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

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Study Consent

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CASE WESTERN RESERVE UNIVERSITY EST. 1826

INFORMED CONSENT DOCUMENT

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

You are being asked to participate in a research study conducted by researchers at Case Western Reserve University. This consent form contains important information about this project and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. Your participation in this research is voluntary.

KEY INFORMATION FOR YOU TO CONSIDER:

What is the purpose of this research?
The purpose of this study is to learn whether participation in the KINDER program (Knowledge and Interpersonal Skills to Develop Exemplary Relationships) can help caregivers to persons diagnosed with dementia to improve the quality of their caregiving relationships. A dementia diagnosis can cause uncertainty and role changes in an existing relationship. The goal of the KINDER program is to give you tools to help manage these changes to support a healthy caregiving relationship and promote high-quality caregiving.

What will I be asked to do if I participate?
Participation in this study will involve completion of a 9-week education program focused on family caregiving relationships. This will include eight lessons completed independently using a digital or print workbook, as well as three group sessions completed over Zoom. You will also be asked to complete one survey before and one survey after participating in the program. Participation is estimated to take 20 hours total, depending how long it takes you to complete lessons, spread over 3 months.

How will I benefit from participation?
You will not directly benefit from participation in this study. The knowledge gained from this research may benefit family caregivers in the future by informing programs to support healthy caregiving relationships.

Why might I not want to participate?
There are several reasons you may choose not to participate. Some caregivers may also feel uncomfortable with the topics discussed, including mental health, disease stages, and elder mistreatment. As with many studies, there is also a risk that confidentiality could be breached. If you have any questions about how we store data to prevent this from occurring or other study procedures, please feel welcome to contact the study team.

Please refer to the Detailed Consent for additional information.

DETAILED CONSENT

You were selected as a possible participant because you indicated interest in participating in the KINDER program, and we believe you may be a family caregiver to an individual living with Alzheimer's disease or a related dementia. We hope to recruit N=42 participants for this research study.

Procedures

During this study, you will be asked to complete three (2) 30- to 45-minute surveys asking about your demographic information, caregiving situations, and relationship with the care recipient. The first survey will be

sent within 2 weeks of your beginning the program, the second will be sent within 1 week after you complete the KINDER Program. All surveys will be completed online. You may also be asked to participate in a qualitative interview by phone or Zoom so we can learn more about your experiences participating in KINDER.

In addition to completing these two surveys, you will be asked to participate in the 9-week KINDER Program. This program will include completion of 8 weekly, self-paced lessons. Lessons consist of a short video vignette, written text, a reading quiz, and reflection exercise. 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.

In addition, you will be asked to participate in three, 1.5-hour group discussion sessions with 4 to 10 other caregivers. These sessions will take place over Zoom video conference. The study team will record sessions to monitor quality of how these sessions are delivered. There is no option to opt-out of these recordings if you choose to participate, though you may choose to turn off your camera or mute your microphone while attending.

Foreseeable Risks and Discomforts

There are some risks to participating in this study. We describe these below to help you make informed choices about your participation.

Breach of confidentiality. There is small probability that data confidentiality could be breached, such that others outside the study team could connect your identifying information (e.g., name, phone number) with information you may provide. Given the sensitive nature of the data collected, which could be potentially embarrassing, we consider this a moderate risk. We will take precautions to make sure no one outside the research team will be able to connect your identifying information (e.g., name, phone number) with other sensitive information you provide. These precautions include:

1) You name and other information that can be used to identify you will not be attached to any form which includes research data. Instead, we will use a numeric code. Only the principal investigator for will have access to a key linking the code to your identity. This key will be stored in a password-protected file on a secure server at Case Western Reserve University.

2) We will ask you to provide information about your caregiving situation and contact information when you enroll in the study. This enrollment data will be stored on a secure server and accessed by a limited number of essential members of the study team.

3) We will destroy all identifiable information that you provide once the study is complete, including contact information.

It is also possible that other caregivers could share information you share about yourself during the KINDER program with others. We will ask all participants to keep information shared during the program private.

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 you or the person for whom you provide care. In some cases, we may contact you and encourage you to submit a report to Adult Protective Services if we believe your or your loved one's safety is at risk.

Negative emotions. Some participants may experience discomfort, such as embarrassment or guilt, when answering questions their caregiving relationship or participant in KINDER program activities. The likelihood and severity of this risk will vary from person-to-person. Please know that you may refuse to answer any of study questions, take a break, or stop your participation in this study at any time. You may also skip

components of the KINDER program if you feel at all uncomfortable. If the study team recognizes signs that you may be experiencing distress, we may try to contact you to share our concerns and help provide you with resources. We encourage you to contact the Alzheimer's Association 24/7 helpline you feel discomfort while completing this study:

Alzheimer's Association 24/7 Helpline:
https://www.alz.org/norcal/helping_you/24_7_helpline

Anticipated Benefits

You will not directly benefit from participation in this study. The knowledge gained from this research may, however, benefit family caregivers in the future by informing programs to support healthy caregiving relationships.

Compensation

There will be no costs to you for study participation. You may receive up to $150 for participating. Payment will be sent using Amazon gift cards. Gift card URLs will be emailed to you after completing study activities. You will receive $75 for completion of the baseline survey and $75 for completing the follow up survey. Payment will be sent within 2 business days of survey completion.

Alternative(s) to Participation

If you choose not to participate in the study, you may still attend the KINDER program.

Voluntary Nature of the Study

Your participation is voluntary. If you choose not to participate, it will not affect your current or future relations with the University. There is no penalty or loss of benefits for not participating or for discontinuing your participation. You are free to withdraw from this study at any time. If you decide to withdraw from this study, please notify the research team as soon as possible.

Confidentiality

Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Research records will be kept in a secure location and access will be limited to the researchers, the University review board responsible for protecting human participants, and regulatory agencies, and a third-party transcription service. In any sort of report, we might publish, we will not include any information that will make it possible to identify a participant.

However, you should understand that in cases where we suspect elder or child abuse or neglect or imminent harm to self or others, we will take the necessary action to prevent such harm or injury, including reporting to authorities.

Identifiable Information

At the end of the study, all information that identifies you will be removed from the study data. While the study is ongoing, most information that identifies you will be kept separate from study data. A list linking the code and your identifiable information will be kept separate from the research data. The only exception to this is your email address, which the study team will store with your study data in order to send you study surveys within our online survey system (REDCap).

Any audio and/or video recordings that can identify you will be deleted. Audio recordings from any qualitative interviews which you complete as a part of this study will be transcribed and de-identified. Once transcribed, recordings will be deleted following publication of study results. Video recordings of KINDER sessions will be

maintained for up to 1 month to complete fidelity monitoring. Once this is complete, video recordings of sessions will be deleted.

Data Retention

The researchers intend to keep the research data indefinitely. All identifiable information, such as your name, will be removed from study data at the end of the study period (i.e., once the research has been published). Your identifiable information that are collected as part of this research will not be used or distributed for future research studies. We may, however, distribute de-identified information collected from you during this study to other investigators such as for secondary analyses.

Significant New Findings

If any significant new finding develop that may affect your decision to participate these will be provided to you.

Contacts and Questions

The researchers conducting this study is Kylie Meyer, PhD. You may ask any questions you have now. If you have any additional questions, concerns or complaints about the study, you may contact the researchers:

Phone: 216-368-1928
Email: knm77@case.edu

If you would like to talk to someone *other than the researchers* about questions or complaints regarding this study, research participant rights, research-related injuries, or other concerns, please contact:

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