

Feasibility and Effect Sizes of the Revised Daily Engagement of Meaningful Activities
Intervention for Persons with Mild Cognitive Impairment and Their Caregivers.

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Abstract

A nurse-led intervention, Daily Enhancement of Meaningful Activities (DEMA), was evaluated for feasibility and effect sizes in a two-group randomized pilot study with 36 MCI patient-caregiver dyads (17 DEMA and 19 attention control). Effect sizes were estimated on 10 outcomes: dyad functional ability awareness congruence; patients' meaningful activity performance satisfaction, confidence, depressive symptoms, communication satisfaction, physical function, life satisfaction; and, caregivers' depressive symptoms and life changes. High feasibility of DEMA was supported by the following indicators: consent, 97.7%; session completion, 91.7%; Time 3 measure completion: 97.2 %. Compared to the attention control group, the DEMA group had higher dyad congruence in functional ability awareness and life satisfaction three months after the intervention and improved physical function at two weeks after the intervention. Although DEMA showed high feasibility and benefits on some health-related outcomes, further testing of DEMA in a larger randomized controlled clinical trial is needed.

Key Words: Clinical trial, mild cognitive impairment, caregivers, feasibility studies, depressive symptoms, quality of life.

Background

Alzheimer's disease (AD) is considered a global health crisis and a major health problem in the United States, and it is the sixth leading cause of death (Alzheimer Association, 2015). Mild cognitive impairment (MCI) has been described as an early symptom of AD, and patients with MCI are at higher risk for developing AD (Albert et al., 2011). As the population ages, the prevalence of MCI is also increasing since nearly 20% of older adults in the United States experience MCI (Wadley et al., 2011). MCI is characterized by cognitive decline that is greater than expected for an individual's age and education level but does not significantly interfere with everyday function (Albert et al., 2011). It is associated with other problems such as increasing neuropsychiatric symptoms, declining functional abilities, and impaired social relationships (McIlvane, Popa, Robinson, Houseweart, & Haley, 2008). In addition, no disease-altering treatment for MCI or AD has been found. Thus, increasing national attention is being focused on non-pharmacological interventions for patients with MCI and their families, as well as clinical trials to improve their health-related outcomes and delay the progression (*National Plan to Address Alzheimer's Disease: 2015 Update*, 2015).

People with MCI are at high risk for decreased physical function, emotional distress, and depressive symptoms, and they often experience problems in communicating with their spouses and others (Panza et al., 2010). Their increasing emotional distress and poor life satisfaction often occur in concert with increasing awareness of declines in functional ability, which often results in disengagement from the daily meaningful activities they once enjoyed (Weiss et al., 2012). Additionally, incongruence between people with MCI and their caregivers in their assessment of level of functional ability may contribute to caregiver anticipatory grief, high levels of subjective caregiving burden, negative psychological outcomes, and increased conflict

in their relationships (Seeher, Low, Reppemund, & Brodaty, 2013). MCI caregivers could be targeted earlier in their caregiving career by providing early behavioral interventions that may lead to prevention of negative outcomes. Thus, providing such early interventions for people with MCI and their caregivers may also be cost-effective over the long trajectory of the illness.

Early behavioral interventions could provide a window of opportunity to assist people with MCI and their caregivers to learn ways to remain engaged in meaningful activities, which in turn may also help address changes in relationships, mood, and quality of life and slow the rate of cognitive decline (Boyle et al., 2012). Such interventions may also enhance decision-making regarding the future and reduce the health care burden to society over time.

Existing interventions for people with MCI and their caregivers often focus on single problems, such as physical activity (Simon, Yokomizo, & Bottio, 2012; Suzuki et al., 2013). The absence of multi-faceted supportive care interventions for people with MCI and their caregivers is striking, especially given that interventions are most likely to be beneficial during this early stage of decline. The Daily Engagement in Meaningful Activities (DEMA) intervention, intended to be delivered by a registered nurse, is structured to provide caregivers an opportunity to articulate emotional needs and work with their MCI care receiver to achieve mutually agreed-upon decisions about an activity plan that addresses the patient's needs. The DEMA intervention may also reduce caregivers' depressive symptoms and lead to positive life changes for them by sharing positive activity engagement and feelings with their care receiver with MCI.

The purpose of this randomized controlled pilot study was to evaluate the feasibility and estimate the effect sizes of DEMA. We hypothesized that the benefits to the person with MCI would be reduced depressive symptoms and improved satisfaction with communication, physical function, and life satisfaction by increasing dyad congruence regarding assessment of the

condition as well as the person with MCI's meaningful activity engagement and sense of confidence.

Insert Figure 1 about here

Conceptual Framework

The DEMA conceptual framework (Figure 1) was developed based on: gerontological theory (Lawton, 1990), the Model of Human Occupation (Kielhofner, 2002), components of Problem-Solving Therapy (PST) (Unützer et al., 2002), and findings from two phenomenology studies of patients living with MCI and their caregivers and a three-phase DEMA intervention development study (Lu & Haase, 2009; Lu, Haase, & Farran, 2007; Lu, Haase, & Weaver, 2013). Based on the framework, the DEMA intervention has several features. First, DEMA involves assessing levels of awareness of functional ability and directing patient-caregiver dyads towards reconciling differences in perceptions and planning for the future. Reconciling differences in perceptions and opportunities for communication, exploration, and feedback about important topics related to planning for the future are aimed at increasing satisfaction with communication. Second, Problem Solving Therapy (PST) is used to assist the dyads to identify and achieve goals, problem-solve relative to barriers, and increase high priority activity participation, which is, in turn, aimed at improving the confidence of people with MCI in initiation and completion of tasks. Third, engaging in a variety of activities improves physical function. DEMA promotes engagement in several meaningful activities which, over the course of the intervention, it is expected to improve physical function. Fourth, DEMA increases autonomy by assisting patients to identify and prioritize activities they want to address first, and

then to share successful activity engagement experiences with family members. Thus, the sense of life satisfaction may be improved through holistic support to engage in meaningful activities. Fifth, DEMA provides an opportunity for individuals with MCI and their family caregivers to address their own concerns, emotional distress, and coping strategies. The interveners assist them to strengthen their useful coping skills and to identify and use available local and national resources.

Design and Methods

A two-group randomized, pre-post intervention design was used to evaluate the feasibility of the DEMA intervention and estimate effect sizes for the DEMA group compared to an information support (IS) attention control condition. The study was approved by the University's Institutional Review Board, and a non-probability sample was recruited. The Figure 2, Consort Participant Flow Diagram provides an overview of study activities.

Insert Figure 2 about here

Setting and Sample

Patients who were a part of MCI-caregiver dyads were recruited from the Indiana University Alzheimer Disease Center Clinical Core Registry and Clinic in Indianapolis. Inclusion criteria for patients with MCI were: aged 60 or older and meeting the established MCI classification criteria (Albert et al., 2011). Patients with significant neurologic disease other than suspected incipient AD or with current major depression were excluded from the study. Caregiver inclusion criteria were: adults with primary responsibility for providing unpaid care to their partner, including monitoring safety and providing social support, and a score of ≥ 4 on the

6-item Mini Mental Status Exam (MMSE) (Callahan, Unverzagt, Hui, Perkins, & Hendrie, 2002). Potential caregiver participants who had diagnosed bipolar disorder or untreated schizophrenia were excluded from the study. For inclusion, both the patient and caregiver had to be able to read and speak English and have access to a telephone.

Sample recruitment and informed consent. Recruitment occurred in two phases. For Phase 1, recruitment and eligibility screening, initial contact with potential study dyads was done via recruitment packets mailed to 149 patients with MCI and their caregivers who either were in the Indiana Alzheimer Disease Research Center Registry or consented to be sent information after receiving a DEMA brochure during a clinic visit. The results of participant recruitment and enrollment are provided in the Consort diagram (Figure 2). For Phase 2, study staff did personal eligibility screening and consent during a follow-up phone call with the 41 dyads who met Phase 1 eligibility. All dyads were fully informed about the study and procedures prior to consent. One declined to participate due to a scheduling conflict. The remaining 40 dyads signed individual consent forms and returned them by mail at least one week prior to their scheduled baseline data collection. Attrition of four dyads occurred following randomization to DEMA, resulting in a total of 36 dyads who completed intervention sessions and measures collection. (See Figure 2).

Sample Characteristics. Baseline characteristics for patients and caregivers are summarized in Table 1. The sample of patients was predominantly Caucasian (87.5%), retired (87.5%), and male (57.5%). Most patients were in the late MCI stage (55.0%) and 40% of patients had depressive symptom scores ≥ 5 on the PHQ-9 (Kroenke, Spitzer & Williams, 2001). Seventy percent of caregivers were female and 82.5% were Caucasian. Most caregivers were spouses (77.5%), retired (65.0%), and nearly one third of caregiver had depressive symptom scores on the PHQ-9 of five or greater (30.0%). No significant differences between the DEMA

and information support (IS) group were detected, except that patients in the DEMA group were relatively younger (mean age = 71.2 for DEMA vs. 76.5 for IS ($p = 0.022$)).

Insert Table 1 about here

Randomization. Immediately following completion of the baseline assessment, the statistician, MTW, randomized participants ($N = 40$ dyads) based on the MCI patient's PHQ-9 score and stage of MCI (early or late). Scores of ≥ 5 points on the PHQ-9 scale are considered mild to severe depression (Kroenke et al., 2001).

Intervention description. The dyads in both the DEMA and the information support (IS) attention control groups received six bi-weekly sessions over three months (2 face-to-face in clinic and 4 via phone) by a study-trained nurse intervener. The interveners, two for each group, were blinded, and all face-to-face meetings took place in a private clinical conference room.

Insert Table 2 about here

DEMA Intervention. The components of DEMA are described in Table 2. DEMA is described in detail in another publication by Lu and her colleagues (2013). DEMA was tailored to patient and caregiver congruence in level of awareness of functional ability and to their types and frequencies of meaningful activity and perceived barriers to engaging in these activities. DEMA uses the principles of problem-solving therapy and, consistent with the overall goals of this intervention, DEMA provided autonomy support by helping patients identify and prioritize

meaningful activities, identify needs and goals, generate manageable solutions, engage in self-selected activities with family support, plan weekly activities, self-evaluate failure and success, and review through problem-solving as needed. The dyads also received a Self-Management Tool Kit of educational material to review and discuss with the intervener, and they were encouraged to use the DEMA activity log at home. Self-reported types of meaningful activities as well as frequency and duration of activities were collected at each session.

IS. Participants in the IS attention control group received two face-to-face meetings to receive an overview of what would happen in the study and an Alzheimer's Association mild cognitive impairment educational brochure. They then received four biweekly follow-up social conversation phone calls and had the opportunity to ask questions related to the educational brochure.

Study fidelity. To enhance, maintain, and track fidelity for both the DEMA intervention and IS groups and to ensure evaluation fidelity, we used Treatment Fidelity Checklist (TFC) strategies related to design, training, intervention delivery, recipient receipts, and enactment (Bellg et al., 2004; Borrelli et al., 2005). Based on the checklist, the following study-specific strategies were used: 1) use of a conceptual model that guided tailoring of the intervention to meet the dyad needs and realistic goals; 2) use of a two-group randomized controlled study design; 3) standardized training of the nurse interveners and subsequent demonstration of “satisfactory” intervention delivery skills, including ability to tailor the intervention; 4) standardized evaluator training; 5) masking participants' group assignment to DEMA or IS for the evaluators; 6) audio-recording of intervention and evaluation sessions; 7) evaluation of participant receipt of the intervention and engagement by asking dyads about their perceived benefits and barriers or challenges to meeting planned weekly activity goals and adherence to the

self-management tool kit, time and frequency of engagement in planned activities, and use of resources provided. Treatment fidelity for both the DEMA and IS sessions were evaluated within 10 days after each session using a quality assurance checklist while listening to the audio tapes.

Measures

Measures were selected based on acceptable and published internal reliability, appropriate readability for older adults, and the study model. Measures were completed at baseline (Time 1), two weeks after the intervention (Time 2), and three months after the intervention (Time 3) via phone by research staff. The Cronbach's alphas of the measures in this study were acceptable and ranged from 0.74 to 0.93, except for the life satisfaction measure ($r = 0.53$). (See Table 3).

Patient outcome measures. *Dyad congruence in functional ability awareness* refers to the extent of agreement between MCI patient and caregiver ratings of patient functional ability as measured by the Dementia Deficits Scale (Snow et al., 2004). A value of 0 indicates complete agreement between patient and caregiver views of functional ability. A value > 0 , means that there was difference between patients and caregivers regarding the rating of functional ability awareness. Cronbach's alphas in this study were 0.80 for both patient and caregiver. *Sense of confidence* refers to the degree of self-confidence MCI patients had about their own ability as measured by the Nowotny Confidence Subscale, 8 items, responded on 4-point Likert scales. The total scores can range from 8 to 32, with higher scores indicating greater sense of confidence (Nowotny, 1989). *Meaningful activity performance and satisfaction* of MCI patients as they engaged in self-identified meaningful activities (classified into five categories: personal care, physical, leisure quiet, productive, and social) were measured by the two subscales from the Canadian Occupational Performance Measure, two items on a 10-point response scale

(Kielhofner, 2002). Higher scores reflect, respectively, greater meaningful daily activities performance and satisfaction. Patients choose up to three meaningful activities and these activities could be different across time and across patients. Therefore, reliability could not be evaluated in this study. *Depressive symptoms* refer to patient self-reported depressive symptoms assessed by the nine-item PHQ-9 (Kroenke et al., 2001). Higher scores indicate more severe depressive symptoms, and the PHQ-9 clinically meaningful cutoff points for depressive symptoms are: *none* (0-4), *mild* (5-9), *moderate* (10-14), *moderately severe* (15-19), and *severe* (20-27). *Satisfaction with communication* refers to the degree of satisfaction with the acts of sharing information, ideas, or feelings among family members or friends, measured by the Communication and Affective Expression Subscales of Family Assessment Device, 12 items on 4-point Likert response scales. Total scores range from 12 to 56 (Miller, Epstein, Bishop, & Keitner, 1985), with higher subscale scores indicating better satisfaction with family communication. *Physical function* was measured by the Alzheimer Disease Cooperative Study-Activities of Daily Living Scale (Galasko et al., 1997), 23 items on 3-point Likert response scales, with total scores ranging from 0 to 53 and higher scores indicating better physical functioning. *Life satisfaction* refers to an overall assessment of feelings and attitudes about an individual's own life. It was measured by the Life Satisfaction Index for the Third Age-Short Form, 12 items on 6-point Likert response scales, with total scores ranging from 12 to 72 (Barrett & Murk, 2006) and higher scores indicating greater life satisfaction.

Caregiver outcome measures. Caregiver outcomes included depressive symptoms and caregiver life changes. *Caregiver depressive symptoms* refers to caregiver self-reports about the presence of depressive symptoms, as measured by PHQ-9. *Caregiver life changes* were measured by the 15-item Bakas Caregiving Outcomes Scale addressing changes in social

functioning, subjective well-being, and physical health as a result of providing care. Lower scores indicate negative life change (Bakas, Champion, Perkins, Farran, & Williams, 2006).

Data Analyses and Power Calculation.

Given the primary aims of this feasibility pilot study, sample size was based on adequacy for effect size estimation, given an estimated 10% attrition rate. A total of 36 dyads were in the pilot study, which was sufficient for conducting and exploring feasibility and effect size estimation (Kraemer, Mintz, Noda, Tinklenberg, & Yesavage, 2006).

The equivalence between the DEMA and IS groups was examined separately for patients and caregivers on demographic characteristics at baseline using Chi square or Fisher's Exact test for categorical variables and *t* tests for continuous variables. General linear mixed models were used to estimate effect sizes and included time, treatment, the interaction of time and treatment, and significant baseline variables. Effect sizes (Cohen's *d*) were calculated for the within-group changes in scores, and the between-group differences in changes scores. Thresholds for interpretation of Cohen's *d* included effect sizes labeled as large ($d \geq 0.80$), medium ($0.50 \leq d < 0.79$), or small ($0.20 \leq d < 0.49$) (Hedges & Olkin, 1985). In addition, we report our exploratory analysis of effect sizes of outcomes for a sub-sample of MCI patients who had PHQ-9 scores ≥ 5 at baseline and their caregivers, because depression is a potential clinical marker for identifying MCI patients at high risk of developing AD (Lee et al., 2012). We believed it was important to understand the effect sizes of DEMA for the sub-sample of MCI patients who had depression symptoms at baseline in the mild to severe range.

Results

Feasibility

Figure 2 provides the study CONSORT flowchart. Indicators of feasibility evaluated included consent rate, program attendance and time, study completion rate, and time required for evaluation.

Consent rate. Forty-one patients living with MCI and their caregivers were screened and met the recruitment criteria for participation. They were approached during an 18-month period, and 40 dyads consented to participate for a consent rate of 97.7 %. One dyad declined participation because of conflict with caregiver work schedule.

Program attendance rate and time spent for each session. Following baseline data collection, a total of 36 out of 40 dyads were accrued. The attrition rate was 10%; of 36 dyads, 33 (91.7%) completed all sessions. The average duration of each session was 46.6 ($SD = 7.7$) minutes for the DEMA group and 31.2 ($SD = 4.7$) minutes for the IS group.

Completed measurements rate. 100% of the dyads completed the T1 measure, 93.1% completed T2, and 97.2% completed T3. The reasons for incomplete measures were illness, weather prohibiting safe travel, patient progression to AD, and caregiver withdrawal.

Data collection length. The amount of time spent on data collection by MCI patients was similar ($p = 0.106$) for the DEMA (Mean = 113.2, minutes; range = 30.0 to 220.0 minutes) and IS groups (Mean = 88.9 minutes, range = 27.0 to 182.0 minutes). Caregiver results were also similar ($p = 0.982$) for DEMA (Mean = 110.2 minutes, range = 34.0 to 162.0 minutes) and IS groups (Mean = 109.9 minutes; range = 38.0 to 199.0 minutes).

Effect size

Meaningful activity performance and satisfaction. Results are summarized in Table 3. Self-selected meaningful activities chosen by MCI patients varied across sections in both groups. For the DEMA group, the most common self-selected meaningful activities in order of

increasing frequency were: active recreation (e.g., walking), socialization, quiet recreation (e.g., crossword puzzles or reading), household management, and personal care. For the IS group, the most common self-selected meaningful activities in order of increasing frequency were: quiet recreation, household management, active recreation, socialization, and paid/unpaid work (e.g., volunteer work).

Between-group effect sizes for change scores for activity performance and satisfaction at T2 and T3 were not compared in this study, because the patients living with MCI were allowed to choose up to three meaningful activities and these activities could be different across time and across patients.

Table 3 about here

Proximal and distal outcomes.

Insert Table 4 about here

As shown in Table 4, the DEMA group exhibited greater *dyad congruence* at Time 3, with a small effect size, compared to the IS group. Among patient outcomes, the DEMA group demonstrated a small positive effect relative to IS on *physical function* at Time 2, and *life satisfaction* at Time 3. Other small effect sizes favored the IS group: *depressive symptoms* at Time 3 as well as *satisfaction with communication* at Time 2 and Time 3. Among caregiver

outcomes, a moderate effect size favoring the IS group was exhibited at Time 2 for *depressive symptoms* and a small effect size at Time 3 for *life change*.

Subset analysis. Subset analyses were conducted for the patients with MCI and caregivers who had depressive symptoms in the mild to severe range at baseline (i.e., PHQ-9 \geq 5) (see Table 5). In the subset, the DEMA group had a moderate positive effect size at Time 2 on (i.e., greater *dyad congruence*) and a small effect size at Time 3. Patients in the DEMA group also had a small effect size (i.e., minimally less *depressive symptoms*) at Time 2 and Time 3; a large effect size (i.e., better *physical function*) at Time 2 and a moderate effect size at Time 3, and a small effect (i.e., minimally higher *life satisfaction* sizes at Time 2 and Time 3). Patients in the IS group had large effect sizes (i.e., greater *satisfaction with communication*) at Time 2 and Time 3. Among caregiver outcomes, the DEMA group had a small effect size (i.e., minimally less *depressive symptoms*) at Time 3, and a small effect size (i.e., minimally fewer *life changes*) at Time 2. The IS caregiver group had a small effect size (i.e., minimally less *depressive symptoms*) at Time 2 and a moderate effect size (i.e., more positive *life changes* at Time 3).

Insert Table 5 about here

Discussion

Aligning with the current movement towards incorporating the concepts of dementia-friendly, dementia-capable, and dementia-positive health into healthcare and community services (Lin & Lewis, 2015), the DEMA intervention focuses on familiar and valued activities

important to patients with MCI . DEMA also assists dyads to learn ways to continue to engage in meaningful activities by using problem-solving techniques.

Feasibility

The findings from this study show that the pilot study design, methods, measures, and interventions are feasible for MCI patients and their family caregivers. The consent rate of 97.7% was higher than expected. We also had high participant retention, high program completion rate, and high measure completion rates at all three measurement time points. Reasons for declining to participate in our study, especially having secondary illnesses, are consistent with other studies (Mody et al., 2008).

Outcomes for patients with MCI.

In addition to establishing feasibility, the aim of this pilot study was to explore effect sizes of the DEMA intervention compared to the information support, low-dose control. Even considering the small sample size, it was surprising that, within the DEMA group, effect sizes for patients with MCI and caregiver groups were quite small or even negligible for all outcomes; and, for both the DEMA and IS groups, most of the effect sizes showed inconsistent patterns of improvement. Possible reasons for the small, negligible, and/or inconsistent effect sizes were that the length of time participants were followed was too short for changes to be detected and/or the sample was too small. It is clear that future studies will need to consider the evaluation timeframe and having booster sessions. The findings also raised questions that have implications for future research design; a usual care group may be a better comparison group, since any attention given to patients with MCI and caregivers may produce unsustainable effects. Also, future studies should explore the kinds and patterns of skill acquisition that occur for the meaningful activities patients with MCI selected and enacted in the DEMA group; these

activities, though assumed to be positive, may at first be difficult to learn and potentially cause some distress.

In reflecting on our findings, given the high percentages of patients with MCI and caregiver depressive symptom scores ≥ 5 , we further explored the impact of depressive symptoms on our ability to detect changes over time (i.e., effect size). This led us to conduct the secondary analysis on a sub-sample of participants with mild to severe depression (PHQ-9 ≥ 5). Surprisingly, even with a very small sample ($n = 7$), effect sizes in the sub-sample of patients and caregivers in the DEMA groups showed more improvement than the full sample of patients and caregivers in the DEMA group. These outcomes include improvement in *dyad congruence in awareness of functional ability* at Time 3, *sense of confidence*, *depressive symptoms*, *physical function*, and *life satisfaction* at both Time 2 and Time 3. In the sub-sample, compared to the IS group, *physical function and life satisfaction* were better in the DEMA patients at both Time 2 and Time 3; *depressive symptoms* were better at Time 3 and *life changes* better at Time 2 in the DEMA caregiver group. These improvements indicate that DEMA may potentially provide even more benefits for those MCI patients and their family caregivers with depressive symptom scores ≥ 5 and their family caregivers.

Clinical implications. Although our study sample size was small and will need evaluation in a larger study, strong evidence of the feasibility and the potential benefits to both patients with MCI and their caregivers was found. Nurses caring for patients with MCI and caregivers may want to consider using aspects of DEMA to provide a holistic patient- and family-centered approach to care for patients with MCI and caregiver dyads using a strength-based, positive health approach that builds on the existing skills and values of these dyads. Specific strategies include (1) engaging the patient with MCI and caregiver to assess strengths

and existing abilities; (2) discussing functional deficits by asking about the dyad's concerns, needs, and current use of available local resources and helping dyads to problem-solve their needs and/or concerns; (3) identifying strategies to enhance communication skills between the patient with MCI and the caregiver, helping the dyad to focus on the patient's self-management skills through meaningful activity engagement; and (4) acknowledging dyad's differing perspectives about memory changes through open and constructive discussion fosters congruence in dyad's awareness of functional abilities and coping skills. Such discussion may help the dyad improve their communication skills and reduce feelings of frustration; patients with MCI reported feeling more capable in engaging in meaningful activities.

Study Limitations. There were several limitations of this study. First, the sample size was small. In the future, a larger, more adequately powered randomized controlled clinical trial is needed to test the revised DEMA intervention using an intent-to-treat design to obtain the potential effect of treatment. Second, the study had the potential for treatment diffusion because the same nurse delivered in-person or phone call sessions to some patients in both groups, due to a nurse intervener's unexpected illness. Finally, the study has limited generalizability to the general population of MCI patients in MCI-caregiver dyads due to potential biases introduced by self-selection. Future studies should consider oversampling of minority patients living with MCI and caregivers, as well as conducting the study with a more ethnically diverse sample.

Conclusion

Based on recommendations from the literature (Lin & Lewis, 2015; Roland & Chappell, 2015), the DEMA intervention was designed to be a multicomponent program using a family dyad approach to address priority needs for engaging in meaningful activity and focusing on familiar and valued activities important to patients with MCI. Using DEMA, the nurse intervener

was able to assist the dyads to learn ways to continue engaging in meaningful activities by using problem-solving techniques. This intervention not only addresses the needs of MCI patients regarding engaging in daily meaningful activities, but also addresses caregiver needs related to their personal response to providing care and living with a person with MCI. In this pilot study, the DEMA intervention showed high feasibility and potential benefits for health-related outcomes. Nurses serve an important role in ensuring that patients with MCI and their caregivers remain as engaged as possible in meaningful activities and in facilitating patients and caregivers to learn ways to effectively communicate their needs and experiences over time. Further testing of an enhanced version of the DEMA intervention in a large randomized controlled clinical trial is needed. Nurses can serve an essential role for providing holistic patient- and family-centered care. They can utilize evidence-based clinical practice to improve health-related outcomes and quality of life and prevent premature disability for people with MCI and their family caregivers, as well as reduce social costs.

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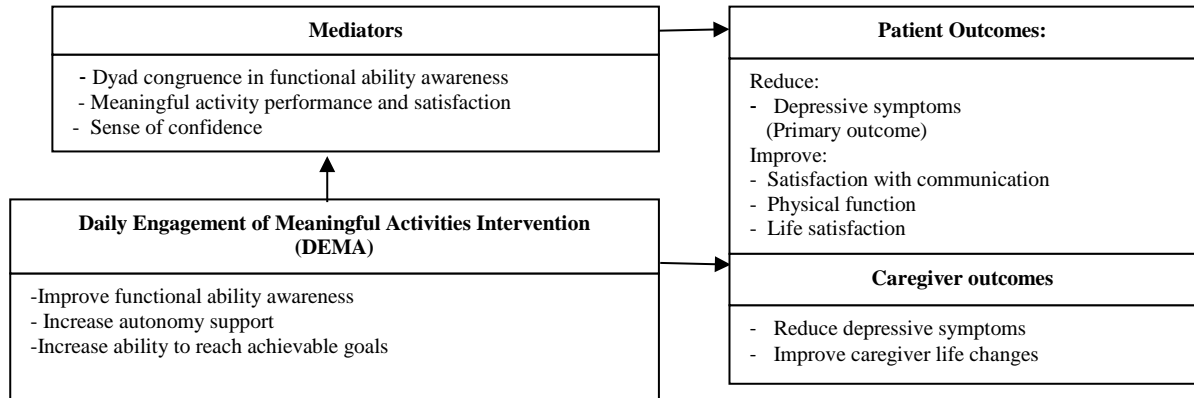
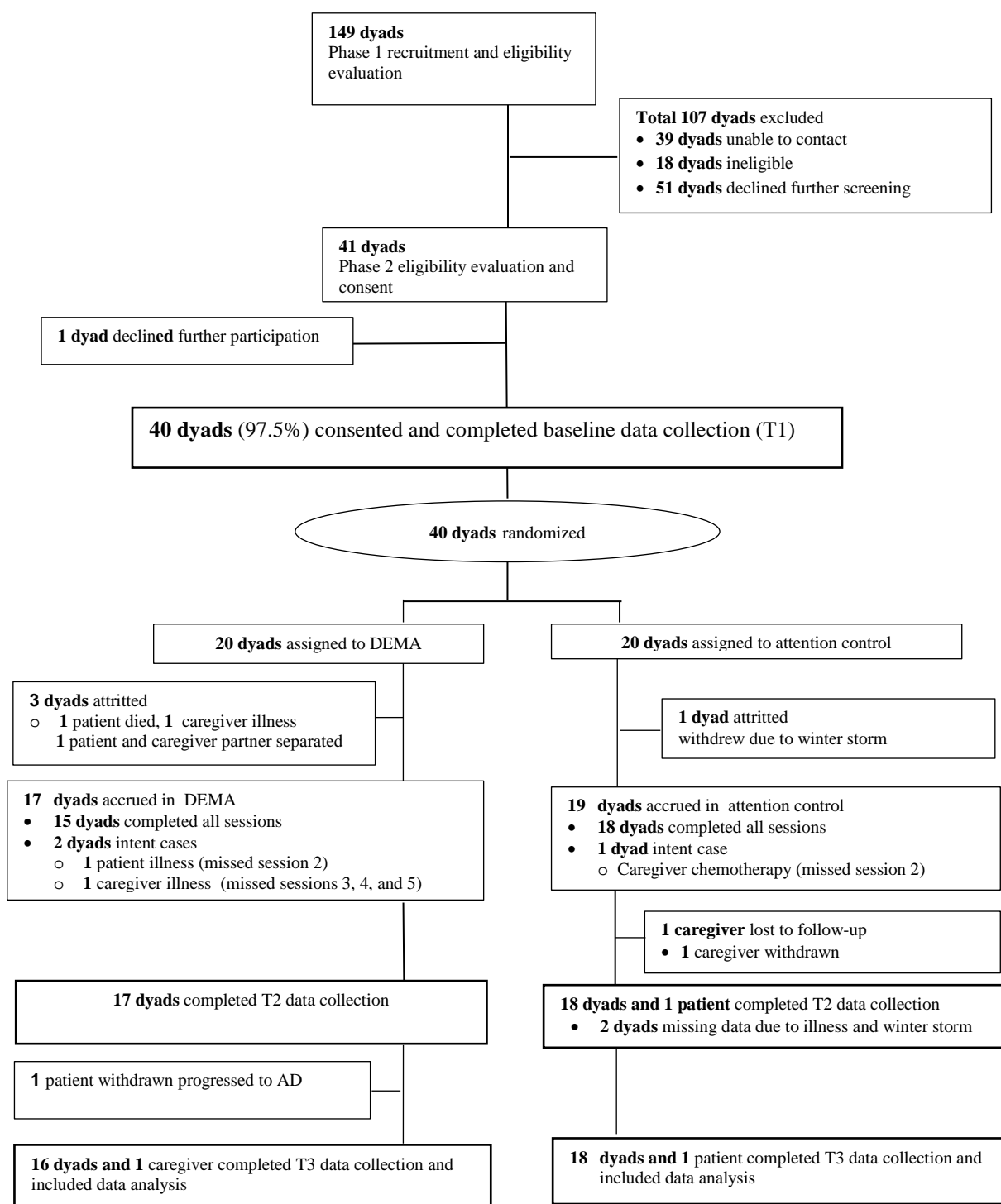


Figure 1. Conceptual Framework of the Daily Engagement of Meaningful Activities Intervention

Figure 2. Consort Diagram



Note: DEMA = Daily Engagement of Meaningful Activities; AD = Alzheimer's disease; T1 = Time 1; T2 = Time 2; T3 = Time 3.

Table 1. Demographic Characteristics of Study Participants at Baseline in the Pilot Study

Characteristic	MCI patient			Caregiver		
	DEMA N =20	IS N =20	P Value	DEMA N =20	IS N =20	P Value
Age (Year)						
Mean (SD)	71.23 (6.84)	76.47 (7.05)	0.022	65.26 (7.23)	70.47 (11.95)	0.105
Gender N (%)						
Male	12 (60.00)	11 (55.00)		5 (25.00)	7 (35.00)	
Female	8 (40.00)	9 (45.00)	0.749	15 (75.00)	13 (65.00)	0.490
Race N (%)						
Caucasian	16 (80.00)	19 (95.00)		14 (70.00)	19 (95.00)	
Africa American	4 (20.00)	1 (5.00)		4 (20.00)	1 (5.00)	
Asia	0	0		1 (5.00)	0	
More than 1 Race	0	0	0.342	1 (5.00)	0	0.107
Education (Year)						
Mean (SD)	16.80 (4.06)	16.15 (3.91)	0.609	15.40 (3.23)	15.85 (2.60)	0.631
Relationship to MCI patient						
Spouse	N/A	N/A	N/A	15 (75.00)	16 (80.00)	
Friends or others	N/A	N/A	N/A	5 (25.00)	4 (20.00)	0.705
Employment N (%)						
Employed, Full Time	2 (10.00)	1 (5.00)		3 (15.00)	6 (30.00)	
Employed, Part Time	1 (5.00)	1 (5.00)		2 (10.00)	1 (5.00)	
Retired	17 (85.00)	18 (90.00)		13 (65.00)	13 (65.00)	
Non Employed	0	0	>0.999	2 (10.00)	0	0.448
MCI Stage N (%)						
Early MCI	8 (40.00)	10 (50.00)		N/A	N/A	N/A
Late MCI	12 (60.00)	10 (50.00)	0.525	N/A	N/A	N/A
PHQ-9 (total score \geq 5) N (%)						
Yes	7 (35.00)	8 (42.10)		4 (20.00)	8 (40.00)	
No	13 (65.00)	11 (57.90)	0.648	16 (80.00)	12 (60.0)	0.168

Note: MCI = mild cognitive impairment; DEMA: Daily Engagement Meaningful Activity (DEMA) group; IS = Information Support; PHQ-9 = Patient Health Questionnaire-9.

Table 2. The Components of Daily Engagement of Meaningful Activity (DEMA)

<p>Session 1: Introduction</p> <ul style="list-style-type: none"> • Introduce Self-management Tool Kit: focused on planning meaningful activity • Meaningful activities engagement overview and assessment: (Functional ability awareness) • Assess history of meaningful engagement • Identify and prioritize meaningful activities • Discuss potential meaningful activity goals • Develop a plan to enact meaningful activity
<p>Sessions 2-6 Part 1: Meaningful activity engagement, autonomy support, goal achievement, emotional needs articulation</p> <ul style="list-style-type: none"> • Review meaningful daily activity goals: how realistic, achievable • Discuss potential barriers to enacting activities and prioritize needs • Re-evaluate decisions about priority activities • Establish individual daily goals • Identify associations between goals and planned activities • Choose manageable solutions/activities • Self-evaluate success and failure • Re-engage in problem-solving as needed • Celebrate successes and re-engage in problem solving PRN • Throughout, encourage patient living with MCI articulation of emotional needs <p>Encourage listening by caregivers, encourage patient living with MCI to share the meaningfulness of activities participation</p>
<p>Sessions 2-6 Part 2. Self-Management Tool Kit 5 topics (1 each session). Discussion of:</p> <ol style="list-style-type: none"> 2) understanding MCI 3) understanding the treatment of MCI 4) understanding and dealing with negative emotional responses 5) learning strategies for living with MCI and dealing with major concerns, and 6) finding available local and national resources

Table 3. Description of Cell Means and Within- groups Effect Size for Meaningful Activity Performance and Meaningful Activity Satisfaction

Patient Proximal Outcome	Within-Group Effects			
	DEMA (n=20)		IS (n=20)	
	Mean ^a (SE)	<i>d</i> [95% CI]	Mean ^a (SE)	<i>d</i> [95% CI]
Average Score of Meaningful Activity Performance ^b				
Baseline (Time 1)	8.46 (0.27)		7.43 (0.47)	
2 Weeks Post (Time 2)	8.42 (0.31)	-0.03 [-0.25, 0.18]	8.40 (0.27)	0.40 [0.22, 0.58]*
3 Months Post (Time 3)	8.04 (0.27)	-0.27 [-0.45, -0.09]*	8.49 (0.24)	0.42 [0.27, 0.57]*
Average Score of Meaningful Activity Satisfaction ^b				
Baseline	8.82 (0.31)		8.19 (0.42)	
2 Weeks Post	9.24 (0.19)	0.35 [0.13, 0.56]*	8.48 (0.37)	0.12 [-0.06, 0.30]
3 Months Post	8.94 (0.27)	0.09 [-0.09, 0.27]	8.71 (0.28)	0.26 [0.11, 0.41]*

Note. Daily Engagement Meaningful Activity (DEMA) group; IS = Information Support;

^aMean and SE (standard error) were estimated from the linear model with repeated measurement.

^bPatient outcomes were analyzed based on the model including age at baseline and time as covariates. Therefore, the adjusted means at each time point were estimated at average baseline ages 74.12.

*Significant effect size if CI does not include zero.

Table 4. Description of Cell Means and Within- and Between-Groups Effect Sizes, Total Sample

Outcome		Within-Group Effects				Between-Group Effects
		DEMA (n=20)		IS (n=20)		
Proximal Outcome	r^a	Mean ^b (SE)	d [95% CI]	Mean ^b (SE)	d [95% CI]	d [95% CI]
<i>Dyad Congruence in Functional Ability Awareness</i>	0.80					
Baseline		4.93 (1.39)		5.70 (1.36)		
2 Weeks Post		6.91 (1.31)	-0.37 [-0.65, -0.10]*	7.13 (1.36)	-0.37 [-0.64, -0.11]*	-0.12 [-0.49, 0.25]
3 Months Post		5.14 (2.00)	-0.03 [-0.29, 0.23]	7.97 (2.06)	-2.78 [-3.13, -2.43]*	0.37 [-0.10, 0.85]
<i>Sense of Confidence</i>	0.93					
Baseline		27.14 (0.89)		25.01 (0.89)		
2 Weeks Post		27.90 (0.89)	0.17 [0.02, 0.32]*	26.25 (0.89)	0.54 [0.38, 0.68]*	-0.14 [-0.31, 0.03]
3 Months Post		27.38 (0.89)	0.09 [-0.06, 0.24]	25.72 (0.85)	0.22 [0.07, 0.36]*	-0.16 [-0.32, -0.002]*
Patient Distal Outcome						
<i>Depressive Symptom</i>	0.70					
Baseline		3.39 (0.92)		4.88 (0.93)		
2 Weeks Post		3.10 (0.89)	0.09 [-0.06, 0.23]	4.10 (0.89)	0.28 [0.13, 0.43]*	-0.16 [-0.33, 0.01]
3 Months Post		2.37 (0.86)	0.19 [0.04, 0.34]*	2.91 (0.82)	0.74 [0.59, 0.89]*	-0.23 [-0.38, -0.07]*
<i>Satisfaction with Communication</i>	0.74					
Baseline		35.87 (1.07)		34.55 (1.07)		
2 Weeks Post		35.80 (1.01)	-0.02 [-0.17, 0.13]	36.28 (1.01)	0.45 [0.30, 0.61]*	-0.48 [-0.65, -0.31]*
3 Months Post		35.83 (1.15)	-0.01 [-0.16, 0.14]	35.80 (1.11)	0.37 [0.23, 0.52]*	-0.40 [-0.56, -0.24]*
<i>Physical Function</i>	0.83					
Baseline		39.53 (1.87)		41.66 (1.92)		
2 Weeks Post		38.69 (2.51)	-0.17 [-0.33, -0.02]*	38.08 (2.63)	-0.51 [-0.67, -0.34]*	0.46 [0.25, 0.66]*
3 Months Post		38.50 (2.04)	-0.21 [-0.37, -0.05]*	40.71 (2.08)	-0.26 [-0.42, -0.11]*	-0.02 [-0.19, 0.16]
<i>Life Satisfaction</i>	0.53					
Baseline		47.12 (1.51)		45.84 (1.51)		
2 Weeks Post		49.11 (1.77)	0.31 [0.16, 0.46]*	47.95 (1.77)	0.54 [0.38, 0.69]*	-0.02 [-0.19, 0.14]
3 Months Post		49.47 (1.50)	0.57 [0.41, 0.72]*	46.91 (1.44)	0.21 [0.07, 0.36]*	0.27 [0.12, 0.43]*
Caregiver Distal Outcome						
<i>Depressive Symptom</i>	0.72					
Baseline		2.85 (0.76)		3.85 (0.76)		
2 Weeks Post		3.32 (0.80)	-0.18 [-0.32, 0.03]	3.02 (0.82)	0.34 [-0.49, -0.18]*	-0.50 [-0.68, -0.32]*
3 Months Post		2.14 (0.64)	0.28 [0.13, 0.43]*	3.27 (0.62)	0.17 [0.02, 0.31]*	0.04 [-0.12, 0.20]
<i>Life Changes</i>	0.91					
Baseline		58.85 (2.34)		55.05 (2.34)		

2 Weeks Post	57.97 (2.02)	-0.08 [-0.22, 0.07]	55.24 (2.05)	0.04 [-0.12, 0.19]	-0.12 [-0.29, 0.06]
3 Months Post	57.99 (2.66)	-0.07 [-0.22, 0.08]	59.33 (2.60)	0.41 [0.27, 0.56]*	-0.46 [-0.62, -0.29]*

Note. Daily Engagement Meaningful Activity (DEMA) group; IS = Information Support

^a*r* indicates Cronbach's alphas, the internal reliability.

^bMean and SE (standard error) were estimated from the linear model with repeated measurement.

^cPatient outcomes were analyzed based on the model including age at baseline, treatment, time, and the interaction of time and treatment as covariates. Therefore, the adjusted means at each time point were estimated at average ages 74.12.

^dOther outcomes were analyzed based on the model including treatment, time, and the interaction of time and treatment as covariates.

*Significant effect size if CI does not include zero.

Table 5. Description of Cell Means and Within- and Between-Groups Effect Sizes, Sub-Sample: Patients with PHQ-9 ≥ 5 at Baseline Only

Outcome	Within-Group Effects				Between-Group Effects
	DEMA (n=7)		IS (n=8)		
Proximal Outcomes	Mean ^a (SE)	<i>d</i> [95% CI]	Mean ^a (SE)	<i>d</i> [95% CI]	<i>d</i> [95% CI]
<i>Dyad Congruence in Functional Ability Awareness^b</i>					
Baseline	5.00 (1.58)		5.00 (2.57)		
2 Weeks Post	5.50 (3.50)	-0.14 [-1.18, 0.91]	9.00 (1.15)	-1.15 [-1.85, -0.45]*	0.99 [-0.80, 2.78]
3 Months Post	1.80 (0.58)	1.40 [0.54, 2.25]*	3.33 (2.33)	0.29 [-0.35, 0.94]	0.38 [-0.66, 1.41]
Patient Proximal Outcome					
<i>Sense of Confidence^c</i>					
Baseline	26.86 (1.64)		23.00 (1.53)		
2 Weeks Post	27.87 (1.63)	1.21 [0.59, 1.83]	23.83 (1.48)	0.31 [-0.10, 0.73]	0.09 [-0.47, 0.65]
3 Months Post	27.45 (1.24)	0.23 [-0.33, 0.80]	23.27 (1.12)	0.17 [-0.25, 0.58]	0.16 [-0.40, 0.72]
Patient Distal Outcome ^c					
<i>Depressive Symptom (PHQ-9)</i>					
Baseline	8.29 (1.39)		8.75 (1.30)		
2 Weeks Post	5.09 (1.51)	0.80 [0.21, 1.39]*	7.48 (1.29)	0.30 [-0.12, 0.71]	0.46 [-0.11, 1.04]
3 Months Post	3.28 (1.14)	1.26 [0.64, 1.89]*	5.34 (0.97)	1.02 [0.58, 1.46]*	0.44 [-0.13, 1.01]
<i>Satisfaction with Communication</i>					
Baseline	37.29 (2.34)		31.88 (2.18)		
2 Weeks Post	36.80 (2.32)	-0.12 [-0.68, 0.44]	35.09 (2.06)	0.73 [0.30, 1.16]*	-0.87 [-1.47, -0.28]*
3 Months Post	34.68 (2.10)	-1.13 [-1.75, -0.52]*	33.38 (1.91)	0.48 [0.06, 0.90]*	-1.45 [-2.10, -0.81]*
<i>Physical Function</i>					
Baseline	39.29 (4.29)		42.57 (4.29)		
2 Weeks Post	41.14 (4.06)	0.48 [-0.09, 1.05]	40.04 (4.00)	-0.62[-1.12, -0.12]*	1.10 [0.46, 1.74]*
3 Months Post	39.46 (3.88)	0.07 [-0.49, 0.63]	40.89 (3.86)	-0.65 [-1.15, -0.15]*	0.74 [0.13, 1.35]*
<i>Life Satisfaction</i>					
Baseline	47.43 (3.16)		45.00 (2.95)		
2 Weeks Post	49.64 (2.60)	0.71 [0.13, 1.29]*	46.37 (2.37)	0.36 [0.05, 0.78]*	0.24 [-0.33, 0.80]
3 Months Post	49.84 (2.63)	1.47 [0.83, 2.12]*	45.45 (2.36)	0.08 [-0.34, 0.49]	0.41 [-0.16, 0.98]
Caregiver Outcome					
<i>Depressive Symptom (PHQ-9)</i>					
Baseline	3.86 (1.65)		4.75 (1.54)		
2 Weeks Post	3.72 (1.94)	0.03 [-0.53, 0.59]	3.87 (1.80)	0.62 [0.15, 1.10]*	-0.24 [-0.83, 0.35]
3 Months Post	1.09 (0.78)	1.55 [0.90, 2.20]*	3.25 (0.72)	0.35 [-0.12, 0.82]	0.38 [-0.22, 0.38]
<i>Life Changes</i>					
Baseline	54.86 (4.00)		51.88 (3.74)		
2 Weeks Post	56.55 (4.90)	0.34 [-0.23, 0.91]	51.95 (4.56)	0.01 [-0.46, 0.48]	0.28 [-0.32, 0.87]

3 Months Post	55.04 (6.68)	0.03 [-0.54, 0.59]	59.91 (6.18)	0.66 [0.18, 1.14]*	-0.77 [-1.38, -0.15]*
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Note. Daily Engagement Meaningful Activity (DEMA) group; IS = Information Support; PHQ-9 = Patient Health Questionnaire-9.

^aMean and SE (standard error) were estimated from the linear model with repeated measurement, except for dyad congruence.

^bDue to small sample size, this outcome was not analyzed by linear model. The Mean (SE) and effect sizes were calculated based on the raw data.

^cOutcomes were analyzed based on the model including treatment, time, and the interaction of time and treatment as covariates.

* Significant effect size if CI does not include zero.