PROTOCOL COVER PAGE

Protocol Title	Social Support Aid for People with Dementia
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ABBREVIATIONS/DEFINITIONS

Include any abbreviations or definitions for key or technical terms you use in your protocol.

- SSA: Social Support Aid
- PWMC: Person with memory concerns
- RCT: randomized controlled trial
- RA: research assistant

1.0 Objectives

1.1 Purpose: Evaluate whether the Social Support Aid (SSA) exerts positive benefits for people with memory concerns' (PWMCs') social connections, communication, and quality of life via an embedded experimental mixed methods design that combines the collection and analysis of qualitative data within a traditional randomized controlled trial (RCT) design.

2.0 Background

2.1 Significance of Research Question/Purpose: See https://aging.jmir.org/2019/1/e13378/

2.2 Preliminary Data: See https://aging.jmir.org/2019/1/e13378/

2.3 Existing Literature: See https://aging.jmir.org/2019/1/e13378/

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome:

Change in Dementia Quality of Life [Time Frame: Baseline, 3-months, and 6-months]

The 21-item modified Dementia Quality of Life instrument is a self-report survey that assesses various domains of quality of life in the person wtih dementia.

Change in Cantril quality of life ladder [Time Frame: Baseline, 3-months, and 6-months]

The Cantril quality of life ladder is a single item survey that asks respondents to rate their overall quality of life on a scale of 0 (bottom of the latter) to 10 (top of the ladder).

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s):

Pleasant events and activities of person with memory concerns [Time Frame: 3-months and 6-months]

The Pleasant Events and Activities-AD Schedule Short Form is a 17-item self-report survey that measures the degree of enjoyment persons with dementia have engaging in a range of activities.

Change in the frequency and quality of social interactions of persons with memory concerns [Time Frame: Baseline, 3-months, and 6-months]

Series of weekly, self-report calendar measures on types and quality of social interactions, developed for this study.

4.0 Study Intervention(s)/Interaction(s)

4.1 Description:

The social support aid technology consists of a smartphone with a facial recognition software application and a smartwatch. Up to 1,000 individuals can be enrolled in

the facial recognition application. Enrollment includes typing individuals names and relationships of the person with memory concern into the application and taking pictures of PWMC's faces at multiple angles. Once enrolled and in view of the smartphone's camera, the SSA's application recognizes the individual's face and alerts the smartwatch. The watch then vibrates and displays the individuals' name and relationship to the PWMC.

5.0 Procedures Involved

5.1 Study Design:

A parallel randomized controlled pilot trial design.

5.2 Study Procedures:

"Following completion of the baseline survey, participants were randomly assigned to either receive the technology or to continue with usual care. Participants were randomized at a ratio of 1:1 using a random number generator. Neither the participants nor researchers were blinded to randomization group. Research assistants met with participants in the intervention group in-person to provide the mobile phone and smartwatch and demonstrate how to use the SSA technology. Participants were given the technology to use at their discretion, and there was no requirement for how many times they had to use the SSA. Throughout the study, research assistants and the SSA developer provided technical support and answered questions regarding the technology. Participants in the control group were given the technology free of charge after completing the study." (see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6715400/)

5.3 Follow-Up

"Data were collected at three time points: baseline, 3 months, and 6 months. Caregivers completed all surveys on behalf of the person with memory loss. Participants were asked for their opinion of their relative with memory loss (eg "How often does your relative feel confident?"). At baseline, surveys for participants caring for a person with memory loss measured ADLs, memory impairment, memory and problem behaviors, social interaction, and quality of life as well as demographic questions asking about themselves and the person with memory loss. Participants with memory loss who did not have a caregiver completed surveys on their own behalf. They received a slightly different version of the survey with questions being asked in reference to themselves (eg, "How often do you feel confident?"). Their baseline survey measured ADLs, memory impairment, social interaction, and quality of life as well as demographic questions about themselves. Surveys administered at 3 and 6 months were identical to the baseline surveys except that they did not include demographic questions. At 3 and 6 months, participants in the intervention group completed an additional feasibility and utility checklist. Participants were given the option to complete an online or paper version of the surveys." (see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6715400/)

5.4 Individually Identifiable Health Information

Survey data per above were relied upon.

6.0 Data Banking

n/a

7.0 Sharing of Results with Participants

7.1 Upon publication of the peer-reviewed manuscript summarizing the findings (see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6715400/; note that the publication is open access), the manuscript was emailed to all participants.

8.0 Study Duration

8.1 Individuals participated in the study for up to 6 months. Participants were enrolled over a roughly 12 month period. All study procedures were completed in roughly 24 months.

9.0 Study Population

9.1 Inclusion Criteria: PWMCs must be: diagnosed by a physician with early-stage Alzheimer's disease, mild cognitive impairment, or a self-identified concern of memory loss; able to complete surveys in English or Spanish; SLUMS score of 20 or above. Care partners of PWMCs must be: 21 years of age and over; self-identify as someone who provides assistance to the PWMC because of their memory loss (these individuals are called ''care partners,'' as these individuals may or may not provide the intensive hands-on care typical of ''caregivers''); and indicate a willingness to use the SSA

9.2 Exclusion Criteria: Those who were not willing to utilize SSA.

9.3 Screening: A research assistant screened potential participants over the telephone or via an online form to determine eligibility.

10.0 Vulnerable Populations

10.1 Vulnerable Populations:

Population / Group	Identify whether any of the following populations will be primary focus of the research (targeted), included but not the focus of the research or excluded from participation in the study.
Children	Choose an item.

Pregnant women/fetuses/neonates	Choose an item.
Prisoners	Choose an item.
Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders	Primary focus of the research
Non-English speakers	Choose an item.
Those unable to read (illiterate)	Choose an item.
Employees of the researcher	Choose an item.
Students of the researcher	Choose an item.
Undervalued or disenfranchised social group	Choose an item.
Active members of the military (service members), DoD personnel (including civilian employees)	Choose an item.
Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	Choose an item.
Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare.	Choose an item.

Individual or group with a serious health condition for which there are no satisfactory standard treatments.	Choose an item.
Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).	Choose an item.
Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research.	Choose an item.

10.2 Additional Safeguards:

The experience of the University of Minnesota research team will minimize the possibility of psychological risks. The unlikelihood of such problems is evident from the absence of any clinically significant problems during the past eight years that Dr. Gaugler has operated various protocols related to dementia caregiving research. The RA will be trained to interview in ways that are non-threatening, friendly, and respectful. We will emphasize to all participants that they do not have to complete any question they do not want to answer, and that the interview may be terminated at any time according to their wishes. We will stress to care partners or PWMCs that their decision to discontinue the study will in no way affect the services they are receiving from the University of Minnesota or other entities.

In the event a care partners or PWMCs does become upset during the interview process, the RA will contact Dr. Gaugler who will be available for consultation. If a participant is in crisis because of their care situation or some other reason, research staff will be instructed to consult with Dr. Gaugler. With the participant's permission, we will then contact the appropriate resource person in an external agency (e.g., the Alzheimer's Association). Based on the research team's experience working with caregiving families, we expect no or very few such instances to occur. If a member of the research team does identify neglect or other potentially inappropriate care practices, the state Ombudsman will be notified to protect the rights of persons with dementia and their families.

10.3 If research includes potential for direct benefit to participant, provide rationale for any exclusions indicated in the table above:

We believed participation in the SSA evaluation would yield benefits for participants. We hypothesized that the SSA would provide PWMCs with greater opportunity for social engagement and thus enhanced quality of life.

11.0 Number of Participants

11.1 Number of Participants to be Consented: 48 participants consented for this study

12.0 Recruitment Methods

12.1 Individuals with dementia, memory loss, or memory concerns, as well as their caregivers, were recruited from the University of Minnesota Caregiver Registry (a registry of caregivers who gave permission to be contacted about opportunities to participate in research), the Minnesota State Fair, and through statewide newspaper advertisements from February to October 2017.

12.2 Recruitment Materials: Email and telephone scripts as well as flyers were used to recruit potential participants.

12.3 Payment: Participants were offered $100 upon completion of the 6-month follow-up surveys/interviews.

13.0 Withdrawal of Participants

Per https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6715400/: "A total of 58 potential participants were assessed for eligibility; of these, all but one met the inclusion criteria. Six of the 58 potential participants were unwilling to provide informed consent and were not included in the study. None of the participants expressed unwillingness to be randomized. Of the 48 participants that were randomized, 44 finished the study (92% retention rate). Two participants with memory loss refused participation after undergoing randomization to the intervention group. Two participants who were caregivers were lost to follow-up, both in the intervention group."

14.0 Risks to Participants

The study had several risks: since the study involved no invasive procedures, we did not anticipate any physical risks to the family member or clients. It was possible, although did not occur, when participants could have become upset with questions or thinking about the person with memory loss or their situations. The potential social or legal risks for participants only related to possible violations of confidentiality which again did not occur. Given our data security procedures, we believed such risks were highly unlikely (we would estimate the likelihood of these risks at 5% or under).

15.0 Incomplete Disclosure or Deception

Not applicable

16.0 Potential Benefits to Participants

16.1 Potential Benefits: There were no direct benefits to participants that were anticipated.

17.0 Statistical Considerations

17.1 Data Analysis Plan From:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6715400/.

"Recruitment, Randomization, and Retention

Chi-square and t tests were used to determine if participant demographics in the intervention and control groups were significantly different (P<.05). Chi-square and t tests were also used to compare participants who were lost to follow-up with those who were not.

Feasibility and Utility

Participants in the intervention group were asked to complete an additional survey at 3 and 6 months to assess their perceptions of feasibility and utility. This checklist included 15 Likert scale items asking participants to rate their level of agreement with statements such as "the technology works well," "SSA was easy to use," and "my relative felt lost using SSA" (α=.89).

Assessment of Intervention Effect

Descriptive statistics were calculated for measures of quality of social interaction and quality of life. Social interaction quality was measured by asking participants to rate their satisfaction with the following types of communication: visits, phone calls, mail correspondence, and computer correspondence. Quality of life was measured using the Pleasant Events Schedule-Alzheimer's Disease (PES-AD; frequency α=.84; enjoyment α=.76) and Dementia Quality of Life (DQoL; α=.92). The PES-AD asks with what frequency and level of enjoyment the person with memory loss experiences a list of pleasant activities (eg, being outside, listening to music, laughing). The DQoL asks participants to use a Likert scale to rate how often the person with memory loss feels a certain way (eg, satisfied, cheerful, angry, worried).

We imputed missing data using a Markov chain Monte Carlo method to conduct a five-fold multiple imputation. Analyses were conducted as intention to treat. Change scores were calculated to determine differences between outcomes at baseline and 6 months. To determine whether changes in satisfaction and quality of life in the intervention group were significantly different than changes in the control group, t tests were used. Statistical significance was assessed using two-tailed tests with a significance level of P=.05.

Qualitative Analysis

Following completion of the 6-month survey, participants in the intervention group were asked to participate in a semistructured interview; 13 individuals agreed to participate. The interviews took place over the phone and lasted between 10 and 30 minutes each. Interviews were transcribed by a professional service and organized into NVivo. Qualitative data were coded using Braun and Clarke's [18] six steps of thematic analysis. HM first read through all transcripts and then generated initial themes. HM and JG discussed and compiled codes into an initial coding framework. Next, HM coded all material and revised the coding framework as needed. The qualitative analysis was guided by the research question: How and why did the SSA work or not work for caregivers and persons with memory loss?"

17.2 Power Analysis: n/a

17.3 Statistical Analysis: Please see section 17.1 above

17.4 Data Integrity: Data cleaning and review of frequencies and other univariate procedures are used to ensure that the final analytic data sets are accurate.

18.0 Health Information and Privacy Compliance

Individually Identifiable Health Information: for guidance regarding the use, collection, storage and sharing outside of the covered entity of identifiable health information please see: UMN Privacy Office Policies and/or Fairview Health Services Privacy Policies, and UMN HIPAA Agreement Templates. For research conducted at Gillette Children's Specialty Healthcare refer to Gillette Research Administration for guidance.

Under the HIPAA Privacy Rule, research studies at the University are permitted to use and disclose protected health information with the authorization of the research participants, or without individual authorization in limited circumstances.

18.1 Select which of the following is applicable to your research:

☐My research does not require access to individual health information and therefore assert HIPAA does not apply.

X I am requesting that all research participants sign a HIPCO approved HIPAA Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization).

☐I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

Appropriate Use for Research: Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

☐ An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

18.2 Identify the source of Private Health Information you will be using for your research (Check all that apply)

☐I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me

X I will collect information directly from research participants.

☐I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.

☐I will pull records directly from EPIC.

☐I will retrieve record directly from axiUm / MiPACS

☐I will receive data from the Center for Medicare/Medicaid Services

☐I will receive a limited data set from another institution

If the limited data set used will contain information from somewhere other than the University of Minnesota or MHealth, then you must enter into a Data Use Agreement with the data source. You may use the University's standard Data Use Agreement or another form approved by the health information Privacy & Compliance Office. Please upload in ETHOS the Data Use Agreement you will use for this transfer of information.

If you do not have a Data Use Agreement in place, you may submit your protocol for review however, you must complete a Data Use Agreement before you can receive the Limited Data Set. If you have questions about Limited Data Sets, please refer to http://www.healthprivacy.umn.edu/policies-procedures/creating-limited-data-set, or contact the privacy office at (612)-624-7447, or by e-mail at privacy@umn.edu.

☐Other. Describe: Describe in detail the source of the information.

18.3 Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

All information was collected from surveys and interviews directly with participants who consented. See above for more information about how data were managed and secured.

18.4 Approximate number of records required for review:

Please see above

18.5 Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes

☐ This research involves record review only. There will be no communication with research participants.

☐Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.

x Communication with research participants will take place outside of treatment settings. If this box is selected, please describe the type of communication and how it will be received by participants.

Communication took place in-person, over the phone, and via email.

18.6 Access to participants

Not applicable; participants were volunteers as detailed earlier.

18.7 Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply).

☐In the data shelter of the Information Exchange (IE)

☐Store ☐Analyze ☐Share

☐In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

☐Store ☐Analyze ☐Share

☐In REDCap (recap.ahc.umn.edu)

☐Store ☐Analyze ☐Share

☐In Qualtrics (qualtrics.umn.edu)

☐Store ☐Analyze ☐Share

☐In OnCore (oncore.umn.edu)

☐Store ☐Analyze ☐Share

☐In the University's Box Secure Storage (box.umn.edu)

☐Store ☐Analyze ☐Share

x In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact:

S:\Public_Health_Center-on-Aging_Gaugler\OLD P Drive\Social Support Aid for Persons with Dementia

x Store x Analyze x Share

☐In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices:

HIPCO requires and will confirm that devices used in this manner are properly encrypted.

☐Store ☐Analyze ☐Share

☐Other. Describe in detail the location and whether the data / specimens will be stored, analyzed, or shared, and in what ways.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a smartform (iPhone or Android devices) that you have not already identified in the preceding questions

☐I will use a server not previously listed to collect/download research data

☐I will use a desktop or laptop not previously listed

☐I will use an external hard drive or USB drive ("flash" or "thumb" drives) not previously listed

☐I will use a mobile device such as an tablet or smartphone not previously listed

18.8 Consultants. Vendors. Third Parties.

Not applicable

18.9 Links to identifiable data:

All data sets from this study have been de-identified, so any link between names of participants and analytic data sets are no longer available.

18.10 Sharing of Data with Research Team Members.
We share and analyze data with research team members via the secure HST Citrix server/environment.

18.11 Storage of Documents:

Please see above. Older completed studies, following study de-identification, are also stored in Mayo storage where appropriate

18.12 Disposal of Documents:

We do not plan to dispose documents.

19.0 Confidentiality

19.1 Data Security: Please see above for our steps to ensure confidentiality of all data as well as its security. The consent form is not located within any medical or similar record of participants.

20.0 Provisions to Monitor the Data to Ensure the Safety of Participants

20.1 Data Integrity Monitoring.

See below

20.2 Data Safety Monitoring. As the proposed project will pose minimal risks to study participants the Principal Investigator (PI), Dr. Gaugler, will serve as the primary monitoring entity of this study. As noted above, the proposed study involves no invasive procedures and there will be no physical risks to study participants. The consideration of need is potentially stressful, and thus there are possible psychological risks for the caregiver a relative with Alzheimer's disease and related dementia (ADRD). The potential social or legal risks for the participants relate only to possible violations of confidentiality.

Ongoing review of protocol and human subjects research compliance occurred during regular project meetings and Dr. Gaugler. During these meetings Dr. Gaugler worked with project staff to minimize research-associated risk and protect confidentiality of participant data. Research staff were trained to interview in ways that were non-threatening, friendly, and respectful. We emphasized to all participants that they did not have to complete any question they did not want to answer, and that the interview could be terminated at any time according to their wishes. We stressed to participants that their decision to discontinue the study would in no way affect the services they are receiving from the University of Minnesota or other entities.

In the event a participant became upset during the interview process (which did not occur), research staff would contact Dr. Gaugler, who will be available for consultation. If a participant was in crisis because of their care situation or some other reason, research staff were be instructed to consult with Dr. Gaugler (which again did not occur). With the participant's permission, we would contact the appropriate resource person in an external agency (e.g., the Alzheimer's Association). If a member of the research team identified neglect or other

potentially inappropriate care practices (which did not occur), the state Ombudsman will be notified to protect the rights of persons with dementia and their families.

All information obtained from participants was strictly confidential and will not be released except at the express written request of the study participant. All electronic data are maintained on Dr. Gaugler's office computer and the HST secure project folder.

21.0 Compensation for Research-Related Injury

21.1 Compensation for Research-Related Injury: Not applicable

21.2 Contract Language: Not applicable

22.0 Consent Process

Note: The process and documentation plan must follow "SOP: Informed Consent Process for Research (HRP-090)" and "SOP: Written Documentation of Consent (HRP-091)."

22.1 Consent Process (when consent will be obtained): Please see above.

22.2 Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception): Not applicable.

22.3 Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained): Not applicable.

22.4 Non-English Speaking Participants: Not applicable.

22.5 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age): Not applicable.

22.6 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent: Please see above.

22.7 Adults Unable to Consent: Please see above.

23.0 Setting

23.1 Research Sites: Please see above.

23.2 International Research: Not applicable.

23.3 Community Based Participatory Research: Not applicable.

24.0 Multi-Site Research

Not applicable.

25.0 Coordinating Center Research: Not applicable

26.0 Resources Available

26.1 Resources Available: Please see above for details on funding and other resources available to conduct this study, which is now complete.

27.0 References

McCarron HR, Zmora R, Gaugler JE. A web-based mobile app with a smartwatch to support social engagement in persons with memory loss: pilot randomized controlled trial. *JMIR Aging*. 2019 Jun 18;2(1):e13378.