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A Pilot One Group Feasibility, Acceptability, and Initial Efficacy Trial of LISTEN for Loneliness in Lonely Stroke Survivors

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Abstract

Introduction: Loneliness is a prevalent problem for adult stroke survivors, and a known contributor to hypertension, secondary stroke, functional decline, poorer quality of life, and mortality in older adults. LISTEN (Loneliness Intervention using Story Theory to Enhance Nursing-sensitive outcomes), a theoretically based behavioral health intervention designed to target loneliness, in a sample of lonely survivors of ischemic stroke.

Objectives: To assess the feasibility and acceptability of LISTEN (Loneliness Intervention using Story Theory to Enhance Nursing-sensitive outcomes) in lonely stroke survivors and to evaluate the initial efficacy of LISTEN for loneliness, depressive symptoms, neurological quality of life, and blood pressure in a sample of lonely survivors of ischemic stroke.

Methods: The study design was framed using the psychoneuroimmunology paradigm and employed a prospective non-randomized one group design. Six adult stroke survivors were recruited from a Neurology outpatient clinic. Once consented and enrolled, participants attended 5 sequential weekly group sessions of LISTEN. Evaluations, field notes, and video recordings of each session were used to assess feasibility and acceptability of LISTEN. Quantitative data was collected at enrollment and at 1, 6, and 12 weeks post last LISTEN session to assess initial efficacy on loneliness (revised UCLA loneliness scale), depressive symptoms (PHQ-9), neurological quality of life (NeuroQoL), and blood pressure. SPSS was used for descriptive and comparative data analysis to examine within subject changes.

Results: LISTEN was feasible to deliver in the selected clinical setting and participants rated LISTEN as highly useful, organized, and clear with an overall rating as excellent for loneliness. Participants reported significant decline in loneliness and improved scores on three subscales of the NeuroQoL; executive function, positive affect and well-being, and satisfaction with social roles. Recruiting stroke survivors for the trial was time intensive for the study team.

Conclusions: Larger randomized trials of LISTEN in stroke survivors are needed to build evidence for the longer term effectiveness of LISTEN on loneliness, depressive symptoms, and quality of life. Future study designs will include planning to diminish barriers to recruitment.

Keywords

loneliness, stroke, LISTEN

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Introduction/Background

Approximately 1/3 of adults who suffer stroke concurrently struggle with depression (Benjamin et al., 2019) or loneliness (Theeke et al., 2014). Loneliness is a unique psychological construct known to increase risk for depression (Cacioppo et al., 2006), cardiovascular illnesses (Bhatti & Haq, 2017), stroke (Brown et al., 2018), second stroke (Valtorta et al., 2016), and acute

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myocardial infarction (Hakulinen et al., 2018). In a recent literature review of loneliness and chronic conditions, 9 of 10 studies comparing stroke survivors to controls concluded that stroke survivors reported more depressive symptoms and loneliness (Petitte et al., 2015).

There is a lack of well-described interventions for loneliness that have been evaluated for translation to clinical practice. Reviews and a meta-analysis of interventions delivered for loneliness recommended that interventions for loneliness should incorporate a solid theoretical base, strategies to target the maladaptive thinking of loneliness, and group delivery methods (Masi et al., 2011). LISTEN (Loneliness Intervention using Story Theory (Liehr & Smith, 2008) to Enhance Nursing-sensitive outcomes), was developed (Theeke & Mallow, 2015) using the process for complex interventions recommended by the Medical Research Council (MRC) (Craig et al., 2013) for the purpose of targeting loneliness.

The LISTEN Intervention

The conceptual basis of LISTEN is framed using both story theory (Liehr & Smith, 2008) and principles of cognitive restructuring (Sharpe et al., 2012). LISTEN was originally designed to be delivered in group sessions to lonely people, aiming to help people with loneliness reframe problematic thoughts associated with loneliness. Participants of LISTEN attend five sequential 2 hour sessions; each beginning with writing (recording for those that cannot write), followed by exploration of five topics designed to facilitate the transition from thinking about loneliness as insurmountable to a mindset of meaningfulness and solutions. LISTEN has previously demonstrated effectiveness for diminishing loneliness and systolic blood pressure in older adults with chronic illness (Theeke et al., 2016).

Based on the results of the first trial of LISTEN, it was determined that LISTEN has potential effectiveness for diminishing loneliness in survivors of stroke (Theeke et al., 2015, 2016). The overall purpose of this project was to assess the feasibility, acceptability, and initial efficacy of LISTEN on loneliness, depressive symptoms, neurological quality of life, and blood pressure in a sample of lonely survivors of ischemic stroke.

Methods

Design

A longitudinal, non-randomized one group design was employed to accomplish the study purpose.

Research Question

The Research Questions for this study was twofold: 1) What is the feasibility and acceptability of implementing

LISTEN for loneliness in a sample of lonely survivors of ischemic stroke? and, 2) What is the initial efficacy of LISTEN on loneliness in lonely survivors of ischemic stroke? The study had two specific aims with corresponding benchmarks for aim 1 and corresponding hypotheses for aim 2 as follows:

Aim 1. Assess the feasibility and acceptability of implementing LISTEN in a sample of adult survivors of ischemic stroke who are experiencing loneliness. The study team considered the following benchmarks of success: (1) Successful recruitment and enrollment of 20 participants within the first three months, (2) Retention of nineteen participants who would attend all five sessions of LISTEN, (3) Positive feasibility evaluations by members of the clinical team, and (4) Participants rating LISTEN as acceptable therapy for diminishing loneliness.

Aim 2. Assess the initial efficacy of LISTEN for loneliness in a sample of adult survivors of ischemic stroke. For Aim 2, we tested the following hypothesis:

H₁ Participants will report less loneliness, fewer depressive symptoms, enhanced quality of life and will measure lower on systolic blood pressure for within group and within person baseline values.

Sample and Setting

Potential participants were recruited from people who had been discharged from the hospital with a diagnosis of stroke [based on the International Classification of Diseases, Ninth Revision (ICD-9) codes] within the prior 2 years of the study, and who were currently scheduled for ongoing follow-up care at the neurology clinic between July 1, 2016 and January 1, 2017. The clinic was located in Morgantown, West Virginia. Recruitment methods included posters and flyers in the neurology clinic. The sampling goal was for 20 participants. The study took place in the clinical trials research unit (CTRU) located in the West Virginia University Neurosciences Institute. This setting was accessible by public transportation, offered parking and accessibility entrances for people with disabilities.

Inclusion/Exclusion criteria

Interested participants were screened to meet the inclusion criteria of aged 21 or older, loneliness score ≥ 40 on UCLA Loneliness Scale, English-speaking, and able to answer questions without proxy (in person and by telephone). Participants with cognitive impairment (MMSE ≤ 23), loss of spouse within 2 years (to control for grief reaction), illness, or institutional living situation were excluded. The study took place in the clinical trials research unit (CTRU) located in the university

Neurosciences Institute, which offered accessibility for persons with disabilities. Informed consent was sought after establishing that potential participants met the initial basic inclusion criteria and it was required for participation. All study participants signed informed consent prior to participating.

Institutional Review Board Approval

Prior to beginning the study, a letter of approval (protocol 1509861611) was obtained from the West Virginia University institutional review board.

Enrollment and Data Collection Procedures

After meeting inclusion criteria, participants were enrolled and initial pre-intervention (Time 0) data was collected. Subsequent to enrollment, LISTEN groups were conducted weekly for 5 weeks with participants enrolling and participating in LISTEN groups and data collection from January 1, 2017 through April 30, 2017. The LISTEN sessions were delivered by a registered nurse and all sessions were audio and videotaped. Participants received a \$50.00 gift card after completion of data collection at each of four data collection time points (enrollment, 1, 6, & 12 weeks post intervention). Feasibility data was collected 1 week after the final LISTEN session from members of the research team and participants, and acceptability data was collected at data collection time 3 (12 weeks post last LISTEN session) from study participants. The taped sessions were reviewed to assure fidelity to the intervention.

Study Measures

Feasibility and Acceptability. Feasibility data was collected using multi-item Likert surveys and field notes to track responsiveness to advertisements, enrollment, retention, attrition, and missed intervention sessions. Acceptability data was collected on multi-item Likert surveys and responses to open ended questions about the structure and delivery of the intervention.

Descriptive Person Factors

Sociodemographics. Study participants self-reported age in years at time of enrollment, gender, ethnicity, marital status, highest education completed, number of people living in home, annual household income, current employment status, county of residence, duration residing in county, and time to travel to university facility.

Mental Status. Participants completed the Folstein mini-mental status exam at enrollment to verify eligibility for inclusion into the study. (Folstein et al., 1975)

Stroke Recovery Information. Date of stroke, days in hospital, post-stroke use of rehabilitation facility, post-stroke use of nursing home, post-stroke use of stroke support group, current use of caregiver, caregiver relationship, and use of paid caregiver.

Social Support. The Medical Outcomes Survey for Social Support (Cronbach's $\alpha = .97$) was used. This scale includes five subscales: Emotional support, tangible support, affectionate support, positive social interaction, and one additional item for social partner. (Sherbourne & Stewart, 1991).

Activities of Daily Living. The Katz Index of Independence in Activities of Daily Living instrument was used to measure functional ability. (Katz et al., 1970) This scale relies on self-reported abilities for basic (6 questions) and instrumental (10 questions) tasks required for independent living including: hygiene, ambulation, elimination, communication, household management, medicine management, and money management. The scale has been reported as both reliable and valid (Cronbach's $\alpha = 0.94$). (Wallace & Shelkey, 2008) Scores on the IADL range from 10-30 with 10 indicating no assistance needed. Scores on the Basic ADL instrument range from 6-18 with a score of 6 indicating no assistance needed.

Chronic Illness Information. Diagnoses of comorbid chronic conditions were self-reported by study participants.

Structure of the LISTEN Intervention

LISTEN©(Theeke, 2020) reflects a precision health approach to healing loneliness Participants of LISTEN attended five 2-hour sequential weekly group sessions with 3-5 lonely adults who had also suffered stroke within the past two years. Each session includes writing (recording for those who cannot write), group reflection on weekly topics, and homework for the first four sessions. The first session begins with a focus on the need for belonging, and subsequent sessions emphasize relationships, place in community, addressing challenges of loneliness, and exploring what might remedy each individual's personal experience of loneliness. Specific information about LISTEN (version 2) is available through listenforloneliness.com.

Study Outcome Measures

Loneliness. Loneliness was measured using the revised 20-item UCLA Loneliness scale (UCLS) which includes 20 items with Likert scale answers that range from *Never* (1) to *Always* (4) for summed scores that range from 20-80 (Cronbach's $\alpha = 0.96$). (Russell et al., 1978)

Depression. Depressive symptoms were operationalized using the Patient Health Questionnaire-9 which includes 9 questions with 4 point Likert scale answers ranging from not at all (0) to nearly every day (3) for a range of scores from 0 to 27. (Wu et al., 2019) The PHQ-9 has been established to be reliable and valid as a screening tool for major depression in primary care. (Arroll et al., 2010)

Health-Related Quality of Life. The Neuro-QoL was used to operationalize quality of life. This scale includes 13 short forms that measure ability to participate in social roles and activities, anxiety, applied cognition (executive and general), depression, emotional and behavioral dyscontrol, fatigue, lower extremity function, positive affect and wellbeing, satisfaction with social roles and activities, sleep disturbance, stigma, and upper extremity function. The tool has demonstrated reliability, internal consistency, and validity. (Cella et al., 2012; Gershon et al., 2012)

Physical Health Measures. Blood pressure was measured using a calibrated sphygmomanometer.

Data Analysis

Data were analyzed using Statistical Package for Social Sciences (SPSS) version 26.0. Prior to analysis, data were cleaned, seeking outliers, impossible, or missing values. Analysis included data exploration of variables for descriptive information. To assess benchmarks, a process evaluation, field notes, and summed evaluations were critically reviewed. To test *initial efficacy* repeated measures ANOVA and paired t-tests were used to compare within-subject changes at the four data collection time points in loneliness, depression, health related quality of life, and blood pressure. Alpha level for significance was set at 0.10 which is consistent for a pilot study with a small sample.

Results

Sample Description

Table 1 reports sociodemographic information for participants who had all suffered stroke within the 2 years prior to enrollment. There were no gender differences on mean loneliness scores at baseline and neither age nor depressive symptoms correlated with baseline loneliness scores. Five participants were discharged to home after stroke, and one to a rehabilitation facility and nursing home prior to returning home. Participants reported a median of 14 days in hospital (*Range 5-55 days*). Three participants had comorbid hypertension, two reported diabetes, and one suffered arthritis. At enrollment, mean minimal status scores were 29.3 (*SD 1.03*) indicating

Table 1. Sociodemographics [Mean Age 57 (*SD 6.23*), 5 Caucasian].

Variable	Category	N (%)
Gender	Female	3 (50)
	Male	3 (50)
Race	White	5
	Non-White	1
Marital status	Married	1 (17)
	Separated/divorced	4 (67)
	Never married	1 (17)
Education	High school diploma	2 (33)
	Associate's degree	1 (17)
	Bachelor's degree	1 (17)
	Master's degree	2 (33)
Household income (\$/year)	0–\$20,000	2 (33)
	\$30,000–\$40,000	1 (17)
	\$40,001–\$50,000	2 (33)
	\$50,001–\$60,000	1 (17)
Relation of others in home	Spouse	2 (33)
	Nobody, lives alone	2 (33)
	Sibling, children or grandchildren	2 (33)
Employment status	Not employed	2 (33)
	Retired	1 (17)
	Working part-time	1 (17)
	Self-employed	2 (33)

Note. *SD* = standard deviation, Totals may not exactly be 100 percent due to rounding.

normalcy. None were currently attending stroke support groups, diagnosed with depression or anxiety.

Participants averaged a 21 minute (*SD 14.14*) commute to the clinic. One participant reported caregiver needs as provided by spouse and none were privately paying for caregiving. Participants averaged 14.5 (*SD 3.67*) on Instrumental activities of Daily Living (IADL) which indicates mild limitations with transportation, grocery shopping, and phone use. Participants were nearly independent with basic activities of daily living such as bathing with a mean score of 6.5 (*SD 1.22*).

In general, participants reported moderate emotional support with a mean of 19.3 (*SD 5.4*, scale range 7-35). Participants reported low tangible support (mean = 10.33, *SD 5.2*, range 4-20), low affective support (mean = 6.0, *SD 2.8*, range 3-15), and low positive social support (mean = 8.3, *SD 3.2*, range 3-15). When asked if they had someone to do things with (the last question on the social support survey), two participants reported never, 2 reported a little of the time, and 2 reported some of the time.

Feasibility and Acceptability

Recruitment was slow and the desired sample of 20 participants was not achieved. Thirteen inquires resulted in 7 enrollees with one enrollee dropping out after the first

session. The six participants traveled by car or the university personal rapid transit system for study sessions. Three participants missed one session each due to illness. Research team members evaluated LISTEN as feasible to deliver in a clinical setting.

All participants rated LISTEN as highly useful, organized, and clear. Homework assignments were rated as highly useful and length of sessions, number of people in groups, time of day for meetings, and number of meetings were rated as appropriate. The environment was rated as hospitable and the overall experience was rated as excellent. Participants reported comfort with video recording the LISTEN sessions. Participants described LISTEN interventionists as understanding, sympathetic, empathetic, open, honest, down-to-earth, knowledgeable, and compassionate. Two participants described personal difficulty with speaking and person difficulty with trying something new as a potential barrier to participation

Initial Efficacy

Mean loneliness scores at enrollment were very high (mean 54.5, *SD* 5.08). In repeated measures comparisons of mean loneliness scores at baseline and 1, 6, and 12 weeks post last LISTEN session, within subject loneliness scores did not change significantly [$F(3, 15) = 2.028, p = .15, \text{partial } \eta^2 = .289$]. However, in paired *t* testing, mean loneliness scores from enrollment to 12 weeks post-LISTEN changed significantly ($t = 2.04, p = .09$). In addition, mean loneliness changed significantly ($t = 2.744, p = .04$) from 1 week post last LISTEN session (mean 57.17, *SD* 6.24) to 12 weeks post last LISTEN session (mean = 51.83, *SD* 3.43) indicating participants continued to become less lonely.

Mean depression scores indicated moderate depressive symptoms at enrollment with mean scores of 11.83 (*SD* 4.21). In repeated measures testing, mean depression scores did diminish to a score of 8.5 (*SD* 3.8) but this change was not significant. In paired *t*-tests, mean PHQ-9 scores diminished significantly from 6-12 weeks post LISTEN ($t = 2.52, p = .053$).

Participants improved on three subscales of the Neuro-QoL. On applied cognition - executive function, participants reported less difficulty with executive function [$F(3, 15) = 2.848, p = .07, \text{partial } \eta^2 = .363$]. Participants reported enhanced positive affect and well-being [$F(3, 15) = 3.156, p = .056, \text{partial } \eta^2 = .387$] which indicates improvement on concepts such as hopefulness, purpose, meaning, balance, and life worth living. Finally, satisfaction with social roles steadily improved [$F(3, 15) = 3.889, p = .031, \text{partial } \eta^2 = .437$] (see Figure 1).

Repeated measures within subject analysis did not show significant decrease in systolic blood pressure [$F(3, 15) = 2.207, p = .130, \text{partial } \eta^2 = .306$]. However, mean systolic blood pressure decreased from an average of 149 (*SD* 30.62) to a mean of 135 (*SD* 19.86) which is clinically relevant in stroke survivors.

Discussion

Study findings elucidate difficulties with recruiting stroke survivors for this type of intervention in Appalachia. The study team has demonstrated cultural competence for recruiting persons with common chronic conditions such as diabetes in Appalachia (Carpenter & Theeke, 2018) so the recruitment difficulties demand new strategies for recruiting stroke survivors.

The positive feasibility evaluations and high acceptability of LISTEN was consistent with the first pilot of

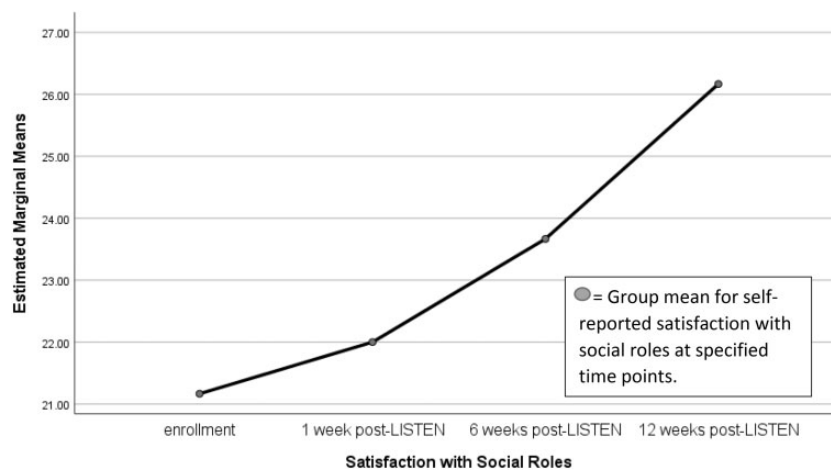


Figure 1. Mean Scores on Satisfaction With Social Roles.

Note. The Neuro-QoL Subscale for Satisfaction with Social Roles has a score range from 10 to 40 with 10 indicating high lack of satisfaction with social roles and 40 indicating high satisfaction with.

LISTEN (Theeke et al., 2015). The efficacious nature of LISTEN provides further evidence that LISTEN is successful as an intervention that targets loneliness (Theeke et al., 2016). LISTEN is rooted in theoretical concepts from story theory (Liehr & Smith, 2008) which likely contributes to its effectiveness as LISTEN honors the individual person's narratives of loneliness.

The high loneliness score of these stroke survivors who concurrently reported relatively low depressive symptoms indicates that it may be important to screen stroke survivors for loneliness. A prior study of 121 stroke survivors in Appalachia indicated similar results with high loneliness scores (Theeke et al., 2014). Knowing that loneliness predicts depression (Wang et al., 2018) makes it logical to infer that addressing loneliness may be one way to prevent the onset of major depression in this population.

For persons who have survived stroke, controlling blood pressure is paramount to the prevention of second stroke. This is the second pilot of LISTEN that has demonstrated a decline in systolic blood pressure which may be an indicator that addressing the problem of loneliness is diminishing the physiological stress response to loneliness and, thereby, contributing to diminished systolic blood pressure. These findings are consistent with the recent review that reported that higher loneliness scores were associated with both higher blood pressure and a reactive inflammatory response (Brown et al., 2018). It is clinically meaningful that the systolic blood pressure at the final study endpoint had diminished to a mean value less than 140 mmHg, as this is the current clinical goal for adequate blood pressure control for persons with acute stroke. (Whelton et al., 2018)

Strengths and Limitations

The small sample size is a significant limitation to the study and diminishes the ability to generalize the study findings.

Implications for Practice

It is important for nurses to consider loneliness, and screen for it when caring for stroke survivors who are struggling with the sequelae of stroke. The three item UCLA loneliness scale could serve as an effective tool for screening in the clinical settings (Hughes et al., 2004). Recognizing and including loneliness in care planning will be the first step for clinical bedside nurses.

Conclusions

Larger randomized trials or comparative effectiveness trials of LISTEN and other interventions for loneliness would provide evidence regarding the longer term

effectiveness of LISTEN on loneliness, depressive symptoms, and quality of life. This project is of translational significance because it establishes feasibility, acceptability, and initial efficacy of LISTEN, an intervention for loneliness, that could be implementable in clinical care of survivors of ischemic stroke who suffer loneliness.

Authors' note

Laurie A. Theeke was inducted last year as a fellow in the American academy of Nursing.

Author Contributions

L. Theeke, J. Mallow, and E. Theeke participated in study conception and design, intervention delivery, data collection, data analysis and interpretation, drafting the article, and revising the article. L. Theeke finalized the manuscript for submission.


Declaration of Conflicting Interests

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