Developing a Distance Education System to Train Savvy Caregiver Program Interventionists: Extending Access and Capacity in Community-Base Delivery of Evidence-Based Interventions

Short title: Savvy System Project

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Principal Investigator: Ken Hepburn

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1. Internal (Emory) Collaborators

Team Member	Area of Expert Contribution	IRB Review
Monica Parker	ADRC Minority Engagement Core Director	Emory
Kate Yeager	Qualitative methods	Emory
Adarsh Char	Instructional Designer	Emory
Melinda Higgins	Statistician	Emory
Carolyn Clevenger	Dementia care provider; distance educator	Emory
Lai Reed	Research Coordinator	Emory

2. External (non-Emory) Collaborators

Team Member	Institution/Organization	IRB Review
Carey Sherman	University of Michigan	Emory
Marsha Lewis	University of Buffalo	Emory
Christy Nishita	Native Hawaiian Aging	Emory
Margaret Moss	University of British Columbia	Emory
Poki'I Balaz	Savvy Caregiver Master Trainer	Emory
Clint Dye	Savvy Caregiver Master Trainer	Emory
Lucas Morgan	Savvy Caregiver Master Trainer	Emory
Ann O'Sullivan	Savvy Caregiver Master Trainer	Emory
John Hobday	Healthcare Interactive, Inc	Emory

3. Background and Significance

This application proposes a four-year Stage I intervention development project, submitted in response to RFA-AG-18-030. We propose to develop a web-based system that uses distance education methods and provides manuals and protocols to train, certify, and monitor the performance of interventionists to deliver the Savvy Caregiver program (Savvy), an evidence-based dementia family caregiver psychoeducation program. The system will greatly increase the scalability of Savvy. Replacing the need for in-person interventionist training,

it will enable organizations – large or small; community-based or statewide – to offer Savvy to their ever more diverse constituents. Provided to groups of 8-12 (typically) individuals caring for family members living with Alzheimer's disease or related dementias (PLWD), Savvy employs a well-established mechanism of action based in Social Cognitive theory to promote caregivers' solution-focused coping behaviors through the acquisition of appropriate knowledge, skills, and outlook and the enhancement of caregiving mastery. The system will provide sponsoring organizations with guidelines and materials for administering Savvy, a program to train and certify staff or volunteer interventionists to lead and locally tailor Savvy, and a process by which to monitor the fidelity of interventionists' performance. Well-trained Savvy interventionists who faithfully embrace the program's core principles and its curriculum and are able to adapt program terms, concepts, and even delivery processes to fit the culture and values of caregiver participants are the key to scaling Savvy up to make it widely available to the growing number of dementia family caregivers in the U.S.

The number of PLWD in the U.S. will rise from 5.7 million to 14 million by 2050, and the number of family caregivers who maintain these persons in the community will rise proportionately from 15 million at present. Several psychoeducation programs, including Savvy, have successfully ameliorated the adverse effects of caregiving, but these programs are only minimally available and accessible. Present in 15 states, principally through Administration for Community Living support, Savvy has served more than 15,000 caregivers over the last decade; this represents only one one-thousandth of the U.S. caregiver population. So far, Savvy has been exclusively disseminated through on-site in-person interventionist training by Savvy authors. This costly procedure has limited dissemination to large agencies that have obtained external grant support. The development of this proposed web-based system will take advantage of ubiquitously available distance education methods and platforms to greatly expand access to Savvy for the many organizations, especially small and local organizations that serve the growing number of diverse PLWD and their family caregivers. The activities proposed focus principally on developing and testing the preliminary efficacy of the web-based system. Manuals, slides, handouts, and workbooks will be concurrently developed/revised to harmonize with the system and guide organizations in administering the Savvy program.

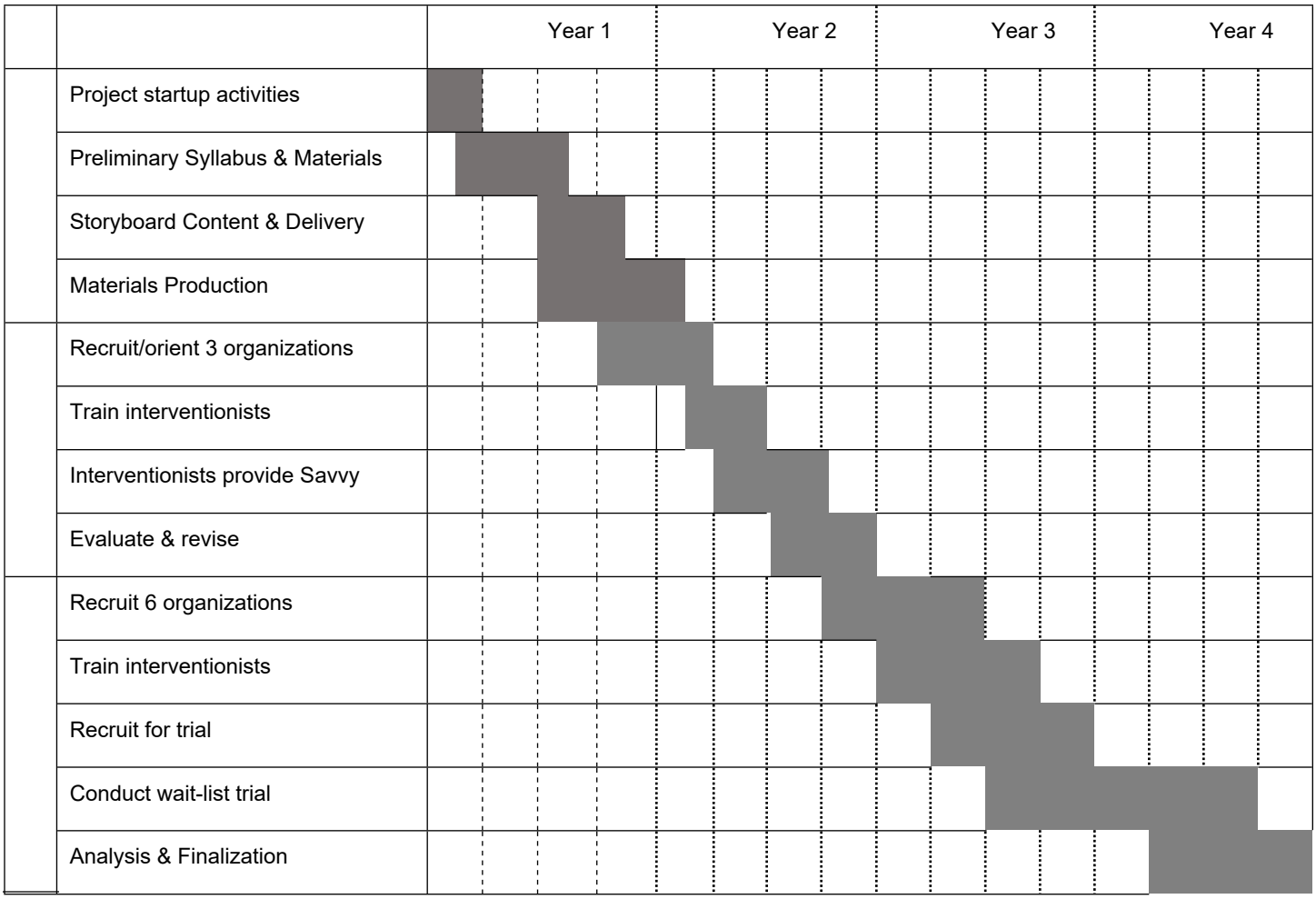
4. Goals/Aims

Aim 1. Develop a prototype web-based system for Savvy interventionist training and certification and an accompanying performance fidelity monitoring process. Development efforts will yield web-based components delivered through freely available course management and survey applications (e.g., Canvas; Articulate Rise) that will enable sponsoring entities to train and certify interventionists who can locally tailor Savvy, monitor the fidelity of their performance in delivering Savvy, and assess the program's impact on caregivers.

Aim 2. Establish the field-readiness of the system. We will engage three community entities serving culturally, ethnically, and geographically diverse constituencies to collaborate with the study team and expert advisory panel in a highly participatory formative test of the prototype system developed through Aim 1 activities. Results and feedback will inform finalization of materials for the Aim 3 trial.

Aim 3. Conduct a field trial of the system. The trial will test the effectiveness of the system and examine its preliminary efficacy in producing expected outcomes (i.e. well-being, mastery) in a diverse group of caregivers participating in programs delivered by newly trained interventionists. Six culturally or organizationally diverse sponsors will recruit 2 individuals each to be trained as Savvy interventionists (12 interventionists) and each sponsor will then recruit at least 20 caregivers to take part in a wait-list, no control group study (N=120) of the performance of the interventionists and the preliminary efficacy of the Savvy program provided by them.

The figure below provides a broad timeline for project activities. While we will begin some Aim 2 activities before all of the Aim 1 activities are complete and some Aim 3 activities before all of the Aim 2 activities are complete, we expect Aim 1 activities to be complete by project month 12 and Aim 2 activities to be complete by the end of the second project year.



We expect dissemination activities – conference presentations; journal manuscripts – to take place across and beyond the life of the project.

5. Study Design

This will be a three-phase project, the goal of which is to establish the readiness of the online learning system for a future Stage III or IV trial that can lead the way to broader use and dissemination of Savvy. In the first project phase, we will develop a prototype web-based system for Savvy interventionist training and

certification and an accompanying performance fidelity monitoring process. This phase will occupy the project's first 14 months and will involve no human subject research participation. Phases 2 and 3 of the study involve human subject research participation. All human subject research activities will be conducted by members of the Emory study team, identified above; no non-Emory study team members will have any contact with Phase 2 and 3 research subjects. The second project phase, which will begin in project month 9 and extend through project month 24, will involve a formative evaluation of the prototype web-based system. In this phase, administrators and interventionists-in-training from 3 collaborating organizations and 36 informal dementia caregivers from these organizations will participate as research subjects. The administrators and interventionists will take part in semi-structured evaluation interviews; the caregivers will be asked to participate in Savvy programs offered by the newly-trained interventionists and they (the caregivers) will be asked to complete pre- and post-Savvy participation interviews both about the effect of the program on them and about their evaluation of the program. Phase 2 results will enable us to revise the interventionist training system, as needed. Once the system is deemed ready, we will, in phase 3, conduct a field test of the system implemented in six culturally and/or organizationally diverse sponsoring agencies. This test will again involve administrators, interventionists-in-training, and 120 dementia caregivers from participating organizations as research participants. The Aim 3 test will principally assess the effectiveness of the system in training interventionists who maintain fidelity to Savvy core principles; this portion of the test involves semi-structured interviews with the administrators, interventionists and a sample of caregivers. The test will also assess the preliminary efficacy of programs led by system-trained interventionists in producing anticipated outcomes in caregiver participants – reduced depression and burden and enhanced caregiving mastery. In this portion of the test, caregivers will be randomly chosen to participate immediately in a Savvy program offered by one of the organization's newly trained interventionists or to participate after a waiting period of 4 months. Those who

take part in the program immediately will be asked to take part in 3 interviews (baseline and then 3 and 6 months after the start of the program. Those in the delayed start group will be asked to take part in 4 interviews (baseline (at the point of signing up for a later program), immediately prior to the beginning of the program and then 3 and 6 months after the start of the program. Standard instruments will be used to assess burden, mood (anxiety and depression), caregiving confidence and mastery, and care recipient well-being.

Organizational structure of the study team

The study was proposed by the Nell Hodgson Woodruff School of Nursing at Emory University, the academic home of the PI/PD, Dr. Hepburn. Although there are investigators involved from a number of institutions and organizations, Emory is the sole site for all research activity associated with the study, and therefore the Emory IRB is the only IRB involved in providing oversight for human research activities. The study is funded by the National Institute on Aging at NIH. The overall goal of the study – and therefore the expectation of the funding agency – is the successful demonstration of an internet-based system that will enable organizations such as state agencies or private entities (e.g., health systems or churches) to implement an evidence-based dementia family caregiver psychoeducation program (the Savvy Caregiver) and make it available to their constituents. The system will include an organizational on-boarding component, a component that will enable the organizations to adapt the Savvy Caregiver to fit the values and customs of their constituents, and a large component designed to train Savvy Caregiver program leaders. The project involves investigators from Emory and also from the University of Buffalo, the University of British Colombia, and two private organizations, HealthCare Interactive, and Family Care Strategies, LLC. Each of the investigators will play three main roles: 1) collaborate in the development of the system; 2) assist in identifying entities (organizations) that would be willing to engage in two phases of testing of the system; and 3) assist in reviewing and interpreting the results

of the evaluation of system feasibility, acceptability, and preliminary efficacy that the Emory team will conduct. As described in the grant application budget, funds flow, per subcontract, to the home institutions/organization of the collaborating investigators to support their roles in the project.

Setting and location

The first phase of the study, linked to Aim 1, does not involve human subject research. It only involves the study team, key consultants, and expert advisors who will work at their respective institutions.

The phase 2 and 3 studies are conducted from a single site, the School of Nursing at Emory University. We will centrally and via Zoom videoconferencing software (from Emory) consent the organizational leaders, interventionists trained by the system we developed and dementia family caregivers engaged in Savvy Caregiver programs provided by system-trained interventionists to participation in a wait-list design study in which caregivers from each site will be randomly assigned to immediate participation in a Savvy program offered by one of the newly trained interventionists or to delayed participation in Savvy (after 4 months). Each participant will be asked to complete the same post-program participation survey via Zoom videoconferencing software (from Emory) as in the Phase 2 study, and each will be asked to take part in four phone or video interviews in which Emory staff will administer well-established and validated questionnaires to assess burden, depression, anxiety, and caregiver competence and mastery as well as care recipient well-being. As in the phase 2 study, a sub-sample of caregiver participants (N=18) will be asked to participate in semi-structured interviews – also completed via Zoom videoconferencing software - focused on their perceptions of the interventionist's program leadership skills, any adaptation experiences, and on ways in which they met their own needs and expectations. In both phases (2 and 3) organizational leaders and system-trained

interventionists will be asked to take part in qualitative formative evaluation interviews conducted by Emory study staff.

Population to be studied

Inclusion Criteria:

Organizational Leaders

a) Able to understand and speak English
b) Affiliated with an organization serving caregivers for family members living with Alzheimer's disease or related dementias
c) 18 years or older

Interventionists

a) Able to understand and speak English
b) Affiliated with a participating organization
c) 18 years or older

Caregivers

a) Able to understand and speak English
b) Caregiver for a person living with Alzheimer's disease or related dementias (PLWD) who is providing informal care for at least 3 hours a day. PLWD should not be bound for institutional care within the next 6 months.
c) 18 years or older

Exclusion Criteria:

Not applicable.

Community Participation

In developing the adaptation element for the interventionist training system, we will employ established models for adapting evidence-based programs. The starting point for these models is an anchoring in an understanding of a program's theory-base and mechanism and the key parts of the program. Such anchoring is central to the organizational on-boarding and interventionist training system. The adaptation models then use dialogue with end users to accomplish adaptation. The adaptation element we will develop will train interventionists to identify concerns among Savvy participants or possibly within the larger community about Savvy terms, concepts, or delivery processes and to arrive at "translation" that makes Savvy more available and acceptable to the populations they serve while maintaining the integrity of the core principles and mechanisms. For example, Savvy originally stressed that caregivers gradually have to assume more control of the care recipient's behavior. Through interactions with caregivers from a variety of backgrounds and advocates of person-centered care, we now speak in terms of a caregiver's need to provide more guidance (or assume more responsibility) for what the person does during the day. Savvy interventionists in Hawaii are finding that adding a "session zero" – a prelude to Savvy – allows Native Hawaiian elders to engage in "talk story," a culturally important process that sets the stage for these elders to give permission to (typically) younger interventionists to train and coach them. No core principles are bent in either case, but the adaptations promote learner receptivity. An adaptation team, consisting of key study team faculty (Nishita, Moss, and Parker) and the project's Master Trainer consultants (Belaz Dye, Morgan, and O'Sullivan) will take the lead in formulating the content and delivery method for this training element.

Recruitment

Each of the three types of recruitment and retention efforts is described below:

Sponsoring Organizations. We seek to recruit 3 organizations for our Aim 2 activities and 6 organizations for our Aim 3 activities; the Aim 2 organizations will be able to continue as Aim 3 organizations. Since these sponsoring organization leaders will be involved in the Aim 2 and 3 studies, we will seek their informed consent for participation in the studies. We are specifically seeking to recruit organizations serving the targeted minority groups, as well as those serving a more mixed or majority clientele. Several of the study team members and program advisors are either directly involved with or have strong contacts with potential sponsoring organizations, and we have already identified preliminary organizational interest in taking part in the project. Beyond those specific contacts, the project Co-PIs, Hepburn and Sherman, can draw on their extensive networks for organizational recruitment. Past experience with organizations that have adopted Savvy testifies to the long-lasting involvement with the program: once adopted, Savvy remains a regular part of the organization's portfolio, so we do not expect organizational retention to prove a problem. Procedures in our Aim 2 and 3 approach involve considerable interaction between the project team and sponsor organization leadership, including the provision of information and feedback that can help these organizations to improved Savvy uptake among their clients. This interaction will also promote retention in the project.

Interventionists. It will be the sponsoring organizations who will identify individuals – from their existing staff or from volunteers whom they recruit – to be trained as Savvy interventionists by the system we develop and to lead Savvy programs that the sponsors organize. Guided by orientation and administrative materials and protocols that we will provide, the sponsors will organize the training, organize the Savvy programs, and conduct regular debriefings with the interventionists. Since these interventionists will be involved in the Aim 2 and 3 studies, we will seek their informed consent for participation in the studies. In

addition to sponsor-based debriefings, the semi-structured interviews we will conduct with the interventionists during the Aim 2 and Aim 3 studies will also provide a linkage for them to the overall study and will, hopefully, provide them with a sense of ownership in the developing system.

Caregivers. It will only be family caregivers who will be part of the clinical trial component of this study (in Aims 2 and 3). Recruitment into the studies will be through referral from the sponsoring organizations. Each organization will recruit caregivers to take part in Savvy programs provided by interventionists trained in the system we are developing. We will provide organizations with materials they can use to announce Savvy and the studies; we will encourage the organizations to insert these materials into their own standard informational templates (i.e., standard logo and graphics). For caregivers willing to do so, their contact information will be provided to the Emory study team. We will arrange a phone or video call with each during which we will explain the study (Aim 2 or Aim 3 – a caregiver will not be able to take part in both), explain eligibility criteria, and seek informed consent (verbally) for participation. We do not anticipate attrition to be a problem in the Aim 2 study; research contact, following consent, will occur over a very brief period of time. All who consent to the Aim 2 study will take part immediately in a Savvy program and in an on-line survey and (for some) in-person interview conducted by phone or video right after the program. Prolonged retention will be more of a challenge in the Aim 3 study. Those taking part will enter a Savvy program either immediately or after a delay based on scheduling at the individual agencies. For those taking part immediately a series of 3 phone or video interviews will bracket their Savvy participation (at baseline then at 3 and 6 months following baseline. For those with a delayed start, we will conduct 4 interviews (upon sign up, immediately prior to the start of the program and then 3 and 6 months after program completion).To foster engagement with the project, we will prepare and distribute to participants a monthly project newsletter,

featuring tips on exercise and healthy eating and profiles of the study team. We will also send birthday and seasonal holiday cards, as appropriate.

Field Methods

Data Collection and Management. Emory study staff will use an IRB-approved phone or video consent process to enroll individuals from the three groups that are targets for our formative evaluation activities, and study staff and team members will gather data from them in the ways described below:

Interventionists. We will conduct three recorded semi-structured video interviews with each interventionist. One will occur immediately after training; this will focus on their sense of the completeness and adequacy of the training program, including the training methods, videos, and materials, and their perceived readiness to lead the program. We will also interview them immediately after the conduct of each of the two Savvy programs they lead, asking them to report on their own performance as interventionists, including any adaptation processes in which they might have engaged, and to reflect on ways the training might be improved to strengthen their skills, including for adaptation. In total: 18 interviews.

Savvy Participants. Using an on-line survey method, we will ask each caregiver to complete the post-program fidelity monitoring survey (see Appendix) that seeks responses to the program (feel more knowledgeable, more competent, better equipped, etc.) and asks them to assess the interventionist's performance and verify that certain key elements of the program were covered (N=36; 6 in 6 groups). We will also conduct recorded semi-structured video interviews with a small sample of participants (N=8-12), selected to achieve maximum variability of relationship to care recipients, gender, racial/ethnic heritage, and rating of the program and the interventionists. Interviews will focus on caregivers' perceptions of the interventionist's

program leadership skills, any adaptation experiences, and on ways in which they met their own needs and expectations.

Organizational Leaders. We will conduct recorded semi-structured video interviews with sponsoring organizations' key contact persons immediately after the interventionist training and then after each of two Savvy offerings. The conversation will focus on identifying ways to strengthen and improve the training, certification, and fidelity monitoring system. We will also seek information about time and resource costs of the program, caregiver demand, and caregiver recruitment and feedback (3 interviews per organization).

Results from Savvy participant quantitative fidelity monitoring surveys will be compiled in a simple spread sheet to allow us to see whether there are any notable problems in interventionist performance either within or across sites or in or across interventionists. Likewise, we will be able to compare caregivers' responses about knowledgeability and competence with responses we have received from other caregivers in Savvy programs provided by interventionists who were trained in person by Hepburn or Sherman.

Once a cohort of 20 consented caregivers has been formed at any local organization, participants will be assigned (through a random procedure administered by Emory staff) to take part immediately in one of the Savvy programs offered by either of the 2 interventionists or to take part in one of the 2 interventionists' programs after 4 months; follow-up phone or video interviews will be conducted at 2, 4, and 6 months lasting each 1-1.5 hours in length. The audio files from interviews will be saved on Emory School of Nursing's secure share-drive within a password protected folder for 5 years post-study completion.

Measures

The table below describes the well-established instruments to be used in caregiver interviews.

Category	Instrument	Instrument Description	Psychometrics
Demographic Information	Demographic sheet Caregiving History	SES, Person living with dementia information, length of caregiving, co-residence with recipient.	Study-developed form (Baseline only)
[Caregiver Vars] Depression	Center for Epidemiological Studies-Depression	A 20 item Likert scale scored 0-3 with somatic and psychological subscales	Alpha=.85; validity well-established[104]
Anxiety	State-Trait Anxiety Inventory	A 20-item 4-point Likert scale is sensitive to changes in transitory anxiety	STAI state sensitive reliability reported at .94[105]
Burden	the Zarit Burden Inventory (ZBI),	A 22-item 4-point Likert scale, widely used in caregiving studies	Used in multiple studies with well-established validity[106]
Caregiver Mastery	Pearlin Mastery, Loss, and Competence	6 brief (3-6 item) Likert scales assessing mastery and loss dimensions	Alpha coefficients from .71-.92.[107]
Caregiver Skill	Caregiver Assessment of Behavioral Skill	17-item self-report assessment of behavioral management skills	Chronbach alphas from 0.75-0.94 with good validity
[PLWA] BPSD	Revised Memory and Behavior Problem Checklist	22-item Likert scale that assesses patient behaviors and caregiver responses to them	Reliabilities of .84-.90 reported for behavior and reaction.[108]

Informed Consent Process

Recruitment

Caregivers in the Aim 2 and 3 studies will learn about the studies from the local organization that is sponsoring Savvy interventionist training and offering the Savvy program to its constituents, using its usual modes and methods of providing information to these constituents. We will provide all collaborating organizations with materials they can use to announce Savvy and the studies; we will encourage the organizations to insert these materials into their own standard informational templates (i.e., standard logo and graphics). These organizations will explain their role in the development project and secure individuals' permission for the Emory study staff to contact them with additional information about the studies; alternately, the announcement materials will provide contact information for the project director at Emory, so individuals can also call directly. Under either scenario, the project will arrange a phone or video conversation with these individuals to assess for study eligibility.

Once eligibility has been established, the project director will provide more information about the components of the relevant study (i.e., Aim 2 or Aim 3). She will allow time for questions, verbally summarizing the material with the subject, and asking subjects to answer a few questions to gauge understanding. For those who remain interested in taking part in the study, we will conduct an IRB-approved phone- or video-based consent procedure. In that procedure, the project director documents, on a pre-established form, that the consent procedure has occurred, the individual has been provided the opportunity to raise questions, has been informed of the voluntary nature of participation and the ability to withdraw from the study without prejudice at any point, and has been told that s/he may continue to raise questions at any point during the study. A copy of the document that the project director signs is then sent to the consenting participant. The original will be retained in a locked cabinet within a locked research room within the School of Nursing. The person will be given information (also on the consent document) about study leadership and how to contact the Project Director, the study Co-PIs, and a neutral informant at Emory.

Participant Discontinuation/Withdrawal from the Study

Participants are free to withdraw from participation in the study at any time upon request. The reason for participant discontinuation or withdrawal from the study will be recorded on the study REDCap. Subjects who receive all or part of the study intervention will not be replaced.

Lost to Follow Up

A caregiver participant will be considered lost to follow-up if he or she fails to complete the scheduled post-intervention follow-up and is unable to be contacted by the study site staff within four weeks of the timepoint.

The following actions must be taken if a participant is determined to be lost to follow-up:

- The research staff will attempt to contact the participant and reschedule the missed appointment for 4 weeks and ascertain if the participant wishes to continue in the study.
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods).
- These contact attempts will be documented in the participant's record in REDCap.

Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

6. Potential Risks/Discomforts to Study Participants

Activities during the first phase of the study do not involve human subject research. The studies in phases 2 and 3 pose very low risks to study participants. The involvement of the participating organizations' administrators and interventionists in training is much in the nature of a quality improvement project; they are openly engaged in a process designed to refine the Savvy interventionist training system, so there are no threats to confidentiality or other forms of injury or harm. For the caregivers involved in the studies, the two main possible risks are to confidentiality and to minor emotional upset that might occur in answering study questions.

Based on prior experience with Savvy Caregiver program research and its implementation in community agencies, we cannot identify any expected serious adverse effects – as defined in the NIA Adverse Event and Serious Adverse Event Guidelines – that might occur to phase 2 and 3 caregiver study participants. Likewise, we cannot identify any expected serious adverse events occurring to those who are trained to become Savvy interventionists or those who administer the organizations within which Savvy is offered.

7. Potential Benefits

For the participating organizations and interventionists, the main potential benefit will be the addition of a capacity for serving clients. The organization will be able to offer an evidence-based program (Savvy), and the interventionist will acquire a new skill. More broadly, the system will be poised to extend the capacity of a wide range of other organizations to offer Savvy. For caregivers who take part in the phase 2 or phase 3 study, they will all have the opportunity to take part in the Savvy Caregiver program, a program that has repeatedly

demonstrated positive outcomes in the areas of caregiver well-being and caregiving competence. But caregivers may or not receive any benefit to taking part in the study.

8. Compensation

Caregiver study participants will receive a $25 honorarium in the form of a gift card following each each data collection event. The gift cards will be sent by mail.

9. Data Analysis: Data Management and Monitoring

Data Collection and Management. Emory study staff will use an IRB-approved phone or video consent process to enroll individuals from the three groups that are targets for our formative evaluation activities, and study staff and team members will gather data from them in the ways described below:

Data Collection

Interventionists. We will conduct three recorded semi-structured video interviews with each interventionist. One will occur immediately after training; this will focus on their sense of the completeness and adequacy of the training program, including the training methods, videos, and materials, and their perceived readiness to lead the program. We will also interview them immediately after the conduct of each of the two Savvy programs they lead, asking them to report on their own performance as interventionists, including any adaptation processes in which they might have engaged, and to reflect on ways the training might be improved to strengthen their skills, including for adaptation. In total: 18 interviews.

Savvy Participants. Using an on-line survey method, we will ask each caregiver to complete the post-program fidelity monitoring survey (see Appendix) that seeks responses to the program (feel more knowledgeable, more competent, better equipped, etc.) and asks them to assess the interventionist's performance and verify that certain key elements of the program were covered (N=36; 6 in 6 groups). We will also conduct recorded semi-structured video interviews with a small sample of participants (N=8-12), selected to achieve maximum variability of relationship to care recipients, gender, racial/ethnic heritage, and rating of the program and the interventionists. Interviews will focus on caregivers' perceptions of the interventionist's program leadership skills, any adaptation experiences, and on ways in which they met their own needs and expectations.

Organizational Leaders. We will conduct recorded semi-structured video interviews with sponsoring organizations' key contact persons immediately after the interventionist training and then after each of two Savvy offerings. The conversation will focus on identifying ways to strengthen and improve the training, certification, and fidelity monitoring system. We will also seek information about time and resource costs of the program, caregiver demand, and caregiver recruitment and feedback (3 interviews per organization).

Results from Savvy participant quantitative fidelity monitoring surveys will be compiled in a simple spread sheet to allow us to see whether there are any notable problems in interventionist performance either within or across sites or in or across interventionists. Likewise, we will be able to compare caregivers' responses about knowledgeability and competence with responses we have received from other caregivers in Savvy programs provided by interventionists who were trained in person by Hepburn or Sherman.

Data Management

Data will be entered at the time of each interview directly into the dedicated project tablet computer and saved on Emory's secure REDCap platform. All data entry screens are set up in REDCap and, where possible, include data delimiters (i.e., skip patterns, valid range limits) to ensure correctness and minimize missing data. Data will be exported weekly and analyzed for data cleaning and verification. Upon completion of each cohort data-gathering point, all data will be merged for scale computation, aggregation, and analysis. In preliminary analyses, descriptive statistics and frequency distributions will be examined to identify outliers and ensure integrity of merged files. For all multi-item scales, internal consistency will be examined using Cronbach's alpha and associated statistics (e.g., item-total correlations, alpha if item deleted).

Preliminary analyses will examine baseline differences among completers and non-completers and by study arm (immediate/delayed) as a randomization check using 2-group comparison tests (t-tests and non-parametric equivalent tests for continuous variables (normally or non-normally distributed) and Chi-Square tests for categorical variables). The association of predisposing factors (demographics, CG history, relationship and care recipient status at baseline) at baseline data with changes in outcomes over time will be examined to identify significant covariates. Where significant associations with baseline measures are detected, these potential confounders will be controlled for in subsequent analyses using covariate model adjustments.

Monitoring

The School of Nursing at Emory University will maintain close contact with every entity within the study and will monitor study activities. We will use a common study web-portal using the Research Electronic Data Capture (REDCap) created and managed in Emory SON. We will create and update study participants' data through REDCap. During data entry, automated checks will be performed that will immediately flag problematic data (e.g., missing, out of range, inconsistent), allowing for the research staff member to address any discrepant data promptly thus increasing data quality. Data entered into the web-based form are immediately stored in a study database and tracked through a journaling process where they are accessible for review by the study team. Suspicious data can be flagged through a query management system, and automated alerts provided to the sites. A complete audit trail is stored for each database modification. Any discrepant data identified through analytic manipulations will be communicated to the sites. Once all queries have been resolved and the database has been deemed "clean", it will be officially locked. All permissions to make changes (append, delete, modify or update) to the database will be removed at that time.

Record keeping and data collection are the responsibilities of the research staff under the supervision of the PI. The investigator is responsible for ensuring the accuracy, completeness, legibility (if hardcopies of worksheets are used), and timeliness of the data reported.

All study's written records will be stored in a locked cabinet for 5 years. Study data will be de-identified and shared with future researchers per written request and IRB approval (Resource and Data Sharing Plans).

10. Plans for analysis

Multi-level mixed effects models (MLM) with random (participant) and fixed (cohort) effects will be employed to test for linear (and non-linear) trajectories of change for the Intervention group versus waitlist

group focusing on the group-by-time effect. To address the primary effect of the Savvy intervention, the Immediate group will be compared to the waitlist delay group, using the first 2 time points (0m-2m) to test for differences between the 2 groups' changes post intervention. Additionally, the combined Savvy intervention effects will be assessed using a paired t-test for the combined immediate group's first 2 time points (0m-2m) with the waitlist delay group's 2 time points before and after beginning Savvy (4m-6m). If there are significant differences between the 2 groups at the time point immediately prior to receipt of the intervention, these "baseline" effects will be included and adjusted for a final analysis of covariance (ANCOVA) model for these change scores. Given that the immediate group will have 3 post-intervention measurements (2m-4m-6m), MLM longitudinal models will also be employed to assess the overall time effects plus planned post hoc comparisons for both the immediate intervention effect and the longer term and sustained effects. Sidak Type-I error rate adjustment (which has higher power than Bonferroni) will be applied for the multiple pairwise time point comparisons. The proposed study design also has the advantage of capturing "baseline" time points for the delay group (0m-2m-4m) which will provide an excellent opportunity to evaluate what if any potential "placebo" effects there may be from being enrolled in this type of study. These initial data captured at 0m-2m-4m for the delay group will also be used to evaluate any potential decline occurring during this time period. All model assumptions will be tested; grand mean centering used to help combat multi-collinearity between variables; and standard diagnostic tests and influence statistics used to test the distributions of the residuals. MLM models utilize all available data for all participants at each time point and have the advantage of adjusting for the missing data over time, where repeated measures ANOVAs do not. Further covariate predictors of missingness (mainly due to attrition) over time will be included to additionally adjust for these confounders124 SPSS v.24 will be used for all analyses at the 5% significance level.

We will use a meta inference process to answer the central question of this project: Can the system train interventionists to maintain fidelity to core SAVVY principles and demonstrate the ability to tailor the implementation to match cultural values of the community? This inference procedure examines both the process (System Effectiveness Study) and the outcomes (preliminary Efficacy Study). The research team will follow a series of analytic steps to create meaning out of the relatively large amount of collected data, incorporating both the quantitative and qualitative components in a dynamic and interactive manner. We will look first at the results interventionists' ability to provide Savvy faithfully and in a manner congruent with local values: What conclusions or trends do fidelity monitoring, caregiver surveys, and interviews with all parties yield? Next we examine the impact of Savvy on participating caregivers to further establish the effectiveness of the system. If caregiver outcomes improve, this will provide a demonstration that system-trained interventionists can faithfully deliver Savvy in such a manner that its mechanism of action can have an expected effect on caregiver participants. If the outcomes do not support the effectiveness of this new system on either or both questions, we have the data to inform further system development work. The outcome of this process will be a finalized interventionist training system, one informed by a contextual understanding of the effects of the system and ready for a next step, a Stage III or IV intervention trial.

11. Training of study team

The Project Director will oversee the training of all staff members on the team, ensuring that they have completed or renewed CITI trainings at appropriate intervals. She will also develop standard operating procedures (SOPs) to ensure that study staff maintains the highest standards of data protection and management. For any staff members who will have participant contact, the project director will provide

opportunity for them to practice interview technique prior to any contacts with human subjects. They will also be monitored regularly to ensure best practices are maintained for data collection. The SOPs will be updated regularly in order to reflect current practices by study staff.

12. Plans for monitoring the study for safety

The project PI (Hepburn) and the project Co-PI (Sherman) will be responsible for ensuring participants' safety in this minimal risk, single-site study. Per concurrence of the NIA Program Officer, because this study is being conducted at a single site, involves fewer than 200 subjects, and is not a clinical trial it does not require a Data Safety and Monitoring Board. Instead, the Associate Dean for Research at the Nell Hodgson Woodruff School of Nursing (Dr. Elizabeth Corwin) has agreed to serve as the Safety Officer for the project.

Frequency of Data and Safety Monitoring

The PI will be informed of any deaths as soon as they occur and will notify the NIA Program Officer and the Safety Officer (SO) within 24 hours of notification; the PI will also inform the Emory IRB of any such events within the time frame specified by the IRB. Beginning with the initiation of study phase 2 activities, the PI (Hepburn) will be responsible for providing quarterly summary reports of SAEs to the NIA Program Officer and the SO. Beginning with the initiation of phase 2 activities, safety reports will be sent to the SO twice a year and will include a detailed analysis of study progress, data and safety issues. Such reports will be developed by the co-PIs but reviewed by key study personnel and, as appropriate, study consultants and advisors.

Content of Data and Safety Monitoring Report

The study PI (Hepburn) will provide semi-annual data safety and monitoring reports to the NIA Program Officer and the SO. Each report will update the previous report. Each report will summarize:

- Overall study status
- Study participant characteristics
- Study recruitment and retention statistics
- Data completeness
- Summary statistics on caregiver and care recipient outcome measures
- Deployment of the risk protocol based on observations or scale scores
- Unanticipated Serious Adverse Events, including Deaths.

DSMB Membership and Affiliation

The Safety Officer for this study will be:

Elizabeth Corwin, PhD, RN, FAAN
Associate Dean for Research
Nell Hodgson Woodruff School of Nursing, Emory University

Dr. Corwin is a well-established researcher, currently supported by an RO1 and a P30 grant from NINR, with an extensive track record of completed externally-supported research. As Associate Dean for Research within the School of Nursing, she heads the Office of Nursing Research; as such, she has at her disposal a variety of methodological and statistical experts, should she need them to fulfill her responsibilities as Safety Officer.

The SO will:

- Review the research protocol, informed consent documents and plans for data safety and monitoring;
- Recommend subject recruitment be initiated after receipt of a satisfactory protocol;
- Evaluate the progress of the trial, including periodic assessments of data quality and timeliness, recruitment, accrual and retention, participant risk versus benefit, performance of the trial sites, and other factors that can affect study outcome;
- Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial;
- Review study performance, make recommendations and assist in the resolution of problems reported by the Principal Investigator;
- Protect the safety of the study participants;
- Report to NIA on the safety and progress of the trial;
- Make recommendations to the NIA and the Principal Investigator concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study;
- If appropriate, review interim analyses in accordance with stopping rules, which are clearly defined in advance of data analysis and have the approval of the SO;
- Ensure the confidentiality of the study data and the results of monitoring; and,
- Assist the NIA by commenting on any problems with study conduct, enrollment, sample size, and/or data collection.

13. Confidentiality

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor. The study documentation, data, videotaped interviews, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

All research activities will be conducted in as private a setting as possible.

The study monitor, other authorized representatives of the sponsor, representatives of the Institutional Review Board (IRB), regulatory agencies may inspect all documents and records required to be maintained by the investigator for the participants in this study. The clinical study site will permit access to such records.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be directly entered into and stored in the password-protected excel database. Individual participants and their research data will be identified by a unique study identification number. All information collected during the study will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the Emory School of Nursing.

The study participant's contact information will be securely stored in a separate password protected excel database for internal use during the study. This document will provide a linkage between name of participant

and a unique study identification number. At the end of the study, this linkage document all paper records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor requirements.

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