RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Dementia Caregiver Chronic Grief Management: A Live Online Video Intervention

Sponsor(s): National Institutes of Health/National Institute on Aging

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to test how an online group-based intervention affects dementia caregivers whose family members live in long-term care facilities. The study aims to improve caregivers': (1) knowledge about late-stage dementia; (2) communication and conflict resolution skills, and (3) skills managing their reactions to loss, including chronic grief.

If you agree to participate in this study, your participation will last for 24 weeks. You will be randomly (like the toss of a coin) assigned to either one of these two conditions: 1) receive the 8-week group-based Chronic Grief Management Intervention-Video-streamed online (CGMI-V) or 2) receive written information about late-stage Alzheimer's disease or a related dementia (minimal treatment). Caregivers in the group-based intervention will receive iPads and earbuds and will be instructed on how to access a secure online site that will host the weekly group meetings.

You will also be asked to complete three assessments over the phone at baseline, week 8, and week 24 of the study that will last approximately 90 minutes each.

During the phone assessments, you will be asked to answer questions about your knowledge about Alzheimer's disease or related dementia, chronic grief, depressive and anxiety symptoms, positive states of mind, conflict with staff and satisfaction with care in the long-term care facility. For a detailed list of study procedures, please see the "*What are the activities you will be doing if you participate in this study?*" section of this consent form.

There are minimal risks to you for participating in this study, which means that there is no more expected risk to you than what you might experience during a typical day. For a detailed list of risks you should know about, please see the "*What are the risks and discomforts of participating in this study?*" section of this consent form.

You may not directly benefit from taking part in this study, but we hope that knowledge gained from this study may benefit other dementia caregivers who placed a family member in long-term care in the future. If you are assigned to the minimal treatment condition, you are not expected to get any benefits from participating in this study.

There are other options available to you if you decide not to participate in this study. An alternative to participating in this study is to participate in a regular Alzheimer's disease or a related dementia caregiver support group.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?
You are being asked to participate in this study because you are a caregiver whose family member diagnosed with Alzheimer's disease or a related dementia (ADRD) has been placed in a long-term care facility within the past 12 months.

How many participants will take part in this study?
Approximately 144 participants are expected to take part in this study.

What are the activities you will be doing if you participate in this study
If you agree to be in this study, you will be asked to participate in the following activities:

- You will be asked to give verbal consent for screening with a few questions and two questionnaires (included in Table 1) to determine you are meeting the criteria to be included in this study.
- Once we determine that you meet the criteria to be in the study and you sign this form, you will be randomly (like the toss of a coin) assigned to either the online group-based intervention (CGMI-V) or to an information-only minimal treatment condition.
- Participants in both conditions will:
    - Undergo a baseline assessment, answering questions about their knowledge about Alzheimer's disease or a related dementia (ADRD), their symptoms of chronic

grief, depression, anxiety, and positive states of mind and about their conflict with staff and satisfaction with care their family member is receiving in the facility.
    - The same questionnaires will be used again 8 and 24 weeks after the baseline assessment.
    - Be asked to complete a brief caregiver/care recipient change in status survey at 8 and 24 weeks.
- Participants in the minimal treatment condition will not attend any group sessions and will only receive written information about late stage Alzheimer's disease or related dementias at baseline (beginning of study).
- Participants in the online group-based intervention condition (CGMI-V) will:
    - Be asked to complete a brief satisfaction survey at 8 weeks.
    - Receive the study manual and study provided iPads and earbuds. They will also receive written and personal instructions on how to use the technology and how to access the online group meetings site using a secure, password-protected connection.
    - Discussion topics include: a) knowledge about ADRD, b) communication and conflict resolution in the long-term care facility environment, c) loses and separation from the family member with ADRD, d) reminiscing about the relationship with the family member with ADRD, and e) readjusting without the family member with ADRD at home.
    - All discussions taking place in the CGMI-V group sessions are considered confidential and all participant caregivers are expected to maintain confidentiality by not sharing any detail of the group sessions with anyone else.
    - Each online group will have no more than 6 caregivers.
    - Each online session will be video and audio recorded for quality assurance purposes and further analyses.
    - Meet online immediately prior to the first session for a brief practice session to get familiarized with the technology and with the group facilitator.
    - Meet weekly, for 8 consecutive (one after another) weeks in up to 60-minute sessions facilitated by a study-provided group facilitator.
    - Each online group-based session will follow the Study Intervention Manual guidelines.

During this study, Dr. Olimpia Paun and her research team will collect information about you for the purposes of this study. Table 1 below summarizes the questionnaires used to collect information from you, the number of questions for each questionnaire, the data collection points and the approximate time it will take to complete the questionnaires. This information is being collected to see if the study intervention makes any difference in the scores of these tests.

Table 1: Data Collection Questionnaires

Variable	Questionnaire	# of Questions	Time (minutes)	Scheduled Time Points (weeks)			
				Screening	Baseline	8	24
Initial Screening							
Chronic grief	Marwit-Meuser Caregiver Grief Inventory-Short Form	18	10	**X**			
Depressive symptoms	Patient Health Questionnaire (PHQ-9)	9	5	**X**			
Background							
Personal Characteristics	Caregiver (CG) and Care receiver (CR) Sociodemographic information	15	5		**X**		
Situational characteristics	CR: Length of time since diagnosis	1	1		**X**		
	CR: Length of time since placement	1	1		**X**		
	CG: Visiting pattern	1	1		**X**		
Caregiver Outcomes							
Chronic grief	Marwit-Meuser Caregiver Grief Inventory	50	20		X	X	X
Depressive symptoms	Center for Epidemiologic Studies Depression Scale-Revised	20	10		X	X	X
Anxiety symptoms	Stait-Trait Anxiety Inventory	20	10		X	X	X
Positive states of mind	Positive States of Mind Scale	6	3		X	X	X
Conflict with facility staff	Family Perception of Caregiving Role	61	25		X	X	X
Satisfaction with care	Family Perception of Care Tool	51	20		X	X	X
Knowledge of ADRD	Family knowledge of Alzheimer's Test	22	10		X	X	X
Follow-up surveys							
CG/CR changes	Change in status survey	5	2			X	X
CG Satisfaction with intervention	Satisfaction survey	9	5			X	X

Will your information be used for research in the future?
Information collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, you will not be asked for additional consent.

Will you be contacted about participating in future research?
If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What are the risks and discomforts of participating in this study?
Risks, and/or discomforts from participation in this study may include:

- Emotional upset related to answering assessment questions about your feelings
- Emotional upset related to discussing losses associated with caring for a family member with ADRD
- Some group members may break confidentiality of group discussions after online sessions

There may be other risks that may happen that we cannot predict.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- The study is cancelled for any reason.

What about confidentiality of your medical information?
This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Olimpia Paun, her study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Olimpia Paun and her study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- Some of this identifiable information may come directly from you and some may come from results of questionnaires of interview.

Dr. Olimpia Paun and her study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- The study Sponsor, the National Institute on Aging
- Rush University Institutional Review Board (IRB)

While you participate in the study you will have access to your medical record, but Dr. Olimpia Paun is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. Your identity will not be revealed on any report, publication, or at scientific meetings. The recorded audio and video-taped group sessions will be double password protected and will be kept indefinitely until it is determined that they can serve no further research purposes.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed above.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Olimpia Paun at 600 S. Paulina St. # 1080, Chicago, IL 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon your completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The Principal Investigator and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. To ensure strict confidentiality is maintained, we will assign identification numbers (ID) to each study participant and enter them into a password-protected, computerized document. This

document will be the only link of the study ID to the participants. Signed consent and authorization to participate forms will be filed separately from completed research instruments. All questionnaires will be identified only by study ID numbers. All computerized data and questionnaires will be kept in a password-protected database that can be accessed only by specified research staff (Dr. Paun, study coordinator, data manager). After 5 years, the raw data will be stripped of all identifiers and all identifying links will be destroyed. The data will then be kept indefinitely until it is determined that they can serve no further purposes.

Your identity will not be revealed on any report, publication, or at scientific meetings.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain (apply) to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. This research study can be found by searching for the following Clinical Trial Registry Number (NCT#): 03593070.

If you disclose actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult, the researcher or any member of the study staff must, and will, report this to Child Protective Services (such as the Department of Family and Human Services), Adult Protective Services, and/or the nearest law enforcement agency.

What are the costs to participate in this study?

There are no costs to you for participating in this research. The study will provide the manual and all information materials for free. iPads will be provided for use only for study purposes with the expectation to be returned at the end of the intervention in a study provided return envelope. Unreturned iPads will be automatically deactivated and rendered useless.

Will you be paid for your participation in this study?

Payment for your time is available if you decide to take part in this study. You will be paid a $25 gift card for each completed assessment (a total of $75) by mail, within 7-10 business days from each assessment point. If you do not finish this study, you will be paid only for the study assessments you have completed.

What if you are injured as a result of your participation in this study?

If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the Principal Investigator know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Olimpia Paun at telephone number 312-942-6996.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the

doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study Principal Investigator.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. Olimpia Paun at 312.942.6996 or email her at olimpia_paun@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Olimpia Paun in writing at the address on the first page. Dr. Olimpia Paun may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT:
By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form. You will be given a signed copy of this consent.

Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant.

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE BY WITNESS/TRANSLATOR:
I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant.

Name of Witness

Signature of Witness	Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature