Title: Life Story Book With Mentally Alert Residents of Nursing Homes

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FULL PROTOCOL TITLE: The Effectiveness of Life Story Book on Depression and Meaning in Life for Mentally Alert Residents of Nursing Homes

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1.0 Objectives

The purpose of this research is to test quantitatively the effectiveness of the Life Story Work (LSW) intervention, with a book product (LSB), for reducing depression and increasing meaning in life (MIL) for mentally alert nursing home (NH) residents.

The overall objective is to improve the quality of life for residents of NHs by determining whether the LSB intervention will have a greater and longer lasting effect compared with care as usual (i.e., decreased depression and increased meaning in life).

Hypothesis I LSB will lead to greater reductions in depressive symptoms than care as usual.

Hypothesis II LSB will lead to a greater increase in MIL than care as usual.

My central hypothesis, formulated from my preliminary research, is that the LSB intervention will improve the quality of life for mentally alert NH residents and will have longer lasting effects than care as usual. If effective, it may offer a non-pharmacological intervention for improving care and quality of life for NH residents.

2.0 Background

Depression and lack of MIL are major concerns for residents of NHs. Residents have been shown to be at an increased risk for depression [1], [2]; with approximately 50% having a diagnosis of depression [3]. Although nearly half of NH residents are diagnosed with depression, depression still remains poorly recognized because it often co-occurs with other chronic medical conditions [3].

The consequences of depression can be devastating for residents which include decreased physical, cognitive and social functioning, greater self-neglect, and an increased risk of morbidity and the risk of suicide [4], [5]. In addition, untreated depression may result in the development of, or the worsening of, medical conditions [6].

Meaning in life has been shown to be a protective factor against depression [7]. Whereas a decrease in MIL has been shown to also have a relationship with deterioration of physical health, cognitive decline, and mortality [8], [9].

Pharmacological interventions for depression are the strategies that are typically used to treat depression in NHs. Furthermore, antidepressant medications have been shown to increase an older adults' risk for falls [10] and despite the many other undesirable side effects for older adults, they are often the first line of treatment for depression [11].

NH policies and programs have emphasized a medical model of care that has focused on quality of care and pharmacological interventions [12]. Unquestionably, quality of care is extremely important, but quality of life is also critical to health [13], [14], and non-pharmacological psychosocial interventions are often undervalued [15]. This common, long-standing practice of using antipsychotic medications is causing serious harm to these frail older adults [16], [17]. The Centers for Medicare & Medicaid Services has led a nationwide directive to reduce the use of antipsychotic medications [18].

The personalization of interventions that allow for exploring autobiographical memories, such as the reminiscence intervention LSB has been shown to have significant effects on depression and psychological well-being.

LSB is a reminiscence intervention designed to provide a person with the opportunity to review their past and capture their life story into something tangible. It involves another person listening and assisting the person to review and sometimes evaluate their life [19].

Each life story is recounted in chronological order, from childhood to their current age, and involves compiling the person's history, stories, information, photographs, texts, memorabilia, into something tangible [20], [21], [22]. This tangible product is then a reminder or visual aid of the individual's life history.

LSB's premise is that every person has a story - a personal history - with events, people, circumstances, actions, feelings, insights, thoughts, learning, and milestones that define who they are [23], [20], [24].

Previous studies for LSB for persons with dementia reported positive outcomes on aspects of cognition and mood [25], [26]. However, there is a gap in the literature regarding the effects of LSB on depression and MIL for residents of NHs who are mentally alert [27], [28]. Mentally alert residents of NHs, who make up almost 50% of the population of NHs, also need effective interventions that maintain their health and well-being.

Improving quality of care and quality of life for older adults living in NHs, while reducing the use of pharmacological interventions, is a critical need [18]**.** The proposed research has the potential to provide a non-pharmacological psychosocial intervention for reducing depressive symptoms and increasing meaning in life for mentally alert nursing home residents. This research is aligned with the mission of National Institute on Aging to support research related to the problems and needs of older Americans and to develop effective interventions that maintain their health and well-being [29]**.**

3.0 Inclusion and Exclusion Criteria

Two Medicare and Medicaid certified NHs, located in Harris and Fort Bend Counties, and freestanding, or ones that are not a part of a hospital or a continuing care retirement community, will be invited to participate in this research.

Residents of the two selected NHs, ages 57 and older and who have the ability to speak English, will be invited to complete an eligibility screening to participate in this study. Eligibility will be determined using the Six-Item Screener (SIS), as measured by a score of 4 or higher for cognitive impairment.

The Six Item Screener (SIS) was specifically developed from the Mini-Mental State Examination (MMSE) to screen subjects for cognitive ability to participate in research studies. The SIS was found to have good test-retest reliability (.705), internal consistency (.82) and sensitivity (.90) [29]. The scale is unobtrusive, only takes 1-2 minutes to complete and can easily be incorporated into the initial eligibility assessments [30]. (*Please see attached screener*).

Exclusion criteria will consist of residents who scored less than 4 on the SIS, indicating cognitive impairment; individuals who do not speak English; and individuals who are not residents of the participating NH.

4.0 Vulnerable Populations

Mentally alert residents of the two NHs are eligible to participate in this study with safeguards included to protect the welfare, safety, privacy and confidentiality of this vulnerable population.

The NH administration will assist in identifying potential participants, but the research team will assure the residents that participation is completely voluntary, and that refusal to participate will not compromise their relationship with the staff or their care.

Due to institutionalization residents are more susceptible to coercion. There is the potential that residents may feel that they cannot refuse participation when asked by staff, due to the fact that residents depend upon that staff for food shelter, health and social services [31]. Again, assurances by the research team will be made that participation is completely voluntary and that they may decline participation.

Using the SIS for screening eligibly also ensures that the participants have the cognitive ability to understand what will happen in the research, what risks may be involved, and that participation is voluntary. In addition, the research team will conduct all eligibility screening in private and the results of the SIS will be kept confidential and will not be shared with the potential participant or the NH staff. Potential participants who do not meet the inclusion criteria will be informed that for this study they are not eligible. No identifying information will be collected from them.

All scoring of instruments administered will be kept confidential and will not be shared with the NH staff.

Residents may have hearing or vision problems and may therefore require more time to have the study explained to them. Information flyers and informed consents will be read to the residents, along with using larger font.

Although this population is vulnerable, this research proposes minimal risk and will directly benefit participants in providing them with a life story book of their own and has the potential to reduce depressive symptoms and increase MIL.

5.0 Number of Subjects

Two nursing homes will be recruited for comparison of LSB with care as usual. A power analyses for a MANOVA, with 2 groups and 2 dependent variables, was conducted in G*Power Version 3.1.9.2 [32] to determine a sufficient sample size. Using an alpha (α) of .05, and a large effect size of d = .94 [33], a sample size of 20 could achieve a power of 95% to detect between group differences.

Prior research in long-term care facilities indicates that oversampling by 15-20 percent is an efficient way to deal with attrition. This study will recruit 24 residents, or 12 residents per NH, to ensure a sample size of 20. From these two NHs, a minimum of 20 NH residents (10 per NH) and a maximum of 24 NH residents (12 per NH) will be recruited.

6.0 Recruitment Methods

Upon IRB approval, the two NHs will be contacted by telephone and email to provide follow-up information about this research study, its objectives and their role in recruitment. (*Please see attached*). A meeting will be scheduled with the request to meet as many of the NH's management team as possible. For these face-to-face meetings informative flyers with background information and simplified research procedures will be provided. (*Please see attached).* In addition, every effort will be made to recognize the NH's contribution to the study including: a plaque for participation, a presentation of the results of the study, and an LSB toolkit donated for continued use with other residents. This toolkit will include: portable scanner, scrapbook albums, audio recorder, USB flash drives and pad and pens.

NH administrators will be asked for the name of a staff member who might serve as an on-site point of contact. This site coordinator would be the research team's point of contact for scheduling, data collection and other communication between the research team, participants and the facility. NH staff have many demands for their time, so this site coordinator will be offered a stipend of $300.00; $150.00 halfway through the data collection (or at post-test 1) and $150.00 when the data collection is complete (or at post-test 2).

Non-probability voluntary sampling method will be used to recruit participants from these two NHs. The NH administration, together with the PI, will identify potential participants. If there is an active resident council at the NH, this group may be contacted in order to introduce the study and recruit potential participants. Every NH, certified by Medicare and Medicaid, must provide a space for councils to meet. Resident councils are a group of residents that meet on a regular basis to discuss concerns, provide suggestions and plan activities for the NH [34].

Additional information meetings will be arranged, as needed, with the assistance of the NH administration, to describe the study and to answer residents', staff, and any family members' questions. (*Please see attached information flyer).*

7.0 Multi-Site Research Communication

N/A

8.0 Study Timelines

- (1) Eligibility screening – 10 minutes
- (1) Initial visit, consents, study overview and instruments 60-90 minutes

- (5) Intervention visits – 60-90 minutes
- (1) Potential visit for NH-B if any edits were required to their LSB 30-60 minutes

Total maximum time for participation after screening = 10 hours

Immediately upon IRB approval, recruitment will begin and will continue until a minimum of 10 and a maximum of 12 from each NH are recruited (Total for both NHs- 20 minimum and 24 maximum). The intervention will begin as soon as recruitment levels are met. Transcription will begin after the first LSB visit and will continue until all LSBs are complete. The intervention will take 10 weeks to complete. At the conclusion of all data collection and transcription activities, data analyses will be conducted. We anticipate that that we will be able to conduct the intervention within four months following IRB approval. Primary analyses should be completed within six months following IRB approval. (*See attached timeline).*

9.0 Study Endpoints

This is a minimal risk study. There are no safety endpoints given, because there are no safety risks associated with the study.

10.0 Procedures Involved

Study Design:

A quasi-experimental switching replication design will be employed to examine the effects of LSB on depressive symptoms and MIL for residents of NHs who are mentally alert by comparing post-test scores, while controlling for pretest scores. Two comparable NHs will be randomly allocated to NH-A or NH-B, indicating which home will begin LSB first, whereas the other home will receive care as usual. Participants in the same NH will receive the same intervention. A summary of the design is as follows:

Nursing Home A (NH-A):	Pretest	LSB	Post-test	CAU	Post-test
Nursing Home B (NH-B):	Pretest	CAU	Post-test	LSB	Post-test

(CAU = care as usual)

Both NHs will eventually receive the LSB intervention, which will provide another opportunity to test outcome measures and allow for two independent implementations of the LSB intervention. This is one of the more ethically feasible designs because all participants will eventually receive the intervention. Furthermore, the additional post-test for NH-A, after one month, will examine the lasting effects of the LSB intervention.

Description of all research procedures being performed and when they are performed:

After identifying potential participants, private informational meetings with the research team which will include the PI and two research assistants -will be conducted with each potential participant where initial screening, using the SIS, will be administered by the PI. (*Please see attached screening script/tool*). If the resident is eligible, and would like to participate, the research team will further explain the study, including the length of the study-10 weeks with six visits, length of the visits 1- hour, three weeks with no visits, and the measures that will be

collected. Full disclosure and written consents will be explained with plenty of time for any questions or clarification before consent forms are signed. The consent form will include the purpose, procedures, risks and costs of participating in the LSB. Again, there will be no costs for participating in the study and the research team will receive no monetary income from the LSB. In addition, the LSB will be the property of the participant, along with any scanned photos or stories written. This will be signed by each participant, each RA, and the PI. A copy of the consent form will be given to each participant. Additional information will be provided for those participants who would like to request their family's cooperation to secure photos and/or memorabilia. (*See attached information sheet).*

Although the recruitment of participants is for mentally alert residents, if they have given durable power of attorney to others, it may be necessary, per their NH regulations, to obtain informed consent from their designated durable powers of attorney [35], [36], [37]. The durable power of attorney will be contacted, permission sought, and the consent form signed. The consent form will also include an agreement that the LSB ownership will be with the participant. [38] A copy of the consent form will be given to the durable power of attorney.

Participants will be notified for scheduling of the LSB intervention, by their preferred method of notification, once recruitment is completed. When participant recruitment levels are met, the research team will contact the participants to schedule their first visit. LSB visits for all participants will begin the same week.

Potential participants who do not meet the inclusion criteria will be informed that for this study they are not eligible. No identifying information will be collected. They will also be informed that a presentation of the study results will be presented at their NH at a later date, to which they are invited to come and hear the results.

Two RAs will be randomly assigned six participants from each of the two NHs. Each will conduct individual LSB sessions with these six participants per NH, or twelve from both homes.

For the first visit, all 24 participants will be individually visited by the PI and the RA assigned to those participants. Each RA will only visit those participants whom they will be providing the intervention. An overview of the study will be reviewed, as well as information regarding the number of visits and length of time for each visit (1 hour). This first visit will also be a time for the participants to get acquainted with their RA. Participants will review the consent form signed in the initial screening interview which will include the purpose, procedures, risks and costs of participating in the LSB, as well as the protection of confidentiality from the RA and the PI. They will also be reminded of their rights as participants. The participants, at the beginning of each visit, will be told that they can stop and rest at any time or may reschedule the session if they become too fatigued to continue.

The PI will administer all measures face-to-face on a tablet, which will include the MLQ and the GDS-12R. In addition, the PI will collect orally from the participants their demographic information and their functional status (Katz ADL) onto a tablet.

At this first visit, a written reminder card will be given to each participant with the date, time and contact information of their RA and their next scheduled visit. (*Please see attached*). Scheduled visits will be done at the most convenient time for the participant with careful consideration of scheduled activities, i.e. meals, naps, medicine. All future visits will be scheduled at this time, with the understanding that the RA will be flexible to the needs of the participant.

NH-B participants will be scheduled for post-tests in 4 weeks, which will include repeating an overview of the study, including the number of sessions and length of time for each session. A written postcard will be given to each participant with the date, time and contact information of their RA for their scheduled post-test. A follow-up postcard will be sent to the participant each week until week # 4, when a reminder phone call will also be made by their RA the day before their visit is scheduled. Until that time, the resident will continue to receive care as usual in their NH.

Description of the Intervention:

Life Story Book. LSB provides a person the opportunity to chronologically share their life experiences and memories [25]. The LSB will include a combination of written information, photographs of significant people, places or events, and personal narratives from the stages of life that the participant would like to include.

The duration of the intervention will be three-1-hour visits, not including the visits for the pretest and the post-tests measures collected, for a total of five visits. Each visit will begin with the RA assessing the environment and the participant's needs, making sure that the participant can hear and see the RA, and that the seating arrangement is comfortable before beginning. Assessing the environment will include: assessing for privacy, lighting, noise level, temperature and seating arrangement [39]. It will be important to monitor the participant's needs for any other difficulties assessed that may need to be tended to and adjustments or accommodations made. This is crucial to adequately accommodate the older adults' needs. Again, the RAs will remain flexible in regard to the length of time per visit for the sake of the older participants. For example, two 30-minute sessions may be used, as could rescheduling for health issues, or other creative ways to accommodate the needs of the participant as much as possible.

Each resident will be guided by their RA through memories of their life using extracted questions from the Life Review and Experiencing Form (LRF) created by Haight & Haight and based on Erik Erikson's life stages model [39]. (Please s*ee attachment)*. The purpose of using these questions from the LRF is to achieve some structure for gathering memories across the life span; beginning with childhood and adolescence, moving onto family, home and finally adulthood and a summary of the life review [39]. Reviewing life from childhood until the present enables the participant the opportunity to think about recalled and reconstructed memories, related facts and significant experiences [39]. Birren & Cochran suggest [21] reminding the older adult of their five senses-touch, sight, taste, hearing and smell- for obtaining details of a story; for example, at a holiday event was their food? Dancing? Singing? While the RA will have the list of questions to guide the participant through life stages, they will use the questions as prompts or suggestions. The RA will listen closely and respond to the participant while encouraging the participant to

lead the dialogue and continue talking and recalling [21], [39]. Participants will be free to decline to answer any questions.

The RA will act as a scribe but will also use an audio recorder. The use of an audio recorder will free the RA up to listen attentively and respond appropriately to their participant's stories. Audio recording will also aid the RA in accurately writing their participant's stories. A professional transcriber will be hired to assist, as needed, for transcription of stories.

Any pictures and/or memorabilia chosen by the participant will be scanned at the NH using a portable scanner. This will ensure that no photos and/or memorabilia are removed from the participants' NH. The research team will print (using a portable printer) and insert these photos into the participant's LSB. The RA may help the participant to create a short caption, in the participant's own words, to be placed under each photo. Again, the resident's family may be contacted, with the approval of the resident, to assist with the collection of newspaper clippings, photographs, and/or other memorabilia. Substitute photos of relevant places may be located on the internet by the RA as requested or needed. For example, a picture of their high school located and printed for their book.

After post-test measures are administered, when the LSB is completed, both the participant and their RA will review the book, obtain clarification and/or corrections and remove anything the participant would rather not have in their book, and finalize the details of the book. The participant will own their own LSB and will have the final say of what is, or is not, included [19], [40]. To ensure that the LSB can be added to and updated, an expandable scrapbook album will be used with additional blank pages added. This also reflects that a person's life story is never finished [41]. If there are corrections to be made, the book will be corrected and returned to the participant as soon as possible.

All audio files will be destroyed immediately after transcription.

A presentation of results will be scheduled where each nursing home will receive a plaque and life story kit for participating in this research. The presentation will include the components of videotaping and/or photographs. A supplemental informed consent form indicating preference to be video recorded and/or photographed at the presentation of results, including a UH Media piece, will be obtained by those participants willing to be identified as participants. Every effort will be made to ensure that participants know this is completely optional and would nullify their previous research consent form signed, in which it was stated that they would not be identified as participants

What data will be collected, including long-term follow-up?

At the first visit the PI will administer the following instruments in face-to-face interviews with each screened participant. Residents' characteristics measures will include socio-demographic data and a functional status survey. The socio-demographic data that will be collected for each participant will include: year born, gender, marital status, level of education, ethnicity, religion, and length of residence in the NH. (*Please see attached instruments).*

Katz Index of Independence in Activities of Daily Living (ADLs) will be administered in order to assess the functional status of the participant's ability to perform activities of daily living independently. This tool is one of the most commonly used tool to measure an older adult's functional status. The Index ranks the adequacy of performance in six areas of function: bathing, dressing, toileting, transferring, continence, and feeding. Persons are scored yes/no for independence in each of the six functions. A score of 6 indicates full function, 4 indicates moderate impairment, and 2 or less indicates severe functional impairment. The instrument is used effectively among older adults in the community and all care settings. This is a scale of the six activities of daily living *[42]*.

Geriatric Depression Scale (Residential) (GDS-12R) is a shortened version of the 30item Geriatric Depression Scale which has been shown to effectively distinguish depressed from non-depressed older adults *[43]*. In 1986, a short form of 15-items (GDS-15) was developed for older adults, from the original 30-item questionnaire, primarily for brevity and for use with older adults with health issues or those with dementia. It was found to have a high correlation with depressive symptoms in previous validation studies *[44]*. Three items were found to not be reflective of residents of nursing homes and these three were omitted from the GDS-15 to create the GDS-12R, which increased the alpha from .76 to .81 *[45]*. The GDS-12R was found to have good internal consistency and test-retest reliability *[45]*. It is a self-report scale of depressive symptoms and uses a yes/no format. The scale measures how the person has felt during the previous week and usually takes 5 to 7 minutes to complete, making it ideal for older adults in residential facilities. Scores ≥ 5 are significant for depressive symptoms *[46]*.

Meaning in Life Questionnaire (MLQ) will be used to measure MIL. Steger et al. MLQ *[47]* has two subscales which assess the presence of meaning (how much a person feels their life has meaning) and the search for meaning (how much a person strives to find meaning and understanding in their life) *[48]*. The two-subscale measure consists of 10 items on a 7-point Likert scale, ranging from 1-absolutely true to 7-absolutely untrue: five items for presence of meaning and five items for search for meaning. This questionnaire has been shown to have high convergent and discriminant validity and has been tested across age, gender, race, and national groups *[47]*, *[48]*. The MLQ questionnaire does not have cut off scores like the Geriatric Depression Scale, but based on numerous studies, a score > 24 indicates a person feels their life has meaning and purpose *[48]*.

The GDS-12R and MLQ will be administered by the PI at three times; pre-test, post-test 1, and post-test 2. These measures will be administered orally to each participant and answers recorded by the PI on a tablet.

One open-ended feedback, qualitative, question will be asked of participants at post-test 2: "What did you think of the experience of participating in Life Story Book?" This question will be documented in writing with no names or ID numbers recorded.

(See attached intervention table/timeline).

11.0 Setting

An IRB modification will be submitted once the nursing homes' information and letters of cooperation are obtained.

The interventions will be conducted at the nursing homes.

12.0 Drugs or Devices

N/A

13.0 Risks to Subjects

We will be administering instruments regarding mood. Participants may experience mild psychological discomfort. The Life Story Book intervention may result in some temporary mild psychological discomfort while discussing the past. The instruments will be administered by a Licensed Master Social Worker. In addition, both RAs will be trained and supervised by the PI on skills for working with older adults-including gauging physical capabilities and the handling of disturbing memories.

An additional foreseeable risk of fatigue for participants may occur during the intervention. The plan for minimizing the fatigue risk is to let the participants, at the beginning of each visit, know that they can stop and rest at any time or may reschedule the session if they are too fatigued to continue. The research team will be extremely flexible and attentive as to adjusting intervention times, assessing for fatigue, being watchful for pain or other symptoms.

Participant risk will be further reduced by conducting the intervention in the NHs which are providing physical and psychological services to the participants.

Although every effort will be made to conduct the intervention in private, there is also the potential risk to the privacy for the participants as other residents or NH staff may hear the stories they are relaying.

There is a minimal risk of violations of confidentiality associated with all research studies. However, safeguards have been established to protect participant confidentially.

Inconveniences for participants will be closely monitored. Scheduled visits will be done at the most convenient time for the participant with careful consideration of scheduled activities, i.e. meals, naps, medicine.

Residents are members of residential communities and their involvement in a study may have implications for other members of the community [31]. One way to address this is to provide a LSB toolkit that can be used by the NH to enable other residents the same opportunity to make their own LSB. A toolkit containing all of the essentials needed for making LSB and will be donated to each NH after the study is completed.

14.0 Potential Benefits to Subjects

Participants will receive a Life Story Book for participating, even if the participant ends participation before all data collection has finished. What has been recorded will be inserted into their own Life Story Book album. Participants will receive the benefit of having their own Life Story Book.

Furthermore, potential benefits participants may experience is lower depressive symptoms and increased meaning in life.

15.0 Provisions to Monitor Data to Ensure the Safety of Subjects

This is a minimal risk study.

16.0 Withdrawal of Subjects

Participants may withdraw from the study at any time without risk of loss of receiving a book, even if it is blank, or only partially full of their stories. Participants will receive their Life Story Book even if they are unable, or choose to stop participation, and/or not complete all measures. For example, if after one or two visits of sharing their life stories, a participant chooses, or is unable to complete the intervention, what has been shared will be transcribed and their LSB will be compiled and given to them.

Individuals whose health is compromised, per advice of NH medical staff, will be withdrawn from the study. The research team, if possible, will advise the participant and have some closure. If appropriate, a book will be given to them, even if it is blank.

17.0 Costs/Payments to Subjects

There are no costs for participating. Participants will receive their own Life Story Book at no cost to them.

Participants will sign documentation to verify that they have received their LSB. This documentation will be kept in a locked file separate from all de-identified study data so that no identifying information could be linked back to participation in this study. (*Please see attached form).*

18.0 Compensation for Research-Related Injury

N/A

19.0 Confidentiality

Provisions will be made to protect all identifiable data in order to protect the privacy and maintain the confidentiality of all participants from recruitment to maintaining the data. These provisions will include the confidentiality of residents who did not meet the eligibility criteria; de-identification of each participant with a study number; a database created and files secured with passwords used only by the research team; components of the study data will be kept in a locked file cabinet; the research team will be well trained in how to maintain participant

confidentiality; and the research team will have completed the required CITI training on ethical conduct of research. To ensure privacy, written agreements between the research team and the participants will be signed to ensure that no stories will be included in their LSB that do not have the express permission of the participants. The LSB will belong to the participant and any information or stories shared will not be disclosed to families or staff to protect the participant. (*Please see attached)*.

Paper Documentation of Screeners, Study Instruments and Receipt: Eligibility screeners, consent documents, and documentation for receipt of the completed LSB will contain participants names (not ID numbers), and they will be kept separate from all other study information in a locked filing cabinet in the PI's office (345A SOCW). The code book with the name and the ID number of the participant will be kept in a separate locked filing cabinet in SOCW room 333, and will be destroyed following data collection. Completed study instruments will only contain the participants' ID number and will be kept on an encrypted and password protected file on the UH SharePoint site. Any data or documentation relating to this study will not be accessed by anyone but the research team.

Each participant will have a participant folder generated on a password protected file on UH OneNote where their transcriptions, notes, photos and/or memorabilia will be stored. The research team will edit and organize the text into a cohesive narrative while adding any photos to the narrative. The research team will make every effort to ensure that the facts are correct and verified with the participants with a first draft before a final printing of their LSB. If the participant would like to have an electronic copy in addition to their book, the research team will copy their LSB folder onto a USB flash drive and give that to the participant with their book.

Audio Recordings: The LSB intervention visits will be audio recorded and members of the research team will transcribe the interviews. A professional transcriber will be hired, as needed, to help with the transcriptions. After transcription, the audio files will be destroyed.

Intervention Notes: LSB intervention notes, that each RA has written, will be used to add to, or supplement, interview audio recording transcripts. Once these notes have been added to, or used to verify transcriptions, the notes will be destroyed.

Scanned Photos and/or Memorabilia: All photos and/or memorabilia will be scanned onto a microSD card which has the participant's ID number on it. This microSD card will be uploaded onto the password protected file folder of the participant on the UH OneNote site. The microSD card will then be wiped clean**.**

Qualitative Question: The answers from the one open-ended qualitative question will be documented in detailed notes and recorded onto a spreadsheet with no identifiable information.

Video recorded and/or photographed for media: There will be a presentation of the results of the study for all participants, nursing home residents, family members, and staff. Participants who would like to be identified as participants and video recorded and/or photographed will have

the option to indicate their agreement on a supplemental consent form.

20.0 Provisions to Protect the Privacy Interests of Subjects

Participants will be provided with some examples of the *Life Review and Experiencing Form* questions as part of the informed consent process; in addition to the purpose of the study and the necessity of disclosing some personal information. This will be clearly explained as part of the consent process. Participants will be informed that only the research team will have access to the LSB intervention transcripts and survey instruments. Participants will also be informed that they can refuse to answer any question or withdraw from the study at any time, without penalty, and without giving a reason for withdrawing from the study.

All survey instruments will be administered by the PI, a licensed master social worker who has experience working with older adults in nursing homes. The LSB intervention will be conducted by two social work/medical professionals who will be provided training, by the PI, for working with older adults in nursing homes. In addition, participants can ask questions about their participation in the research process at any time.

21.0 Informed Consent Process

Once a potential participant is deemed eligible for participation, and agrees to participate, they will be informed that prior to participation an informed consent is required. A member of the research team will obtain the informed written consent and provide a copy of the consent document with the contact information for the PI and the University of Houston IRB. Although no measures for obtaining ongoing consent will be obtained, the consent form will be reviewed at the first visit of the intervention and again at posttest 1. This protocol will be following the SOP: Informed Consent Process for Research.

Adults Unable to Consent

As stated in the procedures, it may be necessary, per the NH requirements, to seek consent from durable powers of attorney. Although the recruitment of participants is for mentally alert residents, if they have given durable power of attorney to others, it may be necessary to obtain informed consent from their designated durable powers of attorney. Many residents execute a health care plan, including a durable power of attorney when they enter a NH and appoint a family member or someone to act on their behalf if they lack decision-making capacity. If necessary, a member of the research team will meet with the durable power of attorney to explain the research study and obtain written consent.

22.0 Process to Document Consent in Writing

This study will follow the SOP: Written Documentation of Consent (HRP-091). (*Please see the attached informed consent document).*

Supplemental consent form for media piece at presentation of results *(Please see attached supplemental consent form).*

23.0 HIPAA

N/A

24.0 FERPA

N/A

25.0 Data Management

Data will be analyzed using IBM SPSS Version 25 [49] and a multivariate analysis of covariance (MANCOVA) will be performed. Descriptive analysis will be conducted to describe participants, including demographic characteristics and their functional status (ADL). Demographic variables will be assessed with t-tests for independent samples (continuous variables) and chi-squared (categorical variables) to determine baseline differences. Prior to conducting the main analysis, data will be evaluated to ensure that assumptions for multivariate tests are fulfilled, including normality, linearity, univariate and multivariate outliers, homogeneity of variance-covariance matrices, and multicollinearity. Data will be inspected for any errors in data entry and for any missing data. Any reasons for withdrawal from the study and the loss to follow-up will be recorded.

A one-way MANCOVA will be performed to test for differences between the experimental group (LSB) and the control group on the 2 outcome measures (GDS-12R and MLQ), while using pre-test scores as covariates. Main effects from pre-test to post-test in both groups will be examined. To look at long term effects, repeated t-tests will be conducted at post-test 2.

Thematic analysis of the qualitative question will be conducted by the research team to identify themes in the data concerning the experience of participating in LSB.

Only the research team will have access to the encrypted and password protected database on which the study information will be stored. All members of the research team will be trained in appropriate data management techniques and the importance of maintaining confidentiality of data. All data will be inputted by the PI and then independently reviewed for accuracy by another member of the research team.

Eligibility screeners, consent documents, and documentation for receipt of the completed LSB will contain participants names (not ID numbers), and they will be kept separate from all other study information in a locked filing cabinet in the PI's office (345A SOCW) until after the study where they will be scanned and kept on an encrypted and password protected file on SharePoint, and maintained by my faculty advisor.

The code book with the name and the ID number of the participant will be kept in a separate locked filing cabinet in SOCW room 333, and will be destroyed following data collection.

Completed study instruments will only contain the participants' ID number and will be kept on an encrypted and password protected file on the UH SharePoint site. Any data or documentation relating to this study will not be accessed by anyone but the research team.

Study transcripts will be de-identified with only the participant's ID number and will be maintained for a period of three years, per UH policy, following the conclusion of data collection, in an encrypted and password protected file on SharePoint, and maintained by my faculty advisor.

The PI will obtain a copy of the study data and documentation, with no identifiable information, on an encrypted CD

All data management procedures were more fully described in the previous section on 'Confidentiality'.

26.0 Specimen Use and Banking

N/A

27.0 Community-Based Participatory Research

N/A

28.0 Sharing of Results with Subjects

The PI contact information will be provided on the informed consent form if participants wish to receive a written copy of the study results.

In cooperation with each NH, a presentation of the study results will be scheduled. Each participant will be sent a personal invitation to this scheduled event.

As detailed in the 'Recruitment Methods' section, every effort will be made to recognize the NH's contribution to the study including: a plaque for participation, the presentation of the results of the study, and a LSB toolkit donated for continued use with other residents.

29.0 Resources

The Graduate College of Social Work (GCSW) is one of fourteen academic colleges at the University of Houston. Founded in 1967, it is a nationally recognized graduate social work program and offers multiple pathways to earn a Master of Social Work degree through traditional, online or hybrid study. Its accredited program offers a range of academic courses, field practicum, numerous community projects, international experiences and five research centers. The College is housed in its own four-story building on campus and includes twenty-four full-time faculty and fifteen adjunct faculty.

The principal investigator, Theresa C. Chrisman has over 10 years of experience working with older adults living in nursing homes and in the community. She is currently licensed as a Licensed Master Social Worker (LMSW), specializing in gerontology. In addition, she is also certified in Reminiscence and Life Story Work. Theresa is currently a doctoral student and has defended her dissertation proposal. She will be working under the guidance of Dr. Allen Rubin at the University of Houston Graduate College of Social

Work. In addition to overseeing the study, Theresa will serve as the eligibility screener and collector of all instruments.

Rubin Allen, PhD, is a Professor of Social Work | Jean Kantambu Latting College Professorship of Leadership and Social Change at the University of Houston. He is an expert on evaluating interventions and disseminating results to practitioners into how to practice guidelines. Dr. Rubin is a well-known and respected expert in the field of social work research and education. He has authored or co-authored over 100 publications in diverse areas. He is the lead author of the bestselling research textbook, Research Methods for Social Work that has been adopted by approximately 40 percent of schools of social work, every year since 1989, and is in its ninth edition. He will serve as a consultant on this study.

Sarah Narandorf, PhD is an Associate Professor of Social Work at the University of Houston. As a licensed clinical social worker, Dr. Narandorf has provided direct clinical interventions to vulnerable populations. In addition, she has developed interventions and is actively involved in promoting research among social work students. She will serve as a consultant on this study

Cheryl Brohard, PhD is an Assistant Professor at the University of Houston College of Nursing and named a 2018 Salute to Nurses Top 15 winner. She has served as an oncology nurse for 37 years and is certified in gerontology. In addition, Dr. Brohard is a certified instructor for Reminiscence and Life Story Work. She will serve as a consultant on this study.

The two NHs that will be recruited will be described upon their consent and letters of cooperation will be obtained. The NHs will be comparable on the following five aspects: number of long-stay residents, overall quality rating, staff rating, type of ownership (private, public or government) and facility size. Each of the NHs participating in this study will have a minimum of 85 residents. According to the Vital Statistics report- *Long-Term Care Services in the United States: 2013 Overview*, there are about 49.6% of NH residents who are mentally alert *[3]*. With approximately 50% of NH residents being mentally alert, there will be approximately 42 residents to recruit from the NHs that house 85 residents.

Two social work/medical professionals will be hired as research assistants. Once they are hired, I will submit an IRB modification with their information.

An IRB modification with the two site coordinators information, along with the nursing home letters of cooperation, will be added.

Recruitment will begin immediately upon IRB approval and will continue until the minimum of 10 and maximum of 12 participants from each NH (Total 20 minimum and 24 maximum) are recruited. Transcription will begin immediately after each LSB visit with participants and data will be analyzed after all data collection is complete. We anticipate that we will be able to complete the intervention three months following IRB approval. The LSB intervention and analyses should be completed within six months following IRB approval.

Adequate psychological and/or medical resources are available and can be provided by the NHs for those who may need it as a result of an unanticipated consequence of research participation.

The research team will communicate on an ongoing weekly basis to discuss any issues that may arise so as to ensure successful execution of this research study. All of the key personnel listed in this study have read and understand this protocol.

30.0 Additional Approvals

Letters of cooperation from the two NHs will be obtained and a modification with IRB will be submitted.