Study Title:	The Grandmother Study: Grandmother Initiatives in Family Transformation (GIFT)
NCT Number	NCT03263923
Document Description:	Study Protocol and Statistical Analysis Plan
Document Date:	7/21/2022
Document History:	The current version, approved on 7/21/2022, removes the highlighting of previously approved changes to the protocol, as requested by the clinicaltrials.gov review process.

Kimberly Volarcik
Executive Director, Human Research Protection Program
Office of Research & Technology Management
10900 Euclid Avenue
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Phone: 216.368.0134
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Dear ClinicalTrials.gov Administrator,

This letter is to inform you that the header of each Case Western Reserve University IRB protocol template incudes the name of the template and the version date. This is how our electronic protocol system was set-up and is required for the IRB administrative processing of protocol submissions.

The "TEMPLATE: CWRU SBER IRB Template V. 09-2019" is administratively required for the NCT03263923: The Grandmother Study: Grandmother Initiatives in Family Transformation (GIFT) record. This is in line with the IRB needing to know the exact version of the protocol template is being reviewed or approved by the IRB for the life of the protocol submission.

Therefore, this is the reason why the protocol template

Please contact me if you have any questions.

Sincerely,

Kimberly Volarcik

IRB Administration Offices
UH IRB Phone: 216.844.1529
CWRU IRB Phone: 216.368.6925

APPROVAL

Principal Investigator:	Carol Musil
Title:	GIFT Web Based Resourcefulness Training for Grandmother Caregivers
IRB Number:	IRB-2014-725
Submission Number:	MOD00023524
IRB Office:	CWRU IRB
Approval Date:	7/21/2022
Effective Date:	7/21/2022
Approval End Date:	N/A
Type of Submission:	Modification
Type of Review:	Expedited
Documents Reviewed:	• 9-15-21 protocol supplement template - updated, Category: IRB Protocol;

The IRB reviewed this submission.

- Per Federal regulation, changes MAY NOT be made to any element of the current research without prior IRB approval, except to eliminate an immediate and apparent hazard to subjects enrolled in the study.
- Per Federal regulation, the research may not continue beyond the Approval End date. You must submit a continuing review form 6-8 weeks before this Approval End date in order to maintain IRB approval. Failure to maintain IRB approval is human subjects non-compliance. Please note that even if your study falls into a category that does not require an Approval End date, the institution may require a yearly "check-in" to confirm the status of the study.

***Approval by the IRB does NOT mean that you have permission to start your study. Prior to starting your study, you may be required to obtain (1) a coverage analysis for studies that involve patient care, regardless of source of funding, and/or (2) a contract with the Sponsor of your study or an agreement with any third-party collaborator that may receive UH or CWRU patient information in any format. Please ensure that all required approvals are obtained before initiation of research activity. ***

The UH IRB operates under HHS Federalwide Assurance (FWA) number 00003937 and IRB registration numbers 00000684, 00001691 and 00008600. The CWRU IRB operates under DHHS FWA00004428 and IRB registration number 00000683.

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

INSTRUCTIONS:

- *Use this template to prepare a document with the information from the following sections.*
- *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. You may delete contents of sections, but will not be able to delete the headings of the sections.*
- *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:

GIFT Web Based Resourcefulness Training for Grandmother Caregivers.

PRINCIPAL INVESTIGATOR:

Carol Musil
Nursing
368-2545
Cmm4@case.edu

OTHER DEPARTMENTS INVOLVED IN THIS STUDY (IF APPLICABLE):

Click here to enter text.

VERSION NUMBER:

Include the version number of this protocol if assigned by an outside entity.
2.0

DATE:

12/4/2019

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.

1.0 Funding

Please list the funder of this project. If there is not a funder, please note that your department pays for your time and resources and should be listed here. 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.

2.0 Objectives

Directions: Describe the purpose, specific aims or objectives. Be sure to also include the hypothesis being tested. 12-04-2019 Modification: Adds a 5th data collection point one year after the last described data point (the 24 week post-intervention collection point) Aim 1: Determine whether the 4-week GIFT intervention, compared to a 4-week unstructured journal-only condition, improves grandmothers' [a] mental health (general mental health and depressive symptoms), [b] physical health (self-rated and general health) and [c] family well-being (family functioning) at 2, 12, and 24 weeks post-intervention. Aim 2: Determine if changes in [a] problem solving/coping (resourcefulness), [b] resources (subjective and instrumental social support), and [c] situational appraisals (appraised stress, appraised reward, and depressive cognitions) mediate the relationships between GIFT and individual and family outcomes at 2 weeks, 12 weeks, and 24 weeks post-intervention. Aim 3. Determine if [a] grandmother demographics (age, race, education, marital status, and employment status), [b] caregiving status, and [c] family demands (intra-family strains) moderate the relationship between the intervention and the outcomes in Aims 1 and 2. **COVID-19 Supplemental Survey** – Participants who expressed an interest in future research at the 4th data collection point will be asked by phone or email to participate in a survey asking about their experiences during the covid epidemic. They will be emailed an online consent form that follows the same signing protocol we have used previously with this sample

3.0 Background

Directions: Describe the relevant prior experience and gaps in current knowledge describing how it will add to existing knowledge. Include any relevant preliminary data. 12-04-2019 Modification: Adds a 5th data collection point one year after the last described data point (the 24 week post-intervention collection point). In 2009, 7.8 million American children age 18 or younger lived with a grandparent, a 64% increase from 1991.116 In most cases, grandmothers are the head of these households, alone or with a spouse. There are two distinct types of such households: grandmothers raising grandchildren whose parents are unable to care for them and grandmothers living in multigenerational homes with grandchildren and their parents. Those who are very involved in caring for their grandchildren are at greater risk of depression and poorer overall health than their non-caregiving peers.3-5 Many grandmothers living with grandchildren are stressed and depressed,6 which has a cascading effect on the family, creating an increased risk for poor

family functioning, especially if the grandmother is raising grandchildren without the children's parents in the home.7-10 Most of the relevant research to date has been descriptive and focused on the stress and health risks, particularly depressive symptoms, of raising grandchildren in grandparent-headed homes, although grandmothers in multigenerational households often face complex stresses as well.11-18 Little research, however, has examined interventions to support grandmothers during their caregiving experience. Transitions from lower levels to higher levels of grandchild caregiving (e.g., starting to raise a grandchild or initiating a multigenerational home) are associated with worsening health problems.19 During and after grandchild caregiving transitions, the presence of positive coping skills and resources, such as resourcefulness and social support, may reduce the negative effects of caregiving and family demands on the well-being of the grandmother and family.19,22 Our prior work links greater resourcefulness with fewer depressive symptoms and better health.11,23-26 We have shown that face-to-face resourcefulness training in older adults, including grandmothers, improves both mental and physical health.27-29 Our descriptive and pilot intervention studies have laid the foundation for grandparent research in the area of resourcefulness,30-34 and we propose to apply this knowledge to a widely accessible intervention that reduces stress and health risks. The purpose of this study is to extend our previously successful face-to-face resourcefulness intervention to a web-based format for grandmothers, a population with which our team has considerable experience. The web- based intervention, Grandmother Initiatives in Family Transformation (GIFT), provides online resourcefulness training using structured reflective journaling to reinforce resourcefulness skills. We will conduct a randomized clinical trial (RCT) comparing the health effects of two online conditions: GIFT vs. unstructured journaling alone. Given the limited interventions available to these groups of women, an intervention that transcends time and place and is available 24 hours a day is expected to bolster the personal and social resourcefulness of grandmothers living with and raising grandchildren, which will in turn affect individual and family health outcomes. In this two-group randomized trial, we will randomly assign 320 grandmothers to a web-based (a) GIFT resourcefulness training (n=160) or (b) an unstructured journal-only comparison group (n=160). Grandmothers' demographic characteristics, caregiving status relative to grandchildren (raising grandchildren versus sharing a home with grandchildren and their parents) and family demands (intra-family strain) will serve as covariates. Study aims are: Aim 1: Determine whether the 4-week GIFT intervention, compared to a 4-week unstructured journal-only condition, improves grandmothers' [a] mental health (general mental health and depressive symptoms), [b] physical health (self-rated and general health) and [c] family well-being (family functioning) at 2, 12, and 24 weeks post-intervention. Aim 2: Determine if changes in [a] problem solving/coping (resourcefulness), [b] resources (subjective and instrumental social support), and [c] situational appraisals (appraised stress, appraised reward, and depressive cognitions) mediate the relationships between GIFT and individual and family outcomes at 2 weeks, 12 weeks, and 24 weeks post-intervention. Aim 3. Determine if [a] grandmother demographics (age, race, education, marital status, and employment status), [b] caregiving status, and [c] family demands (intra-family strains) moderate the relationship between the intervention and the outcomes in Aims 1 and 2. Impact Based on our prior research,27,32 we hypothesize that the GIFT intervention will facilitate better individual and family outcomes directly, and also indirectly by reducing depressive cognitions and perceived stress, by increasing reward and support, and by buffering the effects of caregiving, family demands and demographic factors on outcomes—mechanisms that will be disentangled in this 4 year randomized trial. If our study validates our hypotheses, the GIFT intervention can provide a low-cost, readily accessible intervention to help grandmothers raising grandchildren to improve their own mental and physical well-being and thereby promote better family well-being, outcomes

that will have long-term individual, family, and societal benefits. Study Design We will conduct a two-group RCT with a longitudinal, multivariate design using a convenience sample of 320 grandmothers living with grandchildren age 16 or under. The RCT will compare GIFT Resourcefulness Training (video plus structured journal to practice resourcefulness skills) to the use of an unstructured journal, which has been found to have a small effect on improving stress and depressive symptoms, but significantly less than the resourcefulness intervention.27,52,85 We believe that no "usual care/no-care" control group is necessary to test our hypothesis, given evidence showing the relative stability of the major study variables (physical and mental health, family functioning, resourcefulness, support) over 6.5 years in Musil's descriptive longitudinal study of grandmothers and over 18 weeks in the control group of Zauszniewski's resourcefulness trial with grandmothers. We will extend the time of follow-up and obtain measures of outcomes, mediating variables, and potential moderating covariates at baseline/pre-intervention (T1) and 2 weeks (T2), 12 weeks (T3), and 24 weeks (T4) post intervention to evaluate early, lagged, and extended effects.

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. 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.	*Grandmothers ages 18-64 and/or 64+* of a grandchild aged 18 or under
2.	Live in the same home as one or more grandchildren age 18 or younger and either [a] are the primary caregiver for grandchildren whose parents do not live in the home or [b] help in the care of the grandchildren and live in a multigenerational home with the grandchildren's parent(s). We focus on these two groups because grandmothers raising grandchildren have significantly more stress, depressive symptoms, and problems in family functioning and worse health than other women their age,13,15,16, 17,19 while those living in multigenerational homes often report more transitions, financial problems, and depressive symptoms than grandmothers not living with grandchildren.18,23
3.	
4.	

	Exclusion
1.	Grandmothers who do not reside with grandchildren, even if they provide regular daycare or babysitting for grandchildren
2.	We have excluded grandfathers because they comprise fewer than 3% of grandparents with any caretaking responsibilities and are less likely to live in multigenerational homes
3.	Grandmothers who do not have regular access to a computer or hand-held internet capable device as the study will be completed online

4.	Grandmothers who do not speak English. While we recognize that our English literacy requirement will preclude participation by some otherwise eligible grandmothers. If the GIFT intervention is successful, we will expand our testing and translate instruments and training into Spanish and other languages in future projects

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 enroll up to 350 participants, recruiting nationally across the United States.

6.0 Special/Vulnerable Populations

1. *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/Foster Children
☐ **Pregnant Women**
☐ **Neonates**
☐ **Neonates of Uncertain Viability**
☐ **Employees of CWRU or UHHS**
☐ **Prisoners**
☐ **Illiterate Individuals**
☐ **Non-English Speaking**
☐ **University Students**
☒ **None**

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. *We are not recruiting from special/vulnerable populations.*

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. While we recognize that our English literacy and speaking requirement will preclude participation by some otherwise eligible grandmothers the intervention is not available in languages other than English.

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.)
   - ☒ Social media
   - ☐ Other. *Please specify:* Click here to enter text.

2. Describe when, where, and how potential research participants will be recruited.
   We will seek a national convenience sample of up to 350 grandmothers living with grandchildren, building on strategies we successfully used in our previous research. We will partner with national organizations whose missions support the work of grandparents raising grandchildren and foster intergenerational relationships across various family structures. We have established relationships with several such organizations and will work with them to notify grandmothers who may meet eligibility criteria. Among these groups are Generations United, a national non-profit group focused on intergenerational relationships, and Grandparents.com, with a dedicated section for grandparent caregivers. Both groups reach large audiences of grandparents, health and social service providers, and other consumers. We have a relationship with the Public Children's Services Association of Ohio and their network of national organizations addressing children's needs, including grandparent caregiving (see letters of support). The study will be publicized through each organization's website, printed material, and email, and their network of organizations. In addition, there are over 360 support groups for grandparents in the U.S., most of them focused on raising grandchildren, and we have successfully partnered with support networks in our past recruitment efforts. We will contact these organizations and networks, and they may share both print and electronic advertising materials to inform prospective subjects about the study. Our project manager has organized such recruitment efforts and will lead recruitment all recruitment efforts. In addition, we will register our project at Clinical Trials.Gov and ResearchMatch.org, two online resources that facilitate research-subject recruitment. We will also contact libraries, newspapers, and radio stations as appropriate, and will track subjects' region of the country for purposes of describing the

sample. Because our GIFT pilot study indicated that recruitment can be facilitated by in-person contact, we propose a modest travel budget to attend events for grandmother caregivers in various parts of the country, such as the annual meetings of statewide kinship groups, if needed to meet recruitment goals. Prior: we will use ads in newspapers and flyers and at Grandparents.com and Generations United. We will employ additional strategies but seek approval prior to employing any. New: grandmothers are eligible if grandchildren are age 18 oryounger. 9.7.17 Social Media Strategy: Our Facebook page includes an already IRB approved self-screener, and as previously discussed in person, the Facebook page will be shared with grandparent and related family support groups. Information about the Links to our Facebook page [and the CWRU website (grandmotherstudy@case.edu)] will be included in advertising materials (already approved). We do not plan to use twitter,snapchat or instagram at this time.

3. Describe the source (e.g., from what department, EMR, etc.) of the research participants.
   From the community

4. Describe the methods that will be used to **identify** potential research participants.
   Study staff will conduct a phone screener with potential participants who contact the study. Potential participants will be screened based on the inclusion criteria and willingness to complete the study components.

5. 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?
   The study is open to participation across all 50 states. Based on past research on just Ohio grandmothers living with grandchildren, we do not anticipate difficulty reaching our sample goals.

9.0 Setting

Directions: Describe the sites and locations where your research team will conduct the research. All components of the study will be completed entirely online. Upon request from the participants (or if electronic components are not completed), we may provide paper copies to be completed at the participant's location.

10.0 Consent Process

Indicate whether you will be obtaining consent:

☒ Yes ☐ No

If yes, answer the following questions:

1. Describe where the consent process will take place: The Project Director or research team member will screen prospective participants over the phone to determine eligibility for participation: grandmothers who (a) live with one or more grandchildren under age 18 and participate in their care; (b) understand and write English; and (c) have personal access to a computer or mobile device. If eligible, we will outline the nature and requirements of the study: informed consent, the duration of the study, the timing and content of questionnaires and journal maintenance, and their willingness to participate in the random assignment process.

Those not eligible will be informed of the reason they do not qualify. Name, address, phone number, and email address will be recorded by project staff into a data entry module. After telephone screening, those eligible and verbally agreeing to participate will be sent an informed consent by email and will complete it online.

2. The time that will be devoted to the consent discussion: *As much time as the participant needs to consider enrollment. The online screener includes a prompt for the study staff to ask potential participants if they have any questions. Study staff will be instructed to take as much time is necessary with each potential participant.*

3. Any waiting period available between informing the prospective subject and obtaining the consent: *Participants will be emailed a consent form and can take as much time as they need and consult with anyone they wish before returning the consent form.*

4. Steps that will be taken to ensure the research participants' understanding The phone screening process includes a series of questions regarding eligibility and the opportunity to ask questions of the study staff.

5. Any process to ensure ongoing consent: *Participants will be contacted prior to each data collection point to remind them of the next part of the process.*

6. Steps that will be taken to minimize the possibility of coercion or undue influence to the subjects: *Participants are reminded that participation is voluntary, they can stop at any time and will be compensated for the portions of the study they complete.*

For Adult Participants

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

☒ Yes ☐ No

If yes, 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

☐ I will obtain consent, but request a waiver for pre-screening purposes

☐ 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

1. Give the rationale for the request of a waiver or alteration of the consent process or documentation. *As our study is completed online, completing an online consent document 1) streamlines enrollment by eliminating the need to mail forms back and forth. 2) Serves as a check on computer access, which is one of our inclusion criteria.*

2. Explain how the research involves no more than minimal risk. The research presents no more than minimal risk or harm to the participants and involves no procedures for which written consent is normally required outside of the research context. These are fairly standard tests that an individual could download from the internet if they were interested. Further, the resourcefulness training poses little if any harm and could actually be helpful to some people. Information about the training is also available on the internet, so they could do all of these things on their own.

3. Explain why the waiver or alteration of consent will not adversely affect the rights and welfare of the participants. As we email the form to the potential participants, they have the same access to information as if they received a paper copy.

4. Explain why the research could not practicably be carried out without the waiver or alteration of consent. As we are recruiting nationally, the burden of face to face consents and/or mailing consent forms would be cost-prohibitive, without adding any additional protections to the participants.

5. Indicate if the subjects will be provided with additional information about the study after participation. *Participants will receive a newsletter with results when the study is complete.*

6. If you will obtain consent, but not document consent in writing (e.g. over the phone, verbally, electronic survey, etc.), please describe and provide a rationale.
☐ N/A We will have an electronic consent form that participants will be emailed to read, consider, and electronically sign, on their own time, after verbally assenting during the phone screening process.

7. Describe how you will be documenting that a research participant has consented. Participants will electronically sign both by clicking check box indicating their consent and typing their full name in lieu of a written signature.

**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: While we recognize that our English literacy requirement will preclude participation by some otherwise eligible grandmothers, the intervention is not available in languages other than English. If the GIFT intervention is successful, we will expand our testing and translate instruments and training into Spanish and other languages in future projects

☐ 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.

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

Results will be shared with research participants:

☒ Yes ☐ No

If yes, describe how the results will be shared. Participants will receive a newsletter with results after the study is complete.

Results will be shared with others:

☒ Yes ☐ No

If yes, describe with whom and how the results will be shared. Results will be disseminated via conference presentations and scholarly articles.

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.

Study Design We will conduct a two-group RCT with a longitudinal, multivariate design using a convenience sample of 320 grandmothers living with grandchildren age 16 or under. The RCT will compare GIFT Resourcefulness Training (video plus structured journal to practice resourcefulness skills) to the use of an unstructured journal, which has been found to have a small effect on improving stress and depressive symptoms, but significantly less than the resourcefulness intervention. We believe that no "usual care/no-care" control group is necessary to test our hypothesis, given evidence showing the relative stability of the major study variables (physical and mental health, family functioning, resourcefulness, support) over 6.5 years in Musil's descriptive longitudinal study of grandmothers19, 25 and over 18 weeks in the control group of Zauszniewski's resourcefulness trial with grandmothers.27 We will extend the time of follow-up and obtain measures of outcomes, mediating variables, and potential moderating covariates at baseline/pre-intervention (T1) and 2

weeks (T2), 12 weeks (T3), and 24 weeks (T4) post intervention to evaluate early, lagged, and extended effects. 12-04-2019 addendum: We will also collect information one year after the completion of the 24 week post-intervention follow-up. Each questionnaire is anticipated to take between 15 and 25 minutes to complete. The journals take 1-15 minutes each day that the participants journal up to 28 days. **COVID -19 supplemental survey** Participants expressing an interest in future participation will be asked to complete a survey regarding their experiences during the pandemic. They will be compensated an additional $10 if they complete the survey. Previously collected data will be linked to the Covid-19 supplemental survey, but only using participant's coded identifiers, no using personally identifiable data. 9-15-2021 modification: At the end of the study participants will be given the opportunity to view the video and journal prompt text for the other arm. We will use Qualtrics to display this content but will not collect data. They will have an opportunity to view this material for 28 days. We will not email participants who requested no further contact.

13.0 Study Timeline (optional)

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. ClinicalTrials.gov Identifier: NCT03263923 NIH grant R01NR015999

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). See Q1, Q2, Q3, Q4 ,Q5, **COVID -19 supplemental survey** and weekly journals for control and intervention groups, attached .

16.0 Data Analysis Plan

Directions: Describe the data analysis plan, including any statistical procedures. If applicable, provide a power analysis, and study/safety endpoints. ***Statistical Power Analysis for Sample Size Estimation.*** *For Aim 1, power analysis using G-Power[42] for RMANOVA testing the interaction between group and time, with an alpha of .05, a power of .80 and a sample size of 250 indicates a detectable small effect size of .07, as was obtained for the social support mediators in our pilot study. The major outcome variables show much larger effects (Figure 3), and therefore, the sample size of 250 is adequate. For Aims 2 and 3, power analyses were conducted applying MacCallum, Browne, and Sugawara's[118] calculations to determine sample size for Structural Equation Models. We use the Root Mean Square Error of Approximation (RMSEA) to assess goodness-of-fit of a hypothesized model and the sample data. In testing for power, two hypotheses (close fit and not close fit) are tested. For close fit hypotheses, the higher the power the more likely to reject an incorrect model. For not close fit hypotheses, the higher the power, the more likely to detect a reasonably correct model.[118] The difference in two RMSEAs reflects effect size. RMSEAs of .05 (good fit) and .08 (acceptable fit) are used for close fit hypotheses, while .05 (good fit) and .01 (extremely good fit) are used for not close fit hypotheses.[118] We constructed a multivariate cross-lagged autoregressive model with four waves of data testing how problem solving/coping, resources, and situational appraisals mediate the impact of the GIFT intervention on the individual and family well-being outcomes.[34,55-56] Using the sample size of 250 as an estimate for a close fit hypothesis with an alpha of .05, an RMSEA1 of .05, an RMSEA2=.08, and a model with 124 degrees of freedom, the SEM had a power =.996. For a not close fit hypothesis with an alpha of .05, an RMSEA1=.05, an RMSEA2=.01, and a model with 124 degrees of freedom, the SEM had a power =.984. Thus, our final sample of 250 will provide adequate power.* **Sample size and attrition.** We will enroll 167 subjects per group to achieve a sample of 125 per group at T4. While our prior longitudinal survey research had a low attrition rate (12%) over 24 months, and our web-based GIFT pilot had 92% continuation at 6 weeks, the face-to-face intervention study[27] had 19% loss over 18 weeks, suggesting slightly greater losses by the 24-week follow-up. Therefore, we estimate *25%* attrition over the 28 week study duration (intervention plus follow-up) and plan to enroll a total of *334* subjects. Subjects tend to remain in our studies in large part due to their commitment to grandmother caregiving and the team's sensitivity to diversity, which will again be overseen by Co-I Warner.

17.0 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 destroy identifiers including how and when. Identifiers will be destroyed one year after study completion, in case we conduct a long term follow-up of participants. As previously approved, we cannot prevent Qualtrics from collecting IP addresses, but we will remove them from the SPSS files we save.

2. How are you storing your electronic data?
   - ☐ UH Redcap
   - ☐ CWRU Redcap
   - ☐ CWRU Secure Research Environment (SRE)
   - ☒ CWRU Box
   - ☐ OnCore
   - ☐ UH Secure Network Drive
   - ☒ CWRU Secure Network Drive
   - ☒ Other - List storage method and provide justification: Materials include the information obtained by questionnaires, journals (either structured or unstructured) using an integrated, password-protected system designed by CWRU Information Technology web designers who have consulted on the GIFT project. The system is implemented using Qualtrics and will allow participants to access all study components (video, all surveys, journals and system-related resources) at one secure site. Access to the subject's email address and phone number is necessary for this web-based study. Subject identifying data will be stored separately from other study material. Data will be collected on a firewalled, dedicated server with a backup server in the School of Nursing following established security guidelines for storing Protected Health Information. Only the research team can access the server to retrieve data. Qualtrics allows us to password-protect the entire site and allows project staff to monitor participants' journaling, and for those in the GIFT intervention group, the number of times each person viewed the GIFT training video. Participants move from the T1 baseline questionnaire, to the GIFT Resourcefulness training video for those in the GIFT intervention group, to the 4-week structured GIFT journal or the 4-week unstructured journal, to subsequent questionnaires. Participants will be able to access the site and their information 24 hours a day, 7 days a week, for the duration of the study. We have consulted with the CWRU Full INclusion of persons with Disabilities (FIND) Lab for maximizing ease of use and readability (e.g., contrast, background, font, print and graphic elements). Our Project Manager and research team will oversee that the systems are working smoothly, monitor participants' enrollment in the system and their progress on a weekly basis during the first six weeks after their enrollment, and provide email and telephone reminders. Subjects will be assured that only the study team and the Human Subjects Review Committee and staff members will have access to the information. Data stored on Box or elsewhere will not include any personal identifying information.

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).

3. ☒ I acknowledge that paper research data and documents will be stored in a double-locked secure environment in the following **location:** Although we do not intend to keep paper research documents, any such documents would be kept in a locked office in locked files of the principal investigator.

   ☒ We will not have paper research documents.

4. Will data be shared?

   ☐ Yes
   - List the exact data elements that will be shared: Click here to enter text.
   - Describe how data will be sent: Click here to enter text.

   ☒ No

   ☐ N/A

(Please note: if sharing data, please contact the CWRU Tech Transfer Office to ensure the proper contracts/agreements are in place.)

18.0 HIPAA Authorization

Does this study collect, access, use, or distribute any Protected Health Information (PHI)?

☐ Yes ☒ No

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

☐ HIPAA authorization is in the consent form

☐ 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 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. This is a 2-group treatment trial, with subjects assigned either to GIFT Resourcefulness Training with a 4 week structured journal to reinforce skill development or to group in which women complete 4 week unstructured journals. All subjects are volunteers and non-participation and withdrawal from the study are alternatives to study participation. There are no risks to non-participation or withdrawal from the study No physical or psychological risks other than those associated with daily living are expected for the women who participate in this study. The discomforts of completing the web surveys, journals are minimal. Reflecting on feelings or experiences of being a grandmother raising or living with and caring for a grandchild may make some women anxious, although this has not been our experience previous research; the Intervention Specialist will monitor journal content for signs of subject distress.

Participating in a research study may represent an additional time burden for grandmothers, but we expect the burden of participation to be minimal. Our project staff will be available by email or phone for procedural and technical support with the web-based pilot. Subjects who receive scores of 30 or greater on the CES- D measure of depressed mood (the cut off score for moderately depressed mood) will be referred to their primary care provider for follow-up. If it is learned that a grandchild has been a victim of any type of abuse, or is a danger to him/herself or others, then the appropriate agencies will need to be notified. Additionally, if grandmothers contact us requiring assistance of any kind we will give them United Way's First Call for Help telephone number. The First Call service provides resources on various issues such as legal matters, housing, etc. We also will have a list of local, statewide and national agencies for making necessary referrals.

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. Click here to enter text.
   ☐ N/A
4. Describe the availability of medical or psychological resources that research participants might need. Click here to enter text.
   ☐ N/A

20.0 Provisions to Protect the Privacy Interests of Research Participants

Directions: Describe the steps that will be taken to protect research participants' privacy interests. (consider issues such as physical space, proximity to other, and participant preferences) Only the PI, the Co-Is, the Project Manager and the research assistant(s) directly involved with managing the project and monitoring participation will have access to the data and codes . Identifiers will be destroyed one year after study completion, in case we conduct a long term follow-up of participants. Confidentiality: Every effort will be made to protect participants and keep the study data confidential. Confidentiality will be assured in the following manner. All data collection will be conducted using an integrated, password-protected system designed by CWRU Information Technology web designers who have consulted on the GIFT project. The system uses Qualtrics to allow participants to access all study components (video, all surveys, journal or diary and system-related resources) at one secure site. Data will be collected on a firewalled, dedicated server with a backup server in the CWRU School of Nursing following established security guidelines for storing Protected Health Information. Only the research team can access the server to retrieve data. We will use established web- based technology that is accessible on a standard web browser compatible with an average household or library computer. The LMS allows us to password-protect the entire site. All responses will remain confidential and results will be reported in aggregate form. A single index of subjects' names, identifying information (email addresses, phone and physical address contact information) and research identification numbers will be kept in password project files on password protected files during the data collection phase. Identifying information from the informed consent (email and street address) will be on a tear sheet and stored separately from the consent forms. Downloaded data will be de-identified. Only personnel directly related to the project (Investigators, Project Staff, and IRB and NIH officials) will have access to the data. At the end of the study, the list linking the subject name, contact information and study ID will be destroyed.

Participants will also be told that individual responses will not be shared with others. Subject names will not be used in any reports of the study. Subjects will be assured that only the study team and the Human Subjects Review Committee and staff members will have access to the information. All paper copies of materials will be kept in a locked office in locked files of the research project office. 5-8-20 modification: Researcher Greg Smith of Kent State University has added our Covid-19 questions to their research study of custodial grandmothers. We plan to combine de-identified data (our Covid-19 as well as selected relevant data from prior waves of our research (ex: demographic data, health status data) for the purpose of comparing our samples.

21.0 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.* A possible benefit to subjects in either arm of this study is an opportunity to develop insights into their own behavior and feelings and strategies to help themselves and their family. Participants in the GIFT Intervention Group may benefit from resourcefulness training

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

If no direct benefit, state the potential benefit to society or others. *Do not list compensation.* Importance of the Knowledge to be Gained The number of grandparent-headed homes has increased over the past two decades, primarily due to parental drug use leading to family instability, and recent increases in multigenerational homes due to the economic downturn in 2008. There are very few interventions targeted at grandmothers with extensive or primary caregiving responsibility to grandchildren, who do so typically under stressful conditions, despite evidence of depressive symptoms and worsening health, and effects on overall family well-being. This intervention trial tests GIFT resourcefulness training, a low-cost, easily available set of strategies to help grandmothers living with and raising grandchildren to improve their mental and physical well-being and promote better family functioning. The GIFT intervention is expected to facilitate better outcomes directly, but also indirectly by decreasing stress and depressive cognitions, by increasing reward and support, and by buffering the effects of caregiving and demographic factors on outcomes. Understanding these mechanisms will facilitate improvements in the intervention and generalizing effects to other populations. The risks to participants are minimal to relation to the knowledge to be gained.

22.0 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. We do not anticipate involuntary withdrawal of participants. Participants who choose to stop participating will be compensated for study components that have been completed and will not be contacted for subsequent components.

☐ N/A

23.0 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.

24.0 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. There are no financial costs associated with participation

2. Explain who will be responsible for payment of provided services in the event of insurance denials. N/A

3. List what procedures, drugs, devices, supplies will be paid by the study sponsor or covered by other funding. List the other funding source. N/A

25.0 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.) electronic gift cards as follows: $30.00 for the 1st questionnaire, $50 after the journal and 2nd questionnaire, $30 after the 3rd questionnaire, $50 after the 4th questionnaire, $25 for the 5th questionnaire

☐ 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.

26.0 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

27.0 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. Data will be monitored as it is completed. Journals in progress will be monitored to determine if participants are continuing to participate.

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. Our DSMC will meet twice annually. Members of the committee are as follows: Dr. Barbara Daly (bjd4@case.edu), Dr. Aloen Townsend (alt7@case.edu), & Dr. Shirley Moore (smm8@case.edu). Written reports regarding data collection, sample demographics, and participants requiring followup for elevated depressive symptoms will be provided prior to each meeting.

28.0 Additional Information

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

29.0 Devices

☒ This is **not** device study. The protocol is considered non-therapeutic (non-therapeutic is defined as research not intended to diagnose, prevent, cure, mitigate, treat, etc. a disease or condition) by the FDA. *– please leave rest of this section blank.*

OR

☐ This is a device study. The protocol is considered therapeutic (research intended to diagnose, prevent, cure, mitigate, treat a disease or condition) by the FDA.

1. Is there an IDE (Investigational Device Exemption) for the proposed study?
   ☐ Yes, provide an official letter of support or proof of approval which identifies the IDE holder and IDE number. Please attach this in the SpartaIRB smartform
   ☐ No, see question below:

2. Is the device (and its use) a non-significant risk device for the proposed study design?
   - ☐ Yes, please identify the authorized party who made the determination and provide supporting documentation as applicable. Click here to enter text.
   - ☐ No *NOTE: either an active IDE or an exemption would be required for investigational product use in a therapeutic protocol.*
   - ☐ N/A
3. 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.

30.0 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.

31.0 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.

32.0 References

Click here to enter text.