Study Application (Version 1.1)

1.0 General Information

***Enter the full title of your study:**

Evaluating the Effectiveness of an Online Small-Group Self-Management Workshop for Rural Caregivers of Individuals with Alzheimer's Disease and Related Dementias

***Enter the study alias:**

Workshop for rural ADRD caregivers
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

2.0 Add departments

2.1 and Specify Research Location:

Is Primary?	Department Name
◆	**UCSF** - *138335* - M_MED-CORE-DGIM

3.0 List the key study personnel: (Note: external and affiliated collaborators who are not in the UCSF directory can be identified later in the Qualifications of Key Study Personnel section at the end of the form)

3.1 *Please add a Principal Investigator for the study:

Yank, Veronica, MD

Select if applicable

☐ Department Chair ☐ Resident

☐ Fellow

If the Principal Investigator is a Fellow, the name of the Faculty Advisor must be supplied below.

3.2 If applicable, please select the Research Staff personnel

A) Additional Investigators

Cheng, Jing, PhD
Other Investigator
Chesla, Catherine, RN, PhD, FAAN
Other Investigator
Covinsky, Kenneth E
Other Investigator
Karliner, Leah, MD
Other Investigator

B) Research Support Staff

Barajas, Raquel
Research Assistant
Santoyo-Olsson, Jasmine
Study Coordinator

3.3 *Please add a Study Contact

Agarwal, Sanjhavi
Barajas, Raquel
Santoyo-Olsson, Jasmine
Santoyo-Olsson, Jasmine
Yank, Veronica, MD

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

3.4 If applicable, please add a Faculty Advisor/Mentor:

3.5 If applicable, please select the Designated Department Approval(s)

Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. the Department Chair or Dean).

4.0 Initial Screening Questions

Updated June 2017

4.1 * PROJECT SUMMARY: (REQUIRED) Give a brief overview of this project (250 words or less). Tell us what this study is about, who is being studied, and what it aims to achieve. If you have an NIH Abstract, paste it here: Click on the orange question mark to the right for more detailed instructions.

Among 13 million informal caregivers of individuals with Alzheimer's disease or related dementias, an estimated 1.4 million live in rural areas of the US. These caregivers are a vulnerable group due to their physical isolation and well-documented rural disparities in health care access and quality. Many rural dementia caregivers experience serious health consequences due to caregiving responsibilities that can limit their ability to maintain their caregiving role. Thus, there is an pressing need for effective, scalable, and accessible programs to support rural dementia caregivers so that they can sustain their own well-being and effective caregiving within the home environments of their loved ones.

Online programs offer a convenient and readily translatable option for program delivery because they can be accessed by caregivers in the home environment and at the convenience of the user. *Building Better Caregivers* is an online 6-week, interactive, small-group self-management, social support, and skills-building workshop developed for caregivers of individuals with Alzheimer's disease or related forms of dementia. In our evaluations of the program in non-randomized studies, caregivers experienced significant improvements in stress, depression symptoms, and self-efficacy and partners experienced improved well-being.

Building on these encouraging preliminary findings, we now propose to conduct a hybrid effectiveness-implementation randomized controlled trial that will enroll and randomize 640 rural dementia caregivers into two groups: 320 in the intervention (workshop) group and 320 in the

attention control group. Caregivers will be recruited through 19 community organizations (serving rural communities in 17 states). Primary outcomes will be caregiver stress and depression symptoms. We hypothesize that stress scores and depression symptoms will be significantly improved at 12 months in the intervention group versus control group. We will also identify key strengths (facilitators) and weaknesses (barriers) of workshop implementation. We will use the RE-AIM implementation framework and a mixed methods approach to identify implementation characteristics pertinent to both caregivers and rural community organizations.

If the *Building Better Caregivers* workshop is proven to be effective, this research has the potential to open new research horizons, particularly on how to reach and effectively support isolated dementia caregivers in rural areas with an intervention that is scalable, even in low-resourced settings. If the workshop can achieve its goals with rural dementia caregivers, some of those most isolated, it would also be expected to be scalable in other low-resourced settings (e.g., in urban or suburban environments).

4.2 * HUD DEVICE: (REQUIRED) Does this application involve a Humanitarian Use Device (HUD):

- (•) No
- ( ) Yes, and it includes a research component
- ( ) Yes, and it involves clinical care ONLY

4.3 * TYPE OF RESEARCH: (Click the Help link for definitions and guidance): (REQUIRED)

- ( ) Biomedical research
- (•) Social, behavioral, educational, and/or public policy research
- ( ) Hybrid - includes aspects of BOTH types of research (check this option if your research is mainly social/behavioral but also involves specimen collection or blood draws to look at biological measures)

4.4 * SUBJECT CONTACT: (REQUIRED) Does this study involve ANY contact or interactions with participants:

- (•) Yes (including phone, email or web contact)
- ( ) No (limited to medical records review, biological specimen analysis, and/or data analysis)

4.5 * RADIATION EXPOSURE: Does your protocol involve any radiation exposure to patients/subjects EITHER from standard care OR for research purposes (e.g., x-rays, CT-scans, DEXA, CT-guided biopsy, radiation therapy, or nuclear medicine including PET, MUGA or bone scans): (REQUIRED)

- ( ) Yes (•) No

4.6 * RISK LEVEL: (REQUIRED) What is your estimation of the risk level, including all screening procedures and study activities (Help Text updated 9/13):

- (•) Minimal risk
- ( ) Greater than minimal risk

4.7 * REVIEW LEVEL: (REQUIRED) Requested review level (Click on the orange question mark to the right for definitions and guidance):

- ( ) Full Committee
- (•) Expedited
- ( ) Exempt

4.8 * EXPEDITED REVIEW CATEGORIES: (REQUIRED) If you think this study qualifies for expedited review, select the regulatory categories that the research falls under: (check all that apply)

- [ ] Category 1: A very limited number of studies of approved drugs and devices
- [ ] Category 2: Blood sampling
- [ ] Category 3: Noninvasive specimen collection (e.g. buccal swabs, urine, hair and nail clippings, etc.)
- [ ] Category 4: Noninvasive clinical procedures (e.g. physical sensors such as pulse oximeters, MRI, EKG, EEG, ultrasound, moderate exercise testing, etc.)
- [ ] Category 5: Research involving materials (data, documents, records, or specimens) that were previously collected for either nonresearch or research purposes
- [x] Category 6: Use of recordings (voice, video, digital or image)
- [x] Category 7: Low risk behavioral research or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

4.11 * CLINICAL TRIAL: (REQUIRED) Is this a clinical trial? According to The World Health Organization (WHO) and the International Committee of Medical Journal Editors (ICMJE) a clinical trial is:

- **Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.**

ICMJE requires registration of a clinical trial in a public database (such as ClinicalTrials.gov) prior to enrollment, for eventual publication of results in member biomedical journals. Guidance: Public Law 110-85 requires that all investigators who perform an *applicable clinical trial* must ensure that the trial is registered on a government web site called ClinicalTrials.gov. The FDA requires registration for "applicable clinical trials," defined as follows:

- **For any trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation.**
- **For trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance.**

For additional information on the ClinicalTrials.gov registration process at UCSF and the definition of a clinical trial for purposes of registration, visit the ClinicalTrials.gov section of the UCSF Clinical Research Resource HUB.

(•) Yes ( ) No

Clinical Trial Registration

"NCT" number for this trial:

pending

If you don't yet have the NCT#, type 'Pending.'

4.12 * CLINICAL TRIAL PHASE (REQUIRED) Check the applicable phase(s) (Help Text updated 9/13):

- [ ] Phase I
- [ ] Phase II
- [x] Phase III
- [ ] Phase IV

4.13 * INVESTIGATOR-INITIATED: (REQUIRED) Is this an investigator-initiated study:

(•) Yes ( ) No

4.14 * CANCER: (REQUIRED) Does this study involve cancer (e.g., the study involves patients with cancer or at risk for cancer, including behavioral research, epidemiological research, public policy

research, specimen analysis, and chart reviews):

○ Yes ◉ No

If you don't know if you should answer 'Yes' or 'No,' please **email** the Cancer Center's Protocol Review Committee for help.

4.15 SCIENTIFIC REVIEW: If this study has undergone scientific or scholarly review, please indicate which entity performed the review (check all that apply):

- ☐ Cancer Center Protocol Review Committee (PRC) (Full approval is required prior to final CHR approval for cancer-related protocols.)
- ☐ CTSI Clinical Research Services (CRS) Advisory Committee
- ☐ CTSI Consultation Services
- ☐ Departmental scientific review
- ☑ Other:

* Specify **Other: (REQUIRED)**

National Institute of Health of Health Center for Scientific Review Special Emphasis Panel: Health Disparities in Caregiving for Alzheimer's Disease

4.17 * FINANCIAL INTERESTS: (REQUIRED) Do you or any other responsible personnel (or the spouse, registered domestic partner and/or dependent children thereof) have financial interests related to this study:

○ Yes ◉ No

5.0 Funding

5.1 * FEDERAL FUNDING: (REQUIRED) Is this study currently supported in whole or in part by Federal funding, *even by a subcontract*, OR has it received ANY Federal funding in the past:

◉ Yes ○ No

The IRB is required to compare the grant to the IRB application for studies with federal support. Indicate which portion of your grant you will be attaching:

- ☑ For NIH grants, the Research Plan, including the Human Subjects Section
- ☐ For other federal proposals (contracts or grants), the section of the proposal describing human subjects work
- ☐ The section of your progress report if it provides the most current information about your human subjects work
- ☐ The grant is not attached. The study is funded by an award that does not describe specific plans for human subjects, such as career development awards (K awards), cooperative agreements, program projects, and training grants (T32 awards) OR UCSF (or the affiliate institution) is not the prime recipient of the award

5.2 * DoD INVOLVEMENT: Is this project linked in any way to the Department of Defense (DoD): (REQUIRED)

○ Yes ◉ No

5.3 SPONSORS: Identify all sponsors and provide the funding details. If funding comes from a Subcontract, please list only the Prime Sponsor:

External Sponsors:

View Details	Sponsor Name	Sponsor Type	Awardee Institution:	Contract Type:	Project Number	UCSF RAS System Award Number ("A" + 6 digits)
No Sponsor has been added to this IRB Study						

If the funding is coming through UCSF and you don't know the A or P number, you can search the eProposal side for the contract or grant (this does NOT replace adding the sponsor by name above AND entering the A or P number):

Project Status	Proposal Number	Project Title	Principal Investigator
No Projects are Linked to this IRB Study			

Other Funding Sources and Unfunded Research - Gift, Program, or Internal Funding (check all that apply):

- ☐ Funded by gift (specify source below)
- ☐ Funded by UCSF or UC-wide program (specify source below)
- ☐ Specific departmental funding (specify source below)
- ☐ Unfunded (miscellaneous departmental funding)
- ☐ Unfunded student project

6.0 Sites, Programs, Resources, and External IRB Review

6.1 UCSF AND AFFILIATED SITES (check all that apply):

- ☑ UCSF (including Laurel Heights and all the other sites outside the main hospitals)
- ☐ Parnassus
- ☐ Mission Bay
- ☐ China Basin
- ☐ Mount Zion
- ☐ Helen Diller Family Comprehensive Cancer Center
- ☐ Langley Porter Psychiatric Institute
- ☐ San Francisco General Hospital (SFGH)
- ☐ SF VA Medical Center (SF VAMC)
- ☐ Blood Centers of the Pacific (BCP)
- ☐ Blood Systems Research Institute (BSRI)
- ☐ Fresno Community Medical Center
- ☐ Gallo
- ☐ Gladstone
- ☐ Jewish Home

☐ Institute on Aging (IOA)
☐ SF Dept of Public Health (DPH)

6.2 LOCATIONS: At what locations will study visits and activities occur:

Community organizations will be engaged in all phases of the project via a longitudinal webinar- and list-serve-based Learning Collaborative. The confirmed sites include: California Center for Rural Policy, Humboldt Independent Practice Association, Elder Options, Eastern Idaho Community Action Partnership, Bluegrass Area Agency on Aging and Independent Living, Maine Health, MAC Incorporated (Maintaining Active Citizens), Elder Services of the Merrimack Valley, Inc., University of Nebraska Medical Center (UNMC) College of Nursing, Centralina Area Agency on Aging, North Carolina Department of Health and Human Services, Division of Aging and Adult Services, South Dakota State University, North Central Texas Council of Governments, Area Agency on Aging of North Texas, Area Agency on Aging of the Panhandle, Area Agency on Aging of Tarrant County, Texas A&M Center for Population Health and Aging, Wisconsin Institute for Healthy Aging, and Wyoming Center on Aging, University of Wyoming.

Study participants will be recruited through 19 community organizations (serving rural communities in 17 states). They will provide input on recruitment approaches and will provide organization preferences and suggestion for recruitment of the rural caregivers they serve. All centers have agreed to help with recruitment efforts by distributing flyers, posting flyers, mailings, brochures, radio ads, list-serve, etc.

Intervention group participants: will access the Building Better Caregivers 6-week program online at home. The workshop platform has the capability to track user engagement data such as number of workshop log-ins, website sections visited, number of postings/messages, action plans made and completed, and workshop completion.

Control group participants: will receive a mailed educational packet and two brief staff phone calls.

Survey data will be collected through online surveys completed by caregivers and conducted at baseline, post-intervention (1.5 months), and 6, and 12 months using the secure REDCap application. We will also give participants the option to complete questions by mail or phone interview.

6.3 OFF-SITE PROCEDURES: Will any study procedures or tests be conducted off-site by non-UCSF personnel:

○ Yes ◉ No

6.4 RESEARCH PROGRAMS: Check any UCSF research programs this study is associated with:

☐ Cancer Center
☐ Center for AIDS Prevention Sciences (CAPS)
☐ Global Health Sciences
☐ Immune Tolerance Network (ITN)
☐ Neurosciences Clinical Research Unit (NCRU)
☐ Osher Center
☐ Positive Health Program

6.5 * CTSI CRS SERVICES: (REQUIRED) Will this study be carried out at one of the UCSF Clinical Research Services (CRS) units or utilize CRS services:

○ Yes ◉ No

6.6 * MULTI-CENTER TRIAL: (REQUIRED) Is this a multicenter research trial? By multi-center trial, we mean a study where the protocol is developed by an industry sponsor, consortium, a disease-group, etc., who then selects sites across the nation or in different countries to participate in the trial. The local sites do not have any control over the design of the protocol.

○ Yes ◉ No

6.7 OTHER SITE TYPES: Check all the other types of sites not affiliated with UCSF with which you are cooperating or collaborating on this project: Do NOT check any boxes below if this is a multi-center clinical trial, UCSF is just one of the sites, and neither UCSF nor its affiliates are the coordinating center.

- ☐ Other UC Campus
- ☑ Other institution
- ☑ Other community-based site
- ☐ Foreign Country
- ☐ Sovereign Native American nation (e.g. Navajo Nation, Oglala Sioux Tribe, Havasupai, etc.)

6.10 * RELYING ON AN EXTERNAL IRB: Does this application include a request to rely on an external IRB other than the NCI IRB (e.g. UC reliance, private/commercial IRB, or institutional IRB): (REQUIRED)
Check out the orange question mark to the right to find out if your study is eligible for external IRB review.

○ Yes ◉ No

7.0 Outside Site Information

7.1 Outside Site Information

Click "Add a new row" to enter information for a site. Click it again to add a second site again to add a third site, a fourth site, etc.

Outside Site Information

Non-UCSF affiliated site information:

Site name:
California Center for Rural Policy

Contact name:
Connie Stewart

Email:

Phone:
707-826-3400

For Federally-funded studies only, corresponding FWA#:

*** The research at this site will be reviewed by:**

- ○ The non-affiliated site's IRB or a private IRB
- ○ The non-affiliated site is requesting UCSF to be the IRB of record for this study
- ◉ The non-affiliated site is not engaged in the human subjects research and has provided a letter of support

If the other site's IRB approval letter is available now, attach it to the application. If the IRB approval letter is not yet available, submit it once you receive it.

Or, if the other site is **not engaged** in human subjects research, attach the letter of support to your application.

Outside Site Information

Non-UCSF affiliated site information:

Site name:

Humboldt Independent Practice Association

Contact name:

Rosemary DenOuden

Email:

Phone:

707-443-4563

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

Elder Options

Contact name:

Kristen Griffis

Email:

Phone:

352-378-6649

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

Eastern Idaho Community Action Partnership

Contact name:

Morgan Nield

Email:

Phone:

208-522-5391

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

Bluegrass Area Agency on Aging and Independent Living

Contact name:

Lydia M. Jacobs

Email:

Phone:

859-269-8021

For Federally-funded studies only, corresponding FWA#:

*** The research at this site will be reviewed by:**

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

Maine Health

Contact name:

Margaret S. Haynes

Email:

Phone:

207-661-7001

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

MAC Incorporated (Maintaining Active Citizens)

Contact name:

Leigh Ann Eagle

Email:

Phone:

410-742-0505 x 136

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

Elder Services of the Merrimack Valley, Inc.

Contact name:

Rosanne DiStefano

Email:

Phone:

978-687-7747

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

University of Nebraska Medical Center (UNMC) College of Nursing

Contact name:

Sue Barnason PhD, RN, APRN-CNS, CEN, CCRN, FAHA, FAEN, FAAN

Email:

Phone:

402-472-7359

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

Centralina Area Agency on Aging

Contact name:

Linda H. Miller

Email:

Phone:

704-372-2416

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

North Carolina Department of Health & Human Services Division of Aging & Adult

Contact name:

Alicia Blater, M.S

Email:

alicia.blater@dhhs.nc.gov

Phone:

919-855-3400

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

South Dakota State University

Contact name:

Nancy L. Fahrenwald, PhD, RN, APHN-BC, FAAN

Email:

Phone:

605-688-5178

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

North Central Texas Council of Governments

Contact name:

Doni Green

Email:

dgreen@nctcog.org

Phone:

817-640-3300

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

Area Agency on Aging of North Texas

Contact name:

Rhonda K. Pogue

Email:

Phone:

940-322-5281

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

Area Agency on Aging of the Panhandle

Contact name:

Melissa Carter

Email:

Phone:

806-331-2227

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

Area Agency on Aging of Tarrant County

Contact name:

Donald R. Smith

Email:

Phone:

817-258-8000

For Federally-funded studies only, corresponding FWA#:

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Outside Site Information

Non-UCSF affiliated site information:

Site name:

Texas A&M Center for Population Health and Aging

Contact name:

Marcia Ory, PhD, MPH

Email:

Phone:

979-436-9368

For Federally-funded studies only, corresponding FWA#:

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- ○ The non-affiliated site is requesting UCSF to be the IRB of record for this study
- ◉ The non-affiliated site is not engaged in the human subjects research and has provided a letter of support

If the other site's IRB approval letter is available now, attach it to the application. If the IRB approval letter is not yet available, submit it once you receive it.

Or, if the other site is **not engaged** in human subjects research, attach the letter of support to your application.

Outside Site Information

Non-UCSF affiliated site information:

Site name:

Wisconsin Institute for Healthy Aging

Contact name:

Betsy J. Abramson

Email:

Phone:

608-243-5690

For Federally-funded studies only, corresponding FWA#:

*** The research at this site will be reviewed by:**

- ○ The non-affiliated site's IRB or a private IRB
- ○ The non-affiliated site is requesting UCSF to be the IRB of record for this study
- ◉ The non-affiliated site is not engaged in the human subjects research and has provided a letter of support

If the other site's IRB approval letter is available now, attach it to the application. If the IRB approval letter is not yet available, submit it once you receive it.

Or, if the other site is **not engaged** in human subjects research, attach the letter of support to your application.

Outside Site Information

Non-UCSF affiliated site information:

Site name:

Wyoming Center on Aging University of Wyoming

Contact name:

Christine L. McKibbin, Ph.D.

Email:

Phone:

307-766-2719

For Federally-funded studies only, corresponding FWA#:

*** The research at this site will be reviewed by:**

- ○ The non-affiliated site's IRB or a private IRB
- ○ The non-affiliated site is requesting UCSF to be the IRB of record for this study
- ◉ The non-affiliated site is not engaged in the human subjects research and has provided a letter of support

If the other site's IRB approval letter is available now, attach it to the application. If the IRB approval letter is not yet available, submit it once you receive it.

Or, if the other site is **not engaged** in human subjects research, attach the letter of support to your application.

Outside Site Information

Non-UCSF affiliated site information:

Site name:

Stanford University

Contact name:

Dolores Gallagher-Thompson, Ph.D., ABPP

Email:

Phone:

650-400-8172

For Federally-funded studies only, corresponding FWA#:

*** The research at this site will be reviewed by:**

- ○ The non-affiliated site's IRB or a private IRB
- ○ The non-affiliated site is requesting UCSF to be the IRB of record for this study
- ◉ The non-affiliated site is not engaged in the human subjects research and has provided a letter of support

If the other site's IRB approval letter is available now, attach it to the application. If the IRB approval letter is not yet available, submit it once you receive it.

Or, if the other site is **not engaged** in human subjects research, attach the letter of support to your application.

8.0 Research Plan and Procedures

8.1 This new consolidated section requests information about:

- **Hypothesis**
- **Aims**
- **Study Design**
- **Background and Significance**
- **Preliminary Studies**
- **Procedures**
- **Statistical Methods**
- **References**

Later sections include:

- **Drugs and Devices**
- **Sample Size, Eligibility, and Subjects**
- **Recruitment and Consent**
- **Risks and Benefits**
- **Data and Safety Monitoring Plan**
- **Confidentiality, Privacy and Security**

- **Financial Considerations**
- **Qualifications of Personnel**
- **Other Approval and Registrations**

8.2 HYPOTHESIS: Describe the hypothesis or what the study hopes to prove (Help Text updated 9/13):

We propose to conduct a hybrid effectiveness-implementation randomized controlled trial of the *B uilding Better Caregivers* online self-management workshop among rural caregivers of partners with Alzheimer's disease or other forms of dementia. We hypothesize that stress scores and depression symptoms will be significantly improved at 12 months in the intervention vs. control group (Aim 1). We also will identify the key strengths (facilitators) and weaknesses (barriers) of workshop implementation to characterize its potential to achieve widespread, community-based, real-world implementation in rural America (Aim 2).

8.3 AIMS: List the specific aims:

Aim 1: Evaluate the effectiveness of an online self-management workshop for rural informal caregivers of individuals with Alzheimer's disease. We will perform a 12-month randomized controlled trial of the *Building Better Caregivers* workshop by comparing validated self-reported outcomes for participants in the intervention group (n=320) and attention control group (n=320) on the primary outcomes of caregiver stress and depression symptoms. Nineteen community organizations and three national organizations serving rural communities in 17 states have agreed to partner with us on the proposed trial. We will recruit rural dementia caregivers from the many rural communities they serve.

Aim 2: Identify key strengths (facilitators) and weaknesses (barriers) of workshop implementation. For our implementation evaluation, we will use the RE-AIM framework and a mixed methods approach. To identify implementation characteristics pertinent to caregivers, we will identify patterns of experience across all workshop participants via analysis of implementation questions embedded in trial surveys administered to all participants. To more deeply understand these experiences, we will interview a sample of 60 caregivers—15 per US region (West, Midwest, Northeast, South). To determine implementation characteristics pertinent to community organizations, we will collect data from our partner community organizations on experiences of barriers and facilitators. Analyses will compare and contrast characteristics within and between organizations. Findings will identify essential elements of workshop implementation that should be incorporated into future implementation efforts. Findings on effective and ineffective strategies will inform the implementation of other online programs for rural, caregiver, and Alzheimer's disease populations.

8.4 DESIGN: Briefly describe the study design (e.g., observational, interventional, randomized, placebo-controlled, blinded, cross-over, cross-sectional, longitudinal, pharmacokinetic, etc.):

We will recruit 640 rural dementia caregiver adults through 19 community organizations (serving rural communities in 17 states to implement a randomized, attention controlled clinical trial. Caregivers will be randomized to receive the online intervention (workshop) group or attention control group. The online workshops will be facilitated by trained caregivers who will lead workshops. We will assess both primary and secondary outcomes at baseline, 1.5 months (post intervention), 6 and 12 months, with the main intervention group comparison being at 12 months. Interested control group caregivers also will be offered the workshop after the trial is completed.

Using mixed methods approach we will identify implementation characteristics pertinent to caregivers, identify patterns of experience across all workshop participants via analysis of implementation questions embedded in trial surveys administered to all participants. To more deeply understand these experiences, we will interview a sample of 60 caregivers—15 per US region (West, Midwest, Northeast, South).

To determine implementation characteristics pertinent to community organizations, we will collect data from our partner community organizations on experiences of barriers and facilitators. Analyses will compare and contrast characteristics within and between organizations. Findings will

identify essential elements of workshop implementation that should be incorporated into future implementation efforts. Findings on effective and ineffective strategies will inform the implementation of other online programs for rural, caregiver, and Alzheimer's disease populations.

8.5 BACKGROUND AND SIGNIFICANCE: Briefly provide the background and significance of this study (e.g. why is this study needed) (space limit: one half page):

Approximately 13 million informal caregivers provide critical support to US adults with Alzheimer's disease and other forms of dementia—enabling them to live safer, healthier, and more fulfilling lives in their homes and local communities. Informal caregivers ("caregivers") are usually unpaid family members or friends who help patient care recipients ("partners") manage their health conditions and day-to-day activities. Among dementia caregivers, an estimated 1.4 million live in rural areas. These caregivers are particularly vulnerable due to their geographic isolation and the well-documented rural disparities in health care access and quality. Many rural caregivers experience high levels of stress, depression, and other adverse health consequences due to these responsibilities, which can also limit their ability to maintain their caregiving role. Thus, there is a pressing need for scalable, accessible programs to support rural dementia caregivers so that they can sustain their own well-being and continue to provide care within the home environments of their loved ones.

There are several programs for dementia caregivers, but only two have been evaluated among rural caregivers, and neither used a randomized study design. In addition, well-established dementia caregiver programs (e.g., REACH, COPE, Tele-Savvy) are delivered in-person, one-on-one (e.g., by phone), or at set times of day, which can diminish uptake by caregivers who live in rural areas, cannot leave their partners alone, or have difficulty keeping regular appointments during the day when caregiver responsibilities are most intense. Isolated rural dementia caregivers also crave social interactions with peers. Online small group programs that are accessible at home at any time of day would be an ideal option for many such caregivers.

8.6 PRELIMINARY STUDIES: Briefly summarize any preliminary studies relevant to your proposed research (space limit: one half page):

Our team has developed and pilot tested an online 6-week, highly interactive, small-group self-management and skills-building workshop for caregivers of loved ones with dementia or cognitive impairment. The workshop, called Building Better Caregivers, is based on Self-Efficacy Theory boosted by enhanced social support and builds on substantial evidence from other dementia caregiver interventions and self-management programs. Every part of the workshop is designed to enhance caregiver self-management behaviors, dementia caregiving skills, and peer social support. In our evaluations of the program in non-randomized studies, caregivers experienced significant improvements in stress, depression symptoms, and self-efficacy (Cohen's d standardized effect size range 0.27-0.70), and partners experienced improved well-being (effect size = 0.40). Participation by rural dementia caregivers ranged from 30-50%, and the community organizations that partnered with us expressed enthusiasm for expanding the workshop reach to a greater number of rural dementia caregivers.

Building on these encouraging preliminary findings, we now propose to conduct a hybrid effectiveness-implementation randomized controlled trial of the Building Better Caregivers online self-management workshop among rural caregivers of partners with Alzheimer's disease or other forms of dementia. Effectiveness-implementation trials focus a priori on assessing both clinical effectiveness and implementation and can therefore reduce time to translation.

8.7 * TREATMENT PROTOCOL: Is this a treatment study, i.e. does this study intend to provide treatment to individuals with a medical or psychological condition: (REQUIRED)

○ Yes ◉ No

8.8 * BILLABLE PROCEDURES: Does this study involve any services or procedures (e.g. physical exams, surgeries, lab tests, imaging studies, or drugs) that could be billable to patients, their insurance, Sponsor, or any other entity (answer 'Yes' even if the study is going to pay for all the procedures): (REQUIRED)

○ Yes ◉ No

If you are not sure if your study involves billable procedures, send an email to the **UCSF Office of Clinical Research (OCR)** for help answering this question.

8.9 * COMMON RESEARCH ACTIVITIES: Types of research activities that will be carried out. Check all that apply and describe in more detail in the 'Procedures / Methods' section: (REQUIRED)

- [x] Interviews, questionnaires, surveys
- [ ] Educational or cognitive tests
- [ ] Focus groups
- [ ] Observation
- [ ] Non-invasive imaging or testing (MRI, EEG, pulse oximetry, etc.)
- [ ] Administration of contrast agent
- [ ] Imaging procedures or treatment procedures that involve radiation (x-rays, CT scans, CT-guided biopsies, DEXA scans, MUGA or PET scan)
- [ ] Biopsy conducted solely for research purposes
- [ ] Use of placebo
- [ ] Sham surgical procedure
- [ ] Collection of data from wearable tech such as Fitbit, Apple Watch, Garmin, motion actigraphs, etc.)
- [ ] Fitness tests or other exertion activities
- [ ] Use of mobile health apps or other apps
- [ ] Social media-based research activities
- [ ] None of the above

8.10 * PROCEDURES / METHODS: (REQUIRED)

Describe the research methods and study activities taking place at each site (e.g. what will participants be asked to do and what will members of the study team do?). If there will be multiple participant groups or study sites, explain what will happen with each group or study sites.

If some of the activities would occur even if the person were not in the study, as in the case of treatment or tests performed for diagnostic purposes, clearly differentiate between those activities that will be done solely for research purposes and those that are happening as part of routine care.

Please call our office at 415-476-1814 and ask to speak to someone on the Expedited Review team if you need help differentiating between what parts are research and what parts aren't.

For Aim 1-Procedures for RCT.

Only #1 below will be done if a potential participant does not enroll in the study.

1. **Eligibility:** Eligibility will be determined by an anonymous online screening survey. Potential participants will also be given the option to complete it by mail or phone, if they prefer. Potential participants will be asked their age, gender, to indicate the outreach effort(s) they are responding to in which targeted rural communities, followed by the eligibility criteria: caring for patient with dementia (PWD); able to read and write in English; able to access the internet; providing care for ≥ 10 hours per week.

2. **Informed consent:** After confirming eligibility they will read all consent forms (written at the 6th grade level) online. These will be formatted so that they can print them out if desired. They will be offered the opportunity to discuss the study by email or phone with the study coordinator or PI. Those comfortable doing so will then complete the online consent form (or a mailed hardcopy, if they prefer).

3. **Randomization.** Caregivers will be randomized after completion of enrollment and the baseline survey (see4a). Staff will inform study participants about treatment assignment by e-mail or telephone (according to caregiver preference). Caregivers will be randomized to 6-week intervention or attention control group.

4. **Activities by group:**

a. **Intervention group.** Participants will receive the Building Better Caregivers workshop. Building Better Caregivers is an online 6-week, interactive, small-group self-management, social support, and skills-building workshop developed for caregivers of individuals with Alzheimer's disease or related forms of dementia. Workshop content encompasses two complementary categories—topics that address caregiver self-management and topics that focus on dementia caregiving skills. Workshops consist of 20-25 persons. Each week, participants are asked to log on at least 2-3 times for a total time of approximately two hours. Activities are guided by two peer co-facilitators (caregivers themselves). Caregiver participation does not require "real time" attendance at pre-determined times. Caregivers interact in group discussions and person-to-person communications by making postings on discussion boards and sending individual messages. They can write these at any time of day or night. Such participant interactions are frequent and similar to email, Facebook, or texting exchanges. Each week focuses on the introduction of 2-3 new topics, with some key topics repeated in subsequent weeks. Lessons are then reinforced in the Discussion Center section of the website, where the peer social support occurs.

Information on the workshop facilitators:

All facilitators are originally leaders of another onlinee small group workshop called the chronic disease self-management program and have completed 4 days of training for that program. There are more than 5000 of these people nationwide. Those who are caregivers (of persons with dementia or other chronic conditions) and are interested in receiving additional training are offered the opportunity to become *Building Better Caregivers* facilitators. They then receive additional training in a series of webinars that familiarize them with the workshop and train them to follow the workshop facilitator manual. The manual guides them through all workshop topics, activities, and anticipated participant interactions. Facilitators must demonstrate mastery of the material. Finally, they co-facilitator their first workshop with an experienced facilitator and are mentored by an experienced trainer. Only after this do they become a fully-qualified facilitator. Canary Health (the health technology company that is licensed by Stanford University to administer the workshop) already has a robust cadre of these facilitators that guide workshops for Veteran caregivers. Facilitators can lead workshops remotely from anywhere in the US and are paid to do so. All workshop interactions are recorded on the workshop platform, such that fidelity tracking is streamlined. We will use this to perform fidelity monitoring in the current study. Dr. Yank and research staff will perform intervention fidelity monitoring. We will use a fidelity assessment instrument to evaluate online recordings on a weekly basis. If facilitators stray from the facilitator manual they will receive immediate remedial training from Dr. Yank or Dr. Lorig. If they continue to depart from the manual they will be removed from their role and another facilitator will be brought in to serve as co-facilitator.

Weekly topics that are covered in readings, activities,and discussions include those that focus on caregiver self-management and those that focus on dementia caregiving:

Self-management topics

- Making an action plan
- Problem-solving
- Managing stress
- Managing difficult emotions
- Helpful and unhelpful thinking
- Finding ways to relax
- Health eating
- Physical activity/exercise
- Getting a good night's sleep
- Improving fatigue

Dementia caregiving topics

- Difficult care partner behaviors--how to understand and manage
- Getting help inside and outside the home (e.g., adult daycare, in-home care)
- Managing medications
- Safety concerns (e.g., wandering, driving)
- Communication--how to understand and improve
- Working with health care systems and providers
- Making decisions about medication care (e.g., goals of care)
- Planning for the future/legal issues (e.g., durable power of attorney)
- Finanial issues (e.g., financial planning, wills)

These topics are covered in the Learning Center, discussed in the Discussion Center, and can be reinforced using tools in the My Tools area of the website, which are described further below:

- The Learning Center is where participants learn self-management techniques. Each week, new content is made available. Past weeks' content also remains available. The Learning Center is self-directed in that participants can control the speed and timing of their reading and lessons.
- The Discussion Center is interactive and includes four directed bulletin boards where discussions and interaction occur and are facilitated by the trained facilitators: the action-planning board, the problem-solving board, the difficult emotions board, and the celebrations board.
- My Tools is a personal area accessible only by the participant and contains such tools as journals, exercise monitoring logs, and medication records.

For intervention group fidelity purposes. All workshop interactions are recorded via screen shots on the workshop platform, such that fidelity tracking is streamlined. Dr. Yank, Dr. Lorig or research staff will perform intervention fidelity monitoring. We will use the fidelity assessment instrument to evaluate online recordings on a weekly basis. If facilitators stray from the facilitator manual they will receive immediate remedial training from Dr. Lorig or Yank. If they continue to depart from the manual they will be removed from their role and another facilitator will be brought in to serve as co-facilitator.

b. **Attention control group.** Participants will receive written materials on dementia and caregiver resources and two brief phone calls of 15-30 minutes apiece by research staff. Caregivers in the attention control group will be offered the online workshop after the 12 month trial is completed if they so desire. The written materials and phone call guides are still under development and will be submitted to the IRB for review as a modification request.

For control group fidelity purposes. Phone calls will be recorded. Dr. Yank and the research coordinator will evaluate recordings using a fidelity assessment instrument. Staff who stray from the phone call protocol will receive immediate remedial training. If an RA strays from the protocol again, he/she will be removed from making phone calls. At the outset of the trial, fidelity assessment will occur approximately every 4-5 calls to assure fidelity patterns are quickly established and reinforced. Subsequent checks will occur every 10-12 calls.

5. **Assessments:** Data will be collected at baseline, 1.5 months (post intervention), 6 months, and 12 months. Data will be collected through online surveys completed by caregivers and conducted at baseline, post-intervention (1.5 months), and 6, and 12 months using the secure REDCap application. Assessments are expected to be 20 minutes each. Participants will be given the option to complete surveys by mail or phone interview.

a. **Baseline** questions will ask about caregiver and PWD demographic information (e.g., age, gender, race/ethnicity, education); caregiving relationship to PWD (e.g., spouse, child), and resources participants are accessing (e.g., paid in-home care). Baseline questions also will identify caregiver and partner chronic conditions (e.g., using the Charlson comorbidity index), partner need for assistance with ADLs and IADLs, and dementia characteristics (e.g., diagnosis, length of diagnosis, degree of impairment, presence of behavioral symptoms). Caregiver (CG) stress level (Stress visual numeric scale), CG depression symptoms (PHQ-8 score), Self-efficacy (Revised Scale for Caregiver Self-efficacy), Burden (Zarit Burden Inventory), Strain (Caregiver Strain Index), Global health score, and Healthcare utilization items.

b. **1.5 months**. We will administer the Caregiver (CG) stress level (Stress visual numeric scale), CG depression symptoms (PHQ-8 score), Self-efficacy (Revised Scale for Caregiver Self-efficacy), Burden (Zarit Burden Inventory), Strain (Caregiver Strain Index), Global health score, and Healthcare utilization items. For participants randomized to the

intervention group will be given additional questions on Reach (e.g., how heard about trial, reasons for participation); Implementation (e.g., ease of/barriers to logging into workshop and performing online activities, whether completed the workshop and, if not, why not); and Maintenance (e.g., whether workshop experiences have continued to influence their self-care or caregiving practices or own/partner's health).

c. **6 months**. We will administer the Caregiver (CG) stress level (Stress visual numeric scale), CG depression symptoms (PHQ-8 score), Self-efficacy (Revised Scale for Caregiver Self-efficacy), Burden (Zarit Burden Inventory), Strain (Caregiver Strain Index), Global health score, and Healthcare utilization items. For participants randomized to the intervention group will be given additional questions on Reach (e.g., how heard about trial, reasons for participation); Implementation (e.g., ease of/barriers to logging into workshop and performing online activities, whether completed the workshop and, if not, why not); and Maintenance (e.g., whether workshop experiences have continued to influence their self-care or caregiving practices or own/partner's health).

d. **12 months**. We will administer the Caregiver (CG) stress level (Stress visual numeric scale), CG depression symptoms (PHQ-8 score), Self-efficacy (Revised Scale for Caregiver Self-efficacy), Burden (Zarit Burden Inventory), Strain (Caregiver Strain Index), Global health score, and Healthcare utilization items. For participants randomized to the intervention group will be given additional questions on Reach (e.g., how heard about trial, reasons for participation); Implementation (e.g., ease of/barriers to logging into workshop and performing online activities, whether completed the workshop and, if not, why not); and Maintenance (e.g., whether workshop experiences have continued to influence their self-care or caregiving practices or own/partner's health).

For Aim 2-Procedures for In-depth Interviews.

We will randomly select a sub-set of intervention group caregivers for semi-structured telephone interviews regarding workshop implementation characteristics. We will sample for caregivers (n=60 total) from all US regions (n=15 per region—West, Midwest, South, Northeast) to achieve the expected saturation of themes within 12-15 interviews/region.

In the 30-minute telephone interview we will probe for deeper understanding of the caregiver's impressions of and responses to the workshop. Interviews will be audiorecorded and electronically stored on secure computers. Following each interview, the interviewer will write a summary of the content of the interview to assist with subsequent analysis of audiorecordings. Professionals will transcribe and anonymize recordings.

Interviewers will ask caregivers questions about workshop Implementation and Maintenance (e. g., What helped you be able to participate in the workshop? Are there other things that would have made it easier for you?, What got in the way of your participation in the workshop? Can you describe things that would help you overcome these problems?, What workshop activities did you participate in and why did you? What activities did you not participate in and why not?, What aspects of the workshop most impacted your caregiving? What workshop lessons or skills have you continued to use?, Can you describe the impact the workshop has had on you or your partner?).

For Aim 1 and 2-Procedures for Learning Collaborative.

We will establish a Learning Collaborative for our participating community organizations. The Learning Collaborative will enable efficient collection of implementation data, while simultaneously promoting regional and national networking and peer-to-peer learning among organizations serving similar populations of rural caregivers and PWD. Activities will span Years 1-5.

The Learning collaborative will consist of biannual 90-minute webinars and a longitudinal list-serve to promote discussion and information exchange. All webinars will have a similar structure. Dr. Yank will facilitate these. The first half will be devoted to a discussion of aspects of workshop implementation. We also will track the use of different outreach strategies and subsequent successful (or unsuccessful) recruitment to inform future implementation efforts. The second half of the webinars will include lectures on and discussion of caregiving and Alzheimer's disease topics relevant to the organizations. Organizations will be invited to nominate topics and speakers during study Year 1 and on an ad hoc basis subsequently. Some webinars may be audio recorded for note purposes.

In addition, members will use a list-serve for learning from each other (e.g., discussing challenges, exchanging tips). Periodically, the research team will make posts to the list-serve to prompt group discussion of specific implementation questions, concerns, or success stories. We will also ask for descriptive data related to their organization.

8.12 INSTRUMENTS: List all questionnaires, surveys, interview, or focus group guides that will be used for this study:

If the instruments are not complete or not available because they will be developed as part of this study, describe the basic content or include an outline and submit the final versions to the IRB with a modification for approval prior to use.

Aim 1 Instrument.

Descriptive variables.

- Baseline questions will ask about caregiver and patient with dementia (PWD) demographic information (e.g., age, gender, race/ethnicity, education);
- caregiving relationship to PWD (e.g., spouse, child),
- resources participants are accessing (e.g., paid in-home care).
- caregiver and PWD chronic conditions (e.g., using the Charlson comorbidity index),
- PWD need for assistance with Activities of Daily Living (ADLs) and Instrumental Activities of Daily Living (IADLs),
- PWD dementia characteristics (e.g., diagnosis, length of diagnosis, degree of impairment, presence of behavioral symptoms).

Primary outcomes.

- Caregivers describe high personal stress as one of the most challenging aspects of being a caregiver. We will use a single-item visual numeric scale (range 1-10) developed by our team. Visual numeric scales [VNS] have been shown to correlate well [r = .72] with same-worded visual analogue scales [VAS] and generate higher completion rates.
- We will measure the co-primary outcome of caregiver depression symptoms with an 8-item modified and validated version of the PHQ-9.

Secondary outcomes.

- Self-efficacy will be measured with the 15-item Caregiver Self-Efficacy scale.
- Caregiving burden will be assessed with the 12-item short form of the Zarit Burden Inventory.
- The modified 13-item Caregiver Strain Index will measures caregiver strain.
- Single-item caregiver-reported data will be collected on caregiver and PWD global health, hospitalizations, and emergency room visits.
- We will use the National Health and Nutrition Survey question on global health.
- We will measure healthcare utilization using single-item questions on hospitalizations and emergency room visits that have been demonstrated in multiple studies to be reliable within the 6-month recall time frame we are using, including among dementia caregivers.

For intervetion arm only: We will embed implementation questions administered to all intervention group caregivers at baseline and months 1.5, 6, and 12. Questions will ask about various aspects (e.g., how heard about trial, reasons for participation, ease of/barriers to logging into workshop and performing online activities, whether completed the workshop and, if not, why not; whether workshop experiences have continued to influence their self-care or caregiving practices or own/partner's health).

Fidelity monitoring assessment. We will use the fidelity assessment instrument from pilot studies to evaluate online recordings on a weekly basis for the intervention group. Similarly, we will use a fidelity assessment instrument to evaluate phone calls for the attention control group.

Aim 2 Instrument.

We will develop an instrument that will be adminsted to a randomly selected sub-set of intervention group caregivers for semi-structured telephone interviews regarding workshop implementation characteristics. We will probe for deeper understanding of the caregiver's impressions of and responses to the workshop. This instrument will ask caregivers questions about workshop *Implementation* and *Maintenance*. *Implementation* (e.g., ease of/barriers to logging into workshop and performing online activities, whether completed the workshop and, if not, why not) and *Maintenance* (e.g., whether workshop experiences have continued to influence their self-care or caregiving practices or own/partner's health).

Aim 1 and 2 Learning Collaborative Instrument.

We will collect descriptive information about our partner agencies (e.g., rural region covered, agency type, caregiver services provided, etc.)

Attach any unpublished instruments in the 'Other Study Documents' section of the Initial Review Submission Packet form after completing the study application. Published instruments should NOT be attached.

8.13 * BIOSPECIMEN COLLECTION: Are you drawing any blood or collecting other biosamples (e.g. tissue, buccal swabs, urine, saliva, hair, etc.): (REQUIRED)

○ Yes ◉ No

8.26 STATISTICAL METHODS: Briefly summarize the methods and types of analyses that will be performed:

Aim 1 Data Analysis Methods.

Descriptive analyses. Caregiver and caregiver-reported partner socio-demographic characteristics, chronic conditions, and health utilization outcomes will be summarized as means (±SD), frequencies, percentages, and 95% confidence intervals at baseline and 1.5, 6, and 12 months. The distributions of covariates at baseline will be checked for balance between the two groups with histograms and/or boxplots.

Primary analyses. Primary analyses will compare caregiver stress (stress score) and depression symptoms (PHQ-8 score) between intervention and control groups over time with respective linear mixed effects models. Linear mixed effects models use all available observations in the data, assume data are missing at random, and provide an intention-to-treat analysis. Models will include group, time, and (group*time) interaction terms as fixed effects and community organizations and subjects as random effects to account for the correlation within organizations and subjects due to measurements over time. Covariates with imbalanced distributions between the two groups will also be included in the models to control for potential confounding. The (group*time) interaction term will be used to evaluate if the two groups differ in outcomes over time. The study is powered to allow 30% loss to follow up. To assess for potential differential withdrawal between groups, comparisons of withdrawal rates and time to withdrawal will be performed. Models based on a potential outcome framework will be used to assess treatment effect while accounting for noncompliance and missing data and to examine potential treatment mechanisms/pathways via intermediate variables (such as social support, self-efficacy, caregiving skills). Multiple imputation based on reasonable assumptions on mechanisms of missing data will be used to perform sensitivity analyses.

Secondary analyses. Secondary analyses will use (generalized) linear mixed effect models similar to the primary mixed effect models for continuous, categorical, and count secondary outcomes. Treatment effects in subgroups (e.g. by sex) of our interest will be evaluated using (generalized) linear mixed effect models with corresponding interactions of group, time and sex while controlling for false discovery rate. We expect a small and balanced recall error between the two groups but if recall error is unbalanced, measurement error models will be considered for treatment evaluation. We will examine loss to follow-up by comparing caregivers lost to follow-up to those who complete the study.

Aim 2 Data Analysis Methods.

We will use mixed methods and multiple data sources to generate findings. We will identify facilitators and barriers of workshop implementation pertinent to caregivers.

Data analyses using all intervention caregivers' : We will embed implementation questions in the web-based trial surveys administered to all intervention group caregivers at baseline and months 1.5, 6, and 12. We will perform descriptive and comparative analyses of the survey-based and platform-derived data to identify notable barriers and facilitators of workshop implementation for intervention group caregivers. For example, we will analyze participation rate by caregiver sub-groups (e.g., region, age, gender, race/ethnicity). Findings will identify the degree to which *Building Better Caregivers* successfully achieves the Reach, Implementation, and Maintenance domains of RE-AIM for caregivers.

Data analyses using a subest of intervention caregivers: We will sample for caregivers (n=60 total) from all US regions (n=15 per region—West, Midwest, South, Northeast) to achieve the expected saturation of themes within 12-15 interviews/region. Using data collected through telephone-based 30 minute interviews we will probe for deeper understanding of the caregiver's impressions of and responses to the workshop. Interviews will be audiorecorded and electronically stored on secure computers. Professionals will transcribe and anonymize recordings. A code key linking transcripts to participants will be kept in a secure electronic file accessible to only the study PI and research coordinator. Data analysis will be conducted concurrently with ongoing data collection to ensure timely generation of findings. Interview transcripts and summary notes will be uploaded into NVivo qualitative data management and analysis software. Using NVivo the coding team will perform thematic analysis of interview transcripts. The coding team will consist of the research coordinator and RA. They will read each transcript and assign codes to identify emergent themes and also apply *a priori* deductive codes derived from the RE-AIM framework. After coding approximately 6-7 transcripts, the coding team will convene with Drs. Yank and Chesla (investigators with qualitative research expertise) to compare and discuss individual styles of coding and approaches to achieve coding consistency and begin to identify among emergent codes whether there are relevant sub-codes to be agreed upon. The coding team and investigators will meet for a similar discussion following coding of an additional 6-7 transcripts to assure consistency. After coding is completed, the same group will convene, discuss, and reach consensus on interview themes, qualitative findings, and illustrative quotes.

8.27 REFERENCES: List only the 5-10 most relevant references (a separate bibliography can be attached for reference purposes if this study involves novel approaches, agents, or an emerging technology that the IRB may not be familiar with):

1. Lorig K, Thompson-Gallagher D, Traylor L, et al. Building Better Caregivers: a pilot online support workshop for family caregivers of cognitively impaired adults. *Journal of Applied Gerontology.* 2012;31:423-437. http://journals.sagepub.com/doi/10.1177/0733464810389806
2. Lorig K, Ritter PL, Laurent DD, Yank V. Building Better Caregivers: A pragmatic 12-month trial of a community-based workshop for caregivers of cognitively impaired adults. J Applied Gerontol. 2017 Nov 1:733464817741682. doi: 10.1177/0733464817741682.
3. Ma J, Yank V, Xiao L, et al. Translating the Diabetes Prevention Program Lifestyle Intervention into primary care: A randomized trial. *JAMA Intern Med.* 2013;173:113-121. PMCID: PMC3856315.
4. Fitzgerald JD, Johnson L, Hire DG, et al. Association of objectively-measured physical activity with cardiovascular risk in mobility-limited older adults. *J Amer Heart Assoc.* 2015; 4(2):pii: e001288. PMCID: PMC4345863.
5. Yank V, Tribett E, Green L, Pettis J. Learning from marketing: rapid development of medication messages that engage patients. *Patient education and counseling.* 2015;98: 1025-1024. PMCID: PMC4684954.

9.0 Drugs and Devices

9.1 * DRUGS AND/OR BIOLOGICS: Are you STUDYING any drugs and/or biologics that are either approved or unapproved: (REQUIRED)

○ Yes ◉ No

9.3 * MEDICAL DEVICES: Are you STUDYING any medical devices, in vitro diagnostics, or assays that are either approved or unapproved:(REQUIRED)

○ Yes ◉ No

10.0 Sample Size and Eligibility Criteria

10.1 ENROLLMENT TARGET: How many people will you enroll:

678

If there are multiple participant groups, indicate how many people will be in each group:

For Aim 1 Sample for RCT. We will recruit 640 rural dementia caregiver adults through 19 community organizations (serving rural communities in 17 states to implement a randomized, attention controlled clinical trial. 320 in the intervention group and 320 in the control group for a total of n=640.

For Aim 2 Sample for In-depth Interviews. We will randomly select a sub-set of intervention group caregivers for semi-structured telephone interviews regarding workshop implementation characteristics. We will sample for caregivers (n=60 total) from all US regions (n=15 per region—West, Midwest, South, Northeast).

For Aim 1 and Aim 2 Sample for Learning Collaborative. 19 community organizations (serving rural communities in 17 states) will have at most 2 representatives participating in the Learning Collaborative (n=2*19=38).

10.3 SAMPLE SIZE JUSTIFICATION: Explain how and why the number of people was chosen. For multi-site studies, this is referring to the number that will be enrolled across all sites:

The study is powered on the co-primary outcome with the lowest effect size in pilot studies—the PHQ-8 depression symptoms score (effect size 0.27). We will use a recruitment target of 640 participants. We assume 30% loss to follow-up, thus expecting 448 caregivers (224 per group) will complete the study at 12 months. This sample size of 448 will allow us to detect a PHQ-8 effect size of 0.265 with a power of 0.8 at a significance level of 0.05 (two-sided). The effect size of 0.265 corresponds to a 1.5 difference in PHQ-8 score (range 0-24) between groups assuming a common standard deviation of 5.6. We also will have the power to detect a 1.4 difference in the co-primary outcome of stress score (range 0-10) between the two groups.

If we encounter problems meeting trial enrollment benchmarks, we will work with local organizations and others to find alternative recruitment strategies such as health system-based patient portals or recruitment through national caregiver discussion groups. We also can add additional partner organizations after the start of the study.

10.4 * PARTICIPANT AGE RANGE: Eligible age ranges: (REQUIRED)

- [ ] 0-6 years
- [ ] 7-12 years
- [ ] 13-17 years
- [x] 18-64 years
- [x] 65+

10.5 * STUDY POPULATIONS: Data will be collected from or about the following types of people (check all that apply): (REQUIRED)

- [ ] Inpatients
- [ ] Outpatients
- [x] Family members or caregivers
- [ ] Providers
- [ ] People who have a condition but who are not being seen as patients
- [ ] Healthy volunteers
- [ ] Students
- [x] Staff of UCSF or affiliated institutions
- [ ] None of the above

10.6 * SPECIAL SUBJECT GROUPS: Check the populations that may be enrolled: (REQUIRED)

- [ ] Children / Minors
- [ ] Subjects unable to consent for themselves
- [ ] Subjects unable to consent for themselves (emergency setting)
- [ ] Subjects with diminished capacity to consent
- [ ] Subjects unable to read, speak or understand English
- [ ] Pregnant women
- [ ] Fetuses
- [ ] Neonates
- [ ] Prisoners
- [ ] Economically or educationally disadvantaged persons
- [x] None of the above

10.7 INCLUSION CRITERIA: Briefly describe the population(s) that will be involved in this study. Include anyone that data will be collected from or about (e.g. patients, healthy controls, caregivers, providers, administrators, students, parents, family members, etc.):

For Aim 1 RCT Sample Inclusion Criteria. We will include participants 1) who are 18 years or older, 2) responding to outreach efforts in targeted rural communities, 3) caring for person with dementia (PWD), 4) able to read and write in English, 5) able to access the internet, and 6) providing care for ≥ 10 hours per week*.

*We define "care" as the full range of caregiving activities, rather than a specific sub-set, because national data indicate that most caregivers perform a mixture of tasks. Caregivers performing medium-to-high burden care do so for, on average, ≥ 10 hours/week, assist with ≥ 2 activities of daily living (ADLs) (e.g., dressing) and ≥ 4 instrumental ADLs (e.g., meal preparation), and perform medical tasks, health care coordination, and advocacy. The time threshold of ≥ 10 hours /week is therefore pragmatic, similar to criteria used in other studies, and will identify caregivers experiencing higher burden—those at increased risk for poor personal health outcomes and thus most likely to benefit from the intervention.

For Aim 2 Sample Inclusion Criteria for debriefing interviews with caregivers, must have participated in the Building Better Caregivers workshop.

For Aim 1 and 2 Sample Inclusion Criteria for Learning Collaborative participation are: community member within a community organization that is participating in the Learning Collaborative.

10.8 EXCLUSION CRITERIA: List any exclusion criteria (e.g. reasons why someone would not be included in the study):

For Aim 1 RCT Sample Exclusion Criteria. We will exclude participants who 1) have an anticipated inability to complete the 12-month follow-up (e.g., planned travel), 2) partner living in a skilled nursing or similar facility, and 3) zip code of residence not a US-Census defined rural region.

10.9 * RESEARCH CONDUCTED ON PATIENT CARE WARDS: Do any study activities take place on patient care units at UCSF medical facilities: (REQUIRED)

- ( ) Yes
- (•) No

11.0 Recruitment and Consent

11.1 * RECRUITMENT METHODS: What kinds of methods will be used to identify potential participants for recruitment (check all that apply): (REQUIRED)

- [ ] Medical records review
- [ ] Recruitment registry
- [ ] Re-contact of participants from the investigators' previous studies
- [ ] Referrals from colleagues (attach the 'Dear Colleague' letter or other recruitment materials you will provide to colleagues)
- [x] Referrals from the community / word of mouth
- [x] Advertisements (flyers, brochures, radio or t.v. ads, posting on clinical research sites or social media, presentation of the study at community events/media, etc.)
- [ ] Online recruiting tool such as TrialSpark
- [ ] CTSI Recruitment Services unit
- [ ] Other method (describe below)

Attach your recruitment materials (e.g., flyers, ads, recruitment letter templates, email text, etc.) in the Other Study Documents section of the Initial Review Submission Packet Form.

11.3 DETERMINATION OF ELIGIBILITY: How, when, and by whom will eligibility for recruitment be determined:

Caregiver self-assessed anonymous eligibility screening will occur on the website prior to the verbal consent (by phone) and randomization. The following will be asked on the online screener form to determine eligibility: age 18 years or older; responding to outreach efforts in targeted rural communities; caring for patient with dementia (PWD); able to read and write in English; able to access the internet; providing care for ≥ 10 hours per week. If the online screening form indicates that the person is eligible for participation in the study, it will provide the potential participant with a copy of the RCT study consent form and also for his/her contact information in order to arrange a phone call to perform verbal consent by phone for the RCT study. (Please also see attachment Online consent and screener for the details.)

11.4 * INITIATION OF CONTACT: Who initiates contact (check all that apply): (REQUIRED)

- [ ] Investigators/study team
- [ ] UCSF recruitment unit (e.g. CTSI Consultation Services)
- [x] Potential participant
- [ ] Other (explain below)

11.5 * HOW IS CONTACT INITIATED: (check all that apply): (REQUIRED)

- [ ] In person
- [x] Phone
- [x] Letter / email
- [x] Website or app
- [ ] Other (explain below)

Attach the telephone recruitment script in the Other Study Documents section of the Initial Review Submission Packet Form. If potential participants will initiate contact, attach the telephone screening script that will be used to provide more information about the study and determine if callers are eligible to participate.

Attach the recruitment letter or email template in the Other Study Documents section of the Initial Review Submission Packet Form.

Provide the URL for any website in Recruitment Plan section, or attach a mock-up of the website or the app screens in the Other Study Documents section of the Initial Review Submission Packet Form.

11.6 RECRUITMENT PLAN: Based on the checkboxes you chose above, please provide a narrative describing your recruitment plan. We want to know:

- **Who is conducting the search for potential participants, and how?**
- **How are potential subjects being approached for recruitment? By whom, and when?**

If there will be more than one participant group (e.g. patients, healthy controls, caregivers, family members, providers, etc.), provide details about the recruitment plans for each group. (Recommended length - 100-250 words)

We will use multiple recruitment methods, such as:

- Direct communications with local organizations, spiritual centers, and others. We will send mail and emails and make telephone calls to local senior centers, health centers, senior meal providers, ministerial associations, centers of worship, rural service associations, and Area Agencies on Aging.
- Print media: We will produce brochures and posters and mail them to the local groups described above. We will telephone these sites to ensure receipt and that supplies are replenished.
- Traditional news media: We will write and pay for advertisements, press releases, and public service announcements to be included in local radio and television stations and newspapers.
- Online media: We will generate content for local organizations to insert into emails they send to their communities and pay for postings on local/regional social media sites and web sites (e.g., Craigslist).

We will also ask community partners within the targeted rural areas to help disseminate information about the study.

11.7 * CONSENT METHODS: How will permission to participate (i.e., informed consent) be obtained from each potential participant. If there will be multiple groups and different plans for consenting each, check all that apply. See the orange Help bubble to the right for more detailed guidance. Participants will (check all that apply): (REQUIRED)

- [ ] Sign a consent form at the end of the consent discussion (signed consent)
- [ ] Provide online 'eConsent' using DocuSign or another E-Signature system
- [x] Click through a link in a survey or email after reading about the study and then complete the study online (electronic consent)
- [x] Be told about the study and be given a handout/information sheet and be asked if they agree to participate (verbal consent)
- [ ] Complete the study activities and turn in materials, as in the case of a completed survey that is placed in a drop box or mailed to the study team (implied consent)
- [ ] Not be able to provide consent and will have a family member consent for them, as in the case of a critically ill or unconscious patient (surrogate consent)
- [ ] Not be able to provide consent (emergency waiver of consent - allowed for minimal risk research or greater than minimal risk research with an approved community consultation plan)
- [ ] Not know about the study, as in the case of chart reviews or observations of public behavior (waiver of consent)
- [ ] Other method (describe below)

Attach your consent form, information sheet, or electronic consent text in the Informed Consent Documents section of the Initial Review Submission Packet Form.

11.8

*** CONSENT PROCESS: Describe the process for obtaining informed consent, including details such as who will have the consent discussion and when participants will be asked to sign the consent form in relation to finding out about the study: (REQUIRED)** **We encourage researchers to review our guidance on obtaining and documenting informed consent.**

- **If there are multiple groups being consented differently, provide details about the consent process for each group.**
- **If you are relying on verbal or implied consent, provide details about how that will happen.**
- **For studies using online recruitment and consent or consent via mail, provide details here.**

For Aim 1 Consent for RCT. Once eligibility is determined interested caregivers will have the opportunity to enroll. First, they will read all informed consent information (written at the 6th grade level) online or by printing a copy from online. The consent information will be formatted to be easily printed and read as paper copies if desired. If caregivers prefer, they will have the option of having study personnel send them the consent information sheet by email or in the paper post. Interested caregivers will be scheduled for a phone-based informed consent discussion with qualified study personnel. During that call the study personnel will review the informed consent information sheet out loud, conduct a discussion of it with the potential participant, and address all questions or concerns. At such time as the caregivers confirm that their questions or concerns have been met and the study personnel determines the caregiver understands the study and consent process, study personnel will then obtain verbal consent. Caregivers will verbally indicate that they consent ot participate in the study at that time during the phone call. This will be considered to be verbal informed consent to participate. Once verbal consent is obtained we will mail them a copy of the information sheet.

For Aim 2 debriefing interviews. For the intervention group caregivers who are randomly selected for the semi-structured telephone interviews regarding workshop implementation characteristics. The research staff will explain over the telephone the purpose of the interview, review the informed consent information sheet out loud, address any questions or concerns participants may have, and obtain verbal informed consent prior to beginning the interview. Once verbal consent is obtained we will mail them a copy of the information sheet.

For Aim 1 and 2 Learning Collaborative. For the members of the partner community sites who have agreed to partner with us in this study, the research staff will explain over the phone the purpose of the biannual webinars (to provide input on recruitment preferences for the caregivers they serve, and their experience with implementing and maintaining the Building Better Caregivers online workshop and your suggestions for improving it) community members will be told that some webinars will be audiorecorded and notes will be taken by research staff. These will be electronically stored on secure computers, answer any questions community members may have, read the information sheet out loud, and obtain verbal informed consent prior to their participation in the webinars. Once verbal consent is obtained we will mail them a copy of the information sheet.

* It is important that the people obtaining consent are qualified to do so. Briefly describe the training and experience these individuals have in obtaining informed consent: **(REQUIRED)**

For Aim 1 RCT (participatns who prefer to do verbal consent process by phone) and for Aim 2 debriefing interviews.

For the *telephone surveys*, an experienced staff member will obtain verbal informed consent by utilizing a low-literacy script to explain the purpose interview (learn more about their experience in the intervention), answer any questions or concerns, and ask explicitly if the potential participant agrees to participate in the relevant portion of the project under questions (RCT or one-time 30-minute phone interview for Aim 2). The interviewer will ask questions to make sure that the participant has understood the information.

For Aim 1 and 2 Learning Collaborative. For the *Learning Collaborative*, the PI or experienced research staff will obtain verbal informed consent by utilizing a low-literacy script to explain the purpose interview (learn more about their experience implementing the intervention, recruitment, etc.), answer any questions, and ask explicitly if the potential participant agrees to participate in the webinars and that some may be audio recorded. The PI or research staff will ask questions to make sure that they have understood the information.

11.9 * CONSENT COMPREHENSION: Indicate how the study team will assess and enhance the subjects' understanding of study procedures, risks, and benefits prior to signing the consent form (check all that apply): (REQUIRED) Tip: Review the Consent Comprehension - Learning Notes in the Help bubble at the right for specific questions that can be asked to assess comprehension, consider using the UCSF Decision-Making Capacity Assesment Tool, and review our guidance on obtaining written or verbal informed consent for more detail on how to conduct the assessment.

- [x] The study team will engage the potential participant in a dialogue, using open-ended questions about the nature of the study or the experimental treatment, the risks and benefits of participating, and the voluntary nature of participation
- [x] Potential participants will be asked or shown a series of questions to assess their understanding of the study purpose, procedures, risks and benefits, as well as the voluntary nature of participation (especially appropriate when the consent process happens online or through a mobile health app)
- [ ] Other method (describe below):

Provide details of the other approaches that will be used, if using another method to assess comprehension:

Aim 1 RCT

The study interviewers have extensive experience in obtaining informed consent. Interviewers are trained to provide the participant with ample opportunity to have their questions answered, read all informed consent elements out loud, and confirm with the participant that the information has been understood. They will ask participants to verify that they have understood the critical elements of informed consent (e.g., risks, benefits, what is involved, voluntary nature) by asking them to repeat back what they understood about the consent form. The interviewers are well-trained to address any questions and clarify any points, which the potential participant may have misunderstood.

11.10 * DECEPTION: Does this study rely on some deception or misinformation about what the researchers are observing to get valid data? (REQUIRED)

- ○ Yes
- ◉ No

11.12 * WAIVER OF DOCUMENTATION OF SIGNED CONSENT: Select the regulatory category under which the IRB may waive the requirement to obtain *signed* consent for this study:

- ○ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether they want documentation linking them with the research. 46.117(c) (1)
- ◉ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. 46.117(c) (2)

11.13 TIME: What is the estimated time commitment for participants (per visit and in total):

Study assessments will include (total time = 80 minutes):

Baseline online survey: 20 minutes

1.5-month online survey: 20 minutes

6-month online survey: 20 minutes

12-month online survey: 20 minutes

Study eligibility survey: 5-10 minutes

Frequency and duration of intervention group. Workshops run for 6 weeks. Each week, participants are asked to log on at least 2-3 times for a total time of approximately two hours. Caregiver participation does not require "real time" attendance at pre-determined times. (total time 120 minutes x 6 = 720 minutes or 12 hours over 12 months).

Frequency and duration of control group. Participants will participate in two brief phone calls of 15-30 minutes apiece. (total time 15-30 minutes x 2 = 30 - 60 minutes or .5 to 1 hour over 12 months)

Total eligibility + assessment time = 85 – 90 minutes over 12 months

Total for debriefing interview. Those who are randomly selected to complete the phone 30 minute interview. (total time 30 minutes)

Total for learning collaborative 2x90=180 minutes x 5 years = 900 minutes or 15 hours + 5 hours of phone calls. Total hours 20 hours

IMPORTANT TIP: Ensure this information is consistent with the information provided in the consent form.

11.16 OTHER ALTERNATIVES: Describe other alternatives to study participation, if any, that are available to prospective subjects:

This study does not involve treatment and does not have any significant impact on subject's concurrent or future care, the alternative is simply not to participate in this study.

12.0 Risks and Benefits

12.1 RESEARCH-RELATED RISKS: Check if your study involves any of these specific research-related risks to participants that may need to be disclosed in the consent form:

- ☐ Physical discomforts or pain
- ☐ Risks to employment, or social or legal standing
- ☑ Possible personal discomfort due to sensitive topics (stress, embarassment, trauma)
- ☐ Risk that the study team may observe possible evidence of child abuse, elder abuse, or a threat to self or others that they are required to report

* For any boxes checked above, describe how you will minimize these risks and discomforts, e.g., adding or increasing the frequency of monitoring, additional screening to identify and exclude people with diminished kidney or liver function, or modification of procedures such as changing imaging studies to avoid giving contrast agent to people who are more likely to suffer side effects from it, etc.: **(REQUIRED)**

This is a behavioral intervention with minimal risks.

Potential risks for caregivers taking part in the study may make respondents feel uncomfortable, upset or other emotional responses as a result of answering survey questions or during the interview, but they can refuse to answer or stop the interview at any time.

There is also a risk of loss of confidentiality. We will take steps to protect the privacy of patient information, however we cannot guarantee total privacy. All participant data will be coded in a confidential manner that will protect the identity of the participant. Participants will be assigned a unique identifier, and all data entered into the study database will only utilize this identifier. A list of the participant names and the associated codes will be stored on a secured encrypted server. All study-specific data files will be kept on secure servers that are password-protected and shielded from unauthorized access by firewalls. Only key study personnel will have access.

There is also slight risks for participating in the online workshop intervention (for those who are randomized to receive the Building Better Caregivers workshop initially or who choose to attend it later after the trial is completey (control group participants)). Because workshops consist of 20-25 persons and run for 6 weeks. Each week, participants are asked to log on at least 2-3 times for a total time of approximately two hours. Activities are guided by two peer co-facilitators (caregivers themselves). Caregiver participation does not require "real time" attendance at pre-determined times. Instead, caregivers interact in group discussions and person-to-person communications by making postings on discussion boards and sending individual messages. They can write these at any time of day or night. Participants may respond to workshop modules by experiencing and/or disclosing their experiences of stress and difficult emotions. The workshops are facilitated by peer facilitators who receive rigorous training on the management and triage of participants experiencing difficult emotions, which includes when and how to activate built-in safety protocols—such as contact of the overseeing health professional if a participant indicates they are at any risk for self-harm. Facilitators keep track of all participants by electronically checking in with them at least once weekly during the 6-week workshop. They also observe all online interactions and postings daily throughout the workshop. The activities of the facilitators are themselves reviewed by "Master Trainers" who monitor the fidelity, quality, and safety of workshop delivery. Workshop participants also receive training on how to contact their workshop facilitators.

12.2 RISKS: Describe any anticipated risks and discomforts not listed above:

see section 12.1 above.

12.3

MINIMIZING RISKS: Describe the steps you have taken to minimize the risks/discomforts to subjects. Examples include:

- **designing the study to make use of procedures involving less risk when appropriate**
- **minimizing study procedures by taking advantage of clinical procedures conducted on the study participants**
- **mitigating risks by planning special monitoring or conducting supportive interventions for the study**
- **having a plan for evaluation and possible referral of subjects who report suicidal ideation**

Efforts to provide protection against risks will occur during all stages of the project. Prior to enrollment, the study investigators will explain the study in a clear manner, using language at a 6th grade level. We will attempt to make our informed consent forms at an 6th grade reading level and used bulleted formats to enhance comprehensibility of the forms for persons with lower educational levels. Participants will be given several opportunities to ask questions. To prevent the perception of coercion to participate, study investigators and research staff will inform the participants that they can drop out of the study at any time, and dropping out of the study will not affect the services they receive through our partner community organizations. A copy of the consent form will be given to the participant (online or by mail). The consent form will have contact information for both the study Principal Investigator (PI) and the IRB if they have any questions or concerns.

The Research Assistant (RA) will be trained by Dr. Yank, the PI, who is a self-management expert and practicing primary care physician, with expertise in chronic disease management and caregiver and self-management research. In the course of the study, we will have several safeguards in place to quickly identify and respond to participants who we feel might require professional mental health assessment and services or other forms of medical assessment or care. To decrease the likelihood of an adverse event during the study, the RA will receive intensive training from the PI, Dr. Yank, and the Project Coordinator on procedures for reporting

adverse events, how to recognize symptoms of clinical depression or anxiety, and the need to call the PI when she feels that a participant requires additional services from a mental health or health care professional.

All participant data will be coded in a confidential manner that will protect the identity of the participant. Participants will be assigned a unique identifier, and all data entered into the study database will only utilize this identifier. A list of the participant names and the associated codes will be stored on an encrypted server. Only key study personnel will have access.

The workshop intervention is designed to be appropriate for caregivers of patients with dementia living in rural areas. Participants may respond to workshop modules by experiencing and/or disclosing their experiences of stress and difficult emotions or situations. The workshops are facilitated by peer facilitators who receive rigorous training on the management and triage of participants experiencing difficult emotions, which includes when and how to activate built-in harm protocols—such as contact of the overseeing health professional if a participant indicates they are at any risk for self-harm or harm of others, which in the case of the current study will be study PI Dr. Yank. Facilitators keep track of all participants by electronically checking in with them at least once weekly during the 6-week workshop. They also observe all online interactions and postings daily throughout the workshop. The activities of the facilitators are themselves reviewed by "Master Trainers" who monitor the fidelity, quality, and safety of workshop delivery. The Master Trainer also has the option (and in the case of a harm protocol activation a requirement) of consulting the "Super Trainer" who oversees and trouble-shoots all major workshop deviations or concerns. Workshop participants also receive training on how to contact their workshop facilitators and how to access self-help materials in the workshop and also have available to them a "crisis tab" that contains phone numbers, weblinks and other information for relevant crisis hotlines and related resources.

The *Building Better Caregivers* safety protocol is attached to the IRB application and includes the following characteristics:

- Instructions to facilitator to activate the harm protocol in any situation when the facilitator "perceives there is a possible imminent threat to a participant's or other third party's well being based upon a participant contribution(s) on the Program website"
- Protocolized communication by the facilitator to the participant through the secure internal email exchange within the workshop ("Post Office")
    - The letter language is pre-populated and instructs the participant on what to do (e. g., call 911, contact their doctor) and that a member of the research team will reach out to them. That person will be the study physician and PI, Dr. Yank.
    - Generation of that letter automatically activates the harm protocol and the other harm protocol actions below
- The workshop platform generates automatic emails to the workshop co-facilitator, Mentor, Super Mentor, and study PI and physician Dr. Yank

Once the study physicians receives a harm protocol activation notification, she will telephone the participant or relevant local professionals to assess the situation and determine teh required next steps. If the situation meets the standards of requiring mandatory reporting (e.g., of concern for imminent harm to participant or others), the study physician will perform those activities.

The equivalent harm protocol has been used successfully in the existing provision of a version of the workshop to over 3,000 caregivers of veterans by the Veterans Affairs Health Care System (see Preliminary Studies section of the Research Strategy for details on the workshop for veteran caregivers), with activations of the safety protocol being extremely rare (e.g., average of 3 times in 24 months) with successful resolution with participant safety being assured in all cases. The protocol has never been activated for elder abuse but has been activated in rare instances for the following circumstances:

- Concern about the safety/welfare of the workshop participant (caregiver) in a situation where
    - potential harm might be imposed on him/her by the care partner (e.g., loved one with dementia for whom they are caring)
    - the participant (caregiver) suggested that he/she might be severely depressed and in danger of self-harm/suicide
- Concern about the care partner (not the study participant) hurting himself/herself—in other words, not that they are going to harm the caregiver but that they might harm themself

In the case of the VA workship, when the harm protocol is activated, the systems sends a VA social worker the activation alers and the social worker has performed the function that the study physician will perform in the current workshop being studied. Of note, mandatory reporting of elder abuse is required in all states involved in the study. The PI Dr. Yank, who is a general internal medicine physician will act as the study physician and mandatory reported. She has

experiences serving as study physician on multiple studies in the past. If she is on vacation or otherwise unavailable to serve as study physician, the study physician responsibilities will be met by the back-up study physician, Dr. Karliner, who also is a physician investigator and colleague of Dr. Yank in the UCSF Division of General Internal Medicine and the UCSF Mt. Zion General Internal Medicine Clinic.

In all cases when the PI is alerted to a potential safety issue, whether by the Building Better Caregivers workshop harm protocol or research team members, The PI will proceed to address these as potential adverse events. If the event is determined to be an AE that is moderate or higher in degree, Dr. Yank will then contact the participant directly to assess the situation, make appropriate referrals, make appropriate contact with local health or other authorities in the participant's home state and region, and follow-up with the participant. The participant will have given previous consent for the PI to contact him/her directly when such an assessment is indicated in the opinion of the RA or Project Coordinator or by activation of the BBC workshop harm protocol. Furthermore, study participants will have the full contact information for the study team, including email and telephone contact details, so that problems will be identified in a timely manner, and should be alleviated by the support and coping skills before the problem becomes more serious or chronic. Finally, at the time of enrollment in the study, the study team will provide participants with a list of health resources available to them, which will include mental health services and hotline numbers.

12.5 * BENEFITS: (REQUIRED) Note: These are the benefits that the IRB will consider during their review. They are not necessarily appropriate to include in the consent form.

Possible immediate and/or direct benefits to participants and society at large (check all that apply):

- [x] Positive health outcome (e.g. improvement of condition, relief of pain, increased mobility, etc.)
- [ ] Closer follow-up than standard care may lead to improved outcomes or patient engagement
- [x] Health and lifestyle changes may occur as a result of participation
- [x] Knowledge may be gained about their health and health conditions
- [x] Feeling of contribution to knowledge in the health or social sciences field
- [ ] The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children
- [ ] Other benefit (describe below)
- [ ] None

12.6 RISK TO BENEFIT RATIO: Explain why the risks to subjects are reasonable in relation to anticipated benefits, if any, to the participant or society:

The potential risks are outweighed by the anticipated benefits of reduced depression and reduced stress among caregivers of patients with dementia. Caregivers will receive caregiver self-management and information on dementia caregiving skills, thus potentially can receive direct benefit from the study in terms of greater access to caregiving information and methods for relieving distress. The burden of participating in 4 surveys and a 6-week program is outweighed by the potential benefits associated with developing evidence-based online support for isolated dementia caregivers in rural areas with an intervention that is scalable, even in low-resourced settings. If the workshop can achieve its goals with rural dementia caregivers, some of those most isolated, it would also be expected to be scalable in other low-resourced settings (e.g., in urban or suburban environments).

12.7 * DATA AND SAFETY MONITORING: Do you have a Data and Safety Monitoring Plan (DSMP) for this study (A DSMP is required for Greater than Minimal Risk research): (Click the Help link for guidance on risk determination) (REQUIRED)

(•) Yes ( ) No

This is not required for minimal risk research but the UCSF IRB strongly recommends one to ensure the data collected are adequate to meet the research aims:

13.0 Data and Safety Monitoring Plan

13.2 * DATA AND SAFETY MONITORING PLAN: (REQUIRED)

All greater than minimal risk studies are required to provide a plan. Lack of an adequate plan is one of the most common reasons why IRB approval is delayed.

Instructions:

Describe the plan for monitoring data quality and participant safety. Key areas that should be included in the plan are:

- An explanation of the plan to monitor data collection, study progress, and safety
- A description of who will perform the monitoring and at what frequency (e.g., the PI only, a contract research organization, a Data and Safety Monitoring Board or Data Monitoring Committee, etc.)
- The type of data and events that will be reviewed (e.g., adverse events, breaches of confidentiality, unanticipated problems involving risk to participants or others, unblinded efficacy data, etc.)
- Procedures and timeline for communicating monitoring results to the UCSF IRB, the study sponsor, and other appropriate entities
- Assurance that the research team will adhere to the **UCSF IRB reporting requirements**

As appropriate:

- A plan for conducting and reporting interim analysis
- Clearly defined stopping rules
- Clearly defined rules for withdrawing participants from study interventions

DATA AND SAFETY MONITORING PLAN

Procedures for implementing a Data Safety and Monitoring Plan (DSMP) at the University of California San Francisco have been developed on a campus-wide basis in conjunction with the Institutional Review Board (called the Committee on Human Research at UCSF), the Office of the Vice-Chancellor for Research, and the Office of Clinical Research in the School of Medicine. The Data and Safety Monitoring Plan for the proposed project incorporates the policies on human subject data and safety monitoring specified by the UCSF Committee on Human Research (i.e. UCSF IRB).

1. Risk Assessment – Minimal Risk

This study represents a minimal risk non-therapeutic behavioral intervention. It encompasses a randomized controlled trial among 640 participants with the intervention tested being an online workshop (*Building Better Caregivers*) that focuses on improving participants' self-care practices and skills for dementia caregiving. Data collection is performed through use of online surveys and phone-based interviews. The Research Assistant (RA) will be trained by Dr. Yank, the PI, who is a

self-management expert and practicing primary care physician, with expertise in chronic disease management and caregiver and self-management research. In the course of the study, we will have several safeguards in place to quickly identify and respond to participants who we feel might require professional mental health assessment and services or other forms of medical assessment or care. To decrease the likelihood of an adverse event during the study, the RA will receive intensive training from the PI, Dr. Yank, and the Project Coordinator on procedures for reporting adverse events, how to recognize symptoms of clinical depression or anxiety, and the need to call the PI when she feels that a participant requires additional services from a mental health or health care professional.

For participants who are randomized to receive the *Building Better Caregivers* workshop initially or who choose to attend it later after they have finished participation in the control group, during the workshop they will receive training on healthy self-care practices and perform self-efficacy building activities, including those that may improve their mental and physical well-being. For example, the workshop contains modules on managing stress and difficult emotions including symptoms of anxiety, depression, anger, and fatigue. Participants may respond to these modules by experiencing and/or disclosing their experiences of stress and difficult emotions. In light of this, the *Building Better Caregivers* workshop itself is staffed by peer facilitators who receive rigorous training on the management and triage of participants experiencing difficult emotions, which includes when and how to activate built-in safety protocols—such as contact of the overseeing health professional if a participant indicates they are at any risk for self-harm. Facilitators keep track of all participants by electronically checking in with them at least once weekly during the 6-week workshop. They also observe all online interactions and postings daily throughout the workshop. The activities of the facilitators are themselves reviewed by "Master Trainers" who monitor the fidelity, quality, and safety of workshop delivery. Workshop participants also receive training on how to contact their workshop facilitators. The workshop safety protocols already in place have been used successfully in the existing provision of a version of the workshop to over 3,000 caregivers of veterans by the Veterans Affairs Health Care System (see Preliminary Studies section of the Research Strategy for details on the workshop for veteran caregivers), with activations of the safety protocol being extremely rare (3 times in 24 months) with successful resolution with participant safety being assured in all cases. The *Building Better Caregivers* workshop safety protocol for the purpose of this study will include the addition of the study PI being informed of all safety protocol activations.

In all cases when the PI is alerted to a potential safety issue, whether by the study RA, Project Coordinator, or the *Building Better Caregivers* workshop safety protocol, The PI will proceed to address these as potential adverse events. Adverse events will be graded according to their significance for severe consequences, such as injury or death. If the event is determined to be an AE that is moderate or higher in degree, Dr. Yank will then contact the participant directly to assess the situation, make appropriate referrals, and follow-up with the participant and RA. The participant will have given previous consent for the PI to contact him/her directly when such an assessment is indicated in the opinion of the RA or Project Coordinator of by activation of the BBC workshop safety protocol. Furthermore, study participants will have the full contact information for the study team, including email and telephone contact details, so that problems will be identified in a timely manner, and should be alleviated by the support and coping skills before the problem becomes more serious or chronic. Finally, at the time of enrollment in the study, the study team will provide participants with a list of health resources available to them, which will include mental health services and hotline numbers.

2. Description of Adverse Event Grading and Anticipated Adverse Events

An adverse event (AE) is here defined as any unfavorable and unintended sign, symptom, injury or disease temporarily associated with an intervention or procedure, regardless of whether it is considered related to an intervention or procedure that occurs during the course of the study. AEs will be scored as follows:

0. = No adverse event or within normal limits
1. = Mild AE – not requiring treatment/follow-up
2. = Moderate AE – resolved with follow-up
3. = Severe AE – resulted in inability to carry on normal activities, requiring hospitalization
4. = Life-threatening or disabling AE – results in an immediate risk of death and/or results in persistent or significant disability
5. = Fatal AE

Adverse events categorized as severe, life-threating/disabling, or fatal are by definition serious adverse events. Examples of the types of adverse events we might encounter in the proposed study are as follows:

1. Mild AE (ones that do not require treatment/follow-up): reports of depressive symptoms, anxiety, and stress that do not interfere with normal activities; fatigue from answering study questions (via online survey—and for a sub-set, phone-based interviews); frustration when learning to use the online workshop site; anxiety about the ability to complete activities for the workshop; and worry about loss of confidentiality/privacy.
2. Moderate AE (ones that resolve with treatment/follow-up): experiences of transient episodes of depressive symptoms or anxiety attacks that modestly affect daily activities and resolve with lifestyle, stress management, or usual care approaches.
3. Severe AE (ones that result in inability to carry on normal activities, those requiring hospitalization): patient is so anxious or depressed that they enter a hospital or day-treatment facility.
4. Life-threating or disabling AD (ones involving immediate risk of death or persistent disability): participant threatening or attempting self-harm or harm to others. These events are extremely rare and occur more often in participants with a history of depression.

Given that the proposed intervention is behavioral and educational in nature, we anticipate that mild AEs will comprise the overwhelming majority of reported AEs. The PI, in consultation with the research team, is responsible for evaluating each AE and for and for notifying the project's Data and Safety Monitoring Board and the UCSF Committee on Human Research of the occurrence of adverse events.

3. Description of Monitoring Study Progress and Safety of Human Subject Participants

The Principal Investigator (PI), Veronica Yank, has primary responsibility for the overall conduct of the study and for the safety of research participants. The PI will ensure that (1) the informed consent process is conducted appropriately and that informed consent is obtained prior to proceeding with any study procedures; (2) only eligible subjects, per protocol eligibility criteria, are enrolled in the study; (3) data are collected and analyzed per protocol requirements; (4) procedures are implemented to ensure that the project is consistently monitored for possible adverse events; (5) adverse events are reviewed promptly and reported as required to the UCSF Committee on Human Research (CHR) (i.e., UCSF IRB); and (6) the privacy and confidentiality of study subjects is maintained. While implementation of aspects of the DSMP may be delegated to members of the research team, the PI maintains ultimate responsibility for the project and for the safety of study participants.

The Research Team of PI, Co-Is/Consultants (Drs. Kate Lorig, Ken Covinksy, Catherine Chesla, Leah Karliner, Jing Cheng, Dolores Gallagher Thompson, and Nancy Fahrenwald), Project Coordinator, Data Analyst, and RA will meet quarterly by teleconference to review the progress of the study and address any human subject issues that occur. These discussions may involve adverse event prevention measures, subject accrual issues, research staff training on protection of human subjects, as well as occurrence of adverse events.

The Data Safety Monitoring Plan provides for an external, objective Data and Safety Monitoring Board (DSMB). The DSMB will meet on a scheduled basis as outlined in the DSMB Charter below. The DSMB will review on a scheduled basis reports prepared by the PI, statistician, and data management staff on the progress of the project including data on enrollments, comparison of target to actual enrollment, overall status of the study participants, information on race/ethnicity, gender, adverse events, serious adverse events and other information listed in the DSMB Charter below. The DSMB will also determine whether additional effort is required to foster the progress of the study, whether adverse events were scored and dealt with appropriately (i.e., was the safety and health of the subject addressed, did the subject receive medical attention or medical

referral as needed, etc.) and whether adverse events were correctly and immediately reported to the UCSF Committee on Human Research. The DSMB will determine whether the study should continue, be terminated, or be modified based on observed beneficial or adverse effects.

4. Plans for Assuring Compliance with Requirements Regarding the Reporting of Adverse Events

The PI is responsible for reporting adverse events to the research team, to the DSMB, and to the CHR. Mild and moderate adverse events will be reported within 10 working days of the occurrence or knowledge of the occurrence. Severe, life-threatening or fatal adverse events will be reported immediately to the PI, who will notify the CHR within 48 hours. This means that research assistants will be trained to recognize, respond to, and record adverse events when they occur or immediately after they occur to insure the safety of the human subjects; and to report adverse events to the PI in a timely manner to insure compliance with institutional policies on human subject protection. This also means that research assistants engaged in data collection will be able to contact the PI as soon as an adverse event occurs. Specifically, the PI will report the following information in writing to the DSMB and UCSF CHR: 1) all severe adverse events associated with the study procedures, and/or 2) any incidents or problems involving the conduct of the study or patient participation, including problems with the recruitment and/or consent processes and/or education of participants about managing stress and coping with depression symptoms. The PI also will provide a written report of adverse events of moderate or greater severity during the course of the study to the CHR on an annual basis.

Severe adverse events are very rare in persons engaging in self-management and educational activities, although it is possible that a person with previously unidentified depression, anxiety disorder, or other mental illness may experience an aggravation during times of stress. We will stop the study based on instructions from the DSMB or CHR, which will be notified immediately if a participant in this study experiences a severe adverse event while enrolled in the study.

5. Plans for Performance of Safety Reviews, for Assuring Data Accuracy and Security, and Assuring Protocol Compliance

Safety reviews will be performed by the DSMB as described above. Under the direction of the PI, the security of the data will be safe guarded. As part of the data management and analysis plan, all of the data files will be kept in a secure, locked file. All computer data will likewise be protected. Data will be entered directly into a computer and files will be matched to verify the accuracy of the data. Data will be entered into data files by identification number only. Participants' names will be separated from the data and kept in a locked file cabinet. Access to the file cabinet will be strictly controlled by the PI and a project director. The co-investigators will have access to this information only in the event of an adverse event.

To assure protocol compliance, the UCSF School of Medicine Office of Research will conduct an audit of the project on a periodic basis and evaluate compliance with adverse events reporting and the data safety and monitoring plan as outlined in the proposal.

6. Steps Emanating from Data Review

The review of data may result in early termination of the study (see stopping guidelines section below), in protocol amendment, or in changes to the data collection plan or study forms. Should the protocol be amended as a result of data review, the UCSF CHR will be notified and the amendment approved prior to study amendment implementation unless the protocol amendment must be implemented to protect the immediate safety of the study subjects. In such a case, the protocol amendment will be immediately implemented and the UCSF CHR will be notified directly after protocol amendment implementation.

7. Stopping Guidelines

The study will terminate if subjects experience a significantly large number of adverse events.

8. Plans for Reporting Temporary or Permanent Suspension of a Funded Clinical Trial

The Principal Investigator will be responsible for immediately reporting to the funding agency (i. e., the Program Officer responsible for the grant), any temporary or permanent suspension of the project and the reason for the suspension.

DSMB CHARTER

This Data Safety and Monitoring Board (DSMB) will act in an advisory capacity to the NIH to monitor participant safety and evaluate the efficacy of the intervention that is described in the research plan.

After the DSMB is formed, the initial tasks of the DSMB are to:

- Review the entire IRB-approved study protocol and the Manual of Procedures, with regard to subject safety, recruitment, randomization, intervention, data management, quality control and analysis and the informed consent document with regard to applicability and readability.
- Recommend changes to the protocol to the PI.
- Identify the relevant data parameters and the format of the information to be regularly reported.
- Recommend subject recruitment be initiated after receipt of a satisfactory protocol. If the need for modifications to the protocol, the MOP, consent form, or anything else is indicated by the DSMB and/or the Program Administrator, the DSMB will postpone its recommendation for the initiation of subject recruitment until after the receipt of satisfactory revised protocol(s), etc.

After completion of these initial tasks, The DSMB will meet on a regular schedule approximately two times a year (with additional meetings as needed). Meetings may be convened as conference calls as well as in person. DSMB meetings will be attended by the PI and her designated staff, NIA program staff and the DSMB members. During closed sessions of the DSMB meetings only DSMB members and the NIA Program Officer may attend. The DSMB may request that a designated individual from the study (often the study's biostatistician) who has been approved to have access to unmasked data will also attend the closed session. At these regular meetings, the DSMB tasks are to:

- Review masked or unmasked data as needed and appropriate during the trial.
- These data can be related to efficacy, recruitment, randomization, compliance, retention, protocol adherence, trials operating procedures, form completion, intervention effects, gender and minority inclusion, and subject safety.
- Identify problems relating to safety during the study.
- Identify needs for additional data relevant to safety issues, and request these data from the study investigators.
- Propose appropriate analyses and periodically review developing data on safety and endpoints.
- Semi-annually (and on other occasions if necessary), consider the rationale for continuation of the study, with respect to progress of randomization, retention, protocol adherence, data management, safety issues, and outcome data (if relevant) and make a recommendation for or against the trial's continuation.
- Review and make recommendations on proposed protocol changes, and or new protocols proposed during the trial.
- Send written reports following each DSMB meeting to the Program Officer and PI. Send additional reports on all issues reviewed by the DSMB as needed.
- Provide timely advice on issues regarding data discrepancies found by the data auditing system or other sources.
- Review manuscripts of trial results as requested; the NIA Program Officer may seek DSMB review of manuscripts reporting major outcomes prior to submission for publication.

Membership

The Data Safety Monitoring Board is expected to consist of 3 voting members, with the expectation that 2 members will constitute a quorum. The members will encompass expertise in biostatistics, clinical trials, and dementia caregiving, in addition to any other areas of expertise requested by the NIA Program Officer or NIA Director. DSMB members will have no direct involvement with the study or conflict of interest with the investigators or institutions conducting the study. Members will be nominated and will require approval of the NIA Director after review of their respective Curriculum Vitae and Conflict of Interest Statements. One of the DSMB members will be identified and agree to act as the Chairperson.

Meeting Format

The DSMB meetings will consist of an open and a closed session, both closed to the public because discussions may address confidential participant data. The study PI and key staff members, DSMB members and NIA Project Scientist attend the open sessions. Discussions at these sessions focus on the review of the aggregate data, conduct and progress of the study, including participant accrual, protocol compliance, and problems encountered. Data by blinded treatment group and unblinded data are not presented in the open session. The primary objective of the closed sessions is to review data by blinded study group and, if requested by the DSMB, unblinded data. The closed sessions are attended by the DSMB members, the NIA Program Officer and an unblinded study statistician. The NIA Program Officer attends the closed and open sessions as an observer, not as a DSMB member to answer any policy or administrative questions the DSMB members may have. If necessary, an executive session may be requested by the DSMB and will be attended only by voting DSMB members. The NIA Program Officer is not permitted to attend the executive sessions.

Reports

Interim Reports to the DSMB: Interim reports will generally prepared by the study statistician and analyst in conjunction with the PI and distributed to the DSMB, at least 10 days prior to a scheduled meeting. The contents of the report are determined by the DSMB. Additions and other modifications to these reports may be directed by the DSMB on a one time or continuing basis. Interim data reports will generally consist of two parts. Part 1 (Open Session Report) provides information on study aspects such as accrual, baseline characteristics, and other general information on study status. Part 2 (Closed Session Report) will contain data on study outcomes and safety data. Data files to be used for interim analyses will have undergone established editing procedures to the greatest extent possible.

Reports from the DSMB: A formal report from the Chairperson and approved by the DSMB will be supplied to the NIH within 6 weeks of each meeting. Each report will conclude with a recommendation to continue or to terminate the study. This recommendation will be made by formal majority vote. A recommendation to terminate the study will be transmitted to the NIH as rapidly as possible, by immediate telephone and fax if sufficiently urgent. In the event of a split vote in favor of continuation, a minority report will be contained within the regular DSMB report. The report will not include unblinded data, discussion of the unblinded data, etc. A separate set of notes summarizing the unblinded session will also be created by the DSMB Chairperson and maintained by the NIH. Copies of the blinded DSMB report will be sent to the UCSF IRB in the study.

Access to Interim Data

Access to the accumulating endpoint data will be limited to as small a group as possible. Limiting the access to interim data to the DSMB relieves the investigators of the burden of deciding whether it is ethical to continue to randomize patients and helps protect the study from bias in patient entry and/or evaluation.

Confidentiality

All materials, discussions and proceedings of the DSMB are completely confidential. Members and other participants in DSMB meetings are expected to maintain confidentiality.

13.3 * DATA AND SAFETY MONITORING BOARD (DSMB): Will a Data and Safety Monitoring Board (DSMB) be established: (REQUIRED)

- (•) Yes
- ( ) No

13.4 DSMB DETAILS: Provide details from the DSMB's charter, including meeting frequency, and affiliations and qualifications of members: If the DSMB has not yet been established, submit these details to us as they become available.

As noted in section 13.2 above, DSMB memebers "will require approval of the NIA Director after review of their respective Curriculum Vitae and Conflict of Interest Statements." After our team receives the NIA Director's approval of DSMB members, we will submit a modification request to add their names to the IRB study information.

14.0 Confidentiality, Privacy, and Data Security

14.1 PROTECTING PRIVACY: Indicate how subject privacy will be protected:

- [x] Conduct conversations about the research in a private room
- [x] Ask the subject how they wish to be communicated with – what phone numbers can be called, can messages be left, can they receive mail about the study at home, etc.
- [x] Take special measures to ensure that data collected about sensitive issues do not get added to their medical records or shared with others without the subject's permission
- [ ] Other methods (describe below)

14.2 SENSITIVE DATA: Do any of the instruments ask about illegal or stigmatized behavior:

- ( ) Yes (•) No

14.3 CONSEQUENCES OF A LOSS OF PRIVACY OR CONFIDENTIALITY: Could a breach of privacy or confidentiality result in any significant consequences to participants, such as criminal or civil liability, loss of state or federal benefits, or be damaging to the participant's financial standing, employability, or reputation:

- ( ) Yes (•) No

14.4 EXTRA CONFIDENTIALITY MEASURES: Explain any extra steps that will be taken to assure confidentiality and protect identifiable information from improper use and disclosure, if any:

All research data will be coded and entered into a database (REDCap) that will be password-protected and secured behind electronic firewalls on a secure server. Data from the baseline, 1.5-, 6- and 12-month interviews will use the unique identifier number and will be stored on a HIPAA compliant, secure server using the Research Electronic Data Capture Tool application (REDCap), a data storage platform approved and recommended by the UCSF CHR. Once debriefing interviews

are transcribed (any identifying information will be removed from transcripts), the digital audio files will be destroyed.

Any electronic or hard copy of patients' contact information will be destroyed once data collection and cleaning of the data files is completed. The electronic file of names, addresses and phone numbers of potential participants will never be linked directly to data (survey responses). To protect against a loss of privacy, all participants will be assigned a unique identifier number, which will be used on all data collection forms. No names will be used on the data collection forms. A single master list linking participant id numbers and their contact information will be kept in a password protected electronic file, on a password protected computer, in the locked office of the Project Coordinator of the study. Only the Project Coordinator will have access to the master list linking participant study ID numbers and their names and contact information. This list will be destroyed once the study is complete. No participant names will be used in publications or presentations that result from the study.

14.5 * REPORTABILITY: Do you anticipate that this study may collect information that State or Federal law requires to be reported to other officials, such as elder abuse, child abuse, or threat to self or others: (REQUIRED)

○ Yes ◉ No

14.6 CERTIFICATE OF CONFIDENTIALITY: Will this study obain a Certificate of Confidentiality:

○ Yes ◉ No

14.7 SHARING OF RESEARCH RESULTS: Will there be any sharing of EXPERIMENTAL research test results with subjects or their care providers:

○ Yes ◉ No

14.8 * IDENTIFIERS: Will any personal identifiers be collected: (REQUIRED)

◉ Yes ○ No

Check all the identifiers that may be included:

- [x] Names
- [x] Dates
- [x] Postal addresses
- [x] Phone numbers
- [ ] Fax numbers
- [x] Email addresses
- [ ] Social Security Numbers*
- [ ] Medical record numbers
- [ ] Health plan numbers
- [ ] Account numbers
- [ ] License or certificate numbers
- [ ] Vehicle ID numbers
- [ ] Device identifiers or serial numbers
- [ ] Web URLs
- [ ] IP address numbers
- [ ] Biometric identifiers
- [ ] Facial photos or other identifiable images
- [ ] Any other unique identifier

* Could study records include *ANY* photos or images (even 'unidentifiable' ones): **(REQUIRED)**

○ Yes ◉ No

14.9 DATA DISCLOSURE: Will identifiable information be shared with outside groups:

○ Yes ◉ No

14.11 * DATA COLLECTION AND STORAGE: (check all that apply): (REQUIRED)

Collection methods:

- ☐ Paper-based (surveys, logs, diaries, etc.)
- ☐ Electronic case report forms (CRFs), such as OnCore or another clinical trial management portal
- ☑ Web-based online surveys or computer-assisted interview tool
- ☐ Mobile applications (mobile or tablet-based)
- ☐ Wearable devices
- ☑ Audio/video recordings
- ☐ Other:

* What online survey tool will you use: **(REQUIRED)**

- ☐ Qualtrics (Recommended)
- ☑ RedCAP (Recommended)
- ☐ Survey Monkey (NOT recommended and may require UCSF ITS Security review)
- ☐ Other

* Data will be collected/stored in systems owned by (check all that apply): **(REQUIRED)**

- ☑ UCSF
- ☐ SF VAMC
- ☐ Amazon (Amazon Cloud)
- ☐ Other academic institution
- ☐ 3rd party vendor (business entity)
- ☐ Other (explain below)

14.12 DATA SECURITY: Indicate how data are kept secure and protected from improper use and disclosure (check all that apply): NOTE: Whenever possible, do not store subject identifiers on laptops, PDAs, or other portable devices. If you collect subject identifiers on portable devices, you MUST encrypt the devices.

- ☑ Data are stored securely in My Research
- ☐ Data are coded; data key is destroyed at end of study
- ☑ Data are coded; data key is kept separately and securely
- ☑ Data are kept in a locked file cabinet
- ☑ Data are kept in a locked office or suite
- ☑ Electronic data are protected with a password
- ☑ Data are stored on a secure network
- ☑ Data are collected/stored using REDCap or REDCap Survey
- ☐ Data are securely stored in OnCore

14.13

*** DATA SECURITY: Confirm below that you will keep data confidential: (REQUIRED) I will keep any data sets that include identifiers secure and protected from improper use and disclosure by using methods such as:**

- **Physical Security – Keeping data in locked file cabinets, locked offices, locked suites, and physically securing computers and servers.**
- **Electronic Security – Following UCSF minimum security standards for electronic information resources, which includes (but is not limited to): not storing identifiers on portable devices like laptops or flash drives if they are unencrypted, encrypting portable devices, and storing data in password-protected files and on secure networks.**

(●) Yes

14.15 HIPAA APPLICABILITY: Study data will be:

- [ ] Derived from the Integrated Data Repository (IDR) or The Health Record Data Service (THREDS) at SFGH
- [ ] Derived from a medical record (e.g. APeX, OnCore, etc. Identify source below)
- [ ] Added to the hospital or clinical medical record
- [ ] Created or collected as part of health care
- [x] Obtained from the subject, including interviews, questionnaires
- [ ] Obtained ONLY from a foreign country or countries
- [ ] Obtained ONLY from records open to the public
- [ ] Obtained from existing research records
- [ ] None of the above

15.0 Financial Considerations

15.1 * PAYMENT: Will subjects be paid for participation, reimbursed for time or expenses, or receive any other kind of compensation: (REQUIRED)

(●) Yes ( ) No

15.2 PAYMENT METHODS: Subjects payment or compensation method (check all that apply):

Payments will be (check all that apply):

- [x] Cash
- [ ] Check
- [ ] Gift card
- [ ] Debit card
- [ ] UCSF Research Subject Payment Card
- [ ] Reimbursement for parking and other expenses
- [ ] Other:

15.3 PAYMENT SCHEDULE: Describe the schedule and amounts of payments, including the total subjects can receive for completing the study:

- **If there are multiple visits over time, explain how payments will be prorated for partial completion**
- **If deviating from recommendations in Subject Payment Guidelines, include specific justification below**

Participants will receive $20 cash for the baseline assessment

Participants will receive $20 cash for the 1.5 month assessment

Participants will receive $20 cash for the 6th month assessment

Participants will receive $20 cash for the 12th month assessment

Total payment ($80)

Debriefing interview. Participants will receive $30 cash for the one time 30 minute telephone interview.

15.4 COSTS TO SUBJECTS: Will subjects or their insurance be charged for any study activities:

○ Yes ◉ No

16.0 Qualifications of Key Study Personnel

16.1 **NOTE: This information is required and your application will be considered incomplete without it. If this study involves invasive or risky procedures, or procedures requiring special training or certification, please identify who will be conducting these procedures and provide details about their qualifications and training. Also identify each person who will be involved in the consent process. Click the orange question mark for more information and examples.** **Under qualifications, please include:**

- **Academic Title**
- **Institutional Affiliation (UCSF, SFGH, VAMC, etc.)**
- **Department**
- **Certifications**

November, 2015 - NEW Definition of Key Study Personnel and CITI Training Requirements:

UCSF Key Study Personnel include the Principal Investigator, other investigators and research personnel who are directly involved in conducting research with study participants or who are directly involved in using study participants' identifiable private information during the course of the research. Key Personnel also include faculty mentors/advisors who provide direct oversight to Postdoctoral Fellows, Residents and Clinical Fellows serving as PI on the IRB application. **The IRB requires that all Key Study Personnel complete Human Subjects Protection Training through CITI prior to approval of a new study, or a modification in which KSP are being added. More information on the CITI training requirement can be found on our website.**

KSP Name	Description of Study Responsibilities - Briefly describe what will each person be doing on the study. If there are procedures requiring special expertise or certification, identify who will be carrying these out. Also identify who will be obtaining informed consent.	Qualifications, Licensure, and Training
		Dr. Yank is and Early Stage Investigator and

Dr. Yank, Veronica MD	Principal Investigator. Dr. Yank will be responsible for all aspects of the proposed project.	Assistant Professor, Division of General Internal Medicine, UCSF, and Affiliated Investigator, Veterans Affairs Center for Innovation to Implementation, Palo Alto VA Health Care System. Dr. Yank brings to the work high caliber academic training, a productive research track record, experience with both clinical trials and implementation sciences research, leadership skills in team management, and an in-depth understanding of behavioral and self-management interventions in general and the Building Better Caregiver online workshop intervention in particular. Dr. Yank has worked very closely with proposal Co-I Dr. Lorig on prior research projects. In addition, upon her recent transfer from Stanford to UCSF, she has quickly built an excellent team containing all the necessary additional expertise for the work—including Drs. Covinksy, Chesla, Karliner, and Cheng at UCSF, Dr. Gallagher Thompson at Stanford, and Dr. Fahrenwald at South Dakota State University. In addition to their research expertise, these Co-Investigators and Consultants have impressive credentials for supporting junior investigators and are committed to assisting Dr. Yank in all aspects of her role as PI.
Dr. Cheng, Jing MD,MS, PhD	Senior Statistician. She will contribute expertise in the statistical methods of randomized controlled trials, including those addressing chronic conditions; and statistical expertise in studies of caregivers and families, behavior change and self-management interventions, and aspects of health	Dr. Cheng is Professor, Center to Address Disparities in Oral Health (CAN DO) and School of Dentistry, UCSF, and the UCSF Clinical and Translational Science Institute (CTSI).

	communication and literacy.	
Chesla, Catherine, RN, PhD, FAAN	Co-Investigator. She will contribute, in particular to Aim 2, her expertise on family intervention research, which contextualizes interventions within the broader framework of individuals, families, and communities; qualitative methodologies, including approaches to the collection and analysis of interview data; and community based and translational research.	Dr. Chesla is Professor and Interim Chair, Department of Family Health Care Nursing, School of Nursing, UCSF.
Dr. Covinsky, Kenneth E MD, MD	Co-Investigator. He will contribute, in particular to Aim 1, his expertise on risk factors and outcome measures among older adults, dementia caregivers, and persons living with Alzheimer's disease or other dementias—including their determinants of health, functional status, healthcare utilization, and institutionalization.	Dr. Covinsky is Professor in the Division of Geriatrics, UCSF, and PI of the UCSF Older Americans Independence Center, one of 15 U.S. NIA-funded "Pepper Centers." He also holds a K24 mid-career award for mentoring junior faculty whose research is pertinent to older adults.
Dr. Karliner, Leah MD, MD	Co-Investigator. She will contribute to both Aims her expertise on survey-based research—including design characteristics and technology-mediated delivery; implementation and dissemination health science; health communications among underserved and high-risk patients and families about chronic conditions, hospitalization, and community support needs; and participant recruitment in diverse and underserved communities.	Dr. Karliner is Associate Professor, Division of General Internal Medicine, School of Medicine, UCSF.

17.0 End of Study Application

17.1 End of Study Application Form

To continue working on the Study Application: Click on the section you need to edit in the left-hand menu. Remember to save through the entire Study Application after making changes. If you are done working on

the Study Application: **Important:** **Before proceeding, please go back to Section 4.0 Initial Screening Questions and Save and Continue through the form to make sure all the relevant sections and questions have been included. If you've changed any answers since you started, the branching may have changed. Your application will be incomplete and it will have to be returned for corrections. Once you are sure the form is complete, click Save and Continue. If this is a new study, you will automatically enter the Initial Review Submission Packet form, where you can attach consent forms or other study documents. Review the Initial Review Submission Checklist for a list of required attachments.**
Answer all questions and attach all required documents to speed up your approval.

The UCSF IRB wants your feedback about this new form. Please click the link to take a brief survey about the new application form.