PROTOCOL

Improving Care through Improv: Promoting Mastery in the Moment

NCT Number: 05996718

Protocol Date: 02-27-2024

Improving Care through Improv:

Promoting Mastery in the Moment

PRINCIPAL INVESTIGATOR:

Candace L. Kemp, PhD.

Gerontology Institute, Georgia State University, Atlanta, Georgia

Telephone: 404-413-5216

Email: ckemp@gsu.edu

Funding Source:

This work was supported by a developmental grant to CLK from the Roybal Center for Dementia Caregiving Mastery at Emory University (P30AG064200 – Co-Directors, Hepburn and Perkins) funded by the National Institute on Aging at the National Institutes of Health.

Background and Rationale

Nationwide, over 11 million Americans, mostly family members and friends, provide informal unpaid care to millions of persons living with dementia.[1] As the population ages, these numbers are expected to rise exponentially alongside dementia's deleterious impact on public health and accompanying social and financial costs.[2, 3] Informal care partners play a critical role in the quality of life and care of persons living with dementia[1] and influence their ability to age in place at home[4] rather than relocating to costlier and less preferred formal long-term care settings (e.g., assisted living, nursing homes). Yet, caregiving in the context of dementia frequently involves burden, stress, and emotional strain, all of which negatively influence caregivers' overall health, well-being, self-care abilities, and mortality.[1, 5-8] Such outcomes compromise caregiving and ultimately negatively affect care recipients, including their ability to remain at home.[4] Needed are interventions that bolster informal care partners' ability to succeed in their care roles and minimize negative outcomes.

List of Specific Aims

1. To refine the program, "Improving Care through Improv" for informal dementia care partners.

2. To assess the feasibility, acceptability, and preliminary efficacy of "Improving Care through Improv" through pilot testing

Brief Description of Project Design

- Phase 1 involves refining the training program, "Improving Care through Improv" (Aim 1).

- Phase 2 involves piloting the training program with 40 adult informal care partners of person with moderate dementia to test its effect on self-perceived caregiving mastery through a no-control, pre-post design single-group trial with three time points: baseline; immediately upon completion, and 3-months post baseline (Aim2). The intervention will be delivered to up to 5 groups of 8 to12 participants each. All groups will be exposed to the same in-person training during weekly 2-hour sessions held over a 4-week period. At 3-months post baseline, there will be a 90-minute in-person session to allow for completion of the assessment and to obtain participant feedback.

Procedures/Human Subjects Involvement

Study participants will be exposed to the same in-person group training delivered by study personnel during weekly 2-hour sessions held over a 4-week period. In addition to the four in-person training sessions, participants will be invited to attend a final one-and-a-half hour in-person group meeting, which will involve completion of the 3-month post baseline assessment and invite feedback on the overall intervention experience through

open-ended questions. Participants will complete a self-administered pen and paper survey at all three study time points: baseline; upon training completion; and 3-months post baseline. At baseline, we will collect care partners' demographic details (e.g., age, gender, race, ethnicity, employment status, education, urban/suburban/rural status, relationship to care recipient), and key information pertaining to their caregiving history, experiences, and care recipient.

At all three time points, participants will be asked to complete measures to assess: caregiver mastery, self-perceived stress, anxiety, caregiver burden, and perceived changes in care recipients' behavioral expressions and with associated care partner distress. We also will ask participants to assess their care recipients' quality of life. Participants will complete these self-administered surveys in person with researchers present to answer any questions. The surveys collected at baseline and upon training completion will be distributed and completed at the first and fourth training sessions, respectively.

Three months post baseline, we will reconvene the group and distribute the final survey and invite feedback on the feasibility and accessibility of the intervention. This session will be 90 minutes long. Researchers will take detailed fieldnotes to capture the content of the group discussion, especially their feedback on their intervention experiences. Participants will take part in the training program, "Improving Care through Improv." The training builds care partner skills cumulatively over a series of four classes, each with a separate focus: (1) Yes, and…: Actively listening and observing and offering and accepting interactions; (2) Being in the moment: Meeting people where they are and committing to what is happening; (3) How to collaborate: Give, take, and making your partner look good; (4) Giving up control: Accepting failure, pivoting, being flexible, leaning into uncertainty, and expecting the unexpected. All classes are highly interactive and invite informal caregiver to engage with the instructors and one another. The first class (Yes, and…), will begin with introductions, which will allow instructors and participants to gain familiarity and comfort with one another and share their care situations and experiences. The subsequent three classes (Being in the moment; How to collaborate; and Giving up control), will begin by inviting participants to reflect on the previous week, including care experiences and any attempts to use improv with their care recipients. Each week, an icebreaker exercise will follow opening discussions. Next, the instructors will provide an overview of the weekly topic and illustrate relevant skills through demonstration. Then, they will introduce and teach relevant improv exercises, which will allow participants to model and apply skills, first with the trainers and then amongst other caregivers. Feedback and coaching will follow each exercise. The final 20 minutes of each 2-hour class will be devoted to review, reflection, and group discussion, including how improv skills could be applied to their caregiving

situations. The first and fourth training sessions will involve an additional 30 minutes on top of the 2-hour training to complete paperwork/surveys. During all training sessions as well as the 90-minute three-months post baseline sessions, researchers will engage in participant observation. A detailed observation guide will facilitate observation during all group sessions. Researchers will observe and document in fieldnotes, what transpires, who is involved, what participants do, say, and how they respond to the instructors and one another, as well as their reactions to the materials and exercises. Researchers also will audio record each group session. These recordings will not be transcribed but be available for researcher reference.

Vulnerable Populations

N/A

Number of Participants

Up to 50 participants will be recruited for the pilot test.

Study Timeline

The overall project has a 12-month timeline.

Participants and Recruitment

This project, located at Georgia State University (GSU), will draw on multiple sources to recruit the targeted informal care partners of persons living with moderate dementia into the study. We will recruit a sample of informal care partners of community-dwelling persons living with moderate dementia (4 or 5 on a 7-point dementia-staging scale) from Emory's Integrative Memory Care Clinic (IMCC). Located in Atlanta, GA, the IMCC provides primary care and is a one-stop health-care site for over 600 persons living with dementia. A support letter from Dr. Clevenger, the clinic's Clinical Director, accompanies this application and outlines her commitment to assisting with the study, including designating an IMCC staff member as a study point person to help promote the study. This point person will promote the study to patients' informal care partners and share study information with potential participants. We will advertise the study and solicit volunteers through flyers posted and distributed in the clinic, shared in their newsletter, and sent via email to patients and their care partners. Informal care partners who are interested in potentially participating will be invited to contact GSU researchers by phone or email to obtain further details. The flyer contains contact information and a QR code. Those who reach out to the study team and remain interested after learning about the study will be screened over the phone to ensure they meet study criteria. Individuals who meet the criteria and who wish to volunteer will be

enrolled on an ongoing basis. Pilot testing will begin with the first group once we have recruited at least 8 participants. Research staff will clearly explain the requirements of the study prior to enrollment, obtain several contact avenues (phone numbers, email), and will work with participants as we schedule training sessions to identify days of the week/times of day that might be most convenient. If necessary, we are unable to recruit a sample of 40 participants through the IMCC, we will submit an IRB protocol amendment to expand our recruitment plan through other organizations and sites.
At the recommendation of the advisory team (Aim 1) and ongoing recruitment feedback, we will expand recruitment to allow the flyers and newsletter information to be shared through by advisory team members, researchers, and participants, including snowball sampling. In the process of recruiting potential participants are asking if they may share the information with their peers. We also realize that flyers are posted and electronic communications are sent, they can be shared with others. We wish to include persons not directly recruited through the Emory's memory care clinic but who fit study criteria. In order to further expand recruitment, we wish to advertise on social media through the Gerontology Institute social media accounts with links to a webpage about the project hosted on the Gerontology Institute website. The website will include information from the recruitment flyer.

Inclusion Criteria
Eligible participants will be: 1) 18-years or older; 2) actively engaged in the care of community-dwelling persons living with moderate dementia (4 or 5 on a 7-point dementia-staging scale) who is not likely to be institutionalized within the next 6 months; 3) able to attend at least 3 of the 4 in-person sessions. Participants also will need to be able to read, write, and communicate in English. Screening will take place over the phone when potential participants reach out to the study team and express interest in the study.

Participant Compensation
Each participant will be given $75.00 per in-person session to offset any care or travel costs and a total of $375.00 per person for those who attend all five in-person sessions.

Benefits & Risks
Study participants may benefit by having opportunities throughout the training to share their experiences and perspectives with others. In past, we have found that research participants enjoy the opportunity to talk about their experiences. The group-based interactions also will provide a social outlet, which they may find enjoyable. We anticipate that the training they receive will give them new skills and techniques to use as they perform their care roles. Ideally, these skills, including an ability to “be in the moment,” may enhance their self-perceived caregiver mastery and possibly their self-

reported burden, anxiety, depression, perceptions of care recipients' behavioral expressions and associated care-partner distress and quality of life. We will not state to participants that taking part in the training program will be beneficial to them, although we believe and are hopeful that it will. We also will acknowledge that study participation may eventually contribute to the well-being of other informal care partners. If this intervention shows signs of efficacy, we will pursue additional funding to conduct further tests and ideally scale up the intervention in size and scope, including for instance, training for formal care partners and others. Improv training has the potential to improve dementia care experiences for all types of care partners, health care workers, and others who engage with persons living with dementia in all types of settings.

Participating in this study will involve taking part in an in-person group training program for informal care partners of persons living with moderate dementia. There is a potential risk for discomfort and emotional distress when study participants discuss their caregiving experiences. Taking part in the research surveys also may prove uncomfortable when reflecting on their experiences and on their own and their care recipient's well-being. Another potential for minimal discomfort and emotional distress could arise when participants attempt their homework assignments, which involve apply communication strategies from training sessions in the context of caring for their loved one with dementia. There also is minimal risk associated with potential breach of privacy and confidentiality. Breach of privacy could occur given the group nature of the intervention and our inability to control what participants will share outside of the group. Meanwhile, although there is virtually no risk to the confidentiality of the research data, it is among the potential risks.

Participant Data

Upon enrollment, each participant will be assigned a unique numeric participant code, which will appear on the self-administered questionnaires. Members of the research team will distribute questionnaires to participants during in-person sessions at baseline, upon program completion, and 3-months post baseline. These pen & paper self-administered questionnaires will be filled out by participants in a dedicated meeting space within Emory's Integrated Memory Care clinic (see 8.0). Completed surveys will be transported to Georgia State University by a designated member of the research team. All hard copies of participant surveys and signed consent forms, as well as any other relevant project data and documents, will be kept in a locked cabinet in PI Kemp's locked office, which is located within a locked research suite. All quantitative survey data will be entered into GSU's REDCap data management system. Researcher-generated fieldnotes and memos based on their observations of the in-person sessions will be created in Word files in the project's secure storage folder and stored electronically as described below.

These notes will capture what is happening in the training sessions, including what is being said and done and by whom. We will use participants' initials, rather than their name, in these notes. Only the PI and designated project staff will have access to individually identifiable private information. Participant tracking information will be kept on files that do not identify the project or the respondent and these too will be handled with the utmost confidentiality. The file linking the ID numbers to subjects' identities will be kept in Dr. Kemp's password-protected Georgia State University's Dropbox for Business a secure cloud-based server. All electronic study records, including our quantitative and qualitative databases, and all digital audio recordings, will be stored on a secure, remote, password-protected cloud server, Dropbox for Business. The project will be assigned its own folder accessible only to active research team members with IRB approval. The folder is maintained and monitored by Georgia State University's Technology Services. This storage solution meets NIH's requirements for secure storage. To protect participant privacy, the document linking participant names and study numbers will be destroyed one year after the study ends. We will remove any identifying features and use pseudonyms to protect the anonymity if our qualitative data are shared outside of the research team or used for dissemination purposes. When we present or publish the results of this study, we will not use information that may identify participants. If researchers inadvertently collect identifiable data that are not specified in our protocol, researchers will de-identify the relevant data immediately upon discovery.

Data Analysis Plan

Descriptive statistics will be calculated for all demographics and instrument scores at baseline, completion, and three months after baseline. Internal reliability will be assessed using Cronbach's alpha at baseline. Missingness will be assessed and corrective measures used as appropriate (multiple imputation). Repeated measures analysis of variance will be used with dependent variables across the three time points. Error rate adjustments (Bonferroni or Dunn-Sidak tests) will be made due to the implementation of multiple comparisons across dependent variables. Effect sizes will also be computed and assessed for clinical significance. The percentages of caregivers whose scores improve or decline from baseline to completion and post-completion assessments will be calculated. IBM SPSS for Windows, version 24.0 will be used to perform computations.

Informed Consent

See Appendix A

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APPENDIX A

INFORMED CONSENT

Georgia State University
Gerontology Institute
Informed Consent

Title: Improving Care through Improv: Promoting Mastery in the Moment

Principal Investigator: Candace L. Kemp, Ph.D.
Co-Investigator: Jennifer Craft Morgan, Ph.D.

Sponsor: Emory Roybal Center for Caregiving Mastery and the National Institute of Aging at the National Institutes of Health.

Introduction and Key Information

We invite you to take part in a research study. You will decide if you would like to take part. The purpose of this study is to develop and test a new training program, "Improving Care through Improv." The program involves learning about and using skills from improvisational (improv) theater. The program is designed to teach caregivers of people with dementia ways to manage unexpected care situations. Your role in the study will last 10.5 hours over three months. We will ask you to: complete questionnaires, participate in four two-hour weekly in-person group training sessions. The first and last of these sessions will include 30 minutes to complete surveys. You also will be asked to attend a 90-minute in-person focus group session to get your feedback on the program.

If you are part of this study, although unlikely, there is a possibility of emotional upset. You may personally benefit from being in the study. The training you receive may better equip you to manage challenging care situations. Your involvement will help us improve this program and inform other caregiver training. If you do not want to take part in this study, you do not have to participate.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not

Version Date: 11/29/2023
GSU APPROVED
IRB NUMBER: H23627
IRB APPROVAL DATE: 02/27/2024

include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Purpose

The purpose of the study is to test training for caregivers of persons living with dementia. We are inviting you to take part in this study because you are a caregiver of someone who has moderate dementia. Up to 50 people such as yourself will be in this pilot study. We expect the study to last 12 months.

Procedures

If you decide to be in this study, you will be put in a group of up to 20 caregivers. You will be asked to attend five in-person group sessions over a three-month period. These sessions will be audio recorded for research purposes. Recordings will not be transcribed. You will be asked to fill out questionnaires.

The first month of the study involves two 30-minute registration/survey completion period, and four weekly 2-hour sessions.

Week 1 (150 minutes)

- Fill out a questionnaire about yourself, the person you are caring for, and your care experiences (30 minutes).

- Participate in an in-person group discussion and interactive training session. The session will be led by a member of GSU's research team and an improv educator. You will be asked to introduce yourself and talk about your caregiving situation (120 minutes).

Week 2 (120 minutes) and Week 3 (120 minutes)

- Participate in an in-person group discussion and interactive training session. These sessions will be led by a member of GSU's research team and an improv educator. You will be asked to provide updates

on your care experiences and your use of improv skills at home (90 minutes).

Week 4 (150 minutes)

- Participate in an in-person group discussion and interactive training session. The session will be led by a member of GSU's research team and an improv educator. You may be asked to provide updates on your care experiences and your use of improv skills at home (120 minutes).
- Fill out a questionnaire about your care experiences (30 minutes).

Three months (plus or minus 7 days) following the Week 1 session, you will be asked to attend a 90-minute in-person session. During this session you will:

- Fill out a questionnaire about your care experiences and being in the study (30 minutes).

- Participate in a researcher-led focus-group discussion with your group. You will be asked what you think about the training (60 minutes).

Sessions will be held at Emory's Integrative Memory Care Clinic or Dad's Garage Theatre. The clinic address is: 12 Executive Park Dr NE, Atlanta, GA 30329. Dad's Garage is located at 569 Ezzard St SE, Atlanta, GA 30312. GSU researchers will give you the questionnaires. They will assist, observe, and take notes during all group sessions.

Future Research

We may use your information for future research. We will remove information that may identify you. We will not ask for consent from you if we do this.

Risks

You may experience emotional upset from being in this study. If you become uncomfortable, you may step away temporarily or stop participating at any time. If you experience emotional distress, the researcher can refer you to a qualified mental health provider. Georgia State University and the research team, however, have not set aside funds to pay for this care.

Benefits

You may benefit from the study by becoming better able to perform your caregiving role. The training will teach caregivers of persons with dementia ways to manage unexpected and challenging situations. You may have more confidence and less distress as a caregiver during and/or after participating in the study. You also might enjoy having an opportunity to meet and interact with other caregivers. Even if you do not benefit personally, the information gained may help others in the future. Your participation will help us improve this program and inform future caregiver training.

Alternatives

The alternative to taking part in this study is to not take part in the study.

Compensation

You will receive $75.00 for each of the five sessions you attend. This money is meant to offset care and travel costs associated with your participation. A researcher will give you this money after each session.

Voluntary Participation and Withdrawal

You do not have to be in this study. If you decide to be in the study and change your mind, you can drop out at any time. During group sessions, you can choose to step away or leave the room at any point.

If you do not take part or leave the study early, you will not lose any benefits that you are otherwise entitled to. The study will not affect your medical care or your family member's medical care in any way.

Confidentiality

We will keep your records private to the extent required by law. The following people and groups will have access to the information you provide:

- The Principal Investigator and research staff.
- GSU Institutional Review Board.
- Office for Human Research Protection (OHRP).
- The National Institutes of Health, who funds this research, and people or companies they use to carry out the study.

We will use a study number and initials rather than your name on study records. We will store hard copies of the information you provide in a locked cabinet in Dr. Kemp's locked office. We will store electronic information, including recordings, on a secure password-protected site. These data will be accessible only to research staff through encrypted and password-protected computers. To protect your privacy, the document linking your name and study number will be password protected and stored separately from the information you provide. We will destroy this document and any audio recordings one year after the study ends. When we present or publish the results of this study, we will not use information that may identify you.

We will ask you and your group members to respect others' confidentiality by not sharing identifying details. We ask that you not discuss personal details shared by others in the group sessions. However, we cannot stop others from talking about the group sessions.

Contact Information

You can contact Candace L. Kemp at 404-413-5216 and ckemp@gsu.edu

- If you have questions about the study or your part in it
- If you have questions, concerns, or complaints about the study
- If you experience emotional distress and require referral to resources

The IRB at Georgia State University reviews all research that involves human participants. You can contact the IRB if you would like to speak to someone who is not involved directly with the study. You can contact the IRB for questions, concerns, problems, information, input, or questions about your rights as a research participant. Contact the IRB at 404-413-3500 or irb@gsu.edu.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Consent

We will give you a copy of this Informed Consent Form to keep.

If you are willing to be in this research study, please sign below.

_____

Printed Participant Name Signature of Participant Date

_____

Printed Researcher Name Researcher Signature Date

Version Date: 11/29/2023

GSU APPROVED
IRB NUMBER: H23627
IRB APPROVAL DATE: 02/27/2024