

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

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Consent to Take Part in a Human Research Study

Title of research study: The effectiveness of Life Story Book on depression and meaning in life for mentally alert residents of nursing homes. This research is being carried out by a researcher from the University of Houston, Graduate College of Social Work, Theresa Chrisman. This study is a part of a PhD dissertation and being conducted under the supervision of Dr. Allen Rubin.

Key Information: Life Story Book believes 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. The purpose of this study is to find out how Life Story Book affects residents of nursing homes lives. Does it make things better? Or do they stay the same? This study will measure aspects that affect a persons' quality of life. We will do this by asking questions regarding depression and meaning in life.

What should I know about a research study?

- Someone will explain this research study to you.
- Taking part in the research is voluntary; whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide, and can ask questions at any time during the study.

We invite you to take part in a research study about a reminiscence intervention called Life Story Book because you meet the following criteria: mentally alert, over the age of 57 years, and a resident of this nursing home.

In general, there are two nursing homes who will be participating in this study. This is a nine-week study and each participant will be visited six times, for one hour. For three of those visits, a research team member will listen and write

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your life stories. These stories will be typed, and photos and/or memorabilia can be added to create your Life Story Book.

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The primary risk to you in taking part is: There is the possibility of stress or discomfort when talking about difficult feelings, moods or sad memories. If the visits bring up negative feelings that you would like to discuss with the nursing home physical or mental health staff, a referral will be made.

These feelings should be temporary. Your Life Story Book will be yours with all of the life stories you would like to include in it.

Detailed Information:

The following is more detailed information about this study, in addition to the information listed above.

Two similar nursing homes will take part in this study. For the purpose of this study, Theresa will flip a coin to determine which home will be A and which home will be B, which means, whichever home is A will build their Life Story Book first. While one home's residents are receiving Life Story Book, the other home's residents will continue receiving care as they usually do. We will then switch, and nursing home B will receive Life Story Book and nursing home A will continue receiving care as they usually do.

A research team member will ask you questions about different times in your life beginning at your earliest memories. They will have a list of questions, but you do not have to answer any question you do not like. The life stories will be audio recorded, typed, and nicely printed by the research team. The audio recordings will be deleted after they are transcribed into your stories. If you have any photos or memorabilia that you would like to include in your book, these will be scanned at the nursing home and added to your book. No photos or memorabilia will be removed from the nursing home. The book is a fabric covered scrapbook with sleeves to insert your stories and photos.

Why is this research being done?

Depression and lack of meaning in life is a serious problem for many residents of nursing homes. This research is being done to find ways to help these residents without the use of drugs.

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How long will the research last?

We expect this research study to last for nine weeks. You will be visited for a total of 6 one-hour visits.

How many people will be studied? We expect to enroll about 24 people from two nursing homes to participate in this research study: 12 from each nursing home.

What happens if I say yes, I want to be in this research?

You will be visited at the nursing home six times for about 1 hour.

Week 1: You will be visited by Theresa and a research team member. We will review the study and this consent form again and answer any of your questions. We will also ask you some information about yourself and about activities that you are able to do by yourself. We will also ask you a few questions about if you have felt depressed in the last week and some questions about how you feel about your meaning in life.

Weeks 2, 3 and 4: If your nursing home is chosen to go first to receive Life Story Book, you will have three visits by a research team member so that they can listen to your stories. If your nursing home is chosen to go second, you will wait three weeks before we come back to visit you.

Week 5: You will be visited again by Theresa and a research team member so that we can ask you again a few questions about if you have felt depressed in the last week and some questions about how you feel about your meaning in life.

Weeks 6, 7, 8: If your nursing home was chosen to go second to receive Life Story Book, you will have three visits by a research team member so that they can listen to your stories. If your nursing home was chosen to go first you will now wait three weeks before we come back to visit you.

Week 9: You will be visited again by Theresa and a research team member so that we can ask you again a few questions about if you have felt depressed in the last week and some questions about how you feel about your meaning in life.

We will be asking you the following questionnaires:

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1. Questions to assess your ability to perform activities of daily living independently
2. Depression questions about how you felt the previous week
3. Questions about if you feel your life has meaning
4. Questions about your personal information: for example- age, gender, education

During the three visits listening to your life stories we plan to audio record. We will audio record you during the Life Story Book Intervention and transcribe those stories. Audio recording will free the researcher to listen attentively to your life stories and will help the researchers to accurately type up your stories. All audio files will be destroyed immediately after transcribing the stories.

I agree to be audio recorded during the research study.

I do not agree to be audio recorded during the research study.

If you do not wish to be audio recorded, the researcher will just take notes of your life stories and check with you for accuracy.

What happens if I do not want to be in this research?

You can choose not to take part in the research and it will not be held against you. Choosing not to take part will involve no penalty or loss of benefit to which you are otherwise entitled.

A decision to take part or not will have no effect on your routine care.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you.

If you stop being in the research, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me?

Participants may experience mild psychological discomfort. The Life Story Book intervention may result in some temporary mild psychological discomfort while discussing the past. The questionnaires will be administered by a Licensed Master Social Worker. In addition, the research team members will be trained

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and supervised by Theresa on skills for working with older adults-including gauging physical capabilities and the handling of upsetting memories.

You may become fatigued while you are participating. You can stop and rest at any time or may reschedule the visit if you 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 you may be experiencing.

Will I receive anything for being in this study?

You will receive a Life Story Book for participating. We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include lower depression and an increase in meaning in your life.

What happens to the information collected for the research?

Efforts will be made to keep your personal information private, including research study records, to people who have a need to review this information. Each subject's name will be paired with a code number, which will appear on all written study materials. The list pairing the subject's name to the code number will be kept separate from these materials. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the Institutional Review Board (IRB) and other representatives of this organization, as well as collaborating institutions and federal agencies that oversee our research. We may publish the results of this research. However, unless otherwise detailed in this document, we will keep your name and other identifying information confidential.

With all assurances of confidentiality, we may still have to pass on information if it appears that you, or someone else, is at risk of serious harm.

This study collects ***private information with identifiers (such as name, birthdate, etc.).*** Following collection, researchers will remove all identifying information from these ***data.*** Once identifiers are removed, this information could be used for future research studies

We may share and/or publish the results of this research. However, we will keep your name and other identifying information confidential.

Can I be removed from the research without my OK?

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Individuals whose health is compromised, per advice of the nursing home medical staff, may 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.

Research results

When the research is finished, we will come back to your nursing home to talk to you about what we have learned.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you should talk to the research team at University of Houston, Graduate College of Social Work, Theresa Chrisman, Telephone: 713-447-3334 or Email: tcchrisman@central.uh.edu

This research has been reviewed and approved by the University of Houston Institutional Review Board (IRB). You may also talk to them at (713) 743-9204 or cphs@central.uh.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

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Signature Block for Capable Adult

Your signature documents your consent to take part in this research.

Signature of subject

Date

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of Principle Investigator

Date

Printed name of Principle Investigator

Consent to Take Part in a Human Research Study

Signature Block for Adult with Durable Power of Attorney

Your signature documents your permission for the named subject to take part in this research.

Printed name of subject

Signature of legally authorized representative

Date

Printed name of legally authorized representative

Signature of person obtaining consent

Date

Printed name of person obtaining consent