HRP-503E– Protocol for Social or Behavioral Science or Educational Research
(2017-1)

Protocol Title:
Stress Reduction Study for Partners of Early Stage Dementia

Principal Investigator: Joan Monin

Version Date: 10/30/20

(*If applicable*) Clinicaltrials.gov Registration #:

INSTRUCTIONS
This template is intended to help investigators prepare a protocol that includes all of the necessary information needed by the IRB to determine whether a study meets approval criteria. **Read the following instructions before proceeding:** 1. Use this protocol template for a PI initiated study that includes direct interactions with research subjects. Additional templates for other types of research protocols are available in the system Library: • If the study involves genetic testing, blood draws, or MRIs, do not use this form. Use the biomedical protocol template. • If the study involves secondary analysis of data, use the Secondary Analysis of Data protocol. • For activities that may qualify as exempt research, use the Request for Exemption form (which includes a decision tree to determine whether or not your study qualifies as exempt). 2. If a section or question does not apply to your research study, type “Not Applicable” underneath. 3. Once completed, upload your protocol in the “Basic Information” screen in IRES IRB system.

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SECTION I: GENERAL INFORMATION

1. **Probable Duration of Project:** State the expected duration of the project, including all follow-up and data analysis activities. 7/1/2018- 6/30/21

2. **Study location:** State where the study will take place and in what setting. LEPH 320, Yale School of Public Health and participants homes

If international, complete and submit **International checklist** (http://your.yale.edu/policies-procedures/forms/450-ch-1-international-research-checklist) Note: If your research involves interactions with any embargoed countries you should contact the Director of Corporate Contracts and Export Control Licensing (Donald.Deyo@yale.edu or call 203.785.3817) for guidance on how to proceed.

3. **Help us categorize your research**. Are you using any of the following?

☐ Class Project
☐ Participant Observation
☒ Interviews
☒ Surveys
☒ Focus groups (study is not anonymous)
☐ Research in K-12 schools (submit a School Agreement form for the study)
☐ Deception (submit a Debriefing sheet)
☒ Audiotaping, videotaping or photography of individuals (study is not anonymous)
☐ Public viewing of videotapes or photographs
☐ Yale Psychology Pool (study does not qualify for exemption)
☐ International research sites (attach the International Checklist)
☐ Online (web-based) activities
☐ Social networks

SECTION IV: RESEARCH PLAN

1. **Statement of Purpose:** State the scientific aim(s) of the study, or the hypotheses to be tested.

This project examines the feasibility of the Wish Outcome Obstacle Plan (WOOP) intervention for married or cohabiting, committed couples in which one partner has early stage AD or a related dementia. This includes assessing the potential benefits of the spouse caregiver using WOOP for both partners' self-regulation skills, goal attainment, psychological health, and relational well-being in the early AD context. It is hypothesized that couples in the intervention will experience

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increases in self-regulation skills, goal attainment, psychological health, and relational well-being greater than couples in the wait-list control condition.

2. Background: Describe the background information that led to the plan for this project. Provide references to support the expectation of obtaining useful scientific data.

3.

An estimated 5 million Americans have Alzheimer's disease (AD), most of whom receive care from a family member. Many of these family members are cohabiting spouses with few opportunities for respite. Spouses are most vulnerable to psychological health problems (e.g., depression) because they are often socially isolated and are emotionally intimate with their partner. AD can be devastating for individual and relational well-being. A recent review highlights unique challenges for spouses of persons with early AD: maintaining a sense of togetherness, shifts in the balance of power that can affect each person's identity, empathy and a sense of attunement, and staying resilient in the face of fear, uncertainty, and hopelessness. An increasing number of psychosocial interventions for early stage AD include both care recipients and caregivers. Dyadic interventions address both the needs of the person with AD and the caregiver and show physical and psychological benefits for both partners. Although a wide variety of needs have been targeted in such interventions, the majority provide training in a specific functional domain, such as sleep, physical activity, and cognitive skills. Intimacy and communication-enhancing interventions, such as story-telling and shared decision-making guides, also show promising effects for couples coping with early stage AD.

No self-guided interventions, to our knowledge, target self-regulation skills that can be applied to change behaviors deemed important to caregivers' and care recipients' well-being. We define self-regulation as monitoring and controlling one's own behavior, emotions, or thoughts in response to demands of dementia or having a partner with dementia. Traditional, effective, cognitive interventions, such as Cognitive Behavioral Therapy (CBT) and Acceptance and Commitment Therapy (ACT), teach people to identify and modify their beliefs about a stressor, develop a new behavioral repertoire to deal with the demands of the stressor, and foster activities that promote well-being. Such interventions have successfully reduced caregiver burden and improved subjective well-being. Research also shows that self-regulation interventions are feasible and effective for decreasing depressive and neuropsychiatric symptoms in persons with dementia. Although traditional interventions using CBT and ACT have been successful, there is a need for interventions that are equally effective but less costly and can be made available to a wider population of people in need. Further, while these structured interventions are effective, they are not reliably offered in routine care.

The WOOP (Wish, Outcome, Obstacle, Plan) intervention is self-guided and aimed at enhancing self-regulation skills and health behavior change. It involves a set of straightforward steps individualized to a person's needs that ultimately form a protective cognitive habit. WOOP is a psychological intervention developed to help people understand and fulfill their wishes in their daily lives. It has helped people in multiple health contexts (e.g., back pain, stroke, physical activity, eating behaviors, children with Attention Deficit Hyperactive Disorder, relationship dysfunction). WOOP is based on decades of research showing that people are able to change their behaviors and improve their well-being when they use the following mental steps: identifying a realistic wish, identifying the desired outcome and imagining it, identifying a central inner obstacle to fulfilling that wish and imagining it, and making an "if-then" plan to overcome the obstacle and accomplish the wish. WOOP is straightforward enough so that people with low levels of cognitive impairment and young children can easily use it. WOOP can be taught to people with a brief training session. It can also achieve beneficial results without formal training, as there is a book, video, mobile app, and website (woopmylife.org) explaining the steps. The idea is that WOOP becomes a daily exercise that has lasting benefits on health and well-being, a

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claim supported by multiple longitudinal studies. Although WOOP has successfully been used to improve relationships, it has not been applied to couples coping with early AD. We hypothesize that WOOP will be beneficial in this context.

We focus on married or cohabiting, committed couples in the earliest stage of AD and related dementias for the following reasons. First, early diagnosis can be a difficult time of transition (emotionally and physically) for both partners. The couple will need to make treatment plans and important decisions about the future together. They are also starting to deal with the break-down of communication and differentiating what behaviors are a result of their partner's own will or a product of the disease. Second, this is a time when the partner with AD's cognition is relatively intact so we can assess psychological outcomes and contextual factors in the person with AD.

The overarching aim of the proposed project is to examine the feasibility of WOOP plus a brief AD caregiving psychoeducation component for married or cohabiting, committed couples in which one partner has early stage AD or a related dementia. This includes assessing the potential benefits of WOOP for caregiving spouses' self-regulation skills, behavior, psychological health, and relational well-being in the early AD context which may in turn influence psychological and relationship satisfaction in the person with early AD. We will assign 25 couples to the WOOP intervention and 25 couples to the wait-list control condition and evaluate the following spec aims:

(1) To assess the feasibility of WOOP for spouses of persons with early stage AD or related dementias. We will monitor (a) recruitment, (b) adherence, and (c) missing data and drop out. We will explicitly qualitatively and quantitatively examine how AD-related factors (e.g. cognitive functioning, dementia symptoms, quality of life) impact WOOP instruction and use.

(2) To examine the extent to which WOOP plus brief AD caregiving psychoeducation improves self-regulation skills, behavioral change, psychological well-being, and perceptions of care quality for each partner. Quantitatively, we will examine whether WOOP increases self-regulation skills Difficulties in Emotion Regulation Scale (DERS; Gratz, K. L. & Roemer, L. (2004). Multidimensional assessment of emotion regulation and dysregulation: Development, factor structure, and initial validation of the Difficulties in Emotion Regulation Scale. Journal of Psychopathology and Behavioral Assessment, 26, 41-54) and 17 item self-efficacy (Sherrer & Maddux Self-efficacy Scale, 1982), reduces depressive symptoms (CESD[14]), changes health behaviors[15], and increases positive mood (PANAS[16]).

(3) We will also examine how AD-related factors moderate the effects of the WOOP intervention. Qualitatively, we will examine specific health behavioral changes that are important for couples coping with early AD as they use WOOP.

4. **Research Plan:** Summarize the study design and research procedures using non-technical language that can be readily understood by someone outside the discipline. If working with a Non-Government Organization (NGO) or other organization, be sure to highlight which are research-only activities and which activities would occur regardless of the research. If working with survey firms, please specify what research activities the research firm will be responsible for.

Description of WOOP (Wish, Outcome, Obstacle, Plan): WOOP is a brief, self-guided, intervention sequence that people can use to find and fulfill their wishes and change their habits in daily life. See woopmylife.org for more details. For our intervention, we will ask the spousal caregiver to focus on wishes and goals that will help maintain or enhance their individual daily well-being as they cope with the stressors of caregiving for a loved one with early stage AD or related dementia.

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Using the WOOP card shown in Figure 1, the participant writes down the following:1. Wish or goal: A wish (e.g. “responding calmly when the partner asks a question repeatedly”). 2. Outcome: The most positive outcome of realizing the wish or goal (e.g. “both partners feel respected and happy”). Then the participant vividly imagines the outcome. 3. Obstacle: The most critical internal, controllable, obstacle (e.g., “feeling impatient”). Then the participant vividly imagines the internal obstacle occurring. 4. Plan: The participant answers the following question: What action can I take or what thought can I think to overcome the obstacle (e.g., “take a deep breath, take my partner’s perspective, and answer the question calmly”); then he or she forms an “if” [specified obstacle – when I feel impatient], “then I will” [specified action or thought to overcome obstacle – take a deep breath, take my partner’s perspective, and answer the question calmly] plan. This four-step procedure – Wish, Outcome, Obstacle, Plan – is the only activity involved in the WOOP intervention.

Brief Psychoeducational Training: Before engaging in the WOOP, there will be a brief 20-minute psychoeducational discussion with the spousal caregiver. We will use the National Institute on Aging’s 2015 Guide for “Caring for a Person with Alzheimer’s Disease”. This guide covers topics such as understanding how AD changes people (challenges and coping strategies), helping other family members and others understand AD, planning ahead (health, legal, and finances), keeping the person with AD safe, and adapting activities for people with AD. We will focus mostly on the caregiver coping and self-care sections that will serve as inspiration for WOOP intervention “wishes” during our discussion, but we will encourage the caregiver to read all sections on their own.

At the home visit, or phone or zoom call, the interventionists will work with the caregiving spouse to identify their unique, important wishes. These wishes can address their own or relationship well-being. It is vital that each participant generate their own wishes as these emerge uniquely from participants’ life experiences and present contextual needs. The interventionist will then slowly and quietly walk the participant through the WOOP card activity and answer questions about the process. There is an established set of WOOP training materials, called the WOOP kit, that will be adapted for couples with early AD and guide the session. The kit includes instructions for a written WOOP, a mental WOOP, a WOOP review, prompts, frequently asked questions, a plan refinement guide, and a WOOP card. Participants will be told that they are free to share and discuss their WOOP four-step procedure and their experiences with WOOP with their partners with AD at any time during the study.

Figure 1. WOOP card

Procedures

Drs. Monin and Laws will be trained by Dr. Oettingen in multiple practice sessions which will involve role-playing and practice with guiding couple members through the WOOP activity.

Table 1. The Intervention and Assessment Procedures

Time	
Day 1	**Home Session with Interventionists (Home visits may be replaced by phone/zoom calls.)** **1. Explanation of the study procedures.** **2. Informed consent.** **2.a Administration of the Telephone Interview Cognitive Status (TICS) to both partners.** **3. Baseline survey.** **3. The spousal caregiver will be trained using the NIA caregiving psychoeducation guide and to use the WOOP four-step procedure.** **(1) The interventionist will walk the spousal caregiver through one mental WOOP pertaining to a challenging but feasible wish they have for their own or their relationship's well-being in the next 3 months.** **(2) Participants will identify one challenging but feasible wish for their own or their relationship's well-being to fulfill in the next week and will be guided through the written WOOP.** **(3) The participants will practice a mental WOOP regarding a challenging but feasible wish for the next 24 hours, with the interventionist providing guidance and feedback to ensure that participants understand and can implement WOOP on their own. The interventionist explains the WOOP card.** **(4) Participants will be given a stack of WOOP cards. They will be asked to use WOOP as much as they would like, to practice it in various situations and for different life domains and time frames. They learn that practicing WOOP means playing with it during everyday life.** **The instruction sessions will be audiotaped with the permission of the participants.** **(~60 min) Note: The spousal caregivers will be provided with a paper WOOP kit and access to the video and app. With consultation of the couple, we will make a schedule of days/times for check-in phone calls with the spouse caregiver only.**
Days 4, 7, 10, 13	**WOOP Card Check-In Days** **The spousal caregiver will be asked to complete at least one WOOP exercise and card pertaining to a 24-hour wish about their own or their relationship well-being each morning at a specific convenient time (e.g., after breakfast) every day from Day 1 to 16. We will explicitly check-in with them on Days 4, 7, 10, and 13.** **Phone calls: Interventionists will call the couple each WOOP card day in the early evening to check how the couple is doing, how the spousal caregiver is doing with WOOP, if he/she successfully completed the cards, and to troubleshoot any issues or questions. *Completed cards will be collected at the home visit at Day 16.***

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	The phone calls will be audiotaped with the permission of the participants.
Day 16	**Follow-up Home Visit: Follow-up survey & Booster training. Home visit may be replaced by phone/zoom calls.** **Interventionists will visit the couple again at Day 16 to see how the couple is doing, how WOOP has been, if each the spousal caregiver is continuing to use WOOP, and to troubleshoot any issues or questions. The interventionists will ask to speak to each partner separately and privately. Participants will complete a paper and pencil interview examining the outcomes and contextual factors (see Measures below). (~30 min)**
5 week follow up	**The interventionist will call to check how things are going and provide support related to using WOOP.**
3 month follow up	**3 Month follow up Home Visit. Home visit may be replaced by phone/zoom calls.** **Outcomes will be measured with a home visit survey.Wait-list control condition: After the survey is completed, we will provide an a training session to the spouse caregivers in the wait-list control to use WOOP using the same steps outlined in Day 1.**

Measures

Contextual Factors. At baseline we will assess both partners' demographics, health conditions, relationship factors (e.g. relationship length, number of children), perceived physical and psychological suffering, Telephone Interview for Cognitive Status (TICS) or Mini-Mental State Examination (MMSE), the Neuropsychiatric Inventory, and the QOL-AD to capture dementia symptoms and behaviors, functional impairment, and quality of life. We will assess changeable factors (e.g. dementia symptoms, functional ability) at the Day 16, and 3 month follow-up survey with the NPI and QOL-AD. We will also ask if the participants have been in any behavioral health interventions during the study period. This will help us understand if the present intervention has an effect above and beyond other interventions they be involved in (e.g. caregiver support group, other family caregiver interventions from community resources).

Primary Outcomes (Baseline, Day 16, and 3 months). Perceived stress. The 10 item Perceived Stress Scale (PSS; Cohen et al., 1983). Positive affect. Self-reported positive emotions (e.g., amusement, gratitude, hope) on a 1-5 scale over the past week using the Positive and Negative Affect Schedule. Depressive symptoms. 10-item CESD. Self-regulation skills. We will use the Difficulties in Emotion Regulation Scale (DERS; Gratz, K. L. & Roemer, L. (2004). Multidimensional assessment of emotion regulation and dysregulation: Development, factor structure, and initial validation of the Difficulties in Emotion Regulation Scale. Journal of Psychopathology and Behavioral Assessment, 26, 41-54). Relationship satisfaction. We will assess closeness, partner responsiveness, and mutuality in the past week. We will also specifically ask about the relationship challenges in the context of early AD that were identified in a recent meta-analysis by Wadham et al. (e.g. maintaining a sense of togetherness, shifts in the balance of power within the relationship that can affect each person's identity). Support quality. We will also assess both partners' perceptions of support quality using a 10-item measure developed and validated by Brooke Feeney. Items include "My spouse is always there for me whenever I need him/her", and "I can count on my spouse to comfort and help me when I need it." Items are rated on a scale from 1 (disagree strongly) to 5 (agree strongly). Caregiver burden. Spouses only will complete the short form Zarit Burden Interview which consist of 12 items rated from 0 (never) to 4 (nearly always). Items include, "Do you feel that because of the time you

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spend with your relative that you don't have enough time for yourself?" and "Do you feel angry when you are around your relative?". Behavioral goals and behavior change. At each time point, we will ask participants to complete a health behavior and leisure activity questionnaire. At baseline, we will also ask open ended questions: "What behaviors would you like to change about yourself? About your relationship?" At 2 weeks: "Since you started using WOOP, (1) How have you changed? (2) How has your partner changed? and (3) How has your relationship changed?" See qualitative analysis plan for details. The substantive results of this qualitative analysis will be important for establishing relevant quantitative behavioral change measures in our future R01 Stage 2 RCT. All proposed quantitative measures, have evidence of validity and reliability in the early AD context.

Analysis

Evaluation of WOOP Adaption. We will qualitatively analyze the intervention delivery and content in the following ways. (1) We will audio-record the home training sessions, or phone/zoom calls. Dr. Monin and Laws will evaluate the transcriptions in terms of: participants' understanding of the WOOP information and skills and participants' identification of their own wishes and inner obstacles. We will also identify the difficulties encountered in practicing the WOOP process. (2) WOOP Card Check-In phone calls: Participants will have the chance to talk about their wishes, whether they had fulfilled their wish that day, and what wish they are thinking of for tomorrow. We will ask about difficulties when completing the WOOP or concerns about WOOP. We will ask whether they completed WOOP (a) alone or (b) in collaboration with each other. We will closely monitor the number of completed WOOP cards over the four check-in days. (3) Exit interview: We will ask participants about their experience with WOOP content and delivery (e.g., perceived usefulness, appropriateness of intervention length, how to make WOOP easier to understand). We will ask participants to describe how participating with your partner influenced your experience with WOOP.

Qualitative analysis of the home sessions and all open-ended interviews: All interviews will be recorded, transcribed, de-identified and entered into Atlas.ti. After reviewing and discussing all of the interview summaries, transcripts, and field notes, our team will collaboratively construct a qualitative codebook. We will first code a small sample of interviews using open coding processes where we identify and describe emerging themes. We will produce a draft codebook that will contain codes related to our preconceived themes and topics (i.e., common WOOP wishes in early stage AD caregiving), and also codes for emergent themes that were identified through our open coding process. Research assistants, Dr. Monin, and Dr. Laws will use the draft codebook to code a subset of interviews. We will then meet as a team to evaluate the reliable and consistent application of our codebook, making revisions where needed.

Feasibility Outcomes. We will monitor recruitment, adherence, and missing data. We will also examine descriptively and analytically how contextual factors (e.g. socio-demographics and dementia characteristics) relate to missingness, recruitment, and adherence challenges.

5. **Participant Population:** Provide a detailed description of the types of participants who will be recruited into this study.

We will be recruiting an additional 40 couples to the original goal of 50 couples (for a total of 90 couples) for this pilot study (end total of 45 couples in the WOOP intervention and 45 couples in the wait-list control). Eligibility Criteria. (1) The couple is married or in a cohabiting, committed relationship. (2) One partner has been told by a physician that they have early stage Alzheimer's disease or a related dementia, and this person has a Mini Mental State Examination score of between 16 and 27.(Or a TICS score>20.) (3) The spouse will have to score 27 or higher on the MMSE, or a TICS score>33. (4) Both participants must agree to participate and complete baseline interviews. (5) Both spouses are at least 60 years old.

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6. **Describe** how access to the population will be gained in the study. Recruitment. Participants will be recruited from the Alzheimer's Disease Research Unit, the Adler Center, and the Geriatric Psychiatry department. We will also be doing widespread community recruiting through mass e-mails and flyer distribution via community partners from our other studies such as YCCI, assisted living facilities, Alzheimer's association, Live Well, AARP and other organizations who service those with dementia. A staff member will present information about the study to potentially eligible couples. If both spouses express interest, the couple will be referred to a research assistant who will assess eligibility and explain study procedures. We will keep a record of reasons why participants were ineligible. If eligible, the research assistant will obtain contact information and schedule a home visit, or phone/zoom call. At the home visit, or phone/zoom call, informed consent will be obtained. Note: We refer to couple members as 'spouses' and 'partners with early AD or related dementias' to be parsimonious; however, we will not limit this research to married heterosexual relationships. Sexual minority couples are also likely to benefit from interventions to enhance self-regulation skills, behavior change, and relational well-being. We will also be recruiting from the VA. VA IRB approval will be obtained before interacting with VA participants and staff.

I would like to put in a Seniors Blue Book advertisement to recruit for this study. The following information will be included in the ad. This information is the same as in the already approved YCCI created ad.

Does your partner have early stage dementia?

Stress Reduction Study for Partners of Early Stage Dementia
If you are married or in a committed relationship, are at least 60 years old, and you live with a partner who has early stage dementia, you may be eligible to participate in a study geared towards lowering daily stress and supporting you in your relationship. Participation involves three short home visits, or phone/zoom calls. During the visits, we will teach you a stress reduction technique and ask you and your partner to complete a brief survey. Compensation up to $200 per couple. To learn more or to see if you are eligible to participate, please contact Kathleen Williams (203) 641-5373 or email her at kathleen.williams@yale.edu. HSC #2000021852

I would also like to contact previous participants who have finished the study to share information about a new study for persons with early stage dementia and their adult children. I would like to send them a letter in the mail to their home address with our contact information for the Families Coping Together with Dementia (FACT-AD) Study. The HIC number for that study is 2000024219. See the letter attached.

7. **Participant classification:** Check off all classifications of participants that will be specifically recruited for enrollment in the research project. Will participants who may require additional safeguards or other considerations be enrolled in the study? If so, identify the population of participants requiring special safeguards and provide a justification for their involvement.

☐Children	x☐ Healthy	☐Fetal material, placenta, or dead fetus
☐Non-English Speaking	☐ Prisoners	☐Economically disadvantaged persons
☐Decisionally Impaired	☐ Employees	☐Pregnant women and/or fetuses
☐Yale Students	☐ Females of childbearing potential	

We will be targeting participants with early stage Alzheimer's and related dementias who still have the capacity to make informed decisions.

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NOTE: Is this research proposal designed to enroll children who are wards of the state as potential participants? ☐Yes ☒ No

Inclusion/Exclusion Criteria: What are the criteria used to determine participant inclusion or exclusion?
Eligibility Criteria. (1) The couple is married or in a cohabiting, committed relationship. (2) One partner has been told by a physician that they have early stage Alzheimer's disease or a related dementia, and this person has a Mini Mental State Examination score of between 16 and 27, or a TICS score>20. (3) The spouse will have to score 27 or higher on the MMSE, or a TICS score > 33. (4) Both participants must agree to participate and complete baseline interviews. (5) Both spouses are at least 60 years old.

SECTION V: RECRUITMENT/CONSENT AND ASSENT PROCEDURES

1. Recruitment Procedures:

a. Describe how potential participants will be identified and contacted, and by whom.

Recruitment. Participants will be recruited from the Alzheimer's Disease Research Unit, the Adler Center, and the Geriatric Psychiatry department. We will also recruit from the VA after we obtain VA IRB approval. We will also do widespread community recruiting through the use of mass e-mails and flyers via community partners from our other studies such as YCCI, assisted living facilities, Alzheimer's association, Live Well, AARP and other organizations who service those with dementia. A staff member will present information about the study to potentially eligible couples. If both spouses express interest, the couple will be referred to a research assistant who will assess eligibility and explain study procedures. We will keep a record of reasons why participants were ineligible. If eligible, the research assistant will obtain contact information and schedule a home visit, or phone/zoom call. At the home visit, or phone/zoom call, informed consent will be obtained. Note: We refer to couple members as 'spouses' and 'partners with early AD or related dementias' to be parsimonious; however, we will not limit this research to married heterosexual relationships. Sexual minority couples are also likely to benefit from interventions to enhance self-regulation skills, behavior change, and relational well-being.

Are you collecting any information about the individuals prior to their signing a consent form?
Yes ☐ No ☒

If yes, indicate what information you will be collecting and how it will be gathered *(phone screen, paper questionnaire, etc.)* Click or tap here to enter text.

2. Indicate recruitment methods below. Attach copies of any recruitment materials that will be used.

☒ Flyers	☐ Internet/web postings	☐ Radio
☐ Posters	☒ Mass email solicitation	☐ Telephone
☐ Letter	☐ Departmental/Center website	☐ Television
☐ Through local NGO or other local contact	☐ Departmental/Center research boards	☐ Newspaper
☐ Table set-up / in-person recruitment of public	☐ Snowball sampling	

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☐ Classroom recruitment

☐ Social Media (Twitter/Facebook):

☒ Other: Dr. Marottoli and the social workers at the Adler Center and case managers at the Alzheimer's Disease Research Unit will present information to potential participants

3. Targeted Enrollment: Give the number of participants:

a. Targeted for enrollment at Yale for this protocol 180 participants (90 persons with early AD and their spouses)

b. If this is a multi-site study, give the total number of participants targeted across all sites Click or tap here to enter text.

4. How was this estimate derived?

Guided by NIH reviewer comments.

5. Process of Consent/Assent *(NOTE: When a study includes minors, parent provide permission [not consent] for the child's participation, and the child provides assent for participation)*

Describe the setting and conditions under which consent/assent will be obtained, including parental permission or surrogate permission and the steps taken to ensure participants' independent decision-making.

The consent process will take place at the Adler Center, the Alzheimer's Disease Research Unit or at the participant's home. Or the consent will be mailed or emailed and discussed over a phone/zoom call.

6. Evaluation of Participant(s) Capacity to Provide Informed Consent/Assent: Indicate how the personnel obtaining consent will assess the potential participant's ability and capacity to consent to the research being proposed, if applicable.

At recruitment, Dr. Marottoli and/or a social worker at the Adler Center or a case manager at the Alzheimer's Disease Research Unit will use their clinical expertise to assess whether the person with early stage AD and their spouse are able to understand the procedures of the study and can provide informed consent. Alternatively, when a couple calls in to enroll in the study a TICS will be performed on both partners as above to determine eligibility. (PWD score>20 and partner scores>32)

7. Documentation of Consent/Assent: Specify the documents or verbal scripts that will be used during the consent/assent process. Copies of all documents should be appended to the protocol, in the same format that they will be given or spoken to participants.

See consent form.

8. Non-English Speaking Participants: Explain provisions in place to ensure comprehension for research involving non-English speaking participants. Translated copies of all consent materials must be submitted for approval prior to use. Do you speak the local language? Will you require a translator? (If so, please elaborate on how the translators will be trained).

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Only English speaking participants will be in the study.

9. Are any of the study procedures likely to yield information subject to mandatory reporting requirements? (e.g. HIV testing – reporting of communicable diseases; parent interview -incidents of child abuse, elderly abuse, etc.). Please verify to whom such instances will need to be reported.

Identification of elder abuse is possible, and it would be reported to Dr. Marottoli, the Adler social workers, and law enforcement.

10. **Waiver of Consent/Documentation of Consent: In certain circumstances, the IRB may grant a waiver of documentation of consent, or a full waiver of consent, depending on the study.** If you will request either a waiver of consent, or a waiver of signed consent for this study, complete the appropriate section below.

☒Not Requesting any consent waivers

☐Requesting a waiver of signed consent (e.g., verbal or online consent only):

☐ Recruitment/Screening only *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

☐ Entire Study (Note that an information sheet may be required.)

For a waiver of signed consent, address the following:

- Would the signed consent form be the only record linking the subject and the research? YES ☐ NO ☐
- Does a breach of confidentiality constitute the principal risk to subjects? YES ☐ NO ☐

OR

- Does the research pose greater than minimal risk? YES ☐ NO☐
- Does the research include any activities that would require signed consent in a non-research context? YES ☐ NO ☐

☐ Requesting a waiver of consent (if you are not obtaining ANY consent):

☐ Recruitment/Screening only *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

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☐ Entire Study

For a waiver of consent, please address all of the following:

- Does the research pose greater than minimal risk to subjects?
  ☐ Yes *If you answered yes, stop. A waiver cannot be granted.*
  ☐ No
- Will the waiver adversely affect subjects' rights and welfare? YES ☐ NO☐
- Why would the research be impracticable to conduct without the waiver?
  Click or tap here to enter text.
- Where appropriate, how will pertinent information be returned to, or shared with subjects at a later date? Click or tap here to enter text.

SECTION VI: PROTECTION OF RESEARCH PARTICIPANTS

1. **Confidentiality & Security of Data:** Describe the steps that will be taken to secure the data during storage, use and transmission as outlined in the below sections. NOTE: Data can include paper files, data on the internet or websites, computer files, audio/video files, photographs, etc. and should be considered in the responses to the below sections. All documents and participant information will be strictly maintained according to Yale University IRB and HIPAA regulations to ensure confidentiality at all times. Access to participant information will be limited to a "need to know" basis and all data will be coded to maintain confidentiality. Only those investigators with appropriate Human Subjects training will have access to participant data. All electronic files are encrypted and password protected; paper files are kept in locked file cabinets. All data will be managed to assure strict confidentiality of participants at all times. Data will be kept for five years after the study ends. Data will then be de-identified using a "Safe Harbor" (45CFR164.514(b)(2)) approach consistent with the HIPAA Privacy rule. De-identified data will be certified by a statistician that there is a very small risk that use of the protected health information could lead to a participant being identified. The PI is responsible for the implementation of data de-identification. Only the principal investigator and research team will have access to PHI. De-identified data will be available to the research sponsor (NIH/NIA). Any data, specimens, forms, reports, audio recordings, and other records that leave the site will be identified only by a participant identification number (Participant ID, PID) to maintain confidentiality. All computer entry and networking programs will be done using PIDs only. Information will not be released without written permission of the participant, except as necessary for monitoring by the IRB and NIA. Data collection forms will be kept in a locked filing cabinet in the PI's office. Only the PI and certified study staff will have access to the participant's records. Forms will be coded with subject number; no personally identifiable information will be associated with these forms. Effect reports and annual summaries will not include participant- or group-identifiable material. Each report will only include the identification code.
Click or tap here to enter text.

2. What participant information will you be collecting? Describe the identifiers that will be included or associated with the data and/or specimens (e.g., names, addresses, telephone/fax numbers, email addresses, dates (date of birth, admission/discharge dates, etc.), medical record numbers, social security numbers, health plan beneficiary numbers, etc.) No identifiable self-report data.

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Other potentially identifying information to be collected:

☒Audiotapes

☐Videotapes

☐Faces (focus groups, photographs or other way that an individual would be physically recognized)

☐Potential for identification from the bulk of the information, even if direct identifiers are not collected (deductive disclosure).

3. How will the research data be collected and recorded? Training participants to use WOOP at home and phone call interviews will be recorded with an audio-recorder. Or all training will occur over phone/zoom calls and recorded.

4. If identifiers will be associated with the data and/or specimens, describe whether a record or list containing a code (i.e., code number, pseudonyms) will be used, where the list will be stored, who will have access to the list and when it will be destroyed. Written identifiers will not be associated with the self-reported data.

5. Describe where, how and for how long the data (hardcopy (paper) and/or electronic data) and/or specimens will be stored. Data will be kept for five years after the study ends. Data will then be de-identified using a "Safe Harbor" (45CFR164.514(b)(2)) approach consistent with the HIPAA Privacy rule. De-identified data will be certified by a statistician that there is a very small risk that use of the protected health information could lead to a participant being identified. The PI is responsible for the implementation of data de-identification. Only the principal investigator and research team will have access to PHI. De-identified data will be available to the research sponsor (NIH/NIA). Data collection forms will be kept in a locked filing cabinet in the PI's office. The PI and certified study staff will have access to the participant's records. Forms will be coded with subject number; no personally identifiable information will be associated with these forms. Audio-recordings will be transferred to a secure, password protected, computer that is not connected to the internet at Dr. Monin's Social Gerontology and Health Laboratory at suite 801, 55 Church Street, New Haven. They will be stored there for five years after the study ends. Transcription will occur at The University Center for Social and Urban Research at University of Pittsburgh.

All portable devices must contain encryption software, per University Policy 5100. If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on url http://its.yale.edu/egrc or email it.compliance@yale.edu

6. Identify who will have access to the data and/or specimens. *If the data and/or specimens will be transferred to and/or from outside collaborators, identify the collaborator to whom the data and/or specimens will be transferred and how the data and/or specimens will be transferred.*
The PI and certified study staff will have access to the participant's records. Also, transcription of audiotapes will occur at The University Center for Social and Urban Research at University of Pittsburgh.

7. What will be done with the data when the research is completed? Are there plans to destroy the identifiable data or the link to personal identifiers? If yes, describe how, by whom and when identifiers will be destroyed. If no, describe how the data and/or identifiers will be secured. Data will be kept for five

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years after the study ends. Data will then be de-identified using a "Safe Harbor" (45CFR164.514(b)(2)) approach consistent with the HIPAA Privacy rule. De-identified data will be certified by a statistician that there is a very small risk that use of the protected health information could lead to a participant being identified. The PI is responsible for the implementation of data de-identification. Only the principal investigator and research team will have access to PHI. De-identified data will be available to the research sponsor (NIH/NIA).

8. Will a Certificate of Confidentiality be needed? (*See also the NIH Certificate of Confidentiality Kiosk, http://grants.nih.gov/grants/policy/coc/index.htm)* Yes

SECTION VII: POTENTIAL RISKS AND BENEFITS

1. Risks: Describe the reasonably foreseeable risks, including risks to participant privacy, discomforts, or inconveniences associated with participants participating in the research. *Note: All studies have the potential for risk, if not physical, there may be psychological, reputational, or financial risks or risks to breach of confidentiality.*

   The potential risk to participants in each study is considered to be minimal. In systematic reviews of WOOP for a variety of conditions, no adverse effects were reported. There are, however, theoretical risks of WOOP, including increased symptomology resulting from becoming more self-aware of obstacles for increasing personal and relational well-being. Interventionists will note instances of psychological distress and will consult with Dr. Holly Laws, a clinical psychologist licensed in the state of Connecticut. If participants score in the clinically depressed range of the CESD (indicated by a score of >=16), Dr. Laws will consult with the participant about their depressive symptoms individually, further assessing the participants' level of symptomatology including assessment of past or current suicidal ideation and intent. Participants demonstrating suicidal ideation or intent will be referred to local crisis management services, and provided with psychoeducation regarding safety, 24-hour crisis hotlines, and use of emergency room and calling 911 in the case of acute danger to themselves. Such participants will be excluded from the study, and Dr. Laws will follow up with the participant after the initial assessment to again provide psychoeducation and encourage clinical engagement and seeking of emergency services. For participants endorsing clinical levels of depressive symptoms but no past or present suicidal ideation or intent, Dr. Laws will provide recommendations for community mental health services. Participants with clinical levels of depressive symptoms can participate in the study if their symptoms do not include suicidal ideation or intent and if their level of symptomatology allows them to participate in the WOOP protocol. These clinical judgments will be made by Dr. Laws as needed and patients will be provided with psychoeducation about the importance of addressing clinical depression with a professional and clearly informed that participation in the present work, while it may provide some benefit, is not considered to be a proven clinical intervention but only a research study. Such participants will be assessed by Dr. Laws at each measurement interval to check for changes to symptomatology and assess for safety.

2. Minimizing Risks: Describe the manner in which the above-mentioned risks will be minimized.

   Safety and tolerability will be assessed through participant self-report of psychological symptoms or changes in symptoms since baseline (obtained from adverse event logs and direct query at follow-up phone calls) until completion of the study period. Safety events by grade (mild, moderate, severe) will be recorded and monitored throughout the study to ensure there are no safety concerns about using WOOP with this population.

APPROVED BY THE YALE UNIVERSITY IRB 11/4/2020

3. Data and Safety Monitoring Plan: Include an appropriate Data and Safety Monitoring Plan (DSMP) based on the investigator's risk assessment stated below. (Note: the HSC will make the final determination of the risk to subjects.).

   a. What is your assessment of the overall risk level for subjects participating in this study?

   Based on the safety profile of WOOP, there is minimal risk of adverse events. Should any participants experience adverse effects related to the intervention, these will be reported using a standard form to the Yale Human Investigation Committee and NIA Program Officer. All participants will have direct access (phone and email) access to the Principal Investigator and research staff. If any adverse events occur requiring immediate medical attention, the PI will guide and advise subjects in the medical management of acute and/or emergent reactions. In most cases, this will entail calling '911' and an immediate emergency department referral. Dr. Laws in also a trained clinical psychologist and team member who will be available for consults for psychological health safety cases.

   b. If children are involved, what is your assessment of the overall risk level for the children participating in this study? No

   c. Include an appropriate Data and Safety Monitoring Plan. Examples of DSMPs are available here http://your.yale.edu/policies-procedures/other/data-and-safety-monitoring-plan-template for

      i. Minimal risk
      ii. Greater than minimal/moderate risk

The principal investigator is responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews at the specified frequency [*weekly*]. During the review process the principal investigator will evaluate whether the study should continue unchanged, require modification/amendment, or close to enrollment.

The principal investigator and the Institutional Review Board (IRB) have the authority to stop or suspend the study or require modifications.

This protocol presents minimal risks to the subjects and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), including adverse events, are not anticipated. In the unlikely event that such events occur, Reportable Events (which are events that are serious or life-threatening and unanticipated (or anticipated but occurring with a greater frequency than expected) and possibly, probably, or definitely related) or Unanticipated Problems Involving Risks to Subjects or Others that may require a temporary or permanent interruption of study activities will be reported immediately (if possible), followed by a written report within 5 calendar days of the Principal Investigator becoming aware of the event to the IRB (using the appropriate forms from the website) and any appropriate funding and regulatory agencies. The investigator will apprise fellow investigators and study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project [through regular study meetings, via email as they are reviewed by the principal investigator.] The protocol's research monitor(s), Data and Safety Monitoring Boards, study sponsors, funding and regulatory agencies, and regulatory and decision-making bodies will be informed of adverse events within 5 days of the event becoming known to the principal investigator.

   d. For multi-site studies for which the Yale PI serves as the lead investigator:

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i. How will adverse events and unanticipated problems involving risks to subjects or others be reported, reviewed and managed? Click or tap here to enter text.
ii. What provisions are in place for management of interim results? Click or tap here to enter text.
iii. What will the multi-site process be for protocol modifications? Click or tap here to enter text.

4. Potential Benefits: Identify any benefits that may be reasonably expected to result from the research, either to the participant(s) or to society at large. (*Payment of participants is not considered a benefit in this context of the risk benefit assessment.)*

The potential improved individual and relational well-being of persons with AD and related dementias and their spouses can have far-reaching implications. Not only may the intervention have a positive impact on individuals but also the health care system and broader communities. The relative risk to participant in this pilot work is negligible. The greatest risk may be that participants are involved in an alternative psychological treatment that ultimately proves to be no more effective than the usual care they have already received. Thus, the risk-benefit ratio strongly favors the study participant.

SECTION VIII: RESEARCH ALTERNATIVES AND ECONOMIC CONSIDERATIONS

1. Alternatives: What other alternatives, if any, are available to the study participants outside of the research?

An alternative would be to not participate in this study.

2. Payments for Participation (Economic Considerations): Describe payments that will be made to participants, if any, the amount and timing of payments, and the conditions for receiving this compensation (if applicable). If you plan to hold a drawing, be sure to include the following on any consent or recruitment materials mentioning the lottery: 1) the value of the prize; 2) the sponsor of the prize (this cannot be a federal funding source); 3) the odds of winning; and 4) that there are no restrictions to winning.

Each participant (90 couples= 180 participants)
will be paid in increments, $25 for baseline, $25 for the Day 16 follow-up, , and $50 for the 3-month follow-up for a total of $200 per couple.

3. Costs for Participation (Economic Considerations): Clearly describe the participant's costs associated with participation in the research, if any, and the interventions or procedures of the study that will be provided at no cost to participants.

There are no costs to participants.

We would like to add the following to the consent forms. For those who have already completed the consent, we would like permission to call the participants and ask them this question.

Contact for Future Studies

We ask for your permission to contact you for participation in future studies that our

group may conduct. We may use your telephone number, your email address or your physical address to contact you.

I agree to be contacted regarding future studies I may qualify for: (initial your choice)

_____YES _____No

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