MANUAL OF OPERATIONS AND PROCEDURES

Development of a Reminiscence Therapy Online Platform with Machine Learning to Increase Engagement with People Living with Dementia and Their Care Partners

Prepared by the Benjamin Rose Institute on Aging, Center for Research and Education.

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Co-Investigator: Silvia Orsulic-Jeras

Development of a Reminiscence Therapy Online Platform with Machine Learning to Increase Engagement with People Living with Dementia and Their Care Partners

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LifeBio Memory™

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Study Protocol

Rationale:
Almost 6 million Americans are currently living with Alzheimer's disease (AD) or AD-related dementias (ADRD), and the number of affected individuals is rapidly growing. Symptoms include impaired cognition, resulting in difficulty in performing daily activities and consequent functional dependence on others. The progressive nature of AD and ADRD can result in increasing degrees of care required from professional and family caregivers. Non-pharmacologic interventions positively influence cognition, mood, and other behavioral and psychological symptoms of dementia, and one well-established intervention, life story work (the use of written and oral life histories), serves as an effective technique that can elicit conversation and memories in those living with AD and ADRD. However, generating useful life story materials is a time-consuming task for caregivers. To overcome this barrier, LifeBio Inc. proposed to develop a reminiscence therapy platform, LifeBio Memory™, with a novel machine-learning-based application that converts speech to text and generates life stories to serve as an interactive tool to cultivate communication between people living with dementia and their family and caregivers.

Funding:
The LifeBio Memory™ Project is funded by the National Institute on Aging (NIA) and is a collaboration with investigators from LifeBio Inc. and Benjamin Rose Institute on Aging (BRIA).

IRB Approval:
Benjamin Rose Institute on Aging (BRIA) serves as the single IRB (sIRB) of record given the relevant expertise in human research protections to review the study. The other identified participating sites, i.e., LifeBio, also rely on the BRIA sIRB. Other agreements and reporting responsibilities are determined, as necessary. Sites can communicate via email or phone with the IRB Coordinator at BRIA: Ms. Miriam Rose (mrose@benrose.org; 216-373-1674) regarding any questions and concerns related to the IRB. This study was approved by the Benjamin Rose IRB on 6/25/2020.

Study Organization and Responsibilities

Primary Awardee Site: LifeBio Inc., founded in 2012 as a privately held corporation, is an online storytelling platform company that currently resides in Marysville, Ohio. The initial idea for LifeBio began years ago when Beth Sanders, the Founder & CEO, interviewed her own grandmother on an old tape recorder. That day, she watched as her grandmother "lit up" as she shared priceless memories. Since then, LifeBio helps people ask the right questions to bring out the best memories and stories with the goal of engaging more effectively and creating a lasting and priceless legacy. LifeBio works with thousands of people in the U.S. and around the world to help them capture their life stories and publish biographies. LifeBio also offers tools and reminiscence methods used in senior living and healthcare settings.

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Sub-Awardee Site: Benjamin Rose Institute on Aging (BRIA), founded in 1908, is an over 110-year-old Cleveland-based non-profit organization whose mission is to support caregivers and empower all people to age well through research, consumer-responsive services, and client advocacy. The organization's work is accomplished by deepening the understanding of older adults and their caregivers in a changing society; developing and delivering innovative, high-quality solutions; and promoting effective public policies. BRIA's Center for Research and Education, established in 1961, is one of the nation's premier and longest-standing Centers for applied aging research located in a non-university setting. The Center conducts state-of-the-art research using various methodologies to enhance the lives of older adults, their families, and the service providers who care for them. Specialty areas include family

caregiving; services, interventions, and evidence-based programs; long-term care; active aging; and program evaluation. Because it is part of a service and advocacy organization, the Center is uniquely qualified to collaborate with health and social service providers in translating research findings into evidence-based programs and other useful products and resources. Innovative programs and services are developed by the Center and implemented by service organizations across the country.

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Safety Officer: The safety officer (SO) must maintain independence from the study. Accordingly, the SO will not be directly involved in the design and conduct of the study, and will not have scientific, proprietary, financial, or other interests that may affect independent decision-making. The following SO was reviewed and approved by the NIA. Should there be any questions regarding the independence of the SO, it will be addressed and corrected as necessary.

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Program Officer: The program officer (PO) reviews and approves data and safety monitoring plans, reviews safety reports, reviews proposed protocol changes and new protocols, and reviews Research Performance Progress Report (RPPR).

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Study-Related Questions: Please direct any development-related questions to Beth Sanders (Primary Principal Investigator) and research-related questions to Silvia Orsulic-Jeras (Subaward Principal investigator).

Training Plan

Research Staff:
Prior to beginning tasks on the project, research staff are required to obtain human subject training (or show proper verification of having recently completed such training). Research Assistants receive on-going supervision from the Principal Investigator on a weekly basis, or additional as needed. All BRIA research staff have completed NIH-approved human subjects training.

Residential Care Professionals:
During the full-scale fidelity trial, residential care professionals will be trained in the use of the revised LifeBio Memory™ product using the associated training modules. Enrolled staff will have varying levels of prior training, background in gerontology, and/or experience working directly with older adults. Preloaded tablets with LifeBio Memory™ will be distributed in a staggered manner for self-paced, online instruction. Each staff member is required to complete the training within one week of assignment, as well as a pre-training, baseline survey that collects demographic information, job history, previous experience with life story work, and attitudes towards person-centered care and older adults living with dementia. Other support materials, like frequently asked questions (FAQs), will also be provided for viewing. Staff members also complete a checklist and post-training survey on the tablets that gathers their opinion on 1) the length of time spent on training, 2) whether they had difficulty particular sections/content/materials, 3) whether they felt prepared to conduct life story interviews with older adults living with dementia. 4) whether they felt comfortable with the basic functionality of LifeBio Memory™, 5) whether they felt confident the technology would accurately convey the story of the resident living with dementia, and 6) whether they had specific questions not covered by the FAQs or training. They also have the opportunity to provide comments on their overall experience via open-ended questions.

Communications Plan

The project team at BRIA meets internally on a weekly basis to discuss project tasks and the study at large. The entire project team, including BRIA and LifeBio staff, meets on a weekly basis to provide updates on project tasks and discuss the progression of the study overall.

Project Overview

Narrative:

Non-pharmacological interventions and person-centered care strategies are important elements of care for people with AD and ADRD. Life story work, which uses written and oral life histories to elicit conversation and memories, is an effective intervention for individuals living with dementia; however, because of the time-consuming nature of generating useful life story materials, has not been widely implemented in nursing homes and other care environments. The development of an easy-to-use reminiscence therapy platform, LifeBio Memory™, with a novel machine-learning-based application that converts speech to text and generates life stories to serve as an interactive tool to cultivate communication between individuals living with dementia and their family and caregivers. The LifeBio Memory™ platorm application will elicit and store individuals' stories and photos, and ultimately deliver personalized, point-of-care reminiscence therapy exercises to program users.

Goals and Objectives:

- Develop prototype enhancements of the existing LifeBio program and conduct focus group evaluations of these prototypes with existing or former LifeBio users, dementia care professional familiar with LifeBio, and older adults living with early-stage dementia to help maintain person-centered practices throughout the research process.
- Finalize the LifeBio Memory™ product, which will include the development of a system to automatically record and process individuals' life stories.

Conduct a full-scale fidelity trial of the complete package with care professionals and dementia care dyads within assisted living and nursing home settings.

Study Flow

The table shows the work plan and specific milestones to be reached.

	Months							
	1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24
Specific Aim 1								
Recruit sites/participants for focus groups								
Finalize evaluation materials and group questions								
Hold focus and stakeholder groups								
Analyze focus group data								
Provide recommendations based on focus group findings								
Specific Aim 2								
Set up data system storage								
Design and implement Speech-to-Text and other AI services								
Development and testing of the ML module and tagging								
Automate Search Services								
Development of the Text Summarization feature								
Cross-platform development								
Data mining								
Specific Aim 3								
Finalize focus group materials and questions								
Reconvene focus groups from Aim 1								
Recruit and enroll staff for fidelity trial								
Recruit and enroll residents for fidelity trial								
Conduct Baseline Assessment (Time 1) on Staff and Residents								
Conduct LifeBio Memory™ intervention at sites								
Staff conduct Life Story Interview with Residents								
Conduct Follow-Up Assessment (Time 2) with Staff								
Delivery of LifeBio Memory™ Products								
Conduct Follow-Up Assessment (Time 3) with Staff and Residents								
Analyses								
Prepare final report								

Specific Aim 1: The first Aim of the study takes place during the first 6 months of the 24-month project period.

Month 1: The project PIs from LifeBio Inc. and BRIA hold a kick-off meeting to orient the project teams. LifeBio staff reach out to partnering sites to identify current or former users of LifeBio and staff members who are familiar with LifeBio to invite them to participate in the focus group evaluation. At the same time, two Northeast Ohio Alzheimer's Association Chapters identify individuals living with early-stage dementia who are interested in participating in the focus group evaluation. The design team, led by the LifeBio PI, begins prototyping development for two key features of the LifeBio Memory™ tablet app – automatic speech-to-text voice recording and automatic uploading – for use in the focus group evaluation. The research team, led by the BRIA PI, obtains IRB approval.

Month 2: The research team begin participant recruitment for existing user, staff member, and individuals living with dementia focus groups. The design team improve and further develop final prototypes.

Month 3: The research team finalize all focus group evaluation protocols, materials, and questions, and completed the enrolment process, including obtaining consent, for all focus groups.

Month 4: The research team conduct 7 focus groups - 2 groups of existing users, 4 groups of staff members, and 1 group of individuals living with dementia as stakeholders. Subject payments are also processed.

Month 5: The research team, including the Project Coordinator and Research Assistant, transcribe all the focus group sessions. The research team PI and Co-Investigators, along with the qualitative data analysis expert consultant (Dr. Ruth Walker) lead focus group analysis.

Month 6: The research team prepare reports of focus group evaluation findings and provided recommendations to the design team based on the focus group evaluation findings. The design team revise Aim 2 goals based on significant findings from the research team's report.

Specific Aim 2: The second Aim of the study largely takes place during months 7-12 of the 24-month project period.

Months 7-12: The LifeBio design team setup new data storage for AI/machine learning, design and implement Microsoft Azure Cognitive Services for speech-to-text and other AI services, develop and test a machine learning module and tagging feature, automate search services, develop a text summarization feature, and create an accessible Android and iOS tablet apps and accompanying training materials.

Specific Aim 3: The third Aim of the study takes place during the last 11 months of the 24-month project period, beginning in month 13.

Month 13: The LifeBio design team demoes the new LifeBio Memory™ product features and materials with the BRIA research team.

Months 14-15: The design team conducts final debugging of the app to deploy to Android and Apple tablets. The research team begins preparing to reconvene Aim 1's focus groups and develop new focus group materials and questions based on the completed LifeBio Memory™ program.

Month 15: The research team conducts a second round of focus groups with Aim 1 participants and begins recruiting and enrolling staff and resident participants for the fidelity trial.

Months 16-21: The research team begins baseline data collection (Time 1) for staff and resident participants. Time 1 interviews continue until month 19 as fidelity trial sites are brought on using a staggered design (3 sites at a time). Staff also complete the LifeBio Memory™ training immediately after their Time 1 Interview. Staff then conduct life story interviews with their assigned residents. Follow-up interviews (Time 2) with staff begin within 2 weeks of completing life story interviews. The design team is on-call for technical assistance as needed throughout the training and life story interview period, and up until the final LifeBio Memory™ product pieces (Life Story Book, Snapshot, Action Plan) are delivered to the sites. Final follow-up interviews (Time 3) with staff and residents begin in month 19 and continue through the end of month 21 when the fidelity trial concludes.

Months 21-22: The research team conducts data analysis. The design team makes final improvements to the product.

Months 23-24: The research and design teams prepare the final report and collaborate on a marketing study to prepare for the commercialization of LifeBio Memory™.

Recruitment Procedures

Recruitment for Aim 1 focus group participants occurs during the first three months of the study, from August 2020 through October 2020.

Existing LifeBio Users and Staff Focus Groups: Existing user and staff focus group participants were recruited directly from LifeBio Inc.'s pre-existing user base and sites which have already implemented the program. LifeBio distributed flyers to the identified sites and developed a list of interested participants in both populations. The cover letter, consent form, and flyer included phone numbers, mailing addresses, and email addresses for the PIs and designated IRB. Participants were recruited by LifeBio over the phone and were asked to provide contact information and consent for sharing their contact information with BRIA research staff. Referral forms collected from LifeBio were then shared with the BRIA PI and Project Coordinator using encryption security.

Stakeholder Focus Group: Stakeholders (individuals living with dementia) were recruited through two Northeast Ohio Alzheimer's Association Chapters - Greater East and Cleveland. Recruitment packets were mailed to the individuals living with dementia as well as any persons responsible for the medical decisions of the individuals living with dementia. Items sent in the recruitment packet included: a cover letter, a study flyer, two copies of the consent form (one copy signed and returned, and one copy retained for the person's records), and a self-addressed/postage-paid envelope. Contact information for the research team was also provided with the materials, and individuals were invited to contact researchers with any questions. The consent forms included detailed information about what participation in the study entailed. It also listed all the potential risks of the study, ways in which researchers will protect against the risks, and the likely benefits of the study. In all recruitment materials, it was also made clear that participation in the stakeholder group is voluntary, and that participants can stop participating at any time. Recruitment for the Aim 3 clinical trial is scheduled during months 13-14 of the study, from August 2021 through September 2021.

Staff Participant Recruitment: Staff participants are recruited with assistance from the residential care facility site liaison. Site liaisons assist with distributing flyers to all staff members related to the program, describing study requirements, incentives and the overall goals of the program. Staff are instructed to refer to the flyers with research team contact information if interested.

Residents Living with Dementia Participant Recruitment: Recruitment packets are mailed to persons responsible for the medical decisions of all participants living with dementia. Items sent in the recruitment packet include: a cover letter, a study flyer, two copies of the consent form (one copy signed and returned, and one copy retained for the person's records), and a self-addressed/postage-paid envelope. The cover letter, consent form, and flyer included phone numbers, mailing addresses, and email addresses for the PIs and designated IRB. Individuals are invited to contact researchers with any questions. The consent forms include detailed information about what participation in the study entails. It also lists all the potential risks of the study, ways in which researchers will protect against the risks, and the likely benefits of the study. In all recruitment materials, it is also made clear that

participation in the stakeholder group is voluntary, and that participants can stop participating at any time.

Screening

Focus Groups: Researchers provide a verbal summary of the study of the phone. If the person seems interested in participating based upon the verbal summary, a consent form providing detailed information about the study is provided to the person, including what taking part in the study entails, risks, protection against risks, and potential benefits. Potential participants are encouraged to speak to researchers with questions. If the person decides to enroll, he/she signs the form and returns it to researchers.

Clinical Trial: Researchers screen the potential staff person for fit prior to enrolment in the study. Enrolled staff participants assist with retaining participants and are asked to take part in bi-weekly calls with project staff.

Eligibility

Focus Groups: Focus group participants are required to be at least 18 years old, have previous experience with the LifeBio intervention, speak and read English, and be able to virtually attend the focus group on their own. Existing user and staff member focus group participants are excluded from the study if they were diagnosed with MCI or dementia. Stakeholder focus group members (persons living with dementia) are required to reside in the community, be at least 55 years old, speak and read English, and be diagnosed with dementia. Persons living with dementia are excluded from the study if they show signs of rapid cognitive decline or physical deterioration over the last 6 months, as evidenced by information gained during screening.

Clinical Trial: Staff participants are required to be at least 18 years old, work within a residential care facility participating in the study, speak and read English, and be able to provide or arrange their own transportation to complete research interviews. Residents living with dementia are required to reside with a participating residential care facility, be at least 55 years old, speak and read English, be diagnosed with dementia, and score at least a 15 on the MMSE. Persons living with dementia are excluded from the study if they show signs of rapid cognitive decline or physical deterioration over the last 6 months, as evidenced by information gained during screening.

Informed Consent

Focus Groups: The verbal consent form is read aloud, and verbal consent is established. Those who are interested after hearing an overview of the study, are screened to determine if they meet study criteria, and agree to participate. A copy of the verbal consent form that provides detailed information about the study, including what taking part in the study entails, possible risks, protection against risks, and potential benefits is also provided to the person by mail. Participants are also encouraged to speak to researchers with questions.

Clinical Trial: In all recruitment materials, it is made clear that participation in this study is voluntary, and that participants can stop participating at any time. For those who did not wish to take part in the study, it is made clear that their currently provided services will continue to be made available. It is also made clear to persons responsible for the medical decisions of potential participants that their loved ones will still have a choice as to whether they want to take part in the study. That is, even if a family member provided consent for the study, the resident himself/herself can still decide whether or not he or she wanted to take part in the study (through the assent process, described next). Research staff speak with the participant about the study and provide the person with an assent form. The assent form is a simpler and shorter version of the consent form, with large, easy to read font. The researcher answers any questions that the resident has, and then asks the resident if he or she is interested in participating in the study. If so, the resident signed the assent form. A copy of the full consent form is also made available to the resident in case he or she wants to review the full document.

Participant Retention

Focus Groups: As these participants from Aim 1 are planned to return for Aim 3, we maintain regular contact with focus group participants and provide updates on the project. A follow-up date for the Specific Aim 3 focus groups investigating the prototype is planned following the initial meetings, contact information is gathered, and the groups are notified at regular intervals leading in to the second round – and up to several months out, the groups are notified at one month, two weeks, and one week prior to the second round. A second round of incentives are also handed out to all participants upon completion of the second focus group ($25 for existing LifeBio users and staff members; $50 for stakeholders).

Clinical Trial: In order to maximize participation, research staff are very clear when talking with residents and staff that their participation will include follow-up interviews (one follow-up interview for residents approximately 1-month post baseline; two follow-ups for staff participants, within 1-month of life story interview, and 1-month after delivery of full LifeBio Memory™ product). Because of the short time frame between data collection points, we plan for an attrition rate of approximately 10% from T1 through T3 to ensure that our recruitment and retention goals are met. To address potential attrition over the 3-month participation period, we follow sample retention strategies that have yielded low levels of attrition (approximately 10-13%) in our previous intervention programs:

1) Onboarding meetings with the residential care facility sites, with project staff and site. Onboarding meetings describe the protocols and procedures of Specific Aim 3 and clinical trial.
2) Site liaisons identified within each site assist with the study's recruitment and LifeBio Memory™ implementation, as well as reaching resident and staff participants to complete their research interviews.
3) Research staff hold bi-weekly calls with each site to provide updates on participant recruitment, program implementation, and identify areas where support is needed.
4) Staff compensation of $15/interview for each timewave (Times 1-3) and site honorariums of $500/site are processed upon completion of study requirements.
5) We oversampled to accommodate a reasonable level of attrition.

Study Measurements and Procedures

Main Research Question: Does the LifeBio concept, technology, and training offer a viable model for effectively delivering a person-centered life story intervention across residential care settings by utilizing professionals to deliver the program?

Specific Aim 1:

Develop prototype enhancements of the existing LifeBio program and conduct focus group evaluations (n=38) of these prototypes with existing or former LifeBio users (n=12) and dementia care professionals (n=20) familiar with LifeBio. Convene stakeholder focus group with older adults living with early-stage dementia (n=6) to help maintain person-centered practices throughout the research process.

A tablet-app-based prototype is designed based on features of the current LifeBio intervention to automate tasks that are manually performed at present. The three novel features included voice recording of life story information, automated uploading of voice files to LifeBio cloud storage, and initial enhancements to training materials.

Recommendations of Krueger (2002) are followed in selecting the size and number of groups. Focus group methodology explores participants' and staff members' experience with and need for the LifeBio program and assesses their reaction to the LifeBio Memory™ prototype.

The first set of focus groups consists of individuals who were currently participating or had already participated in the LifeBio intervention. The groups last approximately 90 minutes and provide feedback on the prototype in a semi-structured way. The participants use the prototype with guidance from facilitators in a manner similar to that in the program. They are allowed to manipulate the prototype's tools and offer their opinions about the features that are either present or missing from the prototype and intervention materials.

The second set convenes 4 groups of professionals familiar with the original LifeBio program. The groups reacted to the prototype and discussed whether the prototype and materials met their expectations and needs for training. The group is asked questions about whether the proposed LifeBio Memory™ prototype will produce high levels of acceptability for participants and of treatment fidelity, and if not, what type of modifications would increase acceptability and fidelity. Finally, they discuss whether the enhanced LifeBio Memory™ product could be feasibly implemented within their organizations and the potential hurdles to implementation. The group sessions last approximately 90 minutes.

The third set consisted of stakeholders, or persons living with early-stage dementia. Topics of discussion include: A description of the original LifeBio program and its intended target market (i.e., residential care facilities, families of persons with dementia living at home). The needs of persons living with dementia and how LifeBio can improve to meet these needs. How the LifeBio team can continue to involve persons living with dementia in the development and improvement of the next version, LifeBio Memory™.

Specific Aim 2

Develop LifeBio Memory™, incorporating a system to automatically record and process individuals' life stories.

LifeBio will build the capability to audio record interviews and convert speech to text on web, Android, and iOS-based platforms. They will also use machine learning/artificial intelligence (AI) and tagging to automatically build Snapshot and Action Plan summaries so that they are quickly and easily available to health care providers and caregivers.

A series of key performance indicators (KPIs) are measured throughout development:

- The average time to create the end products (Snapshots, Action Plans, and Life Story Books) and, where applicable, the difference between the current process and the AI-based process.
- The increase/decrease in time to create the end products measured week over week.
- The difference between the amount of data collected via the mobile app and the amount of supplemental data from search services and data tagging. This is also tracked on a weekly basis to obtain the trend over time.
- The total count of the number of distinct data sources that searched and the difference week over week (trending over time).
- The number of aggregated transactions performed against AI services, number of end products created, and cost of the technology to run, all of which is aggregated across daily/weekly/monthly situations.

The success of the LifeBio Memory™ product for the end users.

Specific Aim 3:
Conduct a second round of focus groups with Aim 1 existing or former LifeBio users, dementia care professionals, and stakeholders. Conduct a full-scale fidelity trial of the enhanced LifeBio Memory™ product with staff (n=60) who work within residential care settings (independent, assisted living, and/or nursing home settings) that serve persons living with dementia (n=242).

Focus group participants are reconvened to provide feedback on the revised LifeBio Memory™ software application. Questions focus around improvements made to the prototype and training materials based on the previous suggestions made by the groups. The full functionality of the application is displayed, and additional recommendations and feedback are elicited. Particular attention is paid to training materials for each group (older adults with dementia and staff), with recommendations and fixes addressed prior to implementation in the fidelity trial. The groups are walked through a hands-on demonstration of their respective user experiences, including the training materials, guided interview process, text-to-speech function, multimedia upload function, and the automated production of life story materials, including the Life Story Book, Snapshot, and Action Plan, using machine learning/AI. Following qualitative, open-ended data collection from the focus group sessions, participants are also asked to complete short user-acceptance testing surveys to validate the design and the overall functionality of the application, as well as the changes based on the recommendations suggested in Aim 1.

Care professionals are trained to implement the revised version of LifeBio Memory™ in their organizations. Staff training is scheduled using a staggered protocol, and tablets preloaded with LifeBio Memory™ are the main medium of self-paced, online

instruction. Each trainee is asked to complete the training within one week of assignment, as well as complete a pre-training, baseline survey that collected demographic information, job history, previous experience with life story work, and attitudes towards person-centered care and older adults with dementia. The app also tracks whether trainees view other support materials from the LifeBio Memory™ application, namely, the Frequently Asked Questions (FAQs). After training, the staff trainees complete a checklist and a post-training survey on the tablet that gathers their opinion on:

- The length of time spent on training.
- Whether they had difficulty with particular sections/content/materials.
- Whether they feel prepared to conduct life story interviews with older adults with dementia
- Whether they feel comfortable with the basic functionality of LifeBio Memory™
- Whether they feel confident the technology would accurately convey the story of the resident with dementia.
- Whether they have specific questions not covered by the FAQs or the training.
- They also have the opportunity to provide comments on their overall experience via open-ended questions adapted from our previous evaluation questionnaires used in the pilot program.

Time 1 baseline interviews are conducted with residents living with dementia and staff members. Separate baseline research interviews (developed from earlier work) are conducted by researcher interviewers with each resident and staff trainee.

Time 1 resident interviews include:

- demographic information
- depression, anxiety, agitation, and loneliness
- perception of whether staff have adequate knowledge of their care preferences and interests
- quality of communication/interactions between the resident and staff
- whether staff have an understanding of the resident's life story
- level of tension and frustration with staff
- general well-being and quality of life.

Interviews with staff are conducted on *each* of their assigned residents (2-6 residents per time wave) and include:

- resident depression, anxiety, agitation, loneliness, and incidence of memory and behavior problems
- their current knowledge of resident care preferences and interests
- utilization of person-centered care practices
- quality of communication between the resident and themselves and other staff
- their current understanding of that resident's life history
- level of tension and frustration with the resident
- perception of the resident's overall well-being and quality of life, as well as their self-efficacy related to providing care.

Life story interviews are completed between trained staff and their assigned residents using the LifeBio Memory™ tablet app.

After the research interview is completed, a trained staff member conducts a life story interview with a resident within a two-week period. Treatment fidelity is monitored through oversight of the staff administering the life story interviews. LifeBio Memory™ sessions with residents are audiotaped with the permission of the resident or his/her legal guardian. Trained raters monitor treatment fidelity by rating staff on whether they followed protocols included in their training and used appropriate techniques to elicit life story information from residents. Ratings for each strategy follow a 6-point scale indicating the frequency with which each suggested strategy and/or protocol was used, with scores ranging from 0 (not at all) to 5 (a great deal). Higher scores indicate that the specific strategy was used to a great extent during the interview. Raters begin coding recordings once they reach a threshold reliability greater than an Intraclass Correlation Coefficient (ICC) of .80. Staff participants conducting the resident interviews are prompted to complete a brief electronic survey on the tablet immediately after each of their assigned LifeBio Memory™ interviews with residents.

The survey questions gather information on satisfaction with:

- interviewing the resident/quality of interaction with the resident
- positive experiences and difficulties encountered using the LifeBio Memory™ tablet app
- perceived advantages of the program
- perception of meeting the program goals
- Staff also have an opportunity to provide feedback in open-ended note fields and will give their perceptions of the importance and usefulness of life story work, whether it is likely to improve resident-staff interactions, and the feasibility and acceptability of the program in their facility.

Time 2 research interviews are conducted with staff members within two weeks of completing life story interviews with residents.

Research interviewers conduct post-life-story-interview assessments with staff regarding each of their assigned residents. This shorter survey examines the experience of participating in LifeBio Memory™'s life story interview. Time 2 interviews mirror those of Time 1, except for demographic information. A series of satisfaction items related to the LifeBio Memory™ training and experience administering the life story interview are also included in the Time 2 interview.

Final LifeBio Memory™ materials are delivered, and a complete evaluation of the program is completed. Within 4 weeks of baseline (Time 1), final LifeBio Memory™ materials are delivered and implemented. A Life Story Book, Snapshot Summary, and Action Plan are delivered in a digital or printed format according to the needs of the care environment. Time 3 resident and staff interviews mirror Time 1, except for demographic information, and also include satisfaction measures directly related to the use of the complete LifeBio Memory™ product, with specific items related to use of the Life Story Book, Snapshot Summary, and Action Plan. The data collected through Time 3 staff interviews informs the commercialization plan, specifically regarding staff perceptions of the acceptability and feasibility of automated processes in the LifeBio Memory™ app, potential reasons why residents decline participation or and/or do not complete the LifeBio Memory™ protocol at various steps of the recruitment process, challenges and opportunities in delivering LifeBio Memory™, and modifications needed to sustain the program in different communities.

Safety Reporting

Potential Risks for Participants: loss of confidentiality, overtaxing or overburdening respondents with dementia, adverse reaction.

Protection Against Risks

Loss of Confidentiality: To protect against the loss of confidentiality, a variety of safeguards are in place. First, all data obtained in research interviews is kept on secure servers and in locked cabinets at Benjamin Rose. Second, all participants are given an Identification (ID) Number; the master code sheet is kept only by the Subaward Principal Investigator (Ms. Orsulic-Jeras) and the Research Project Coordinator (Ms. Cordell). Therefore, only the PI and Project Coordinator have access to individually private information about human subjects. All data collection forms use only the ID numbers. Any electronic protected health information (ePHI) collected on human subjects is transmitted to, stored by, and accessed, via a HIPAA-compliant secure cloud provider. Such services secure the data while in transmission from the local machine to the servers and have high-level encryption in place to secure the data once it has arrived. The system ultimately chosen is certified as HIPAA-compliant has all possible modern safeguards, including but not limited to encryption, high-strength passwords, firewalls, intrusion detection, virus protection, audit trails, provision of a Business Associate Agreement (BAA), and secure off-site backup. Third, the hard copy data forms are transported from sites to Benjamin Rose in a locked briefcase or laptop case. Fourth, regarding security on the individual single board computers, all of the machines are password-protected. Antivirus, firewall, and security software are installed and regularly updated. The machines are also housed within a locking plastic case that protects them from physical attack.

Overtaxing or Overburdening Respondents with Dementia: Research interviewers are trained to use techniques and clinical procedures to avoid overtaxing or burdening respondents and to enhance communication. In past studies, we have implemented interviewing procedures specifically designed for aged and/or impaired persons. Examples include giving visual cues (choice cards), scheduling interviews at times when fatigue is less likely, and being sensitive to respondents' emotions (e.g., allowing for pauses in the interview process or taking a break so they can regain composure). Instruction in these techniques are an important part of the project's interviewer training. In addition, at the start of each interview, respondents are reminded that they are free to decline to answer any question and can end the interview whenever they choose.

Adverse Reaction: In the unlikely event that a respondent has an adverse reaction, two safeguards are in place to resolve the situation. First, the researchers involved in the study are experienced in working with this population and are prepared for coping with a respondent's emotional reactions. Ms. Orsulic-Jeras has over 20 years of experience working directly with individuals living with dementia, as well as residential care facility staff. Second, respondents have access to the services of their referring community service agency, including experienced social workers, and are also able to receive referrals to appropriate regular communication with sites and

referring organizations to identify any problems that might arise. These procedures have been used extensively in past research.

Adverse Event Collection and Reporting

Ms. Orsulic-Jeras and Ms. Sanders will be informed of any serious adverse events as soon as they occur and notify the Data and Safety Monitoring Team within 24 hours of notification.

In the event of an adverse event, the following information will be reviewed:

- Participant's study status.
- How the participant was recruited into the study and the efforts that took place to retain him/her.
- The nature of the adverse event and a determination of how the participant's safety has been threatened as a result.

In most mild cases (i.e., increased stress), a recommendation will be made to discontinue the individual's participation in the intervention and/or to withdraw the participant from the study. In moderate cases (i.e., unable to cope), the participant will be referred to an identified expert (the Alzheimer's Association, a geriatric care manager, or licensed clinical social worker, etc.). If the adverse event is deemed to be very serious (i.e., suicidal risk or the health/well-being of the participant is in jeopardy), the case will be reported to the appropriate authorities to intervene on the situation immediately.

Any significant adverse events will be reported to the IRB, the NIA Program Officer, and the Safety Officer within 48 hours of knowledge of occurring. A summary of all other adverse events will be reported to the NIA Program Officer and Safety Officer quarterly, unless otherwise requested.

Potential Benefits for Participants

Increase knowledge and understanding of life story work, dementia and its consequences, and about services that might be useful now or in the future.

Enjoyment of sharing information about both positive and negative feelings related to their work, especially related to their own needs.

Enhance knowledge and theory about training residential care facility staff to implement cutting-edge life story work.

Alleviate staff burden, enhance person-centered care practices, and improve resident well-being, health and quality of life.

Data will provide both an empirical basis and practical foundation for professionals to use when working with residents with dementia from a variety of backgrounds throughout their professional caregiving career.

Data Flow

Attrition:
Recommendations of Krueger were followed in selecting the size and number of groups. No difficulties are expected in recruiting participants to participate in the focus groups given the positive reactions and exceptionally low attrition rate of our LifeBio pilot that used a longitudinal design using three waves of data collection with 75% completing in the first wave, 92% completing in the second, and 99% completing in the third. In addition, ten percent attrition or less was estimated between project enrollment and completion of the life story interviews in the clinical trial.

Data Analysis and Coordination:
The research team and technology consultants conduct a review and thematic analysis of the data. Broadly, the analysis focuses on the feasibility of the modified LifeBio intervention as a viable solution for implementing person-centered care in residential care facilities.

In addition to monitoring fidelity, the effectiveness of the training in relation the professional staff's ability to conduct the intervention in a manner that maintains the high levels of acceptability and feasibility found in the pilot study is determined. Analysis of variance will be used to analyze responses to evaluation questions by groups (staff and residents) with respect to the program's importance and usefulness and their satisfaction. Investigators also examine whether resident outcomes (e.g., depression, anxiety, and loneliness) changed as a result of the participating in the program.

Retention of Study Documentation

Per Benjamin Rose institute on Aging Policies and Procedure 800A: Client Record System, disposal of the records following a minimum of seven (7) years shall be done to ensure the confidentiality of the client and administrative records. Client and administrative records shall be burned or shredded depending on accessibility and cost of these procedures. The Sr. Vice President & COO or his/her designee is responsible for supervision of the disposal of all records.

Data Management

NVivo: Focus group transcripts are loaded into NVivo, a mixed-method qualitative analysis software, for ease of analysis. A variety of tools, such as word frequency queries, text search, sentiment analysis, and coding matrices were used to validate constructs and themes that formed basis of the thematic coding structure. Them, the codes and themes from the open, inductive, and axial reads of the research team's initial readings of the project are loaded into the software and tagged line by line in a deductive approach. After transcripts are coded, the coder's project files are merged, and the team utilizes the coding comparison tool within NVivo to calculate a Cohen's Kappa Score to determine inter-rater reliability. In the event of disagreements or discrepancies between coders, the sections identified by the software are brought to the larger research group and discussed until a consensus is reached and a high level of inter-rater reliability of .85 is reached. NVivo also allows for the opinions and design preferences of existing LifeBio users, staff members, and persons living with dementia to be compared in coding matrices. The reporting of these coding matrices allows for the identification of proposed changes or recommendations for improvement.

Access Database: A database was created in access to store all project-specific documentation including referral logs, participant mailing addresses, completed screens, communication logs, survey responses.

Quality Control Procedures

Standard Operating Procedures. The study's standardized operating procedures (SOP) document is located in the study's electronic record on BRIA's secure network with appropriate backup systems (filename: LifeBIO_SBIR_SOP.docx). [Document still in progress].

Reports

A report was submitted to NIA on March 13, 2021 after the completion of Aim 1

A final report will be submitted upon the completion of Aim 3.

Data and Safety Monitoring Activities

The Principal Investigators (PIs), Ms. Orsulic-Jeras and Ms. Sanders, hold responsibility for ensuring participants' safety on a daily basis during their participation. Data and safety monitoring is assured by the study's research team senior key personnel: The subaward PI (Ms. Orsulic-Jeras) and Project Evaluators (Dr. Powers and Dr. Ejaz). Dr. Ejaz is a licensed independent social worker (LISW), while other senior key personnel are experts in the field of dementia and comprised the study's Data and Safety Monitoring Team. This team, joined by an independent Safety Officer (SO), acts to monitor participant safety, evaluate the progress of the study, review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses.

The PIs meet weekly with members of the research team either in-person or by teleconference to review the study's progress, review data quality, and participants' safety. At these meetings, an evaluation of the progress of the study is reviewed, including periodic assessments of data quality, timeliness of recruitment, the appropriateness of the strategies for recruiting participants into the study, assessing the participants' risk in using the LifeBio Memory™ materials, and other factors that might have affected the study's outcomes. In addition, safety reports are sent to the SO at least twice a year and include a detailed analysis of study progress, data and safety issues.

Study Completion Procedures

Successful completion of this study delivers a final LifeBio Memory™ product that was tested by its potential customers, aimed at facilitating and enhancing communication between people living with dementia and their family and caregivers.

Dissemination

ClinicalTrials.gov

The Subaward Principal Investigator (Ms. Orsulic-Jeras) ensures that processes are in place to achieve and maintain compliance with the following policy requirements for all clinical trials proposed in this application:

Clinical trial registration information is submitted to ClinicalTrials.gov no later than 21 calendar days following the study start date. Clinical trials registration initially took place for this study on 9/28/2020. The Subaward PI maintains the accuracy of the record content, resolves problems, and leads all content update and modifications within the record. Clinical trial summary results information is submitted to ClinicalTrials.gov no later than 1 year following the study completion date.

Clinical trial information submitted to ClinicalTrials.gov is verified, updated and corrected in accordance with all applicable deadlines established in the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR 11.64).

Publications

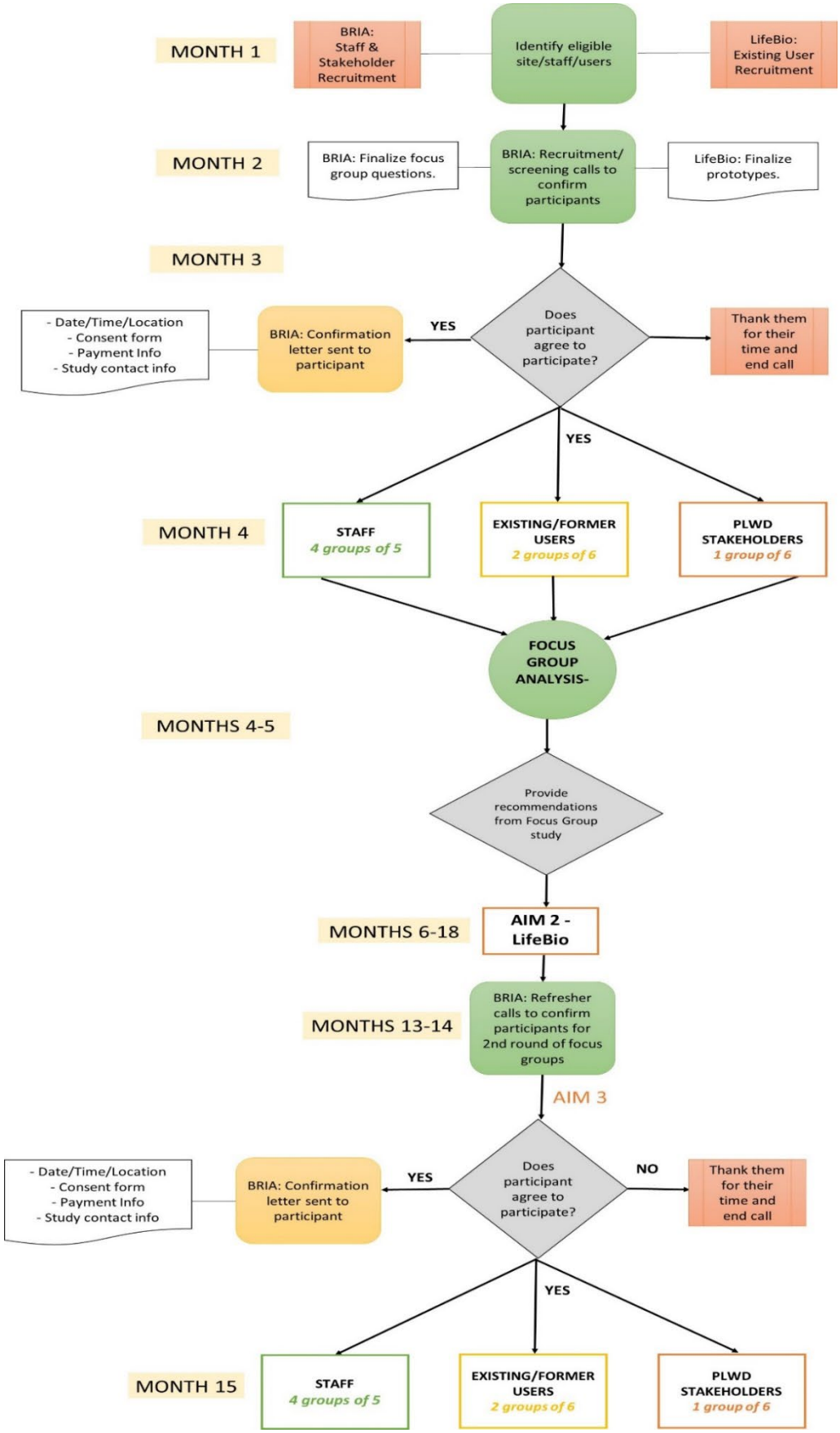
Basic results of the Aim 3 clinical trial will be reported in the ClinicalTrials.gov record within 12 months of trial completion. Research manuscripts and other publications will be submitted according to the research team's publication plan. All publications will be tracked throughout the project period and reported accordingly in annual and final project reports.

References

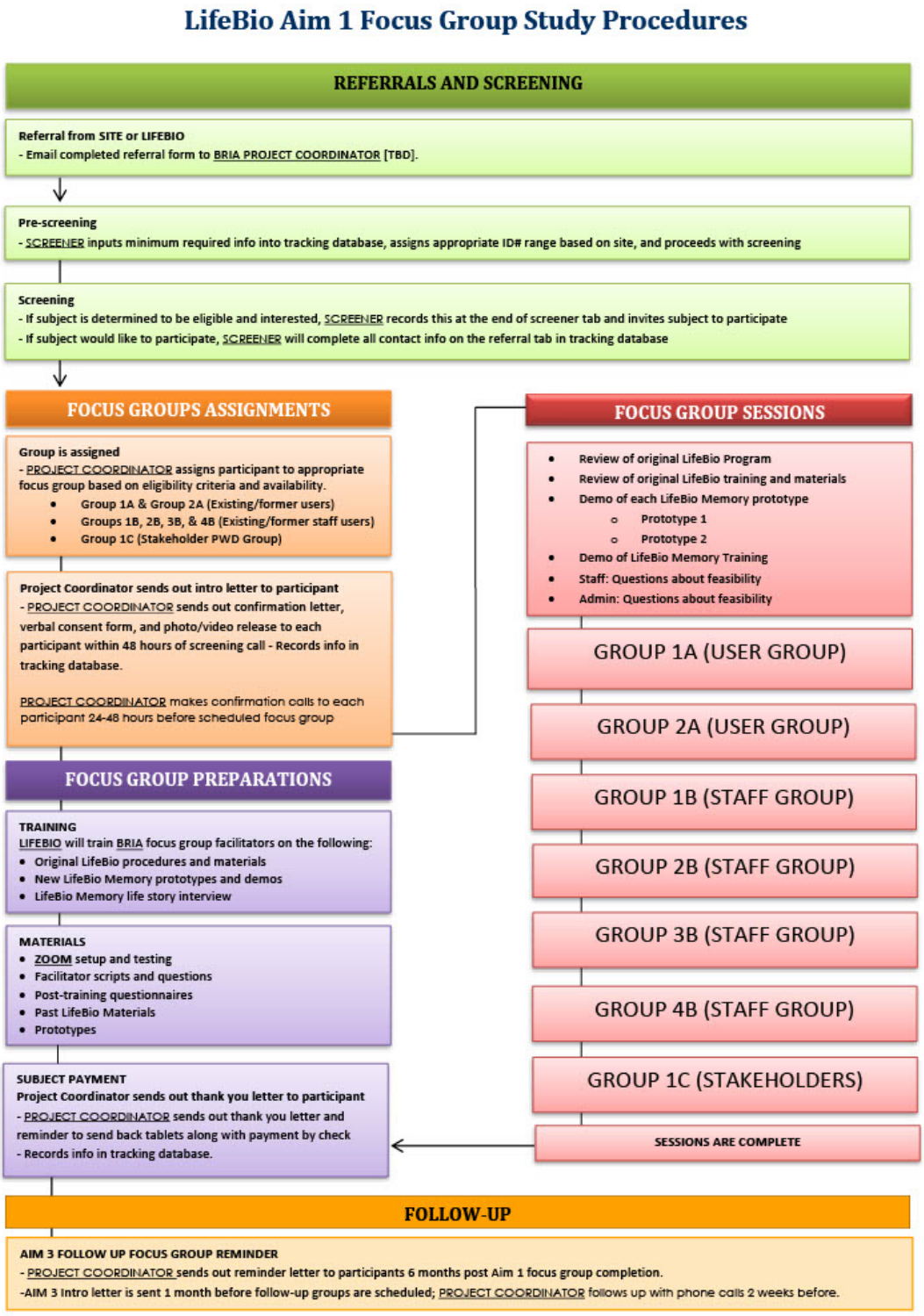
Krueger, R. A. Designing and Conducting Focus Group Interviews. (2002).

Appendix

Aim 1 Flowcharts



Aim 1 Focus Group Study Procedures



Aim 1 Recruitment Flyer

LifeBio

BENJAMIN ROSE INSTITUTE ON AGING
SERVICE • RESEARCH • ADVOCACY

FOCUS GROUP RESEARCH OPPORTUNITY

WE NEED YOUR OPINION!

ABOUT

LifeBio is a life story review program for older adults that has been used in senior living and health care organizations. LifeBio is an evidence-informed approach that reduces loneliness while increasing social connectedness, feelings of happiness, and overall well-being of residents.

ELIGIBILITY

Organization:

-Familiar with the LifeBio program
-Have purchased the LifeBio program in the past
-Are currently using LifeBio within the facility or home
-Have available staff that could participate in 2 group discussions over a 1-year period

Staff:

- Work at a participating independent living, assisted living, or nursing home
- Experience with dementia
- Age 18+
- Willing to contribute roughly 4 hours of their time over a 1-year period

Funded by National Institute on Aging

STAFF FOCUS GROUP SESSIONS

Each staff person will participate in a 2-part focus group study led by Benjamin Rose researchers. They will be asked their opinion on various LifeBio materials as well as new LifeBio Memory features.

- **Part 1**: A 1.5 to 2 hour virtual discussion group in November 2020.
- **Part 2**: A second 1.5 to 2 hour discussion group approximately 9 months later.

SESSION PAYMENTS

- Staff will received $25 for each part they participate in. Payments will be issued by check at the end of each Focus Group part.

Don't you wish you had a record of your great-grandparents' life stories? LifeBio asks a series of questions using an online template of autobiographical and biographical questions that have been carefully crafted to bring out interesting events and milestones in one's life. Topics such as family history, childhood memories, historical events, school and work experiences, early adulthood, and life lessons and beliefs are discussed and captured for generations to come to enjoy.

In this project, we are developing a new and improved product called LifeBio Memory that we will design to help you help your residents with dementia share their lives with family, staff, and others. We need your help to make this program the best it could be!

CONTACT US

Ashlee Cordell
Project Coordinator
ACordell@benrose.org
216-373-1722

To be contacted: Fill out the information below BY MONDAY, OCTOBER 12, 2020.

Name: _____ Organization: _____

Position:

Email: _____ Phone: _____

*RETURN THIS FORM TO: _____

Aim 1 Recruitment Script for Stakeholders

Invitation to participate in a group discussion about LifeBio

We would like to invite you to participate in a small group discussion about a life story program called LifeBio. The purpose of the discussion is for you to provide your opinions about what you like or don't like about the LifeBio program and materials we will show you. Your participation in the group will give us valuable information on how to improve the program to benefit future LifeBio participants. With your help, we will be able to help others who are living with dementia.

You are being asked to take part in a group of 4 to 8 persons living with dementia, who have some experience or no experience with LifeBio, but have valuable experiences to share with our research team on how to best design programs with your values and preferences in mind. The group will be moderated by a member of Benjamin Rose's research staff and last about 60 minutes.

Your opinions are valuable to us. To thank you for your time and effort, we will reimburse you $50 for participating. In about 9 months, we will invite you back to view our revised program and ask for your feedback again. We will reimburse you another $50 for participating in the second session.

Why is it a group discussion? Why not interview me one on one?

A group discussion is beneficial because it helps participants to hear different points of view and it allows everyone to react to each other's ideas. Since our goal is to help future LifeBio participants, we want to encourage brainstorming of different ideas so that we can learn from the group how to improve the program.

Would I need to do anything to prepare?

No advanced preparation is needed to participate in the group. A computer with internet connection is required, since due to Covid-19, these focus groups are now taking place in a virtual format. In advance of the session, you will be receiving a tablet in the mail that will include some of the features we'll be discussing. You will be asked to give the group leader your opinions about them, such as what changes or improvements, if any, you would recommend. Once the session is done, you will send the tablet back to LifeBio (postage and materials will be included for you). You will receive the tablet back before the second round of focus groups. At the conclusion of the second round of focus groups, you will be able to keep the tablet if you completed both sessions. Another person living in your home may help you with the computer or tablet if needed.

What will you do with the information?

The discussion will be audio and video-recorded for research purposes only. We will ask you for your explicit permission to use this information for any other purpose (for example, to include in training material or in a presentation, etc.). The information will be kept strictly confidential and discussed only with Benjamin Rose and LifeBio researchers. Your participation is voluntary, meaning you can choose to discuss or not to discuss any of the topics or questions, and may leave the focus group at any time.

The procedures for the discussion have been reviewed by and received approval by the Institutional Review Board at Benjamin Rose Institute for Aging. Funding is provided by the National Institute on Aging, Grant #1R44AG089566-01.

Questions? The leaders of the research team are Silvia Orsulic-Jeras and Beth Sanders. If you have any questions regarding the group discussion or your participation in it, please call 216-373-1625 or 937-303-4574, or e-mail them at sjeras@benrose.org or bsanders@lifebio.com.

You will receive a phone call from LifeBio or Benjamin Rose Institute on Aging within one week of receiving this letter. If you do not want to be contacted further about this project, please let the caller know you are not interested, and you will be removed from our list.

The procedures for the discussion have been reviewed by and received approval by the Institutional Review Board at Benjamin Rose Institute for Aging. Funding is provided by the National Institute on Aging, Grant #1R44AG069586-01.

Video Recording Consent

RELEASE AND CONSENT
FOR USE OF VIDEO RECORDING

This agreement is made this_____day of_____, 2020, by and between_____("Releasor"), LifeBio Inc., and Benjamin Rose Institute on Aging, hereby referred to as "The LifeBio Project Team".

I, the undersigned, an individual of legal age or representative, hereby grant and release to the LifeBio Project Team, its successors, officers, directors, representatives and assigns, the right to record Releasor's name, likeness, voice, biographical and other information concerning Releasor in connection with the LifeBio Project Team's business purposes on film, digital image, videotape, audiotape or any other means of recording, and to edit such film, digital image, videotape, audiotape or other means of recording, and to incorporate and use the same in the sole discretion of the LifeBio Project team for any and all business purposes, including but not limited to promotion in various media.

I authorize the LifeBio Project Team to use or authorize the use of any such recordings, whether edited or not, for any and all business purposes at any time or times and in all digital and camera-ready formats.

I further grant the LifeBio Project Team the exclusive right to copyright any recordings and/or edits of my likeness, name, voice, and other information for use by the LifeBio Project Team, and hereby releases the LifeBio Project Team, its successors, officers, directors, representatives and assigns, and all others who are or may be authorized by the LifeBio Project Team to use said recordings and/or edits, from all claims, liabilities and expenses which Releasor now has or may hereafter acquire.

Name of individual being recorded: _____

Address: _____

_____

_____

Phone: _____

Email Address: _____

Signature: _____

Date: _____

Focus Group Enrollment Letter

BENJAMIN ROSE INSTITUTE ON AGING
SERVICE • RESEARCH • ADVOCACY

CENTER FOR RESEARCH AND EDUCATION
11890 Fairhill Road
Cleveland, OH 44120
216.791.8000 fax: 216.373.1613
www.benrose.org

November 2, 2020

Dear [Insert Name],

On behalf of the LifeBio Memory program, thank you for agreeing to participate in a group meeting to discuss your experiences with LifeBio. We will also ask your opinion about some changes we hope to make to LifeBio so that the process of creating a life story will be more efficient and enjoyable. Your input is particularly valuable, as we hope to create a product that is representative of what individuals living with dementia value most.

In this mailing, you will be receiving the following:

- This letter explaining the time/date of your meeting and your Zoom log-in information.
- Instructions on how to log-in to Zoom for the focus group meeting.
- A copy of the consent form you were read on the initial phone call with Ashlee.
- A video release form.

In addition, you will be receiving a box of materials from LifeBio, Inc. Included in that box will be:

- An iPad tablet you will be using for the focus group.
- Instructions for accessing the information on the tablet.
- A packet of print materials for LifeBio.
- Instructions for mailing back the tablet.

The meeting will be held on **Thursday, November 12th via Zoom**. Your meeting time and Zoom log-in information is as follows:

Time (EST): 10:00-11:00 AM

Zoom Meeting ID: 816 2412 0123
Zoom Passcode: 757091

Two days before your scheduled session, Ashlee will give you a call to go over the Zoom log-in information and assist you with any technological needs you may have in advance of the meeting. Ashlee will call you:

- **Tuesday, November 10th between 12:00-5:00 PM.**

Please have your video release form and Zoom log-in information ready.

BENJAMIN ROSE INSTITUTE ON AGING
SERVICE • RESEARCH • ADVOCACY

CENTER FOR RESEARCH AND EDUCATION
11890 Fairhill Road
Cleveland, OH 44120
216.791.8000 fax: 216.373.1813
www.benrose.org

As a token of our appreciation you will receive a small stipend of $50 within a couple of weeks of the focus group meeting. The information you share in the discussions will be used only for research purposes to improve the LifeBio program. Your thoughts and opinions will be kept confidential and not shared with anyone outside of the group. In 9 months or so, we will be inviting you to come back to answer similar questions, and to show you the improvements we have made to LifeBio Memory so you can provide us with more valuable feedback.

If you have any questions or concerns about the meetings, please don't hesitate to contact me. If you have questions about the meetings or any aspect of our study, you may contact me, Silvia Orsulic-Jeras, Principal Investigator, via email at sjeras@benrose.org, or by phone at (216) 373-1625.

Sincerely,

Silvia Orsulic-Jeras

Silvia Orsulic-Jeras, M.A.
Subaward Principal Investigator
Research Associate
Center for Research and Education
Benjamin Rose Institute
216.373.1625
sjeras@benrose.org

Ashlee Cordell, MGS
Project Coordinator /
Research Assistant
Center for Research and Education
Benjamin Rose Institute
216.373.1722
acordell@benrose.org

Cognitive Screen (T-MMSE)

Now I'd like to ask you a few questions and give you some problems to solve. Please try to answer as best as you can.

1. What (5)

	WRITE DOWN RESPONSE	Incorrect	Correct
year is this?		0☐	1☐
season is this?		0☐	1☐
month of the year is this?		0☐	1☐
is today's date?		0☐	1☐
day of the week is this?		0☐	1☐

2. What (4)

	WRITE DOWN RESPONSE	Incorrect	Correct
county are you in?		0☐	1☐
state are we in?		0☐	1☐
city/town are you in?		0☐	1☐
is the name of the place/room you are in?		0☐	1☐

3. I am going to name three objects. After I have said all three objects, I want you to repeat them. Remember what they are because I am going to ask you to name them again in a few minutes. (3) **"ball" "car" "man"** Please repeat the three items for me.

RECORD EXACT RESPONSE		0☐ 1☐ 2☐ 3☐
NUMBER OF TRIALS		

SCORE ONE POINT FOR EACH CORRECT ANSWER. IF RESP DOES NOT REPEAT ALL THREE, REPEAT UNTIL THEY HAVE LEARNED ALL THREE, OR UP TO A MAXIMUM OF 5 TIMES. ALLOW 20 SECONDS FOR REPLY. SCORE FIRST RESPONSE ONLY.

4. Spell the word WORLD. Now would you spell WORLD backwards? (5)

D L R O W	RECORD EXACT RESPONSE		0☐ 1☐ 2☐ 3☐ 4☐ 5☐

SCORE ONE POINT FOR EACH LETTER IN THE CORRECT ORDER. ALLOW 30 SECONDS.

5. Now what were the names of the three objects that I asked you to remember? (3)

RECORD EXACT RESPONSE		0☐ 1☐ 2☐ 3☐

SCORE ONE POINT FOR EACH CORRECT ANSWER: BALL CAR MAN. ALLOW 10 SECONDS.

6. Could you please tell me what the object is you are speaking into? (TELEPHONE) (1)

RECORD EXACT RESPONSE		0 ☐ 1 ☐
ALLOW 10 SECONDS.		
7. I'd like you to repeat the following phrase after me: "No ifs, ands, or buts." (1)		
RECORD EXACT RESPONSE		0☐ 1☐
ALLOW 10 SECONDS.		
8. I'd like you to "say hello, tap the mouthpiece of the phone 3 times, then say I'm back." (3)		
FIRST COMMAND	0☐	1☐
SECOND COMMAND	0☐	1☐
THIRD COMMAND	0☐	1☐
SCORE ONE POINT FOR EACH CORRECTLY PERFORMED COMMAND. ALLOW 30 SECONDS.		
9. Could you please give a phone number where you could be reached? (1)		
RECORD EXACT RESPONSE		0☐ 1☐
SCORE ONE POINT FOR A COMPLETE PHONE NUMBER REGARDLESS OF ACCURACY.		
TOTAL NUMBER CORRECT OUT OF 26: ____ / 26		

Verbal Consent Form

Purpose/Introduction

Hello, this is (NAME) from the Benjamin Rose Institute on Aging. The reason for my call is to invite you to participate in a research study that will develop and evaluate training materials and electronic applications for the LifeBio Memory program. These materials will be designed to help individuals with dementia document their life stories in the form of life story booklets and summaries about their lives. We believe that when staff know more about their residents, they can provide more personalized and higher quality of care to them.

Study Procedures

Your participation in the project will include participation in one of the following focus groups at the beginning of the study, then once again approximately 9 months later. The group you will participate in is checked below:

☐1) STAFF FOCUS GROUP: 120-minute focus group with 5-6 other **professionals** who are familiar with and have participated in the LifeBio program; or

☐2) LIFEBIO USER GROUP: 90-minute focus group with 5-6 other **individuals who have used LifeBio** to capture their own or a family member's life story.

☐3) STAKEHOLDER GROUP: 60-minute focus group with 4-5 other **individuals with a diagnosis of dementia** who have not participated in the LifeBio.

Focus groups will be led by Benjamin Rose project staff who will ask participants questions designed to gain feedback and recommendations for: 1) revising, as necessary, existing LifeBio intervention materials, 2) designing the new electronic applications, and 3) enhancing the prototype features and associated training materials. For research purposes, the group discussion will be digitally recorded. These recordings will be destroyed once they have been used to document the responses given by the group.

Groups will be held at a central location as convenient to you as possible. You may voluntarily end your participation in the focus group and/or refuse to respond to specific questions at any time.

Risks

There are a few possible risks of participating in this program. The potential risks to you from participating in the program include the possibility of an adverse emotional or psychological reaction to questions that will be discussed in each focus group. The focus group leaders you will be working with have been trained to recognize and address any signs of distress that you may have during your group. If at any point during the focus group you become upset or agitated, the leader may suggest that you end your participation. If a major issue arises that our group leaders are unable to handle, you may wish to seek professional assistance through a social service agency that we can refer you to. Again, if you do not wish to answer a question, you can choose not to participate in that specific discussion.

Benefits

Participation in this program may aid in improving information and services for persons with memory challenges and their families.

Alternatives to Participation

Because of the nature of this research, the only alternative is not to participate in this study.

Financial Information

There is no cost to you for participation in this study.

Confidentiality

All information you give is confidential, unless you or your loved one is being abused, neglected, or exploited by another person. Our staff are required by law (Ohio Revised Code 5101.60) to report such concerns to the Adult Protective Services unit of the County Department of Job and Family Services. All data collected from this study will be de-identified to protect your privacy.

Compensation/Cost

Stakeholder focus group participants will receive a total of one hundred dollars ($100) for participation in each of the two rounds of focus groups. One check (of $50) will be mailed to you from Benjamin Rose to your home within two weeks after you have attended your first focus group. The second check of $50 will be mailed to you two weeks upon completion of the second round of focus groups. Community service organizations will be compensated for their staff's time as part of their contractual arrangement with the Principal Investigators.

Summary of Your Rights as a Participant in a Research Study

Your participation in this research study is voluntary. If you decide to join the study, you may withdraw at any time and for any reason, without penalty or loss of benefits. If information from this study is published or presented, your identity will not be revealed. If new information becomes available that changes the risks or benefits of this study, you will be notified. Once notified, you may decide whether or not to continue participating.

Contact Information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. Silvia Orsulic-Jeras (Principal Investigator) can also be contacted at (216) 373-1625.

Signature

Providing verbal consent indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By providing consent, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form was provided to you.

The person listed below gave verbal consent to participate in this study.

_____ Date_____

Printed Name of Participant

_____ Date_____

Signature of Person Obtaining Consent

_____ Date_____

Signature of Principal Investigator (Affirming subject eligibility
for the study and that informed consent has been obtained.)

Statistical Analysis Plan (SAP)

LifeBio Memory Digital Reminiscence Platform

Study Title:	Development of a Reminiscence Therapy Online Platform With Machine Learning to Increase Engagement With People Living With Dementia and Their Care Partners
Study Registration Number	NCT04769466
Sponsor	Benjamin Rose Institute on Aging 11890 Fairhill Rd Cleveland, OH, 44120 USA
Collaborator:	National Institute on Aging (NIA)
Protocol Number:	1908-216
Phase:	Phase 2
Statistical Analysis Plan Version	Version 1.0
Statistical Analysis Plan Date	September 8, 2025
Sub-Principal Investigator:	Silvia Orsulic-Jeras, MA Benjamin Rose Institute on Aging 11890 Fairhill Rd Cleveland, OH, 44120 USA

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	Position/Title: Senior Research Scientist
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Abbreviations:

AE	Adverse Event
CES-D	Change in Center for Epidemiological Studies Depression Scale
CI	Confidence Interval
CMAI	Change in Cohen-Mansfield Agitation Inventory
GCDMP	Good Clinical Data Management Practices
ICI	Change in Individualized Care Instrument
IRB	Institutional review board
ITT	Intent to Treat
MMSE	Mini Mental Status Examination
PCCAT	Person-Centered Care Assessment Tool
PLWD	People (or Persons) Living with Dementia
PP	Per Protocol
SAP	Statistical Analysis Plan
SCIDS	Sense of Competence in Dementia Care Staff
SD	Standard Deviation
SPSS	Statistical Package for the Social Sciences
QoL-AD	Change in Quality of Life Alzheimer's Disease

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1. Administrative Information

The primary objective of this study is to assess the efficacy and safety of LifeBio Memory to increase engagement with people living with dementia and their care partners.

This document outlines the statistical methods to be implemented during the analyses of data collected within the scope of Benjamin Rose's Protocol "1908-216".

This Statistical Analysis Plan (SAP) has been developed in accordance with NIH guidance for clinical trial and behavioral research SAPs, ensuring transparency, reproducibility, and alignment with the study protocol.

1.1 Approvals and Oversight

- The SAP must be reviewed and approved by the following individuals prior to database lock and initiation of any analysis:
- Principal Investigator (PI) – ensures alignment with study objectives and protocol.
- Sponsor/Study Funder – ensures compliance with funding requirements and reporting standards.
- Lead Statistician – ensures that planned analyses are appropriate, reproducible, and methodologically sound.

1.2 Version Control and Updates

- Any revisions to the SAP after initial approval must be documented with rationale, date, and approvers.
- Updated versions will be clearly labeled (e.g., v1.1, v2.0) and stored securely alongside previous versions.

1.3 Deviations from SAP

- Any deviations from the prespecified analyses outlined in this SAP (e.g., due to unexpected missing data patterns, assumption violations, or post hoc exploratory analyses) will be documented in the final study report, including:
    - Description of the deviation
    - Reason for the deviation
    - Date and personnel responsible for the decision
- Deviations will be reported transparently in any manuscripts or regulatory submissions to maintain integrity of the study findings.

1.4 Compliance with Regulatory and Institutional Policies

- This SAP, along with all associated datasets and outputs, will adhere to:
    - Institutional review board (IRB) requirements
    - NIH/NIA policies on data management and reporting
    - Good Clinical Data Management Practices (GCDMP)

2. Introduction

2.1 Study Background

The LifeBio Memory project is a behavioral intervention designed to enhance the well-being of residents living with dementia and to support staff in delivering person-centered care. The program uses structured life-story interviews, while providing staff with training and tools to better understand residents' preferences and histories. Previous research indicates that life-story interventions may improve quality of life, reduce depressive symptoms, and increase social engagement among persons living with dementia, while also enhancing staff competence and job satisfaction.

The current study is a non-randomized, pre-post evaluation designed to assess changes in resident and staff outcomes following participation in the LifeBio Memory program over a 4-week period. The study includes two primary participant groups: residents living with dementia and staff who facilitate/support the intervention.

2.2 Study Objectives

- Primary Objectives:
    - To evaluate the effect of the LifeBio Memory program on resident outcomes, including depressive symptoms (CES-D), quality of life (QoL-AD), agitation (CMAI), loneliness, and satisfaction with care.
    - To evaluate the effect on staff outcomes, including attitudes toward persons living with dementia, dementia care competence, job satisfaction, and person-centered care practices (PCCAT and ICI subscales).
- Secondary Objectives:
    - To examine changes in residents' cognitive status (MMSE) and staff knowledge of resident life stories/preferences.
    - To assess program feasibility, training effectiveness, and satisfaction among both residents and staff.
- Exploratory Objectives:
    - To explore any potential sub-group differences (e.g., staff role, site-level differences) and consistency of outcomes across measures.

2.3 Purpose of the SAP

This Statistical Analysis Plan (SAP) specifies all planned analyses for the LifeBio Memory project prior to database lock and unblinding of outcome data. The SAP ensures that analyses are:

- Prespecified and reproducible, minimizing risk of bias;
- Transparent, with detailed plans for handling missing data, quality control, and statistical testing;
- Aligned with study objectives, allowing clear interpretation of primary, secondary, and exploratory outcomes.

2.4 Scope of the SAP

This SAP covers:

- Definition of analysis populations (residents and staff, ITT and complete-case).
- Data cleaning, missing data handling, and quality control procedures.
- Descriptive statistics, primary and secondary analyses, and effect size reporting.
- Subgroup and sensitivity analyses, as well as approach to multiplicity.
- Reporting conventions, including tables, figures, and adherence to the CONSORT extension for non-randomized trials.

3. Study Design

The LifeBio Memory project is an interventional, parallel assignment, non-randomized, open-label study evaluating the effects of a structured life-story intervention on residents living with dementia and the staff who facilitate their life story interviews.

- Participant Groups: Two primary groups will be assessed:
    1. Residents living with dementia participating in LifeBio Memory intervention.
    2. Staff who facilitate or support the intervention.
- Data Collection: Outcomes will be assessed at baseline (Time 1) and 4 weeks post-intervention (Time 2). Training outcomes will be assessed immediately following the completion of intervention training videos.

3.1 Sample Size & Power

- Planned Enrollment: Based on the study proposal and prior pilot data, at least 20 residents per site across eight sites (n=160 residents) were planned for recruitment. Staff participants were included according to the number of residents assigned to them (2–6 residents per staff participant).
- Power Analysis: The study was powered to detect small-to-moderate effect sizes (Cohen's d = 0.35–0.40) for paired t-tests on primary outcomes with 80% power and a two-sided α = 0.05, assuming 20–25% attrition.
- Baseline Assessments: Demographic variables and cognitive status (MMSE) were collected at baseline. Descriptive analyses will summarize these characteristics for residents and staff.

3.2 Actual Analyzed Sample

- Residents: 107 participants included in final analyses.
- Staff: 53 participants included in final analyses.

3.3 Randomization / Masking

- The study did not include randomization or blinding due to feasibility and practical considerations.

3.4 Analysis Populations

- Intention-to-Treat (ITT): All participants with baseline and at least one post-intervention measure. ITT analyses will use mean substitution for missing items within allowable thresholds (≤50% missing per scale).
- Per-Protocol (PP): Participants completing baseline and 4-week follow-up without major protocol deviations. Analyses restricted to this population will serve as sensitivity analyses.

4. Outcomes

4.1 Primary outcome (Residents & Staff)

	Title	Description of Primary Outcome Measures
1	Change in Center for Epidemiological Studies Depression Scale (CES-D)	10-item Measure of depressive symptomatology; Scale: 0 (rarely or none of the time) to 3 (most or almost all of the time); Possible scores range from 0 (minimum) to 30 (maximum). Higher scores indicate higher frequency of reported depressive symptomology.
2	Change in Satisfaction With Care in the Nursing Home Scale	Measurement of resident satisfaction with care in a long-term care facility; 8-items measured on a scale of 1 = generally yes and 0 = generally no; Possible scores range from 0 (minimum) to 8 (maximum). Higher scores indicate higher satisfaction with care at the resident's facility.
3	Change in Quality of Life Alzheimer's Disease (QoL-AD)	13-item Quality of life scale for an individual living with Alzheimer's Disease: rated on a scale of 1 (poor) to 4 (excellent); Possible scores range from 13 (minimum) to 52 (maximum). Higher scores indicate higher quality of life.
4	Change in Cohen-Mansfield Agitation Inventory (CMAI) - Short Form From Baseline	14-item Measurement of agitation that was completed by the staff for each resident they were assigned to conduct a life story interview with at baseline and post-intervention (proxy completed by staff on behalf of each resident) rated on a scale: 1 (never) to 5 (several times an hour) scores can range from 14-70, with higher scores indicating higher frequency of agitated behaviors of persons living with dementia as reported by those staff conducting their life story interviews.
5	Change in Staff Attitudes Towards Residents Scale From Baseline	Measurement of the attitudes of long-term care staff towards the residents under their care includes 4-items on a 5-pt scale of 1= never to 5=always, scores ranging from 4 to 20, higher scores indicate more positive attitudes toward residents.
6	Change in Individualized Care Instrument (ICI)	13-item subscale of the ICI scale "knowing the person"; rated on a scale from 1 (strongly disagree) to 4 (strongly agree); Possible scores range from 13 (minimum) to 52 (maximum). Higher scores indicate staff feel they know the resident(s) more.

	Subscale - Knowing the Person - From Baseline	
7	Change in The UCLA 3-Item Loneliness Scale From Baseline	3-item Measurement of feelings of loneliness; rated on a scale: 1 (hardly ever) to 3 (often), ranging from 3 to 9, higher scores indicate higher feelings of loneliness.
8	Resident Satisfaction With the LifeBio Memory Program	A total of 9-items were developed from the pilot and current study to understand residents' acceptance and satisfaction with the LifeBio Memory program. Participants answered either "no" (0) or "yes" (1) to each item, with total scores ranging from 0 to 9 (higher scores indicating high satisfaction with the LifeBio Memory program).
9	Change in Perceived Importance of Life Story Work Among Staff	A 3-item measure related to the importance of life story work with residents; items are rated on a scale from 1 = strongly disagree to 5 = strongly agree, scores ranging from 3 to 15, with higher scores indicating staff feeling life story work is more important.
10	Staff Satisfaction With LifeBio Memory Program	On the follow-up post-evaluations, staff were asked to rate their overall satisfaction with the LifeBio Memory program. A total of 8-items developed from the pilot and current study were rated on a 1 (strongly disagree) to 5 (strongly agree) scale. Possible scores range from 8 (minimum) to 40 (maximum). Higher scores indicate higher satisfaction with the program.
11	Change in Sense of Competence in Dementia Care Staff (SCIDS) Scale From Baseline	17-item measurement of staffs' overall sense of dementia care competence; rated on a scale: 1 (not at all) to 4 (very much) with scores potentially ranging from 17-68, higher scores indicating higher sense of competence in dementia care among staff.
12	Change in Person-Centered Care Assessment Tool [Sub-Scales I and II] From Baseline	10-item measurement of staff experience with person-centered care in their current care community; rated on a scale: 1 (strongly disagree) to 5 (strongly agree), scores ranging from 10-50, higher scores indicating higher agreement with experience providing person-centered care.
13	Change in Direct Care Worker Job Satisfaction Scale From Baseline	9-item measurement of staff satisfaction with different aspects of their job; rated on a Scale: 1 (very dissatisfied) to 4 (very satisfied), potential scores ranging from 9-36, higher scores indicating higher satisfaction with their job.
14	Change in Individualized Care Instrument (ICI) Subscale - Resident Autonomy Subscale - From Baseline	15-item Measurement of staff perceptions about resident's autonomy; rated on a Scale: 1 (never) to 5 (very frequently), potential scores ranging from 15-75, higher scores indicating staff perceiving residents having more frequent autonomy.
15	Change in Individualized Care Instrument (ICI) Subscale - Staff and Resident	7-item measurement of staff perceptions of their communication with residents; rated on a Scale: 1 (never) to 4 (always), scores ranging from 7-28. higher scores indicating higher frequency of staff to resident communication about their care.

	Communication Subscale - From Baseline	
16	Change in Individualized Care Instrument (ICI) Subscale - Staff to Staff Communication Subscale - From Baseline	10-item measurement of staff perceptions of staff to staff level communication, rated on a scale from 1 (never) to 4 (always), scores ranging from 10-40, higher scores indicating more frequent staff to staff communication.
17	Staff Perceptions About the Feasibility of the LifeBio Memory Program Protocol	7-items were developed (rated on a 1 = strongly disagree to 5 = strongly agree response scale) and administered on the follow-up post-evaluation to understand staff's perceptions about the feasibility of the program protocol once interviews were complete and materials (i.e., Action Plans, Life Story books, Snapshots) were delivered (e.g., Within the first 2-weeks of delivery, I was able to present the residents' Action Plans during a team meeting"). Possible scores range from 7 (minimum) to 35 (maximum). Higher scores indicate higher feasibility with the implementation of program materials.

4.2 Secondary outcomes (Residents & Staff)

- MMSE, Staff knowledge of resident life stories and care preferences.

	Title	Description of Secondary Outcome Measures
18	Change in Mini Mental Status Examination (MMSE) From Baseline	Screening for resident cognitive status, scores can range from 0-30, lower scores indicate more cognitive impairment (higher scores indicate less cognitive impairment).
19	Change in Staff Adequate Knowledge of Residents' Care Preferences From Baseline	1-item asked of staff for each resident they interviewed on a scale of 1 = not at all well, to 5 = extremely well ("How well do you know the resident's care preferences?")
20	Change in Staff Adequate Knowledge of Residents' Life Stories From Baseline	1-item asked of staff for each resident they interviewed on a scale of 1 = not at all well, to 5 = extremely well ("How well do you know the resident's life story?")

4.3 Other Prespecified (Staff)

	Title	Description of Other Pre-specified Outcome Measures
21	Length of Time Staff Spent on LifeBio Memory Training	Item related to staff time spent on LifeBio Memory training

22	Preparedness Of Staff Conducting Life Story Interviews	Staff self-rated preparedness to conduct life story interviews with residents and set up their accounts following training; two 1-item survey questions rated on a scale from 1 = strongly disagree to 6 = strongly agree. Higher score on each item means stronger agreement towards feelings of being prepared to conduct a life story interview with a person living with dementia using the LifeBio Memory app and setting up their account using the LifeBio Memory app.
23	Staff Training Needs Being Met With LifeBio Memory Training	Staff overall feelings of needs being met with the LifeBio Memory Training Program. Staff were asked, "Overall, how well does the LifeBio Memory App training meet your needs?" On a scale from 1 = not well at all to 5 = extremely well.
24	Staff Objective Knowledge of LifeBio Memory Training Content	Staff completed an 11-item quiz post-training (tested on content detailed in the training videos). It was a multiple choice type quiz, and average score represents total number of correct items on the quiz. Scores could range from 0 to 11, with the staff ranging from 5-items correct to 11-items answered correctly. Higher scores indicate higher number of quiz items answered correctly.

5. Statistical Considerations

All analyses will follow a prespecified Statistical Analysis Plan and adhere to best practices for exploratory behavioral and clinical research. Analyses will be conducted in SPSS (Version 28.0.1.1), with syntax retained to ensure reproducibility. Statistical tests will be two-sided at $\alpha = 0.05$, with 95% confidence intervals reported alongside p-values. Given the exploratory nature of the study and multiple outcomes, effect sizes (Cohen's d for t-tests, partial η^2 for ANOVA, Pearson's r for correlations) will be emphasized in interpretation.

Primary analyses will focus on pre - post changes within residents and staff, with paired-samples t-tests used for continuous outcomes and descriptive summaries for program-specific measures. Secondary and exploratory analyses will include additional intervention specific and knowledge outcomes, as well as subgroup analyses when applicable. For all parametric tests, assumptions of normality, homogeneity of variance, and linearity will be assessed, and nonparametric alternatives will be applied if assumptions are violated.

Finally, due to the exploratory study design, no formal multiplicity correction will be applied. However, results will be interpreted with caution, emphasizing consistency across outcomes and practical/clinical significance. Transparency will be maintained by reporting all prespecified outcomes, documenting handling of missing data, and providing effect sizes alongside inferential statistics.

5.1 General Principles

All statistical analyses will adhere to standard practices for clinical and behavioral research and will be conducted in a reproducible and transparent manner.

5.1.1 Analysis Software

- All analyses will be performed using IBM SPSS Statistics Version 28.0.1.1.
- Syntax will be retained to ensure reproducibility.

5.1.2 Significance Level and Confidence Intervals

- All hypothesis tests will be two-sided with a significance threshold of $\alpha = 0.05$, unless otherwise justified (e.g., exploratory analyses).
- 95% confidence intervals (CIs) will accompany point estimates for all primary and secondary outcomes to convey precision.

5.1.3 Effect Sizes

- Effect sizes will be reported for all inferential analyses to complement p-values and provide practical significance:
    - Cohen's d for paired or independent-samples t-tests
    - Partial η^2 for ANOVA or repeated measures designs
    - Pearson's r for correlations
- Effect size interpretation will follow conventional thresholds (small, medium, large) and be considered in context of the exploratory nature of the study.

5.1.4 Analysis Populations

- Complete-case: Analyses restricted to participants with no missing data on the outcome of interest.

5.1.5 Assumptions and Model Checks

- For parametric tests (t-tests, ANOVA, Pearson correlations), assumptions of normality, homogeneity of variance, and linearity will be evaluated using:
    - Shapiro–Wilk test and Q–Q plots (normality)
    - Levene's test (homogeneity of variance)
    - Scatterplots (linearity for correlations)
- If assumptions are not met, appropriate nonparametric alternatives will be considered (e.g., Wilcoxon signed-rank test, Spearman correlations).

5.1.6 Interim Analyses

- No interim analyses are planned due to the exploratory and short-duration nature of the LifeBio Memory project.

5.1.7 Reporting Conventions

- All results will include sample sizes (n), descriptive statistics (mean, SD, median, IQR as appropriate), p-values, 95% CIs, and effect sizes.
- Any deviations from the pre-specified analyses will be documented and justified.

5.2 Missing Data

Procedures for handling missing data will follow published guidelines for patient-reported outcome (PRO) measures and psychometric scales.

- Item-level missingness for composite scales:
    - If a participant is missing more than 50% of the items on a given measure, no total score will be calculated and the case will be excluded from that outcome analysis.
    - If less than 50% of items are missing, the participant's total score will be calculated using mean substitution at the item level. Specifically, the individual's mean score across available items will be imputed for missing items, and the total score will be computed based on the expected number of items in the scale.
    - This approach is consistent with recommendations for handling missing items in multi-item questionnaires where internal consistency is expected (Enders, 2010; Fayers & Machin, 2016).
- Examples of application in this study:
    - UCLA Loneliness Scale (3-item short form): If 2 or more items are missing, no total score will be calculated. If 1 item is missing, the mean of the two available items will be substituted.
    - Resident Satisfaction with Care Scale (8 items): If ≤3 items are missing, the individual mean will be substituted for missing items; otherwise, the score will not be calculated.
    - Quality of Life–AD Scale (13 items): If ≤6 items are missing, mean substitution will be applied; otherwise, the score will not be calculated.
    - CES-D 10-item form: If ≤5 items are missing, mean substitution will be applied; otherwise, the score will not be calculated.
- Dataset-level handling:
    - No advanced imputation methods (e.g., multiple imputation, maximum likelihood) are planned due to the modest sample size and exploratory nature of the project.
- Documentation:
    - All imputation procedures will be implemented in SPSS using standard syntax with explicit commands.
    - All decisions about missing data will be logged, and final datasets will be archived with accompanying metadata to preserve transparency.

Citations

- Enders, C. K. (2010). *Applied Missing Data Analysis*. New York: Guilford Press.
- Fayers, P. M., & Machin, D. (2016). *Quality of Life: The Assessment, Analysis and Interpretation of Patient-Reported Outcomes* (3rd ed.). Wiley.

- Little, R. J. A., & Rubin, D. B. (2019). *Statistical Analysis with Missing Data* (3rd ed.). Wiley.

5.3 Descriptive Statistics

- All study variables will first be summarized descriptively to characterize the sample and provide context for subsequent analyses.
- Continuous variables (e.g., age, MMSE scores, CES-D, QoL-AD) will be summarized using means, standard deviations (SDs), medians, interquartile ranges (IQRs), and ranges, as appropriate. Normality assumptions will be assessed visually (histograms, Q–Q plots) and statistically (Shapiro–Wilk test).
- Categorical variables (e.g., gender, education) will be reported as counts and percentages.
- Baseline characteristics will be summarized separately by participant type (resident, staff), and group-level comparisons will be presented descriptively only (i.e., no inferential tests for baseline balance given the non-randomized design).

5.4 Primary Analyses

- The primary analyses will evaluate pre–post changes within residents and staff across the outcomes of interest.
    - Residents: Paired-samples *t*-tests will be conducted comparing baseline (T1) and 4-week (T2) scores for:
        - Center for Epidemiologic Studies Depression Scale (CES-D)
        - Quality of Life in Alzheimer's Disease (QoL-AD)
        - Cohen-Mansfield Agitation Inventory (CMAI)
        - Loneliness scale
        - Satisfaction with Care measure
    - Staff: Paired-samples *t*-tests will be conducted comparing baseline and 4-week scores for:
        - Staff attitudes toward persons living with dementia
        - Dementia care competence
        - Job satisfaction
        - Individualized Care Inventory (ICI) subscales
        - Person-Centered Care Assessment Tool (PCCAT)
    - Program-specific outcomes: Descriptive statistics and paired-samples *t*-tests will summarize outcomes related to satisfaction with the LifeBio program, feasibility of implementation, and training outcomes (e.g., perceived preparedness, confidence in using LifeBio).
    - For all paired *t*-tests:
        - Results will be reported as mean differences with standard deviations, t-statistics, degrees of freedom, p-values, and 95% confidence intervals.
        - Effect sizes (Cohen's *d*) will also be reported.
    - In cases where normality assumptions are substantially violated, nonparametric alternatives (Wilcoxon signed-rank test) may be considered and reported as sensitivity analyses.

5.5 Secondary Analyses

- Secondary analyses will explore additional outcomes not designated as primary but still relevant to the LifeBio Memory project.
    - Residents: Mini-Mental State Examination (MMSE) scores will be analyzed using paired-samples *t*-tests (baseline vs. 4 weeks).
    - Staff: Knowledge of resident life stories and personal preferences will be analyzed using paired-samples *t*-tests.
    - Exploratory analyses: Where appropriate, subgroup analyses (e.g., stratification by site) will be conducted to explore heterogeneity of effects. These analyses will be treated as exploratory and interpreted with caution.
- Results will be reported consistently with the primary analyses, including p-values, 95% confidence intervals, and effect sizes.

5.6 Multiplicity

- Given the exploratory nature of this project and the inclusion of multiple outcomes, formal adjustment for multiplicity (e.g., Bonferroni or Holm corrections) will not be applied. Instead, the following principles will guide interpretation:
    - Primary vs. Secondary Outcomes: If designated, primary outcomes will be the main focus of interpretation. Secondary outcomes and subgroup analyses will be considered hypothesis-generating.
    - Subgroup and Sensitivity Analyses: Comparisons across subgroups (e.g., completers versus non-completers, site-level differences) will be viewed as exploratory and interpreted cautiously.
    - Interpretation Strategy: Results will be evaluated in terms of effect sizes, 95% confidence intervals, and the consistency of findings across related measures, with attention to clinical and practical significance.
    - Transparency: All pre-specified outcomes will be reported regardless of statistical significance to minimize selective outcome reporting.

5.7 Subgroup Analyses

- Baseline Comparisons Between Groups
    - To assess whether participants who completed the study protocol differ from those who did not at baseline, independent samples t-tests will be conducted for all continuous baseline outcome variables (e.g., MMSE, agitation, quality of life, depression, loneliness, satisfaction with care).
    - Assumptions: Levene's Test for Equality of Variances will be used to assess homogeneity of variance. If assumptions are violated, the t-test results under "equal variances not assumed" will be reported.
    - Effect Sizes: Cohen's d will be calculated to estimate the standardized mean difference between groups. Effect sizes will be interpreted as small (~0.20), medium (~0.50), and large (~0.80).
    - Significance Threshold: All tests will use two-tailed significance testing with $\alpha = .05$.

6. Data Management

All study data will be managed to ensure accuracy, integrity, and confidentiality, in compliance with institutional policies, NIH/NIA guidelines, and Good Clinical Data Management Practices (GCDMP).

[All study data will be captured in a secure electronic format at the Benjamin Rose Institute. To ensure accuracy, double-entry verification will be performed, and any data queries will be documented and resolved prior to analysis. Before analysis begins, all datasets will be de-identified to protect participant confidentiality.]

6.1 Data Capture

- Data will be collected in a secure electronic format using the Benjamin Rose Institute on Aging's approved data systems, with access restricted to authorized study personnel only.
- Where paper case report forms (CRFs) or checklists are used in the field, data will be entered electronically by trained study staff within 5 business days of collection.

6.2 Data Entry and Verification

- A double-entry process will be used for quantitative data to minimize transcription errors.
- Automated range checks and logic checks (e.g., impossible dates, out-of-range scores) will be built into the data entry system to prevent invalid entries.
- Data queries will be generated automatically or manually by the data management team and documented in a query log. Queries will be reviewed and resolved by the study coordinator or PI prior to database lock.

6.3 Data Cleaning and Quality Control

- Regular data quality checks will be conducted (e.g., completeness, consistency across timepoints, adherence to allowable ranges).
- Any modifications to the dataset (e.g., corrections, imputations) and collected surveys will be documented with date, rationale, and responsible staff initials to maintain a full audit trail.
- Interim datasets may be produced for monitoring, but final analyses will only be performed after database lock.

6.4 Confidentiality and De-Identification

- All datasets used for analysis will be de-identified by removing direct identifiers and replacing participant IDs with unique study codes.
- A master linking file will be stored separately on a secure, access-restricted server and accessible only to the PI and designated data manager.
- All electronic data will be stored on encrypted, password-protected servers that comply with institutional IT security standards.

6.5 Data Retention and Archiving

- Study data will be retained for at least 7 years after completion of the study, consistent with institutional policy and NIH requirements.

- At study closeout, data will be archived in a secure format, with clear documentation of file structures, variable definitions, and metadata to support future re-use if permitted.
- If applicable, de-identified datasets may be shared with NIH data repositories (e.g., NIA-approved archives) following sponsor and IRB approval.

6.6 Data Access and Oversight

- Access to the data will be role-based, with permissions granted according to study responsibilities.
- A data manager will oversee ongoing data integrity, maintain audit trails, and ensure compliance with this SAP.
- Any breaches or irregularities will be reported to the PI and IRB per institutional policy.

7. Quality Control

Quality control procedures will be applied throughout the study to ensure accuracy, reliability, and adherence to protocol.

- Training and Standardization: All staff involved in data collection and entry will receive standardized training, with refresher training provided as needed.
- Ongoing Monitoring: The data manager will conduct routine checks for completeness, timeliness, and consistency. Discrepancies will be logged, investigated, and resolved in collaboration with the PI.
- Audit Trail: All data modifications will be documented with date, rationale, and staff initials.
- Pre-analysis Review: Prior to database lock, a final quality review will be conducted, including verification of key variables against source documents, reconciliation of missing data, and confirmation of resolution of all outstanding queries.
- Documentation: A QC log will be maintained to document all procedures performed, issues identified, and corrective actions taken.

These measures ensure that all analyses conducted under this SAP are based on high-quality, reliable data.

8. Reporting

- Results reported according to **CONSORT extension for non-randomized trial**
- Tables/Figures will include:
    - Participant flow (CONSORT diagram)
    - Baseline characteristics (by staff/resident)
    - Pre-post outcome tables (means, SDs, p-values, effect sizes)
    - Subgroup analyses where applicable.

8.1 Reporting Standards

- Results will be reported in accordance with the CONSORT 2017 extension for non-randomized trials and best practices for transparent reporting of clinical and implementation studies. Reporting will also comply with ClinicalTrials.gov

requirements, including timely submission of summary-level results within 12 months of study completion.

8.2 Planned Tables, Figures, and Listings (TFLs)

The following tables and figures will be included in study reports and publications:

- Participant Flow: A CONSORT-style diagram summarizing enrollment, exclusions, intervention completion, and analysis populations (staff and residents).
- Baseline Characteristics: Tables summarizing demographics, cognitive/functional characteristics, and relevant staff/resident attributes by study group.
- Pre–Post Outcomes: Summary tables of primary and secondary outcomes, reporting means, standard deviations, sample sizes, p-values, and effect sizes (Cohen's d).
- Subgroup Analyses: Where applicable, outcomes stratified by relevant subgroups (e.g., completers of the intervention versus non-completers).
- Supplementary Figures: Graphical displays of key outcomes over time (e.g., line graphs, bar charts).

8.3 Statistical Summaries

- Continuous variables will be reported using means and standard deviations (or medians and interquartile ranges, as appropriate).
- Categorical variables will be reported as counts and percentages.
- All hypothesis tests will be reported with p-values and 95% confidence intervals.
- Effect sizes will be presented for primary and secondary outcomes.
- Missing data will be summarized by frequency and percentage.

8.4 ClinicalTrials.gov Reporting

- Results will be uploaded to ClinicalTrials.gov following registry requirements.
- Only summary-level data will be reported (no individual-level data).
- Pre-specified outcomes from the protocol and SAP will be included to ensure consistency and transparency.
- Adherence to reporting timelines will be maintained in compliance with NIH/NIA expectations.

8.5 Transparency and Deviations

- Any deviations from the pre-specified analysis plan will be documented, justified, and reported in both the ClinicalTrials.gov results submission and any manuscripts.

- Protocol deviations (e.g., exclusion due to missing >50% of composite variables) will be summarized in tabular form.
- Harms/adverse events (if applicable) will be reported descriptively.

8.6 Dissemination

- Findings will be disseminated in peer-reviewed publications, presentations at national conferences, and summary reports for participating sites and stakeholders.
- Supplementary materials (e.g., detailed statistical outputs, additional tables/figures) may be provided in online appendices.
- No individual participant data (IPD) will be shared outside the study team unless required by the sponsor or IRB.