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Accelerated Resolution Therapy for Early Maladaptive Grief Study Protocol

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Abstract

The objective of this manuscript is to present the protocol of a study aiming to test the effects of Accelerated Resolution Therapy® (ART) on pre-loss grief and prolonged grief among older adult family caregivers. This study also aims to better understand predictors of response to ART®, and cognitive processes that occur among grieving individuals following ART®. Design: The study is a double-blinded, randomized clinical trial. Setting: This study takes place at both inpatient and outpatient palliative care and hospice programs at two Mayo Clinic sites. Participants: Participants include older adult (≥ 60 years) immediate family members who are primary caregivers of someone with an advanced illness and life expectancy of less than 12 months. Intervention: Participants are randomized to either the ART® intervention group or the attention control group. In the ART® intervention, caregivers engage in imaginal exposure, lateral eye movements, and imagery rescripting via 4 sessions lasting 1-1.5 hours each. The attention control group receives a standard social work intervention, including education, resources, and active listening, which is matched for time and attention. Both interventions will longitudinally follow caregivers from active caregiving into bereavement. Outcomes Measured: The primary outcomes of pre-loss grief and prolonged grief will be measured with the Pre-Loss Grief 12 item (PG-12-R) before the care recipient's death, and with the Prolonged Grief-13 (PG-13-R) afterwards.

Keywords

pre-loss grief, prolonged grief disorder, family caregivers, accelerated resolution therapy, grief intervention, mixed methods

Maladaptive grief negatively impacts 25-40% of older adult family caregivers (FCGs) of persons with advanced illness, contributing to increased morbidity and mortality, reduced independence, and diminished immune function.[1-4] Maladaptive grief results from the stress and trauma that FCGs endure as they witness the decline and eventual death of their family members and reduces the availability of emotional reserves needed to prepare for the impending death.[5] The maladaptive grief trajectory is two-fold: (1) severe and dysfunctional grieving prior to bereavement, known as pre-loss grief, and (2) prolonged grief disorder, diagnosable at 6-12 months post bereavement.[6-9]

FCGs suffer numerous losses prior to bereavement including relationships, financial resources, and time for hobbies and social activities.[10,11] These losses, combined with witnessing the physical decline of their ill family member and deaths of multiple close family and friends, contribute to the devastating impact of maladaptive grief among older adult FCGs.[8,12] Pre-loss grief and prolonged grief disorder are acute and then chronic stress reactions, respectively, to highly traumatic events such as illness and death,[5] yet there is little research evaluating the efficacy of trauma-based interventions for the prevention and/or treatment of maladaptive grief.[13] Intervening early in the grief trajectory (during pre-loss grief) may prevent prolonged grief disorder and its negative consequences.[14,15]

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Accelerated Resolution Therapy (ART®) is a promising form of trauma-based psychotherapy[16] with demonstrated efficacy in treating acute stress-related disorders, depression, and prolonged grief.[17-21] Our previous waitlist controlled trial demonstrated that ART alleviates prolonged grief disorder among older adult FCGs.[16] However, the prolonged period of unresolved grief among participants (1-3 years post-death) suggests the need for earlier intervention, with the potential to facilitate normal grieving and recovery and reduce the duration of psychological suffering. Cognitive processes influence coping and grief symptoms,[22] yet changes in cognitive processing of grief following ART® have not been fully explored. Our preliminary findings suggest that ART® promotes (1) changes in cognitive appraisal and (2) integration of loss, allowing individuals to process grief more effectively.[23]

This article describes the protocol for the study dated 06.28.2024 entitled "Accelerated Resolution Therapy for Early Maladaptive Grief: A Clinical Trial" (NCT05624879). The specific aims are to:

1. Test the efficacy of ART® compared with an attention-control condition on pre-loss grief and prolonged grief among older adult FCGs.
2. Examine the personal, social, and psychological factors associated with ART® treatment response (defined as post-ART scores <30 on the PG-12-R and <30 on the PG-13-R post-bereavement).
3. Examine changes in cognitive appraisal and integration of loss over time using mixed methods. All associated hypotheses, variables, and instruments are in Table 1.

Methods

Study Design, Sample and Setting

This is a double blinded, randomized, controlled two arm clinical trial.[24] We will enroll and randomly assign 440 primary caregivers (age ≥ 60 years) of an immediate family member of someone with a serious, life-limiting illness. The sample size calculation is based on Aims 1 and 2. We conservatively powered the study to detect a small effect size of 0.3 (Cohen 1988). We determined that a total of 308 participants would be needed to detect an effect size of 0.3 with 80% power at 5% significance level using GEE approach. Based on similar studies in this population,[25] we expect an attrition rate of up to 30% and therefore will recruit 220 per group (total n = 440). Sample size and power were generated using NQuery Advisor (v 7). SPIRIT (2013) reporting guidelines for clinical trial protocols were used.[26]

Recruitment will occur at Mayo Clinic (Jacksonville, FL and Rochester, MN). Each site has both inpatient and outpatient palliative care programs and there is a hospice for the Rochester site. We will also recruit from community organizations in the Jacksonville, FL and Rochester, MN areas including community hospices, places of worship or spiritual practice, caregiving organizations, and community clinics.

Eligibility Criteria

All persons recruited for potential study participation will be evaluated by a clinical research coordinator who will assess eligibility for enrollment. Eligible participants must: (1) be 60 years of age or older, (2) be the primary caregiver of an immediate family member who has a life expectancy of less than 12 months, (3) have a score of 30 or higher on the Prolonged Grief 12-R, and (4) deny active suicidal ideation or intent.

Individuals will be excluded for the following: (i) since becoming a FCG, they have engaged in another trauma based psychotherapeutic regimen (eye movement desensitization and reprocessing, prolonged exposure therapy, trauma focused cognitive behavioral therapy) that could influence response to ART; (ii) self-reported or clinically assessed major psychiatric disorder (e.g., bipolar disorder, schizophrenia); (iii) score of ≥2 on the adapted CAGE questionnaire indicating alcohol/drug dependence; (iv) cognitive impairment (SPMSQ>4 errors). Persons with major psychiatric disorders, alcohol abuse, and cognitive dysfunction are unlikely to be able to fully engage in ART due to diminished cognitive resources and impaired recall. Individuals who participate in support groups, individual counseling, grief counseling and/or bereavement support groups either before or after the death will be permitted to enroll and participate in the study. We will collect this information at each time point and control for counseling and support group participation in the final analyses.

Recruitment

In addition to receiving referrals from palliative care providers and community settings, potential participants will be identified through the electronic health record (EHR) and provided with study information through a variety of communication modes including patient portal, email, in person, and telephone.

Sampling Strategy and Blinding

Consented participants will be randomized into one of two groups (ART or control group). To ensure that the groups are balanced in biological sex and relationship to the patient (spouse/partner, parent, or adult child), we will stratify by both variables. We will generate a randomization list for FCGs at each site to assign the groups using stratified randomization in SAS 9.4 software. Participants will be informed that the purpose of the study is to compare two psychoeducational interventions for grief, but specific intervention (and control)

Table 1. Aims, Hypotheses, and Associated Measures for Accelerated Resolution Therapy for Early Maladaptive Grief Study.

Specific Aim	Hypotheses	Variables and Instruments
Aim 1: Test the efficacy of ART® compared with an attention control condition on pre-loss grief and prolonged grief disorder among older adult family caregivers.	**H1a.** Participants in ART® will have lower levels of pre-loss grief at T2, compared to the attention control condition. **H1b.** ART Participants will have lower levels of prolonged grief disorder at six (T3) and 13 months (T4) post-bereavement, compared to the attention control participants.	**Pre-loss grief:** Prolonged Grief-12-Revised (PG-12-R) **Prolonged grief disorder:** Prolonged Grief-13-Revised (PG-13-R), Structured Clinical Interview for Prolonged Grief Disorder (SCI-PGD)
Aim 2: Examine personal, social, and psychological factors associated with ART® treatment response (defined as post ART scores <30 on the PG-12-R and <30 on the Prolonged Grief Disorder-13 post-bereavement).	**H2.** Personal, social, and psychological factors including multiple traumatic life events/losses, lower levels of physical and mental functioning, higher caregiver burden, and lower social support will predict response to ART®.	**Depression:** Personal Health Questionnaire (PHQ-9) **Anxiety:** Generalized Anxiety Disorder Scale (GAD-7) **Social Support:** NIH Toolbox Item Bank v2.0- Emotional Support and Loneliness **Trauma Symptoms**: PTSD Checklist for DSM-5 (PCL-5) **Life Stressors:** Social Readjustment Rating Scale- Short Form (SRRS-SF) **Pessimism:** Revised Life Orientation Test (LOT-R) **Physical/Mental Health:** PROMIS- Global Health **Perceived Stress:** NIH Toolbox Item Bank v2.0- Perceived Stress **Caregiver Burden:** Caregiver Role Overload **Attachment Style:** 4-Group Model of Attachment Styles
Aim 3 (exploratory): Examine changes in cognitive appraisal and integration of loss over time using mixed methods.	**H3.** Cognitive appraisal and integration of loss will improve in the ART® group compared with the attention controls.	**Cognitive appraisal:** Stress Appraisal Measure **Integration of Loss:** Integration of Stressful Life Experiences Scale- Short Form (ISLES-SF) **Appraisal and Integration:** Qualitative interviews

information as well as study hypotheses will be withheld for blinding purposes. Research coordinators who will be responsible for consenting and data collection, will be blinded to group assignment.

Interventions

A summary of timing of interactions with participants is found in Table 2. Participants assigned to the ART® group will receive four ART® sessions of 1-1.5 hours each (Table 3). ART®, developed by Laney Rosenzweig, includes imaginal exposure, lateral eye movements, and imagery rescripting. ART® sessions focus on providing relief from the distress related to an anticipated loss and shifting focus from distress and loss back to the relationship. This includes visualizing the loss as currently anticipated in negative ways and then moving towards visualizing the loss in a preferred way. Caregivers are also encouraged to consider future anticipated events and different outcomes to be explored.

Participants assigned to the control group (Table 3) will receive four-time and attention matched sessions of a standardized social work intervention consisting of structured education and provision of emotional support. The education content focuses on resources provided through palliative care and hospice programs, as well as in the community.

Outcomes

The primary outcome of pre-loss grief and prolonged grief (Aim 1) will be measured with the Pre-loss Grief-12 item-Revised (PG-12-R)[27,28] and Prolonged Grief-13-revised (PG-13-R)[27] that are psychometrically sound (Table 1). Possible risk factors including biological sex, socioeconomic status, relationship to the dying person, satisfaction with palliative/hospice care, attachment style, pessimism, history of previous traumas and losses, physical and mental health, social support, and caregiver burden will be assessed (Table 1) for aim 2. Integration of loss and cognitive appraisal will be assessed

Table 2. Summary of Participant Interactions.

Timepoint	Study/Intervention Procedures
T1/Enrollment	Completion of self-report baseline measures.
Weekly	Research staff will facilitate 4 weekly ART® sessions (pre-bereaved), or time and attention-matched usual care. Participant is randomized immediately prior to session 1.
T2/Immediately following the final intervention period	Completion of self-report measures and scheduling of interview.
Monthly	Research staff will contact participants once a month to check on their progress and remind them of the timing of follow-up data collection.
T3/6mos post-bereavement	Completion of self-report measures and clinical grief assessment after the death of their loved one.
T4/13mos post-bereavement	Completion of self-report measures and clinical grief assessment after the death of their loved one.

Table 3. ART® **Intervention Components and Comparison With Attention Control Condition**.

ART Intervention®			Attention Control
Imaginal exposure: Therapist elicits physiological reactions associated with auditory or visual recall of the traumatic/distressing experience of the illness of the care recipient and traumatic elements of the caregiving experience.	**Number of sessions**	4	4
Imagery rescripting: After processing all physiological reactions induced by imaginal exposure, imagery rescripting is used. Imagery rescripting is defined as working directly with imagery to modify negative emotions, aid in identification of finding positive meaning, and ameliorate distress. It is based on the process of memory reconsolidation, which allows for the addition of positive content to the recall of negative, highly emotional experiences.	**Length**	1-1.5 hours each	1-1.5 hours each
Lateral eye movements: As physiological and emotional reactions emerge, participants are instructed to focus on body-centric reactions while tracking the clinician's hand as it oscillates left to right a short distance from the eyes.	**Content**	Imaginal exposure, lateral eye movements, imagery rescripting	Standard care including education, resources and active listening
	Focus	1) management of expected loss 2) changes in the relationship 3) changes/loss of role imagined future	1) philosophy of palliative care and hospice programs 2) symptom management 3) social work services 4) pastoral care 5) support groups 6) end of life decision making and advanced directives 7) resources for family support

qualitatively through semi-structured interviews and quantitively with validated self-report tools for aim 3.

Participant Timeline

Participants will take part in the study for at least 14 months, including 4 weeks of intervention/control, and 13 months of follow up post-bereavement. Assessments occur upon enrollment (T1), following the final ART® or control session (T2), 6 months post death (T3), and 13 months post-death (T4) of the ill family member. Following T2, semi-structured interviews will be conducted with a subset of 20 participants in the ART® group to gain an in-depth understanding of changes in cognitive appraisal and integration of loss. See Figure 1 for the study flow.

Safety and Ethical Considerations and Institutional Review Board Approval

The study was approved by the Mayo Clinic Institutional Review Board (IRB). Family caregivers will incur minimal risk by participating in the study. All interactions between

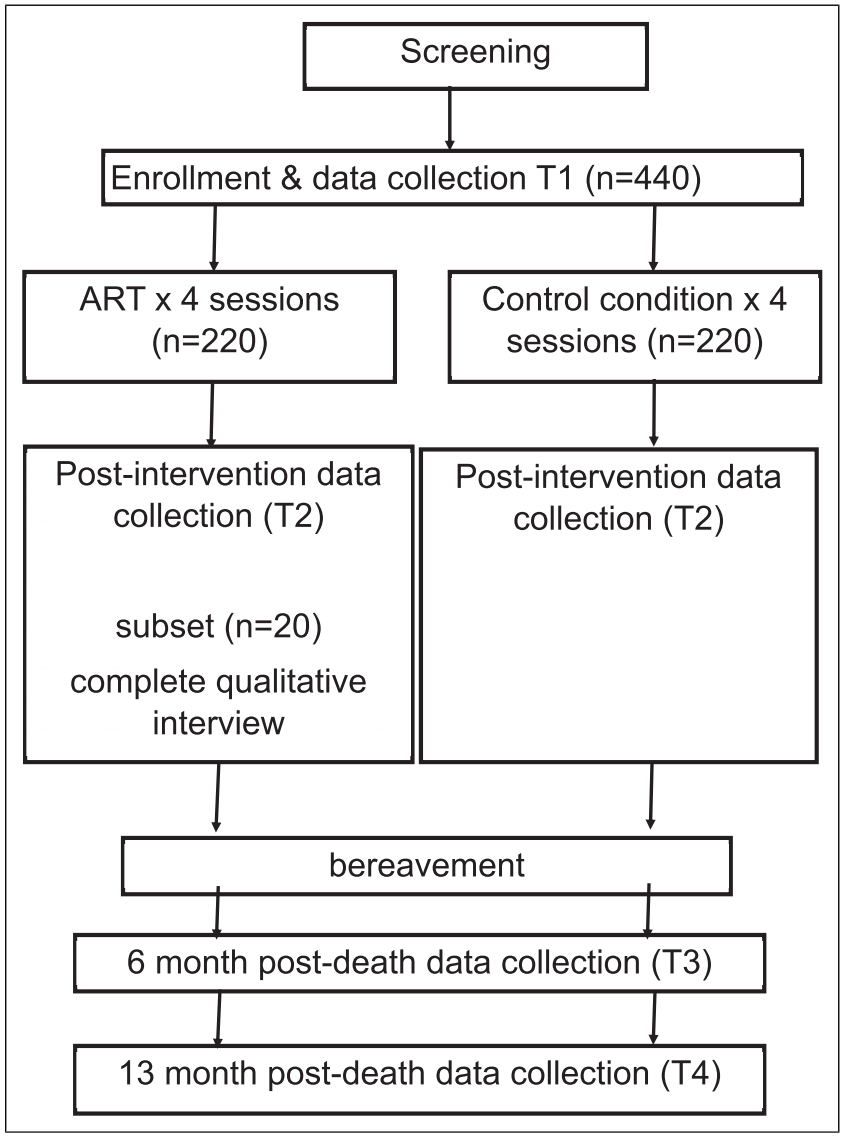

Figure 1. Study flow.

study staff and participants will take place in private. Participants will be assigned a unique study ID for identification during the study. It is anticipated that some participants may withdraw from the study or become lost to follow-up after their loved one's death due to a desire to avoid thoughts about the events surrounding the death. To mitigate risk of attrition, study staff will contact each participant once a month and remind them of the timing of follow-up data collection. Condolence cards will be sent following a care recipient death. We will provide participants with $25 as remuneration following the completion of data at each time point.

Although small, there is some risk that receipt of psychological therapy, particularly trauma-focused therapies such as ART, can potentially worsen psychological symptoms. In addition, there could be a temporary increase in distress as a result of treatment. Some participants may experience reactions during a treatment session that neither they nor the clinician may have anticipated, including a high level of emotional or physical sensation. Following the treatment session, the processing of incidents and memories may continue and result in the emergence of other dreams, memories, and feelings. Participants who show unexpected evidence of psychological symptoms or distress through the completion of the study will receive appropriate intervention, including counseling and treatment by the social worker interventionist or a Mayo Clinic psychologist/psychiatrist. Any serious adverse events will be reported to the DSMB and IRB within 48 hours of the PI or study team becoming aware of the event.

Those with active suicidal ideation will be excluded or withdrawn from the study. To ensure such patients' safety, we will follow the established practice of further evaluation in the

Table 4. Project Timeline.

YEAR	1				2				3				4				5			
ACTIVITY/Quarter	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Obtain IRB approval																				
Advertise/hire/train staff																				
Screen & accrue participants																				
Baseline & F/U data collection																				
ART Participant interviews																				
Qualitative data analysis																				
Complete quantitative data entry																				
Quantitative and mixed methods data analysis																				
Write report, abstracts & pubs																				
Plan for Implementation study																				

emergency department. During treatment sessions, the social worker interventionist will carefully monitor response to the intervention protocol. If there is evidence of significantly heightened anxiety or distress, the therapist will temporarily stop the session and intervene through the use of counseling and relaxation methods to restore the participant to a calm state. Should a participant report significant distress related to ART or their psychological condition that is indicative of an adverse event (AE), they will receive counseling with a licensed mental health counselor and an on-call psychiatrist will be consulted. As determined safe by the psychiatrist, patients may also be permitted to follow up with their own mental health providers.

Data Collection, Participant Retention, and Data Monitoring

Tables 1 and 2 describe the data collection timepoints, outcomes, and measures used in this study. At pre-specified intervals, participants will be sent a link by email with instructions on how to complete the surveys. We will use the secure REDCap network to collect and store all study data. Study staff will review all entered data to check for discrepancies and missing data and will provide telephone support for needed assistance with electronic survey completion. Flexibility in scheduling of interventions will be permitted to accommodate caregivers with numerous responsibilities. Any participant who completes at least 75% of intervention session, either ART intervention or control) and provides follow-up data within 3-5 days of their last intervention will be considered as completing the study, based on effective ART dosing in earlier studies.[16,20,29] Study staff will send a card expressing condolences following a death of a care recipient. An external Data Safety Monitoring Board (DSMB) was appointed by the National Institutes of Health/National Institutes of Aging to monitor the safety of the study. The DSMB will review the study data on an annual basis.

Data Analyses Plan

All analyses will be performed using the intention to treat (ITT) principle and conducted according to best practices outlined in the Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting parallel group randomized trials and its extension to randomized trials of non-pharmacologic treatment. Analysis will be performed using SAS 9.4.

Aim 1 Analysis

Changes from enrollment T1 to T2 for pre-loss grief and T3 to T4 for prolonged grief disorder will be calculated for all patients from both groups using two sample t-tests or Wilcoxon rank sum as appropriate. If there are any imbalances between the groups on any variables measured at baseline, we will use linear regression to compare the two groups, adjusting for those variables to account for the imbalances and other possible confounders such as FCG seeking other counseling services or interventions during pre-loss period. Time to death post last ART® session and death characteristics (place/cause of death, and perceived level of FCG preparation) will be accounted for as covariates. This will allow us to assess efficacy of ART at each of the 3 follow-up visits respectively. An overall effect of the ART® intervention from enrollment to 6 months and enrollment to 13 months post death on each of the outcomes of interest will be assessed with linear regression models using generalized estimating equations (GEE) to account for repeated measures (i.e., correlation within individuals). For the mixed model analyses, we will specify an unstructured covariance matrix, which is less restrictive than a fixed or an autoregressive covariance structure. The analyses for prolonged grief disorder will be conducted similarly, but with the addition of pre-loss grief as a predictor.

We will conduct GEE to examine changes of the outcome over the follow up (i.e., at baseline, completion of

intervention, 6 mos. and 13 mos. post death of the care recipient). GEE is available for both continuous (e.g., CGI, PCL-5, PHQ-9) and dichotomized outcome using identity and logit link functions, respectively. GEE provides consistent estimates of parameters and covariance using working correlation matrix incorporating correlation within-subject. Optimal correlation structure will be selected using Akaike's information criterion (AIC).[30] With a selected correlation structure, the model will estimate the interaction between time and intervention groups to exam difference of changed outcomes between two intervention groups. Time will be in linear form but could be subjected to quadratic or categorical form, as necessary. Potential covariates will be selected by comparing between two intervention groups and testing association with the outcome variables at baseline. The intervention effects will be estimated by time-group interaction in GEE controlling for selected covariates.

While GEE uses all longitudinal data that is collected, for other procedures, following Schafer[31] and Bennett,[32] we will perform multiple imputation for missing values using Proc MI (SAS version 9.4) if there is greater than 10% missing. For Aim 1 we will run GEE with multiple imputed data sets consisting of observed and imputed data. Multiple imputed data sets will be obtained from a conditional distribution of missing values based on observed data with the missing completely at random (MCAR) assumption.

Aim 2 Analysis

Our strategy for identifying predictors of ART® will be to (1) identify predictors of response in all participants, then (2) test for interaction effects between intervention groups and predictors. To determine if participants respond to ART® (binary), we will fit logistic regression models to predict the binary responses (defined as post ART scores < 30 on the PG-12-R and scores < 30 on the Prolonged Grief-13, post-bereavement) within timepoints. Guided by bivariate analyses, we will fit models, controlling for age and sex, examining our potential predictors including exposure to multiple traumatic life events/losses, lower levels of physical health (PROMIS-Global health) and mental health (GAD-7, PHQ-9, C-SSRS), higher caregiver burden (Caregiver Role Overload), lower social support (NIH Toolbox Item Bank v2.0 – Emotional Support, Loneliness). We will report odds ratios with 95% confidence intervals. Goodness of fit will be assessed using Hosmer and Lemeshow and the models' ability to discriminate between responder vs non-responder will be reported as area under the receiver operating characteristic curve (AUC). An AUC of 0.7 and higher will be considered acceptable.[33] Thus, we will select characteristics with AUC of 0.7 as predictors of response. To identify predictors of ART response, we will examine interaction effects between intervention groups (ART vs control) and the predictors using GEE predicting the response status over time (i.e., T2, T3, and T4).

Prior to multivariable logistic regressions, we will reduce the number of predictors by running simple logistic regressions with each candidate. From simple logistic regressions, we will calculate AUC of each predictor to measure the ability to identify the response. Predictors with AUC of 0.70 or above will be included in multivariable logistic regression, and predictors highly correlated with others (multicollinearity) will be removed using variance inflation factor (VIF>4).

Aim 3 Quantitative Analysis

To test the efficacy of ART® on cognitive appraisal and integration of loss by intervention group, we will fit a series of multilevel multiple regression models for each outcome), controlling for demographic confounders, clinic, and other significant predictors from the bivariate analyses. The level 1 sub-models will estimate how each participant's cognitive appraisal (or integration of loss) changes over time (T1, T2, T3, T4). They will codify the relationship between inter-individual differences in the change trajectories and time-invariant characteristics of the individual. Level 2 sub-models will estimate initial cognitive appraisal and rate of change in cognitive appraisal over the four timepoints. Cognitive appraisal will be modeled in terms of random subject effects (intercept and time trends) to account for individual differences in how participants' cognitive appraisal changes over time. The time-invariant predictors will be treated as fixed effects (i.e., clinic, biological sex) in the model. We will begin with a linear model for time but will investigate a quadratic effect as well. We will include time-varying covariates (i.e., depression, anxiety) and thus will be able to focus on within-subjects effects, that is, whether differences in the covariates (relative to the subject's average over time) influence cognitive appraisal. We will first examine main effects and whether the rate of change in our outcomes varies over time between intervention groups (i.e., interaction effects). We will test for interactions (moderators) by clinic, demographic characteristics, and others, if suggested by the analyses. We will conduct subgroup analyses by biological sex and by relationship to the patient for all outcomes and will test for interactions with sex in multivariate analyses. As the appropriate analysis of study data will require multiple comparisons, we will use Bonferroni-Holm adjustments for multiple comparisons.

Aim 3 Qualitative Analysis

To ensure trustworthiness of the data, the interviewer will verify the transcripts against the original recorded interviews. Interviewer notes made during and after the interview will be added to the transcripts. We will read transcripts and assign codes (descriptive conceptual labels) to excerpts ("meaning units" consisting of words, phrases, or longer narratives) related to the context and traumatic experiences during caregiving. Coding will be completed independently by at

least three members of the research team with any differences reconciled by consensus. Following identification of initial codes using NVivo qualitative software, the investigators will meet and obtain consensus on a final list of codes, and a codebook for thematic analysis. We will separately code a subsample of transcripts to achieve coding reliability using Cohen's Kappa ≥ 0.75. Careful documentation of coding definitions and decisions will be kept, ensuring confirmability and trustworthiness of results. Confirmability of results will be further supported by use of direct quotes from participants which allows others to evaluate the coding scheme independently.

Aim 3 Data Integration

Simultaneous triangulation, using quantitative and qualitative methods will be used to enhance validity and ensure the most comprehensive approach to answering the research question.[34,35] We will use a convergent design by assessing parallel constructs for both types of data and comparing them in a side-by-side information matrix, to identify points of convergence or divergence.[36] The quantitative data includes measures of cognitive appraisal and integration of loss and the interviews will provide in-depth information about their thought processes when dealing with stressful situations (cognitive appraisal) and perceptions of current and future losses following ART®. Our mixed method includes the participants' voices and ensures that the quantitative findings are grounded in their experiences. The context is provided to augment our understanding of the changes in scores from baseline to post completion of therapy. Thus, the qualitative and quantitative provides validation for each other creating a solid foundation for assessing the intervention.[37]

Benchmarks

The primary benchmarks for success include: (1) meeting monthly recruitment targets of 12-13 participants; (2) delivery of ART®/Control intervention sessions; (3) clinical data collection and follow-up; and (4) data analyses, publication of results. We will hold weekly study staff meetings to monitor progress and ensure timely completion of all benchmarks.

Timeline

Briefly, this study will be conducted over 60 months. Participants will take part in the study for at least 14 months, including 4 weeks of intervention, and 13 months of follow up post-bereavement. Recruitment will occur over 42-months and allows sufficient time during the study period to finalize data collection. The project timeline can be found in Table 4.

Potential Challenges and Limitations

There are potential challenges in this study. Life expectancy can be difficult to predict, therefore the timing of post-death follow-up may be challenging and individuals may remain in the study for a longer time than expected. Identifying FCGs in need of intervention can be difficult. To address this, we have focused on palliative care/hospice settings because patients are nearing the end of their disease trajectory, and their FCGs are more likely to be experiencing pre-loss grief. Not all FCGs may be able to come to an intervention site. Transportation will be provided if needed and scheduling of intervention sessions will remain flexible.

Conclusions

This trial tests ART® in a new population, older adult FCGs with pre-loss grief. It will provide critical information on the efficacy of the ART® intervention as a potential first-line treatment option for pre-loss grief, preventative option for prolonged grief, contribute new information about characteristics of individuals most likely to benefit from ART®, and enhance understanding of changes in cognitive appraisal taking place following ART®.

Declaration of Conflicting Interests

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