assess for differences in falls and healthcare utilization based on monthly check-in surveys. Lack of response was assumed to reflect no falls or utilization that month. In addition, we used descriptive statistics and qualitative content analysis,³⁴ using a previously developed coding scheme,¹⁶ to summarize responses to the final evaluation survey.

3 | RESULTS

Participants were recruited from November 2020 to January 2023. Data collection ended May 2023. We assessed 603 dyads for eligibility: 375 (62%) declined to participate, 129 (21%) were ineligible, and 99 (16%) consented (Figure 1). The primary reasons for declining participation were lack of interest (68%) and time commitment (15%). The primary reasons for ineligibility were lack of care partner (40%)

and moderate/severe dementia (26%). Two dyads who consented were excluded from all analyses: one withdrew prior to randomization; another was ineligible after randomization. Participants who enrolled were more likely than those who declined to participate to have Alzheimer's disease (30% vs 18%) and less likely to have mild cognitive impairment (MCI; 13% vs 33%) (Appendix B, Table B.1).

Due to time and funding constraints, the seventh cohort only included 10 participants, all of whom were assigned to the intervention group; 24-week data were not collected. The final sample size was 97 dyads (54 Moving Together, 43 Waitlist): 15 withdrew prior to the 12-week assessment, and an additional six dyads withdrew prior to the 24-week assessment (22% total). The most common reasons for withdrawal were health issues ($n = 6$) and lack of interest ($n = 5$). There were no significant differences between participants who withdrew and those who completed the study (Appendix B, Table B.2). Participants who did not withdraw attended an average of 18 ± 5 classes (75%). After completing the intervention, 17 dyads chose to continue classes, and 12 continued on a paid basis.

Characteristics of study participants are shown in Table 1. PWCI had a mean \pm SD age of 76 ± 11 years and education of 16 ± 3 years; most were male (57%) and White (82%). Diagnoses included

TABLE 1 Baseline characteristics of the study participants.

	Moving Together (n = 54)	Waitlist (n = 43)	Total (n = 97)
People with cognitive impairment (PWCI)			
Age, years	76.2 (11.3)	76.8 (9.7)	76.4 (10.6)
Gender, female	21 (39)	21 (49)	42 (43)
Race			
Asian	5 (9)	3 (7)	8 (8)
Black or African American	4 (7)	1 (2)	5 (5)
Hispanic/Latino/a/x	1 (2)	2 (5)	3 (3)
Non-Hispanic White	42 (78)	36 (84)	78 (80)
Other/not reported	2 (4)	1 (2)	3 (3)
Education, years	16.8 (2.8)	16.2 (3.1)	16.5 (3.0)
Diagnosis			
Alzheimer's disease	17 (31)	12 (28)	29 (30)
Dementia unspecified	15 (28)	4 (9)	19 (20)
Mild cognitive impairment	6 (11)	7 (16)	13 (13)
Mixed dementia	1 (2)	4 (9)	5 (5)
Vascular dementia	5 (9)	5 (12)	10 (10)
Other/not sure	10 (19)	11 (26)	21 (22)
Quick dementia rating scale	7.8 (2.3)	7.5 (2.9)	7.7 (3)
Care partner (CP)			
Age, years ^a	63.3 (11.8)	68.9 (11.0)	65.8 (11.7)
Gender, female	44 (81)	32 (74)	76 (78)
Race			
Asian	9 (17)	5 (12)	14 (14)
Black or African American	5 (9)	0 (0)	5 (5)
Hispanic	1 (2)	4 (9)	5 (5)
Non-Hispanic White	36 (67)	33 (77)	69 (71)
Other/not reported	3 (6)	1 (2)	4 (4)
Education, years	16.7 (2.8)	17.0 (3.2)	16.8 (3.0)
Relationship to PWCI			
Spouse or partner	34 (63)	31 (72)	65 (67)
Child or child-in-law	15 (28)	9 (21)	24 (25)
Paid	3 (6)	1 (2)	4 (4)
Other	2 (4)	2 (5)	4 (4)

Note: Values reflect mean (SD) for continuous variables and N (%) for categorical variables. Missing data are as follows: CP education (n = 1).

^aCPs in the Moving Together group were slightly younger than the Waitlist group ($p = 0.018$). No other differences were statistically significant at baseline.

Alzheimer's disease (30%), dementia unspecified (20%), MCI (13%), vascular dementia (10%), mixed dementia (5%), and other/unknown (22%). CPs had a mean \pm SD age of 66 ± 12 years and education of 17 ± 3 years; most were female (78%) and White (75%); 67% were spouses/partners and 25% were adult children. CPs were slightly younger in the Moving Together group compared to the Waitlist group (63 vs 69 years, $p = 0.02$), but there were no other significant differences between groups at baseline in demographics (Table 1) or outcome measures (Table B.3). Moving Together participants returned

a slightly lower percentage of their monthly check-in surveys than the Waitlist group ($66 \pm 37\%$ vs $80 \pm 29\%$, $p = 0.046$).

3.1 | Primary outcomes

From baseline to 12 weeks, Moving Together PWCI reported significantly improved QOL compared to Waitlist participants (difference = 2.2, $p = 0.046$, ES = 0.474, Table 2). Similarly, from 12 to 24 weeks,

TABLE 2 Raw scores, estimated differences, and effect sizes: primary and secondary outcomes.

	Moving Together			Waitlist			0 to 12-week difference (95% CI)	12 to 24-week difference (95% CI)	Cohen's d effect sizes
	Baseline	12 weeks	24 weeks	Baseline	12 weeks	24 weeks			
Primary outcomes									
PWCI	n = 53	n = 45	n = 33	n = 43	n = 35	n = 32	n = 96	n = 83	
Quality of life^a	37.9 (4.4)	38.8 (5)	37.8 (6)	39 (5.2)	37.9 (6)	39.7 (5.5)	2.2 (0.01, 4.39)	-2.6 (-4.44, -0.72)	0.474, 0.663
CP	n = 54	n = 47	n = 33	n = 43	n = 40	n = 33	n = 97	n = 87	
SF-12, Physical ^a	50.9 (9.6)	49.6 (10.3)	49.5 (11.2)	50.2 (8.9)	50 (9.1)	51.2 (8.5)	-0.9 (-4.12, 2.4)	-0.4 (-4.31, 3.49)	0.095, 0.005
SF-12, Mental ^a	49.6 (10.5)	48.9 (8.2)	46.1 (11.1)	49.7 (9.2)	48.8 (9.9)	48.4 (9.5)	0.6 (-2.75, 3.92)	-2.1 (-6.95, 2.73)	0.096, 0.167
Secondary outcomes									
PWCI	n = 53	n = 45	n = 33	n = 43	n = 35	n = 32	n = 96	n = 83	
Well-being^a	35.9 (5.4)	36.3 (5.7)	35.2 (6.3)	35.6 (4.9)	34.7 (6.2)	36.4 (4.9)	1.6 (-0.62, 3.74)	-2.9 (-5.27, -0.57)	0.353, 0.632
Isolation^b	8.8 (3.8)	8.1 (3.8)	8.2 (3.4)	8.4 (3.3)	7.9 (3.6)	7.8 (2.9)	-0.2 (-1.97, 1.56)	-0.4 (-1.84, 0.98)	0.089, 0.237
Mobility^a	31.1 (4.5)	31.1 (4.9)	30.9 (4.2)	31.6 (4.5)	30.3 (6.2)	30.2 (5.6)	1.6 (-0.26, 3.51)	-0.5 (-1.98, 1.08)	0.430, 0.162
Cognitive function^a	11.5 (5.2)	11.6 (5.5)	10.6 (5.5)	11.5 (5.7)	10.8 (5.9)	10.1 (5.6)	0.3 (-0.96, 1.58)	-0.1 (-1.29, 1)	0.075, 0.058
CP	n = 55	n = 47	n = 34	n = 43	n = 39	n = 33	n = 98	n = 86	
Stress management^a	12.7 (4.1)	14.3 (3.3)	12.4 (4)	13.3 (5)	13.2 (5.1)	13.9 (4.6)	1.6 (0.24, 3.01)	-2.6 (-4.23, -0.98)	0.484, 0.742
Healthy days^a	15.6 (2.9)	15.9 (2.1)	14.9 (3.1)	15.8 (2.3)	15.8 (2.3)	15.9 (1.8)	0.4 (-0.71, 1.49)	-1.3 (-2.57, -0.01)	0.174, 0.522
Self-efficacy^a	28 (5.6)	28.4 (7.6)	28.5 (5.8)	29.2 (6.6)	29.5 (7.9)	30 (6.3)	0.3 (-2.36, 3.01)	-0.6 (-4.02, 2.74)	0.071, 0.114
Burden^b	8.5 (5.1)	9 (5)	10.4 (5.4)	8.9 (5.2)	8.7 (5.6)	9.2 (5.3)	0.6 (-0.77, 2)	0.4 (-1.32, 2.18)	0.187, 0.075
Isolation^b	8.4 (3.7)	8.3 (3.5)	8.9 (3.7)	7.7 (3)	8.1 (3.1)	8.8 (3.5)	-0.4 (-1.65, 0.81)	-0.2 (-1.48, 1.09)	0.139, 0.081
Positive affect^a	13.5 (3.4)	13 (3.1)	12.8 (3.4)	12.9 (3.4)	13.3 (3.1)	14 (3)	-0.8 (-1.94, 0.31)	-0.6 (-2.11, 0.82)	0.286, 0.145
CP sleep difficulty^b	3.5 (2.7)	3.7 (3)	3.7 (2.8)	3.9 (2.6)	4.1 (2.5)	3.7 (2.5)	0.2 (-0.62, 1.1)	0.7 (-0.32, 1.75)	0.153, 0.395
PWCI sleep difficulty^b	2.8 (2.5)	2.5 (2.2)	3.2 (2.9)	2.7 (2.7)	2.8 (2.9)	2.6 (2.1)	-0.4 (-1.21, 0.34)	0.8 (-0.21, 1.87)	0.226, 0.348
PWCI mobility^a	30.1 (5.2)	29.7 (5.9)	29.6 (5.3)	29.3 (5.5)	28.5 (7)	28.9 (5.9)	0.2 (-1.52, 1.88)	-1.2 (-2.92, 0.49)	0.030, 0.382
PWCI cognitive function^a	27 (6)	29.5 (5.9)	27.4 (8.5)	26.3 (5.5)	27.5 (5.9)	29.1 (6)	0.8 (-1.62, 3.15)	-3.1 (-5.73, -0.41)	0.048, 0.473

Note: Means (standard deviations) are reported unless indicated otherwise. Baseline, 12-week, and 24-week values are raw. The mean differences, 95% confidence intervals, and effect sizes are estimated from linear mixed models from the interaction between group and time. Bolded values are statistically significant (p < 0.05).

Abbreviations: CP, care partner; PWCI, people with cognitive impairment; SF-12, 12-item Short Form Health Survey.

^aHigher scores are better.

^bLower scores are better.

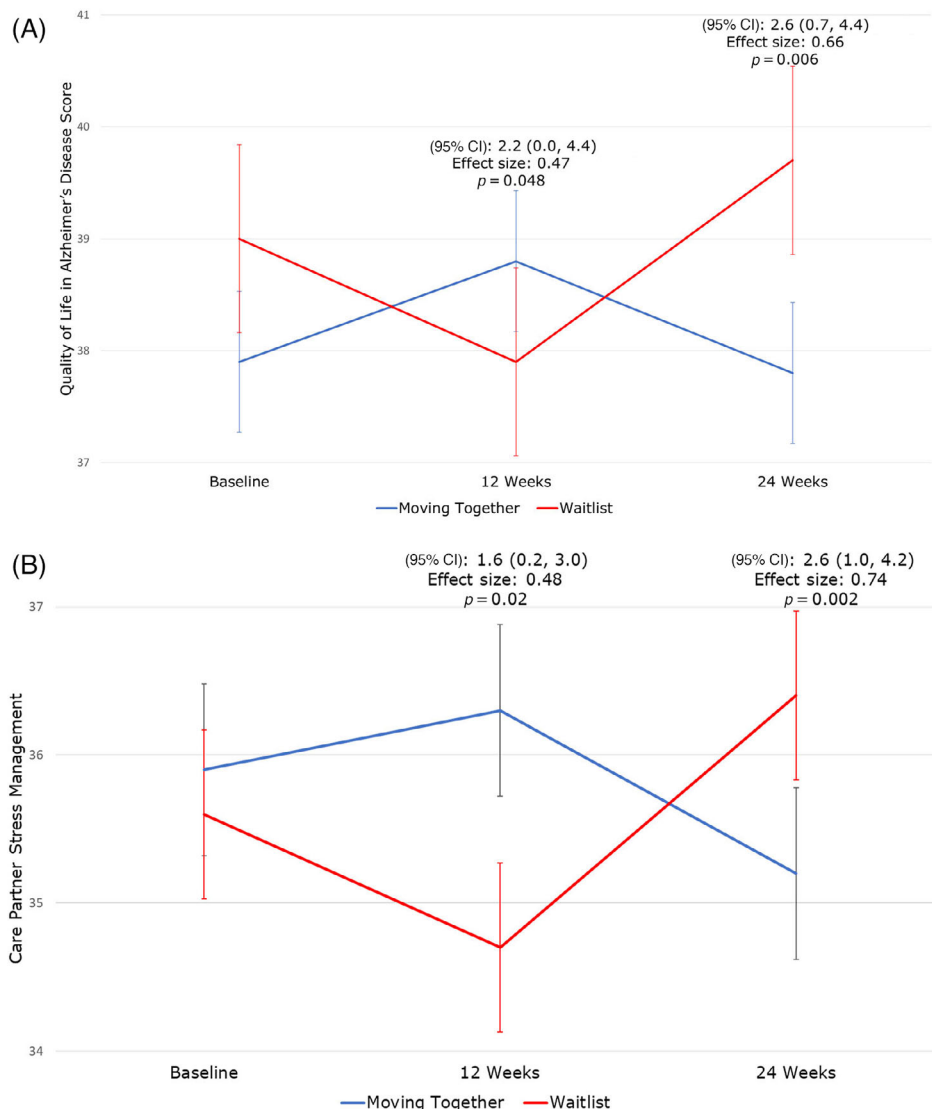


FIGURE 2 Quality of life and stress reduction between the Moving Together and Waitlist groups over time. (A) In both groups, participants with cognitive impairment reported improvement in quality of life when they were participating in Moving Together and decline when they were not participating in Moving Together. Although the 95% confidence intervals overlap at 12 weeks, the difference in the change between groups was statistically significant from both baseline to 12 weeks and 12 to 24 weeks. (B) Similarly, care partners self-reported ability to manage stress improved in both groups when they were participating in Moving Together and declined when they were not participating in Moving Together, resulting in significant differences in change between groups from both baseline to 12 weeks and 12 to 24 weeks.

PWCI in the Waitlist group reported significantly improved QOL when participating in Moving Together classes compared to the Moving Together group after completion of the program (difference = 2.6, $p = 0.006$, ES = 0.663, Figure 2). These patterns were further confirmed using participants as their own controls and comparing change in QOL when they were “on” versus “off” Moving Together (difference = 2.4, $p = 0.01$, ES = 0.318, Table B.4). Individual line plots are shown in Figure B.1.

Qualitative analyses of open-ended evaluation survey responses provided additional insights into which QOL domains were most affected by Moving Together (Table 3). PWCI reported increased emotional well-being (“engaged and enjoyment”), social connection (“more connected to the world”), physical function (“greater flexibility and

mobility”), and body awareness (“sense of relaxation and awareness of my body”). CPs additionally reported a positive impact on their relationship with PWCI.

There was no evidence of differences between groups in CP QOL based on the SF-12 in any analyses (Table 2).

3.2 | Secondary outcomes and mechanisms of action

Stress management ability increased significantly more from baseline to 12 weeks in the Moving Together group than the Waitlist group (difference = 1.6, $p = 0.022$, ES = 0.484, Table 2). In addition, CPs in the

TABLE 3 Qualitative analyses of evaluation survey responses.

Domain	Participant type	Illustrative quotations
Social connection	PWCI	<p>I felt more caring about the other people participating.</p> <p>I liked being involved socially. It was good to be active and I enjoyed being with a crowd. It's more fun to do be doing something together. It made me feel better being active.</p> <p>I think participation with a group made me feel more connected to the world, happier and energized.</p>
	CP	<p>I enjoyed the social aspects.</p> <p>Connecting with understanding group members and facilitator.</p> <p>I liked the way that everyone shared things about ourselves.</p> <p>We liked the opportunities of decreasing our isolation.</p> <p>The other people in the class and the camaraderie that was built and open discussions we had.</p>
Emotional well-being	PWCI	<p>More at peace.</p> <p>It was calming in my current situation.</p> <p>Felt more relaxed and calm.</p> <p>Engaged and enjoyment.</p> <p>I had been struggling with not really caring about things and not being motivated to do more than I had to. I am now feeling more energetic and enjoying and appreciating things more.</p>
	CP	<p>Slowed me down. Calming.</p> <p>Realize benefits of relaxation, learned relaxing techniques</p> <p>I was able to use some of the techniques to help myself relax when needed.</p> <p>Time for me to focus on self care for myself.</p>
Physical function	PWCI	<p>More energy. Less aches and pains.</p> <p>Less back pain.</p> <p>My muscles became looser and my movements more fluid</p> <p>Greater flexibility and mobility.</p>
	CP	<p>More ease of movement, less stiffness even on days without the class.</p> <p>My posture is better. I turn and look over my shoulder better when driving both because of the focus the class made when we did our twisting exercises, and because my body actually feels better after the exercises we did.</p> <p>I found myself more relaxed and my blood sugar and balance improved.</p>
Present-moment body awareness	PWCI	<p>I became more aware of the connection of brain and body.</p> <p>A sense of relaxation and awareness of my body.</p> <p>Better breathing.</p> <p>The breathing exercise is helping me fall off to sleep. I'm a male that needs to urinate several times each night. The duration from waking, urination and return to sleep is usually less than 10 min.</p>
	CP	<p>Slowing down and pausing to take a deep breath before trying to manage too many multitasks.</p> <p>Better breathing, reduced stress, keeping safety in mind, appreciating my body and being aware of movements.</p> <p>Better connection to the present moment and body/breath awareness.</p>
Dyad relationship	PWCI	<p>My partner took more notice of my needs in general, not just during class time. I think he also took more seriously my concerns about my memory.</p> <p>She was fun. We were dancing together. It was fun not just doing it myself.</p>
	CP	<p>More relaxed, good for the care relationship for us to do something together that involved other people, and that didn't involve doctors or medicine.</p> <p>Increased closeness to my partner with dementia.</p> <p>I felt more connected to study partner.</p> <p>Closeness to my love one, spending time next to each other, giggling and laughing and discovering something together.</p>
Cognitive function	PWCI	<p>Having to think more.</p> <p>I became more patient with learning a little at a time.</p> <p>The movement exercises helped make memory a little clearer and I always looked forward to joining the program.</p>
	CP	<p>Calmer and able to focus.</p>

(Continues)

TABLE 3 (Continued)

Domain	Participant type	Illustrative quotations
CP Stress management	PWCI	The movement helped her to relax and see things a little clearer. She became somewhat more understanding.
	CP	I started using deep breathing when I was in stressful situations or when trying to fall asleep. I feel less resistant and fearful to our situation and hence more relaxed. More positive and empathetic. I also felt a change in my perspective of seeing [my spouse] and myself as patient/caretaker and instead, I see ourselves as a couple, supportive of each other in different ways. Also, observing how supportive and appreciative the other couples were with each other was moving and made an impression on me. I feel less resistant and fearful to our situation and hence more relaxed. I suppose, I must be surmising that if others in more advanced stages are managing their situation well, that we'll be able to do that, too.
Falls & Balance	PWCI	The course opened my mind to subtle signals that I'd not felt or recognized before. I now use these to help stabilize myself. This is particularly useful in standing and sitting. Enhanced balance and freedom of movement. My balance was improved. Sometimes trying the new way of getting up from sitting position (scooting to front of chair then standing up using more of thigh muscle instead of using rocking motion momentum).
	CP	More strength. More balance. More confidence. More acceptance of her own rhythm. More joy. She fell several times in the first part of the year; she's not even really worried about falling right now. Every so often she'll kind of trip and almost fall, and so far, she's caught herself. She got motivated to stand, and ultimately walk. I was terrified she would never walk again and I couldn't take care of her because I can't lift and move her, even though she weighs 95 lbs. It kept her out of Assisted Living.

Note: Domains based on adapted QOL conceptual models from Smith, et al.,⁴⁶ and Daley, et al.⁴⁷ and prior qualitative analysis of Moving Together pilot study data.¹⁶ See Trial Protocol in Appendix A for details.

Abbreviations: CP, care partner; PWCI, people with cognitive impairment.

Waitlist group reported significantly improved ability to manage stress when participating in Moving Together from 12 to 24 weeks compared to the Moving Together group post-intervention (difference = 2.6, $p = 0.002$, $ES = 0.742$, Figure 2). Ability to manage stress also was significantly better when CPs served as their own controls and we compared change “on” versus “off” Moving Together (difference = 2.4, $p < 0.001$, $ES = 0.422$, Table B.4).

Qualitative analyses provided additional evidence of improved CP ability to manage stress when participating in Moving Together, such as improvements in relaxation, capacity to remain calm, and using breathing to manage distress as well as increased patience and empathy. For example, one CP stated, “I started using deep breathing when I was in stressful situations or when trying to fall asleep.”

Mediation analyses revealed that the primary drivers of improved PWCI QOL were self-reported well-being and CP-reported improvements in stress management (Figure 3, Tables B.5 and B.6). The total effect of Moving Together on QOL was a 2.1-point average improvement (95% confidence interval [CI]: 0.9, 3.2; $p < 0.001$). Moving Together significantly increased PWCI self-reported well-being, which in turn increased their self-rated QOL (indirect effect, 1.1; 95% CI: 0.3, 2.1; $p = 0.01$). Moving Together also significantly increased CP-reported ability to manage stress, which in turn increased PWCI self-rated QOL (indirect effect, 0.5, 95% CI: 0.2, 0.8; $p = 0.002$).

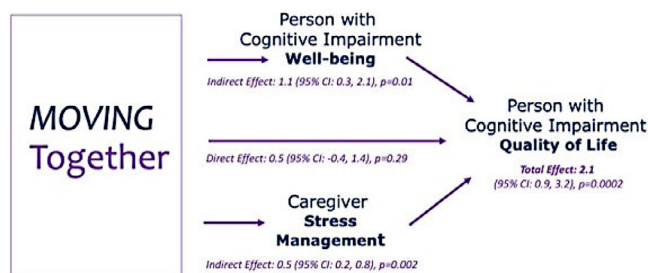


FIGURE 3 Mediators of improvements in quality of life (QOL) in people with cognitive impairment (PWCI) due to Moving Together. Mediation analyses revealed that the total effect of Moving Together on QOL for PWCI participants was mediated by indirect effects through self-reported improvements in well-being and care partner (CP)-reported improvements in ability to manage stress. The direct effect was no longer significant after accounting for these indirect effects.

These quantitative findings were supported by qualitative findings (Table 3). For example, one CP reported that the classes helped her feel “[m]ore relaxed, good for the care relationship for us to do something together that involved other people, and that didn’t involve doctors or medicine.”

There were no consistent differences between groups in other secondary outcomes (Table 2).

3.3 | Falls and healthcare utilization

Exploratory analyses suggested possible reduction in falls during Moving Together. From baseline to 12 weeks, significantly fewer falls were reported in the Moving Together group compared to the Waitlist control group (16 vs 26, $p = 0.043$) (Table B.7). In addition, the proportion of participants who fell was lower in the Moving Together group compared to the Waitlist group (17% vs 29%) although this was not statistically significant ($p = 0.16$). However, a different pattern was observed from 13 to 24 weeks: there were significantly more falls in the Waitlist group when they participated in Moving Together compared to the Moving Together group post-intervention (11 vs 31, $p = 0.007$), although the proportion of fallers was similar (27% vs 29%, $p = 0.74$). When using participants as their own controls, the odds of falling were 30% lower “on” versus “off” Moving Together (7 vs 10), although this difference was not statistically significant (Table B.8).

Many open-ended responses described noticeable changes in strength, balance, mobility, and falls. For example, one CP reported that she observed in PWCI “More strength. More balance. More confidence. More acceptance of her own rhythm. More joy. She fell several times in the first part of the year; she’s not even really worried about falling right now. Every so often she’ll kind of trip and almost fall, and so far, she’s caught herself.” A PWCI reported that “[t]he course opened my mind to subtle signals that I’d not felt or recognized before. I now use these to help stabilize myself. This is particularly useful in standing and sitting.”

Few participants reported being hospitalized or visiting the emergency department during the study period, and there were no significant differences between groups in any analyses (Table B.7).

3.4 | Satisfaction

Moving Together Experience scores were high for both CPs (mean \pm SD: 3.5 ± 0.5) and PWCI (3.3 ± 0.6). Final evaluation surveys were completed by 61 CPs (63%) and 49 PWCI (51%), of whom only 4 CPs and 4 PWCI had withdrawn from the study. Among those who completed the survey, satisfaction ratings were high, with 94% of CPs and 75% of PWCI rating the program as good or excellent. NPS were 54 (excellent) for CPs and 35 (favorable) for PWCI.³⁵

3.5 | AEs and serious AEs

Fifty-four AEs were reported in the Moving Together group (43 PWCI, 11 CPs), including 12 serious AEs (SAEs; seven hospitalizations, three medical/surgical interventions, two other). Fifty-two AEs were reported in the Waitlist group (37 PWCI, 15 CPs), including four SAEs (two hospitalizations, two medical/surgical interventions). Fall-related

AEs were reported less frequently in the Moving Together group ($n = 15$) than the Waitlist group ($n = 28$). Only one AE was considered possibly study-related (low back pain during class).

4 | DISCUSSION

We performed a randomized, controlled trial of the online, livestreaming, Moving Together program for dyads of PWCI and CPs using a waitlist design. We found that PWCI reported better QOL when participating in Moving Together, and CPs reported improved ability to manage feelings of stress (eg, by focusing on breathing). In addition, QOL improvements in PWCI were mediated by their self-reported improved feelings of well-being and CP-reported improved ability to manage stress. Although there was substantial variability and within-group changes were small, the clinical meaningfulness of these results is supported by (1) the magnitude of the standardized effect sizes, (2) the consistency of the effect when the Waitlist group participated in the program, (3) the consistency of the effect when using participants as their own controls and comparing changes “on” versus “off” Moving Together, and (4) qualitative statements made by PWCI and CPs about their subjective experiences.

We also found preliminary evidence that Moving Together may reduce falls in PWCI, although the results were not consistent between the Moving Together and Waitlist arms. One possible explanation is that the Waitlist group may have had a higher fall rate at baseline, making the between-group comparisons less meaningful. Unfortunately, we did not collect data on falls prior to the start of the intervention. Because we cannot control for the baseline fall rate, we focus on our analysis using participants as their own controls. Although these numbers are small, this analysis suggests 30% fewer falls when participants were “on” versus “off” Moving Together. Qualitative data also support a reduction in falls in some participants. A larger study focused on falls is needed to confirm these results.

We also observed that the benefits of Moving Together in the intervention group were not sustained after completion of the 12-week program. It is possible a longer intervention period (eg, 6 or 12 months) is needed to support longer-term benefits. It also is possible that, as with most types of physical activity (including mind-body movement such as yoga or Tai Chi), the benefits are most likely to persist if the activity becomes habitual.

These results are important for several reasons. First, there are very few evidence-based programs that improve QOL for PWCI living in the community. Systematic reviews and meta-analyses of RCTs have found that caregiver coping strategy-based interventions, particularly in combination with tailored activities for PWCI, significantly improve PWCI QOL (standardized mean differences: 0.24 to 0.84).^{5,6} There also is evidence that reminiscence therapy and cognitive/social stimulation improve QOL.⁷⁻⁹ However, these interventions are typically delivered in-person, which makes them difficult to scale. Most other pharmacological and non-pharmacological interventions do not affect PWCI QOL.^{5,6,36-39} Second, online interventions for PWCI have mainly focused on CP education and support, finding significant

reductions in CP depression, but little evidence of impact on PWCI QOL.⁴⁰⁻⁴² A telephone- and internet-based supportive care intervention improved PWCI QOL, but this was based on CP report rather than PWCI self-report.⁴³ Moving Together is unique because it is a dyadic, online program that PWCI and CPs can do together from anywhere they choose, as long as they have access to a device that enables videoconferencing and have an adequate internet connection.

Our study has several important strengths. We used an RCT design with a waitlist control group, which enabled all participants to experience the intervention and also allowed us to perform a variety of sensitivity analyses. Attendance and retention rates were comparable to other studies in this population.⁴⁴ We enrolled participants from across the U.S. We pre-specified primary and secondary outcomes, utilized a conceptual framework to study potential mechanisms of action, and blinded research staff who collected outcome data. An independent biostatistician performed all analyses.

Limitations include relatively high education levels, low participation of Black and Hispanic individuals, and a relatively small sample size of 97 dyads. These issues are common in clinical trials⁴⁵ and may result in selection bias. Additional studies are needed to determine whether results from this study generalize to more diverse groups with lower education. In addition, there was a lack of congruence between quantitative and qualitative results for several of our secondary outcomes, most notably physical functioning and social isolation. This may be explained by ceiling effects or lack of sensitivity for quantitative measures, or they may suggest that qualitative benefits were limited to a subset of participants and not observed in the entire group. Additional research is needed to clarify these discrepancies.

We also observed higher enrollment rates in those diagnosed with Alzheimer's disease versus MCI. This likely reflects our requirement that PWCI have a CP participate with them, since individuals with milder symptoms are less likely to need or have a regular CP.

In summary, this clinical trial found that the online, livestreaming, Moving Together program significantly improves quality of life for people living with cognitive impairment and helps CPs manage stress. We also observed preliminary evidence of reduced falls in participants.

AUTHOR CONTRIBUTIONS

Deborah E. Barnes: Obtained funding for the study, oversaw study design and conduct, and drafted and revised the manuscript. She was not directly involved with participant recruitment, outcome data collection, or data analysis. Fei Jiang: Performed all quantitative data analyses and contributed to manuscript revision. Cynthia Benjamin: Obtained funding for the study and contributed to study design, interpretation of results, and manuscript revision. Jennifer A. Lee: Oversaw development and delivery of the intervention and instructor training and contributed to manuscript revision. Rebecca L. Sudore: Contributed to study design, interpretation of results, and manuscript revision. Wolf E. Mehling: Contributed to study design, interpretation of results, and manuscript revision. Margaret A. Chesney: Contributed to study design, interpretation of results, and manuscript revision. Linda L. Chao: Contributed to interpretation of results and manuscript revision. Francesca Nicosia: Performed all qualitative data analyses and

contributed to study design, interpretation of results, and manuscript revision.

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CONFLICT OF INTEREST STATEMENT

Dr. Barnes, Dr. Chesney, and Dr. Mehling are co-inventors of the Preventing Loss of Independence through Exercise (PLIÉ) program that serves as the foundation for Moving Together and have the potential to earn royalties. Dr. Barnes is co-founder, stockholder, and Chief Science Advisor for Together Senior Health, Inc. The University of California, San Francisco (UCSF) Conflict of Interest Advisory Committee management plans requires disclosure of this conflict. In addition, Dr. Barnes may not participate directly in participant enrollment, outcomes assessment, or data analysis. Ms. Benjamin is co-founder, stockholder, former Chief Executive Officer, and current Chief Strategy and Innovation Officer for Together Senior Health. Ms. Lee is a stockholder and Senior Moving Together Instructor and Trainer for Together Senior Health. Other investigators have nothing to disclose. Author disclosures are available in the [Supporting information](#).

DATA AVAILABILITY STATEMENT

Dr. Barnes and Dr. Jiang had full access to all the data in the study and take responsibility for the integrity of the data and accuracy of the data analysis. Dr. Jiang performed all quantitative data analyses. Dr. Nicosia performed all qualitative data analyses.

DATA SHARING

A deidentified dataset that includes final, individual-level data on which publications are based will be uploaded to a private section of Together Senior Health's website at the time of online publication. Investigators who want to use the data will be required to fill out an online form that includes their contact information, research question and qualifications. In addition, they will need to certify that they will not use the

data for commercial purposes and will not attempt to reveal personal or private information or to re-identify study participants. Those who are approved will be provided with a temporary code that will allow them to download the dataset.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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