Knowledge and Interpersonal Skills to Develop Exemplary Relationships (KINDER): Pilot Study

NCT: NCT05783102

Study Protocol

Document Last Updated: 2/13/2024

[USE THIS TEMPLATE IF YOUR PROJECT INCLUDES SURVEY, INTERVIEWS, FOCUS GROUPS OR EDUCATIONAL RESEARCH ACTIVITIES WITH NO BIOMEDICAL/CLINICAL COMPONENTS]

INSTRUCTIONS:

- *Use this template to prepare your IRB Protocol.*
- *Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, please mark as N/A.*
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
- *Consider using a different color font for your answers.*

PROTOCOL TITLE:
Include the full protocol title.

Knowledge and Interpersonal Skills to Develop Exemplary Relationships (KINDER): A Pilot Study

PRINCIPAL INVESTIGATOR:
Name: Kylie Meyer, PhD

DATE: 1/30/2024

Indicate the origin of this protocol (who conceived of and leads the development of the protocol regardless of funding):

☒ Investigator initiated *(Investigator(s) developed protocol, regardless of funding)*
☐ Industry *(Pharmaceutical, Device, etc.) (Industry developed protocol)*
☐ Federal *(NIH, DOD, etc.)*
☐ Cooperative Group *(SWOG, GOG, etc.)*
☐ Other - Please specify: Click here to enter text.

Has this study been disapproved by or withdrawn from any other IRB?
☐ Yes ☒ No
If so, please explain: Click here to enter text.

Does this study involve cancer research or cancer-related issues?
☐ Yes ☒ No
If yes, indicate the PRMC number: Click here to enter text.

Is this a student led study?
☐ Yes ☒ No
If yes, is the student: ☐ Undergrad ☐ Graduate Student ☐Other Click here to enter text.
If yes, is the project: ☐ Capstone ☐ Master's thesis ☐ PhD dissertation
☐Other Click here to enter text.

Is this work part of a larger collaborative research project where more than one institution is participating in the research? (*In collaborative projects, data/specimens/results are often shared between researchers at the participating institutions, and they will publish together.)*

☐ **No** ☒ **Yes**

If yes, please explain.

This is a pilot study that involves collaboration with investigators at the University of Southern California, where there are two other investigators consulting on the intervention design, study design and grant applications related to this work. We will likely publish together. In some cases, researchers from USC may help deliver the KINDER program as facilitators. **However, due to the sensitive nature of the data and mandatory reporting laws, only investigators at Case Western Reserve University will be involved in data collection.** This will prevent the risk of confidentiality being breached by limiting who can see data.

1.0 Funding

If this study is grant funded, is the money coming directly to CWRU from the study sponsor?

☐ Yes☐ No ☒ N/A, not grant funded

2.0 Objectives

Directions: Describe the purpose, specific aims or objectives. Be sure to also include the hypothesis being tested. **Aim 1:** Test the preliminary efficacy of KINDER. The investigators hypothesize caregivers will report improved resourcefulness (mediator for future study) and relationship quality (primary outcome) following participation. Further, caregivers will report higher quality of care and reduced frequency of verbal mistreatment (distal outcomes). **Aim 2:** Determine acceptability among caregivers and feasibility with satisfaction surveys and fidelity reports.

3.0 Background

Directions: Describe the relevant prior experience and gaps in current knowledge describing how this study will add to existing knowledge. Include any relevant preliminary data. **What is KINDER?** KINDER is a psychoeducational intervention to prevent and mitigate the occurrence of verbal-type elder mistreatment by family caregivers to persons living with dementia. Content focuses on building healthy and respectful caregiving relationships (Benton & Meyer, 2022). KINDER focuses on verbal mistreatment among families living with dementia, since it is estimated that one- to two-thirds of family caregivers engage in potential mistreatment, of which verbal mistreatment is the most common type (Cooper et al., 2009; Orfila et al., 2018; Pickering et al., 2019; Wiglesworth et al., 2010). Beyond verbal mistreatment, KINDER also seeks to promote high-quality care by family members, including provision of care that is respectful (Christie et al., 2009; Dooley et al., 2007). KINDER was developed by Kylie Meyer, PhD, at Case Western Reserve University's Frances Payne Bolton School of Nursing and

Donna Benton, PhD, at the University of Southern California's Leonard Davis School of Gerontology. **How does KINDER address elder mistreatment in an in a new way?** KINDER draws on lessons learned from child maltreatment and intimate partner violence (Meyer, 2017). Specifically, KINDER is modeled after the ePREP online intervention to support healthy romantic partnerships, which was later found to reduce incidence of verbal and physical abuse (Braithwaite & Fincham, 2007; Braithwaite & Fincham, 2014). KINDER addresses multiple contextual, interpersonal, and individual risk factors for interpersonal strain and potential mistreatment among care partners (Meyer et al., 2022). To ensure acceptability among caregivers and cultural relevance of the program, KINDER structure and content were informed by 9 focus groups with racially and ethnically diverse caregivers across Los Angeles (Rath et al., 2019). **What are caregivers asked to do when they participate in KINDER?** KINDER was developed to balance best practices in psychoeducation (e.g., built-in opportunities to practice new skills) with ease of participation for busy caregivers. To make it easier for caregivers to participate, KINDER is primarily delivered over eight, self-administered lessons. Each lesson begins with a story-based video, based on scenarios we heard in focus group. Videos are followed by a reading that elaborates on topics raised in videos. To reinforce learning, caregivers may also complete a reading quiz, a reflection, and a practice exercise. Caregivers are asked to complete 1 lesson/week using a digital PDF or printed workbook. Based on caregiver feedback, we are now integrating small group discussion sessions by Zoom to allow caregivers to learn from each other and "digest" information learned during self-administered lessons. The figure below illustrates the schedule for participation.

Overview of KINDER schedule

For an example of one of the story-based video vignettes, click here: https://www.youtube.com/watch?v=1H_Id0djpkA **What do caregivers think of KINDER?** We completed qualitative interviews with caregivers who participated in a pilot study of the initial version of KINDER (Meyer et al., 2023). Caregivers reported overall satisfaction with the program. "I just I love this program," said one caregiver, "It resonated with me and it's something that I will continue to use and talk about to others." (Participant 5). Echoing this enthusiasm, another caregiver said of KINDER, "I think it's a game changer in our lives. I really do." (Participant 8). Another caregiver described how she thought KINDER affected her caregiving: So just even the thought of the program made me feel as though it was going to help me ease into the challenge of caregiving in a more natural way and in a kinder way, and a more caring, authentic way, as opposed to something that is obligatory, you know? (Participant 9) We also found that caregivers were comfortable with videos and readings that addressed potential elder mistreatment, as described by the caregiver quoted below. "It was even, well six and seven that you find yourself becoming so angry and so frustrated that you just feel like

you're at your wits end. That's stressful. It's hard to, if you haven't been there to think that you might even go there because of what you're dealing with." (Participant 7) Findings from qualitative interviews also revealed likely theoretical mechanisms underlying KINDER, include relationship turbulence theory and resourcefulness theory (Meyer, In Review). KINDER is being revised to better integrate theory-based components, including development of personal and resourcefulness skills known to reduce caregiver strain and support mental health (Zauszniewski, 2016; Zauszniewski et al., 2016). The purpose of this study is to test the revised version of KINDER, including resourcefulness as a middle-range theory. Findings will inform future efficacy-testing that can provide insight into how to prevent the occurrence of verbal-type elder mistreatment and low-quality care of family caregivers to persons living with dementia.

Please add relevant references at the end of the protocol, not at the end of this section.

4.0 Inclusion and Exclusion Criteria

Directions: Describe how individuals will be screened for eligibility.

Participants may complete eligibility screening by phone or begin the screening online. Participants who complete screening online will receive a telephone follow up to complete any questions they may have missed and answer questions they may have.

Using the tables below, describe the inclusion and exclusion criteria that will define who will be included and excluded in your final study sample.

	Inclusion
1.	Is age 18+
2.	Provides care to a family member or friend living with Alzheimer's Disease or a related dementia. This does not have to be diagnosed.
3.	Participant helps with at least 1 activity of daily living (e.g., bathing) or 2 instrumental activities of daily living (e.g., shopping)
4.	Participant provides at least 8 hours of assistance to the care recipient per week
5.	Participant does not intend to place the care recipient in a skilled nursing facility within 3 months of consenting into the study

	Exclusion
1.	Does not read and speak English
2.	Does not have reliable access a computer and internet

5.0 Number of Research Participants

Directions: Indicate the target number of research participants to be accrued locally, and, if this is a multi-site study, indicate the total number of research participants to be accrued across all sites.

Example language that can be used: We will enroll 25 subjects at CWRU and plan to enroll 150 subjects study wide. We will aim to enroll N=46 participants in order to achieve a sample

size of N=34, which will enable us to detect a medium effect size using a single-sided paired t-test using an alpha of 0.05 at 0.80 power.

6.0 Special/Vulnerable Populations

Indicate specifically if you will include each of the following special populations by checking the appropriate box:

- ☐ **Adults unable to consent**
- ☐ **Minors (infants, children, teenagers)**
  - ☐ Wards of the state (e.g. Foster Children)
- ☐ **Pregnant Women** (only if targeted)
- ☐ **Neonates**
- ☐ **Neonates of Uncertain Viability**
- ☒ **Employees**
- ☐ **Prisoners**
- ☐ **Illiterate Individuals**
- ☐ **Non-English Speaking**
- ☐ **Students**
- ☐ **None**

1. If the research involves students or employees, describe how you will recruit so that:
   a) Employers or educators do not know if someone participated (until after grades have been assigned in the case of educators)
   b) Employers or educators do not *directly* recruit their own students or employees, and anything else to prevent feelings of coercion to those subordinate to their employer or educator.
   The study team would like to acknowledge that we are requesting employees at the USC FCSC to complete fidelity reports when completing the intervention, such that these individuals are providing study data. In order to ensure employees do not feel forced to complete these forms, we have added the following language at the top of the fidelity data collection form and facilitator workbook. This section reads: "**Voluntary nature of fidelity reports for facilitators.** Facilitators who deliver KINDER at community sites are NOT required to complete fidelity self-reports (i.e., completion is voluntary), but are encouraged to do so to support the current research study. If you choose to complete the fidelity report, the information you provide will not be anonymous. This is because it is possible to determine who facilitated a particular session on a given date. However, your individual responses will not be shared with your supervisor. Researchers may share aggregate results to support quality improvement. If you have any questions, please contact the study's principle investigator, Kylie Meyer, PhD, at knm77@case.edu."

2. If the research involves individuals that are included in a special/vulnerable population, describe the additional safeguards included to protect the rights and welfare of the individuals for each population indicated. Click here to enter text.

3. If excluding pregnant women, illiterate or non-English speaking individuals, provide a scientific rationale for the exclusion. Inconvenience or cost is not an acceptable

rationale. Non-English speakers are excluded at this research stage as the intervention is not yet known to be efficacious. Once indications of efficacy are found, we will consider testing a translated version of the intervention. Those who are not literate are also excluded, given these individuals would not be able to participate in the intervention being tested.

7.0 International information

☒ This is **not** an international study – *please leave rest of this section blank.*

☐ We will be conducting this research at the following international sites:
Click here to enter text.

☐ We are recruiting participants outside of the US from the following locations:
Click here to enter text.

☐ We are sending data outside of the US to the following locations:
Click here to enter text.

☐ We are receiving data from outside of the US from the following locations:
Click here to enter text.

8.0 Recruitment Methods

Note: Attach all applicable recruitment materials to the last section of the Smart form under "Recruitment Materials."

1. Which of the following methods will be used to recruit research participants? – *Select all that apply*
   - ☐ Email
   - ☐ Phone call
   - ☐ Letter
   - ☒ Advertisement (e.g., poster, flyer, etc.)
     - ☒ I attest that advertisements will only be placed **with permission**
   - ☒ Social media
     - Indicate the platform(s): Facebook
     - ☒ I attest that recruitment information will only be posted **with permission**
   - ☐ Other. *Please specify:* Click here to enter text.

2. Describe when, where, how and by whom potential research participants will be recruited. Individuals involved in recruitment should be identified by role and not by name (e.g. study coordinator, co-investigator, research assistant).
   Information about the KINDER study will be shared with community partners who work directly with family caregivers so they may share information in newsletters and "e-blasts" as well as social media sites. Caregivers may also learn about the program on Eventbrite and may indicate whether they wish to be contacted about the study. Individuals who are not study participants but who register to attend will also be contacted by email to complete the satisfaction survey and/or non-participation survey.

3. Describe the feasibility of recruiting the required number of suitable research participants within the agreed recruitment period. For example, how many potential research participants do you have access to?
   We plan to recruit participants for up to 1 year to reach 46 participants. The PI has successfully recruited this number of caregivers using a similar study design in the past. The likelihood of a recruitment success is enhanced by working with community partners who already provide services to family caregivers, such as the USC Family Caregiver Support Center. Further, the study team will use a dynamic recruitment plan, wherein we will regularly assess recruitment patterns at twice monthly team meetings to evaluate the need to make modifications depending on the pace of recruitment.

9.0 Setting

Directions: Describe the sites and locations where your research team will conduct the research.

This research will be conducted at Case Western Reserve University. Because this is a digital intervention intended to reach caregivers' nationally, we do plan to work with community organizations across the US to reach caregivers. Researchers at other universities (i.e., University of Southern California) may also consult on this study but will not be involved in data collection. In some cases, these researchers may share study flyers and information, but will not otherwise be involved in the enrollment process. No identifying study participant information will be shared with community partners or research consultants.

10.0 Consent Process

Indicate whether you will be obtaining consent:

☒ Yes ☐ No

If yes, answer the following questions:

1. Describe who will consent the subjects and where the consent process will take place: The principal investigator will review the consent document with participants by telephone after confirming participant eligibility either online or by phone. The participant will then receive an email with a link to the downloadable consent document. The participant will be able to open a PDF version of the consent document and will be asked to provide their electronic signature their consent to participate in REDCap. They will receive an email confirmation of consent with a copy of the consent form attached.

2. The time that will be devoted to the consent discussion: Based on experience with prior protocols using a similar approach, it is estimated that the consent discussion will take approximately 15 minutes to complete by phone. Participants may also take as long as they wish while the study is ongoing to review and sign the consent form. If it has been more than 2 months since a caregiver completed eligibility screening when the consent form is returned, they will be rescreened to ensure ongoing eligibility.

3. Any waiting period available between informing the prospective subject and obtaining the consent: Participants are allowed to request time to think about

enrolling in the study after learning they are eligible. We will share that this option while completing the consent process.

4. Steps that will be taken to ensure the research participants' understanding: The PI will check with the participant to ask if they have any questions about the information provided while describing each section of the consent form. Important information, such as that participation in the study is voluntary and researchers' obligation to report suspected mistreatment, will be emphasized to ensure participants understand these important points. The PI will also listen for signs that the participant does not understand the information shared correctly. Further, participants are asked to answer questions about the study consent form before signing. Caregivers will not be able to sign the consent form until questions are correctly answered.

5. Any process to ensure ongoing consent: Ongoing consent will be assumed so long as the participant completes surveys. We also include a note at the beginning of the survey to remind participants that the surveys are voluntary, and they may pause, stop, or skip questions if they wish

6. Steps that will be taken to minimize the possibility of coercion or undue influence to the subjects: Participants will be reminded during recruitment and enrollment that they may still participate in the KINDER program, regardless of whether they participate in the study.

For Adult Participants

Indicate if you will be asking for a waiver or alteration of consent process or documentation (consent will not be obtained, or written consent will not be documented)

☒ Yes ☐ No

If yes, explain how the research involves no more than minimal risk. We will send a satisfaction survey and/or survey asking about reasons for non-participation to non-study participants, and may invite these individuals to participate in a qualitative interview about the experiences participating in KINDER. In all cases, data collected pertains to caregivers' individual experiences with the program, and is not related to their own private health information. Further, survey data will be anonymous while interviews will be kept confidential..

Indicate which part of the consent process you are requesting be waived or altered and the rationale for requesting the waiver or alteration:

☒ I will obtain consent, but not participant's signature.

1. Give the rationale for the request of a waiver of signed consent. Individuals who are enrolled into the main study but who may be able to provide feedback about the program's acceptability may be less likely than

study participants to complete a full consent process in order to participate in low risk data collection activities, like the satisfaction survey

2. Please describe how you will be documenting that a participant has consented. Completion of surveys and/or the qualitative interview will be understood to mean they have consented.

3. Indicate if the subjects will be provided with written information about the study, and provide justification if you will not be providing a written explanation of the research. Yes. Survey forms include written information about the study in the introduction. Those participating in the qualitative interview will receive a copy of the interview information sheet..

☐ I will obtain consent, but request a waiver of some of the elements of consent (e.g. use of deception).

☐ I will not obtain any consent, and I am requesting a full waiver of consent.

If you are requesting an alteration of consent, or a waiver of consent, please answer the following:

1. Give the rationale for the request of a waiver or alteration of the consent process. See above regarding rationale for waiver of signed consent.

2. Explain why the waiver or alteration of consent will not adversely affect the rights and welfare of the participants. All relevant study information, including voluntary nature of participation, will be provided before data is collected.

3. Explain why the research could not practicably be carried out without the waiver or alteration of consent. Those individuals who do not volunteer to participate in the main study may be even less likely to participate in other data collection activities regarding intervention acceptability, but may provide insight that differs from that of study participants.

4. Indicate if the subjects will be provided with additional information about the study after participation. No, because data collected from surveys will be anonymous.

**Be sure to upload a consent script or information sheet with your study protocol*

Additional Considerations for Consent Process with Adults

Non English Speakers *(Please select one)*

☒ I am **not** enrolling non-English speaking individuals in this research study. The following is justification for why non-English speaking individuals cannot be enrolled: We are testing the KINDER intervention to determine its feasibility and acceptability of the intervention. KINDER is not yet an evidence-based program. Once we determine its value as an evidence-based program, we will begin to consider cultural and language translation.

☐ I will be targeting non-English speaking adults

1. Describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study. Click here to enter text.

2. List the language(s) other than English that will be targeted: Click here to enter text.

☐ I am **not** targeting non-English speaking individuals. If a non-English speaking individual is eligible for the study, we will use the following procedures to enroll:

1. Describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study. Click here to enter text.

2. List the language(s) other than English that will be targeted: Click here to enter text.

Adults Unable to Consent

☒ I am **not** enrolling adults unable to consent in this research study – *please leave the rest of this section blank.*

☐ There is an anticipated direct benefit to the subject. Explain: Click here to enter text.

☐ There is NOT an anticipated direct benefit to the subject. Explain: Click here to enter text.

1. Describe the process to determine whether an individual is capable of consent. Click here to enter text.

2. List the individuals from whom permission will be obtained in order of priority (e.g. durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child). Click here to enter text.

3. For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in the research. Click here to enter text.
   ☐ N/A

4. Describe the process for assent of the research participants. Indicate:

- Which subjects that are unable to consent will be required to give assent? If not all, explain why. Click here to enter text.

- Describe whether assent of the research participants will be documented and the process to document assent. Click here to enter text.

☐ The subject will be informed about the research to the extent compatible with the subject's understanding.
☐ Subjects will be closely monitored.
☐ The subject will be withdrawn if they appear unduly distressed.

Research Participants Who Are Not Yet Adults (infants, children, teenagers)

☒ I am not enrolling participants who are not yet adults in this research study. *– please leave the rest of this section blank*

1. Will parental permission be obtained from:
   ☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child
   ☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child
   ☐ Requesting a waiver of parental permission

   If you are getting parental/guardian permission:
   a. Indicate how you will be documenting the permission:
      ☐ Signed consent form
      ☐ Requesting a waiver of documentation of parental permission

   b. Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's participation in research. Click here to enter text.

   If a waiver of parental permission is being requested:
   a. Describe how the study is designed for a subject population for which parental/guardian permission is not a reasonable requirement to protect the subjects, if applicable. Click here to enter text.

   b. Describe how the research could not practicably be carried out without the waiver of parental permission. Click here to enter text.

   c. Indicate if the subjects will be provided with additional information about the study after participation. Click here to enter text.

2. Will assent be obtained from:
   - ☐ all of the children
   - ☐ some of the children
   - ☐ none of the children

   If assent will be obtained from some children, indicate which children will be required to assent. Click here to enter text.

   If assent will be obtained from none of the children, indicate the rationale. Click here to enter text.

   When assent of children is obtained, describe how it will be documented. Click here to enter text.

3. For children who are pregnant, describe how assent and permission are obtained. Click here to enter text.
   ☐ N/A

11.0 Sharing of Results with Research Participants

Individual test or research results will be shared with research participants (this is not referring to sharing through standard academic channels, e.g., publishing, presentation, etc.):

☐ Yes ☒ No

If yes, describe how the results will be shared. Click here to enter text.

Individual test results will be shared with others (e.g., lab results given to a primary care physician):

☒ Yes ☐ No

If yes, describe with whom and how the results will be shared. In cases where the investigators suspect risk of harm to self or others, we may share information collected from research data with appropriate parties. For example, if we observe suspected elder mistreatment that rises to a level where we need to report (e.g., Endorsement of 4 or more items on the Modified Conflict Tactics Scale as "6 to 10" or "More than 10 times." See "Call Script for Perceived Risk of Harm"), the study team may share survey items responses about self-reported mistreatment with Adult Protective Services in a report.

12.0 Study Design/Procedures

Directions:

1) Describe the overall study design (e.g.: single visit, single-blind, double-blind, non-randomized, randomized, blood draw, investigational drug, device etc.).
2) Provide a description of all study-related research procedures being performed, including the length of time involved.
3) Include procedures being performed to monitor research participants for safety or minimize risks.

4) Describe the source records including medical or educational records, which will be used to collect data about subjects.
5) Include a description of any device being used to collect data (e.g., eye tracker, step counter). If the device itself is being studied, include additional information in Section 29.

Overall Study Design. We propose to conduct a single-arm pre- and post-test intervention study to evaluate the preliminary efficacy, as well as the acceptability and feasibility of the KINDER program. Participation includes completion of a 9-week intervention, as well as completion of two surveys (baseline and follow up). Total study participation is estimated to take 20 hours depending how long it takes caregivers to complete lessons and will be spread over 3 months. **Intervention.** KINDER is a 9 week digitally delivered psychoeducational intervention to promote healthy caregiving relationships by building caregiver resourcefulness, for the purpose of improving quality of care and preventing verbal elder mistreatment. Content includes a mix of synchronous and asynchronous activities, including three 1.5-hour group facilitated Discussion Sessions by Zoom, 3 check in calls with a facilitator of approximately 20 minutes each, and 8 independent lessons consisting of a story-based video, reading, reading quiz, reflection, and self-care goal. Lesson topics include understanding a dementia diagnosis, communicating with person you care for about challenging topics, finding a balance between safety concerns and independence, and more. Each lesson takes an estimated 1 hour to complete. Independent KINDER lessons can be completed using a printed or digital copy of the KINDER Workbook. **Interventionist Training.** Interventionists will undergo at least 2 hours of didactic training, in addition to self-study and shadowing or co-facilitating Discussion Sessions. Didactic training will include a review of the KINDER program and its underlying theory, review of the workbook and discussion sessions, and review of the facilitator guide. Didactic sessions will include active learning components, such as role-play of facilitator calls to participants. Before delivering sessions independently, facilitators will either shadow or co-facilitate KINDER sessions with another trained facilitator or the PI. **Screening and Enrollment.** Participants may complete eligibility online or by phone. If a participant completes the eligibility screening online and is eligible, they will receive a telephone follow up call from the study team member notifying them. (If the participant is not eligible following screening, they will receive an email notification.) During this call, the study team member will review the consent form with the participant and answer any questions they may have. If the caregiver would like to participate, they will be sent an email with a link to the consent form to complete. Interested caregivers who complete the eligibility screening by phone will undergo the same process, except the screening call will also include review of information in the consent form if the participant is eligible. **Recruitment.** Participants will primarily be recruited by contacting those caregivers who register to participate in KINDER on Eventbrite. Caregivers will be asked to indicate whether they would like to be contacted by researchers about a study on the KINDER program. The research team will then follow up to provide more information, altering between phone and email. (See Participant Communications.) Other methods of

recruitment include sharing flyers at community organizations and Facebook social media posts. **Data Collection.** Data collection will be primarily conducted in REDCap using self-administered surveys. A baseline survey will be sent within 2 weeks of the caregiver attending Discussion Session 1. The follow up survey will be sent immediately following completion of the intervention. Participants will receive up to 3 reminders to complete surveys. Caregivers who attend KINDER who do not participate in the study will also be invited to complete an anonymous satisfaction survey via REDCap. In addition to participant surveys, we will also ask facilitators, who are not members of the study team, to complete a facilitator monitoring report, call logs, and participant attendance forms to monitor adherence to protocols and intervention exposure. An observer from the study team will also complete a fidelity monitoring report using recorded discussion sessions. Some participants will also be asked to participate in a one-on-one semi-structured qualitative interview by phone or Zoom so we can learn more about experiences participating in KINDER. Participants will be purposefully selected, so as to ensure the representation of caregivers from various demographic backgrounds and caregiving situations. Further, we will send a satisfaction survey to all KINDER participants to learn more about their experiences participating in the program to support its ongoing improvement. For those who do not attend any or <2 discussion sessions, we will also send a survey asking about reasons for non-participation. **Safety Monitoring.** The PI will complete a safety monitoring report once every 3 months of this study. Information will include the number of individuals recruited, enrolled, dropped out, demographic information on participants, and descriptive information on study variables including the proportion of missing data for each variable.

13.0 Study Timeline (optional)

	Pre-Screening	Visit 1	Visit 2	Visit 3	Six week Follow up
Estimated time requirement of visit					
Data Collection					
Study Procedure 1					
Study Procedure 2					
Study Procedure 3					
Phone Call Questionnaire					

14.0 ClinicalTrials.gov Information

Directions: If this study has been registered on ClinicalTrials.gov, provide the ClinicalTrials.gov identifier and the investigator/sponsor responsible for registering. If this study has not been registered on ClinicalTrials.gov, provide the rationale as to why and

if/when it will be. If it does not meet the requirement for being registered on ClinicalTrials.gov, please state that.

This study is registered on ClinicalTrials.gov at NCT05783102.

15.0 List of Data to be Collected

1. *Indicate what identifiers you will collect*

☒ Name
☒ Address *(e.g., Zip code, other geographical designation, etc.)*
☐ Dates related to an individual *(e.g., Date of admission, birth, surgery, etc.)*
☒ Telephone number
☐ Fax number
☒ Email address
☐ Social security number
☐ Medical record number
☐ Health plan beneficiary number
☐ Account number
☐ Certificate/license number
☐ Any vehicle or other device serial
☐ Device identifiers or serial numbers
☐ Web URL
☐ Internet protocol (IP) address
☐ Finger or voice prints *(includes audio recordings)*
☐ Photographic images *(includes video recordings)*
☐ Other: Any characteristic that would uniquely identify the individual
If other, please explain: Click here to enter text.

2. List all other data to be collected for the research study. Attach all data collection tools on the Local Site Documents page of the SpartaIRB smart form (Other Attachments). **Eventbrite Registration:** Name, email, phone number, mailing address, year born, gender, race, ethnicity, education, financial strain. (Participants are notified that demographic information is optional to provide and will be used by the study team.) **Screening:** Year born, caregiving status, hours of caregiving, access to technology, care recipient functional ability, plans for nursing home placement, name, email, phone number. Interested participants are notified that they may also provide demographic information to help the study team understand differences between those eligible and ineligible for participation. These items are consistent with those required by the NIA CROMS data collection items: biological sex, gender identity, sexual orientation, race, ethnicity, highest level of education, marital status, financial strain, kin relationship to care recipient, primary language. **Off-Study Reason.** Reason for withdrawing from study; reason for ending intervention participation **Baseline Demographic Information:** Year born, gender identify, race, ethnicity, marital status, education, current employment, financial strain, kin relationship to care recipient, primary care status, living situation

with care recipient, length of care, weekly hours of care. **Baseline and Follow Up Survey Measures:** Revised Memory and Behavior Checklist, Dyadic Relationship Scale, Depressive Cognitions Scale, Relational Certainty, Resourcefulness, Caregiver Self-Efficacy Scale-8, Modified Conflict Tactics Scale, Task Management Scale Index, Exemplary Care Scale. **Satisfaction:** Satisfaction with the KINDER program and components **Reason for non-participation.** Reason the registered individual did not attend KINDER or attended <2 sessions. **Facilitator Call Log:** Completion of facilitator calls with participants **Facilitator Fidelity Form:** Name of facilitator and session date, perception of sessions (e.g., participant engagement, adherence to session agenda), participant attendance

16.0 Online Data Collection

☐ We will not collect data through an online platform.

1. List the online platform to be used. The preferred platforms are REDCap and Qualtrics, as these provide good data security and have options for collecting data without individually identifiable information.
   All data will be collected using REDCap

2. If your intent is to collect the data without identifiers linked to an individual (including IP addresses), describe how you will ensure that no identifiable information will be associated with the data.
   - ☐ Qualtrics: enable Anonymize Responses setting (removes IP addresses and location data)
   - ☐ REDCap: use of the Public Survey Link
   - ☐ REDCap: use of a Participant List without a Participant Identifier field
     (Note: this does maintain a connection between the data and the individual, but it is only accessible to REDCap support personnel and not the researchers. Data collected in this manner should not be referred to as anonymous, but rather as data that is deidentified to the researchers).
   - ☐ Other: Click here to enter text.

17.0 Data Analysis Plan

Directions: Describe the data analysis plan, including any statistical procedures. If applicable, provide a power analysis, and study/safety endpoints. **Participant Demographic Characteristics** Participant characteristics, including demographic and caregiving information (e.g., kin relationship) will be reported using frequencies, percentages, means, and standards of deviation. *Comparison of Study and non-study participants.* Demographic characteristics of study and non-study participants collected from Eventbrite will be compared using t-test and chi-squared bivariate analyses, as well as frequencies and percentages. This will help the study team determine differences between caregivers who register for KINDER as a community program, and those who enroll in the study. *Reasons for ineligibility and/or study or intervention withdrawal.* The study team will also report the most frequent reasons for study or intervention withdrawal, as well as reasons participants were screened as ineligible, using frequencies and percentages. **Outcomes.** We will evaluate study outcomes using paired-t-tests comparing mean scores on all psychosocial outcomes collected before and after the intervention.

Satisfaction Surveys. To analyze items included in the satisfaction surveys, we will provide a percentage of each response for each item collected (e.g., 80% of caregivers "Agreed" or "Strongly Agreed" with this statement). A similar approach will be taken to evaluate reasons for non-participation. **Fidelity Reports** Fidelity reports will be evaluated using total scores averaged across all KINDER Discussion Sessions observed. We will be report these in aggregate and separated by facilitator and observer reports. We will divide reports by scores for adherence and quality. Scores will be reported using a percentage, as prior reports indicate 80% or more on fidelity scores indicates acceptable levels of fidelity. In addition—to examine variability in scores—we will also report this information using means and standards of deviation. **Qualitative Interviews** Qualitative interviews will be transcribed verbatim and identifying information removed. To conduct our thematic analysis, at least two members of the research team will read at least 2 transcripts and will decide on a preliminary codebook. The codebook will be applied to an interview and refined further prior to applying codes to the remaining interviews. At least two coders will analyze each transcript independently and will meet to compare codes and discuss differences in coding until agreements met. A second round of coding will be conducted to integrate new codes added during coding. **Statistical Power and Same Size** Our goal is to recruit at least N=46 of these caregivers into a research study to test preliminary efficacy. This *N* supports our ability to detect a small to moderate effect size.

18.0 Confidentiality of Data

1. To maintain the confidentiality of the data:

   ☒ I will use a unique study identifier to code individuals' identifiable data and will store the master list separate from the study data.

   ☐ I will use a unique study identifier to code individuals' data, but it will never be linked to a master list.

   ☐ Other- please explain: Click here to enter text.

   Provide a plan to maintain or destroy identifiers once analysis of identifiable information is complete. Once all data collection is complete and results are posted to ClinicalTrials.gov, we will delete all identifying information collected. This will include downloading all de-identified data from REDCap and storing in an encrypted Box folder.

   ☒ I attest that any recordings (audio or video) saved to a portable device will be deleted by formatting the device's storage memory.

How are you storing your electronic data?

☒ CWRU Redcap
☐ CWRU Secure Research Environment (SRE)
☒ CWRU Box
☐ OnCore
☐ CWRU Secure Network Drive
☐ Zoom Cloud
☐ Portable device (must be encrypted, not just password protected)

☒ Other - List storage method and provide justification: *Click here to enter text.*

Please note: if you're storing or entering your electronic data in any system other than an approved system listed above, please contact the CWRU IRB (cwru-irb@case.edu).

2. ☐ I acknowledge that paper research data and documents will be stored in a double-locked secure environment in the following **location:** Click here to enter text.
   ☒ We will not have paper research documents.

3. Will data be shared?
   ☒ Yes
   - List the exact data elements that will be shared: Data will be shared for the purpose of transcription, where we will send audio files to a third party. We will also share the names of participants enrolled in the research study with KINDER facilitators, who are not study team members. This is because facilitators will be asked to complete a call log and share attendance data for caregivers who are enrolled in the research study, and so will need to be able to distinguish between study participants and those caregivers who are attending KINDER without participating in the study..
   - Describe how data will be sent: Audiofiles will be uploaded to GMR Transcription services using their secure portal. Transcribed text documents will be emailed to the PI. Facilitators will receive an email with the names of study participants in a password protected Excel file.

   ☐ No
   ☐ N/A

If sharing data, please complete a request to ensure the proper contracts/agreements are in place: https://case.edu/research/faculty-staff/technology-transfer/material-transfer-data-use-agreements

18.0 HIPAA Authorization

Does this study collect, access, use, or distribute any Protected Health Information (PHI)?
Protected Health Information (PHI) is (1) any individually identifiable health information transmitted or maintained in a medical record, paper or electronic, or (2) designated data set that was created, disclosed, or used in the course of providing a health care service such as diagnosis, payment or treatment.

☐ Yes ☒ No

If yes, indicate how HIPAA authorization will be obtained (check all that apply):

☐ HIPAA authorization is in the consent form
☐ I am receiving a Limited Data Set under a Data Use Agreement (DUA)
☐ Requesting a full or partial waiver of HIPAA for prescreening
  ☐ I will complete the Request for Waiver of HIPAA Authorization form. *See SpartaIRB Library*
☐ Requesting a full or partial waiver of HIPAA

☐ I will complete the Request for Waiver of HIPAA Authorization form. *See SpartaIRB Library*

19.0 FERPA Authorization

Does this study collect, access, use, or distribute any personally identifiable information from student records or personal education information from an education program (defined as: any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education)? This includes, but is not limited to, classroom assignments and course evaluations.

☐ Yes ☒ No

If yes, how do you plan to get written authorization from the student (or parent if the student is a minor)?

☐ I will incorporate FERPA language* into the consent and obtain written and dated signature or authorized electronic signature using REDCap

☐ I will incorporate FERPA language* into a separate form and obtain written and dated signature or authorized electronic signature using REDCap

20.0 Risks to Research Participants

1. List the reasonably foreseeable risks such as breach of confidentiality, discomforts, hazards, or inconveniences to the research participants related to their participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Include the physical psychological, social, legal, and economic risks.
   Breach of confidentiality. There is small probability that data confidentiality could be breached, such that others outside the study team could connect participant identifying information with study data. Given the sensitive nature of the data collected, which could be potentially embarrassing, we consider this a moderate risk which would be irreversible. It is also possible that other caregivers could share information from group discussion sessions with others. This scenario is slightly more likely than study data being breached, however may be less harmful as caregivers can choose what they share with others during sessions. *Report to Adult Protective Services.* In rare cases, we may be required to contact Adult Protective Services if we perceive there to be a risk of harm to the participant or the person for whom they provide care. In some cases, we may contact the caregiver encourage them to submit a report to Adult Protective Services if we believe their or their loved one's safety is at risk. This process could be quite stressful for family caregivers, who may also experience adverse effects of stigma from this process. In very rare cases, legal consequences may occur if APS finds evidence of mistreatment. The study team's intention with reporting cases of mistreatment is to protect vulnerable older adults and help care partners connect to critical services if needed. *Negative emotions.* Some participants may experience discomfort, such as embarrassment or guilt, when answering questions their caregiving relationship or

* FERPA language: 1. Specify the educational records that may be both accessed and used in the research. 2. State the purpose of the access and use of records. 3. Identify to whom the records disclosure may be made.

participant in KINDER program activities. The likelihood and severity of this risk will vary from person-to-person. We provide resources to family caregivers who experience negative emotions throughout the intervention program and in the consent form.

2. If applicable, indicate which experimental procedures may have risks to the research participants that are currently unforeseeable. Click here to enter text.
   ☒ N/A
3. If applicable, describe the risks to others who are not research participants. There is a very small chance that, should Adult Protective Services be contacted by the study team, the older adult living with dementia (care recipient) may lose their family caregiver if APS finds indications of mistreatment. This would be a severe outcome, but also a potential benefit if care being provided placed the care recipient at risk of harm.
   ☐ N/A
4. Describe the availability of medical or psychological resources that research participants might need. Click here to enter text.
   ☐ N/A

21.0 Provisions to Protect the Privacy Interests of Research Participants

Directions: Indicate the measures that will be taken to protect research participants' privacy interests. Select all that apply:

☐ In person interactions will be conducted in a private space where conversations would not be overheard by others -- this could be at a specific location determined by the research team or at a location that the participant chooses.

☒ For online/remote data collection, participants will be advised to choose a location that would be private.

☐ Researchers will only contact participants if permission has been given to do so.

☒ Other: When participants join the KINDER discussion sessions by Zoom, they will be reminded to keep information they learn about other caregivers private. Access to survey data will be limited to qualified study team members. The study key will only be accessible to the PI. (The PI will therefore be responsible to sending participant online surveys, since these are connected using participant email addresses in REDCap.)

22.0 Potential Benefit to Research Participants

☐ There is potential benefit to research participants.

Describe the potential benefits that individual research participants may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits. *Do not list compensation.* Click here to enter text.

☒ There is **no** direct benefit to research participants.

If no direct benefit, state the potential benefit to society or others. *Do not list compensation.* We cannot know whether participation in KINDER will benefit participants directly, as we are still determining the evidence-base. However, it is possible caregivers will learn new information such as about local community resources.

23.0 Withdrawal of Research Participants

Directions: Describe the anticipated circumstances under which research participants will be withdrawn from the research without their consent. Also include the procedures that will be followed when a research participant withdraws or are withdrawn from the research, including partial withdrawal from procedures with continued data collection.

Participants may be withdrawn from the study if they 1) do not complete the baseline survey or 2) miss 2 or more group-based sessions. Participants may continue to participate in the KINDER program if this occurs but will be removed from the study. If this does occur, the PI will send an email to the participant to notify them. We will keep all data collected until withdrawal unless asked not to by a participant. We will attempt to contact participants to learn about their reason for withdrawal. See "Call Scripts for Caregivers Who Go Off Protocol"

☐ N/A

24.0 Alternatives to Participation

Directions: List other options to participation. If subjects will be compensated with extra course credit, the course instructor offering extra course credit must provide alternatives to earn extra course credit. The alternative assignment must require equal or less time and effort for the same amount of earned extra credit that you can earn through participation in research. If there are other available clinical treatments, what would be included if a subject continued on standard of care therapy. If there is a viable alternative you must list it in the consent.

Click here to enter text.

☒ The alternative is for research subjects not to participate.

25.0 Costs to Research Participants

☒ There are **no** costs to research participants or their insurance companies (there are no clinical visits or billable procedures.) – *please leave rest of this section blank*

1. Describe what costs research participants will be responsible for as a result of their participation in the research, including but not limited to: clinical services required by the protocol deemed billable to insurance, transportation to study visits, parking, costs of drugs, cost of therapy, lost broken or stolen devices, etc. Click here to enter text.

2. Explain who will be responsible for payment of provided services in the event of insurance denials. Click here to enter text.

3. List what procedures, drugs, devices, supplies will be paid by the study sponsor or covered by other funding. List the other funding source. Click here to enter text.

26.0 Research Participant Compensation

☐ There is no compensation or reimbursement for research participants – *please leave rest of this section blank*

☒ There is compensation for research participants.

Describe the schedule, payment method, and payment total of any incentives or compensation that research participants will receive for participation in the research (e.g., gift cards or cash with amount, t-shirts, devices, bags, swag, etc.) Participants will be eligible to receive up to $150 for participating in this study, or $75 per survey completed. We will distribute payment by email using an Amazon gift card URLs. This will be sent within 2 business of the participant completing teach survey. While this amount is high for survey completion activities, it is comparable to other studies which require intervention participation. Some caregivers may also be invited to complete a qualitative interview, and will received $25 as a thank you.

☐ There will be reimbursement for research participants.

Describe the schedule, payment method, and payment total of any reimbursement that research participants will receive for participation in the research (e.g., gift cards or cash with amount, etc.) Click here to enter text.

27.0 Compensation for Research Related Injury

Describe who will pay for the costs of medical treatment and/or compensation in the event of a research related injury:

☐ Funding agency is providing some/all payment for injury

☐ Funding agency is providing no payment for injury

☒ N/A

28.0 Provisions to Monitor the Data to Ensure the Safety of Research Participants

1. Describe how often the data will be monitored for completeness, accuracy and adherence to the protocol. The PI will complete a safety monitoring report once every 3 months of this study. Information will include the number of individuals recruited, enrolled, dropped out, demographic information on participants, and descriptive information on study variables including the proportion of missing data for each variable. We will also report on the number of reports made to Adult Protective Services for each time period.

2. Indicate if there will be a Data and Safety Monitoring Board or Committee:

   ☒ There will **not** be a formal Data and Safety Monitoring Board/Committee.

   ☐ There will be a formal Data and Safety Monitoring Board/Committee.

Provide information about the DSMB/C including the contact information of the committee member(s) (as applicable); whether it is independent from the study sponsor; how often it meets; the type of data that will be used; written reports, etc. Click here to enter text.

29.0 Additional Information

If you have any additional information regarding your study not covered in the template, please include it here.

30.0 Devices

Does the study include the use of a device that is integral to the study question?

☐ **Yes** – *Answer the questions below.*
☒ **No** – *Leave the rest of this section blank.*

☐ There is an active IDE (Investigational Device Exemption) for the proposed study.
Attach an official letter of support or proof of approval which identifies the IDE holder and IDE number to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device has obtained a 501k clearance.
Attach 501k documentation to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device meets the criteria for an IDE Exemption.
Download the IDE Exemption Form from the SpartaIRB library (HRP-580) and attach to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device (and its use) is a non-significant risk device for the proposed study design.
List devices here and provide the PI's rationale for the non-significant risk device determination. Click here to enter text.

If the research involves device(s), describe your plans to use, store, handle, administer and track those device(s) to ensure that they will be used only on research participants and be used only by authorized investigators. Click here to enter text.

31.0 Community-Based Participatory Research

☒ This is **not** a community-based participatory research project – please leave the rest of this section blank

☐ This is a community-based participatory research project
Describe the involvement of the community in the design and conduct of the research.
Click here to enter text.

Note: Community based research is research that is conducted as an equal partnership between academic investigators and members of a community. In Community Based Participatory Research (CBPR) projects, the community participates fully in all aspects of the research process.

32.0 MULTI-SITE RESEARCH (when CWRU is the IRB of Record)

Does this project have multiple sites?

☐ **Yes**

☒ **No** – please leave the rest of this section blank

Non-Local Site Information for Multi-Site Studies

*If this is a multi-site study where you are the **lead investigator,** list the following information for each relying site:*

1. Name of site: Click here to enter text.
2. PI of relying site: Click here to enter text.
3. Name of IRB contact: Click here to enter text.
4. Phone number of IRB contact: Click here to enter text.
5. Email address of IRB contact: Click here to enter text.

Non-Local Recruitment Methods for Multi-Site Studies

*If this is a multi-site study and research participants will be recruited by methods **not under the control of the local site** (e.g. call centers, national advertisements) describe those methods. Local recruitment methods are described above.*

1. *Describe when, where, and how potential research participants will be recruited.* Click here to enter text.
2. *Describe the methods that will be used to identify potential research participants.* Click here to enter text.
3. *Describe the materials that will be used to recruit research participants.* Click here to enter text.

Multi-Site Research Communication Plan (when you are the lead investigator)

*If this is a multi-site study where you are the **lead investigator**, describe the processes to ensure communication among sites including:*

☐ *All sites will have the most current version of the protocol, consent document, and HIPAA authorization*

☐ *All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record)*

☐ *All modifications have been communicated to sites, and approved (including approval of the site's IRB of record) before the modification is implemented*

☐ *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies*

☐ *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies*

☐ *All local site investigators conduct the study in accordance with applicable federal regulations and local laws*

☐ *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy*

*If this is a multi-site study where you are the **lead investigator,** describe the method for communicating to engaged participant sites the following:*

1. *Problems:* Click here to enter text.

2. *Interim results:* Click here to enter text.
3. *The closure of the study:* Click here to enter text.

33.0 References

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Wiglesworth, A., Mosqueda, L., Mulnard, R., Liao, S., Gibbs, L., & Fitzgerald, W. (2010). Screening for abuse and neglect of people with dementia. *Journal of the American Geriatrics Society*, *58*(3), 493-500. https://doi.org/https://doi.org/10.1111/j.1532-5415.2010.02737.x Zauszniewski, J. A. (2016). Resourcefulness. *West J Nurs Res*, *38*(12), 1551-1553. https://doi.org/10.1177/0193945916665079 Zauszniewski, J. A., Lekahk, N., Burant, C. J., Variarth, M., & Morris, D. L. (2016). Preliminary Evidence for Effectiveness of Resourcefulness Training in Women Dementia Caregivers. *J Fam Med.*, *3*(5).