

Protocol

1. Project/Grant Title: Adaptability and Resilience in Aging Adults (ARIAA)-2B

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3. Trial Registration: NCT04068922

4. Abstract: Growing evidence supports the presence of dysregulated pain modulation in older adults, an effect which may heighten age-associated risk for chronic pain. While persistent pain is common in older adults, chronic low back pain is the leading cause of disability in this population and results in significant impairment in psychosocial and physical functioning. Given reports of suboptimal treatment of pain in older adults, improvements in pain management in this cohort are of critical importance. Resilience is characterized as a dynamic process resulting in positive adjustment and adaptation after exposure to adversity. The benefits of resilience in health-related functioning are manifold, and evidence suggests that resilience plays an important role in fostering adaptive physiological and affective responses to pain. Given this, capitalizing on positive resources is a promising target for enhancing pain adaptation, and is especially salient to older adults given the burden of high-impact pain in this group. Therefore, the aim of this project will be to conduct a Stage I pilot study and examine the feasibility and acceptability of a resilience intervention for chronic low back pain among older adults. Using a Science of Behavior Change approach, the proposed study will examine intervention-related benefits in psychosocial and physical functioning, and assess whether changes in targeted resilience mechanisms result in improvement in pain-associated outcomes. Achievement of these aims will provide a rich platform for future intervention research and will forge a path toward investigating psychological therapies of resilience that improve pain and disability among geriatric populations.

5. Background: Chronic low back pain (cLBP) is the leading cause of disability worldwide (1, 2) and represents the most therapeutically-challenging pain condition among older adults (3), affecting approximately 12 million individuals over the age of 65 (4, 5). It is one of the top reasons for seeking healthcare and is frequently associated with impairments in psychological, cognitive, and physical functioning (6-8). Further, evidence suggests that the prevalence of disabling back pain increases with age (9), thus adding to its tremendous disease burden. Because older adults are among the fastest growing cohorts in the United States, both the incidence and burden of cLBP is expected to increase considerably. Despite this, pain management is frequently suboptimal among older adults as pharmacological therapies show limited clinical efficacy and a greater risk of side effects, polypharmacy can result in adverse drug reactions, and multimorbidities common to geriatric populations complicate pharmacological treatment (3). As such, the demand for safe and effective therapeutic targets to reduce pain burden in later life is of critical importance.

Historically, research has been hampered by a predominant emphasis on the exploration of risk factors for chronic pain and relative inattention to identifying protective factors that facilitate optimal pain outcomes. This represents a significant knowledge gap as emerging literature suggests that individuals with chronic pain have the ability to exhibit resilience (10). Conceptualized as a dynamic, multilevel construct, resilience is a process through which dispositional resources (e.g., trait positive affect, social ties) and mechanisms (e.g., state positive affect, positive social interactions) enhance functioning, thereby promoting recovery, sustainability, and growth (11). In essence, resilience is the ability to sustain adaptive functioning despite exposure to adversity. Extant evidence signifies that resilience (and its underlying facets) is associated with attenuated experimental pain sensitivity (12), lower clinical pain and disability (13), and higher levels of psychological functioning (14).

While aging is commonly viewed as a period of frailty, disability, and decline, there is evidence that older adults have the capacity to improve resilience in later life despite ongoing stressors (e.g., pain) (15). Given the rapid growth of the older adult population and the general losses commonly associated with aging, recent years have witnessed a burgeoning interest in promoting adaptive functioning in this population through interventions that augment resilience and successful aging. In the context of pain, this offers advantages over conventional psychological interventions that focus primarily on the reduction of negative symptoms, an approach that does not necessarily lead to optimal functioning. While limited, a growing body of literature supports the use of resilience-based interventions in chronic pain, with positive outcomes observed in affect regulation, clinical pain severity, physical and psychosocial disability, functional performance, well-being, and pharmacological use (16-19). Despite the public health importance of chronic pain in older adults, research examining the effectiveness of psychosocial interventions in this cohort remains limited.

6. Hypotheses and Specific Aims: Chronic pain is one of the leading causes of disability, affecting over 100 million people in the United States and resulting in tremendous health care costs and psychological burden. Older adults are disproportionately impacted by pain, with an estimated 60-70% of people over the age of 65 reporting persistent pain. Given the rapidly expanding aging population, the identification of viable interventions to reduce pain burden in later life is a chief directive. Moreover, in light of the current opioid crisis, initiatives to produce safe and effective nonpharmacological approaches to pain management are urgently needed.

Using a Stage Model approach (20), the primary aim of this study is to examine the feasibility and acceptability of a resilience intervention for chronic pain among older adults. Intervention modules will specifically engage hope, self-efficacy, positive affect, and pain acceptance as these factors demonstrated the strongest relationships with clinical pain, disability, and psychological functioning from the PI's previous work (NIH K99 Award). Chronic low back pain (cLBP) will be the targeted population given that it represents the most debilitating and therapeutically-challenging pain condition among geriatric populations. We will conduct a pilot study to test the feasibility and acceptability of the intervention in this patient population (primary aim), explore whether the intervention engages the proposed resilience targets (i.e., hope, self-efficacy, positive affect, pain acceptance), and assess whether changes in these factors result in improvements in pain outcomes (i.e., NIH Science of Behavior Change approach (21)). Achievement of these aims will provide a strong framework for future intervention research examining mechanisms that promote adaptive health and pain-related functioning in aging populations.

Specific Aim 1: *Conduct a pilot test to examine feasibility, acceptability, and tolerability of a resilience intervention for older adults with cLBP.* We will assess adherence and retention rates, and evaluate ratings of acceptability through brief assessments and eliciting qualitative feedback from participants at post-intervention. **Hypothesis 1.** Individuals in the resilience intervention will report high adherence to and satisfaction with the intervention.

Specific Aim 2: *Assess whether a resilience intervention facilitates improvements in hope, self-efficacy, positive affect, and pain acceptance and whether changes in these processes result in improved pain-related outcomes.* Intervention modules will be adapted from the existing positive psychology literature and validated self-report measures will be used to verify engagement in the specific resilience targets. **Hypothesis 2.** We hypothesize that a resilience intervention will improve pain severity, pain interference, negative affect, and quality of life by increasing hope, self-efficacy, positive affect, and pain acceptance.

7. Research Plan:

General Overview of Procedures. All potential participants will undergo an initial phone screening interview, via telephone or in person. The initial screening will include questions regarding pain, age, and additional health history information to ensure that no exclusion criteria are present. Those who meet study inclusion criteria will also be screened for COVID-19 using the COVID-19 phone screening form. If still eligible, participants will be scheduled for an individual baseline assessment during which informed consent will be reviewed, medical and demographic history will be obtained to ensure eligibility, questionnaires will be administered, and a physical performance battery will be conducted to examine lower extremity function. At the completion of the baseline assessment, eligible participants will be scheduled for a 7-week program (90 min/session) in which participants' complete activities designed to enhance hope, positive affect, pain acceptance, and self-efficacy. Participants will complete weekly home activities and will be asked to bring the home assignments into each session. Participants can miss only one session without making it up or up to two sessions if made up with individual sessions in person, over the phone, or using a PHI Zoom call. Given evidence that intervention effects on pain and psychological outcomes in older adults are strongest when delivered using group-based approaches (relative to an individual format) (22), we have chosen to administer our protocol via groups.

Participants. We will recruit adults, ages 50+ years, from the community and physician referral. To permit sex-stratified exploratory analyses, an equal number of men and women will be targeted (23). Participants must endorse pain in the lower back region (i.e., space between the lower posterior margin of the rib cage and the horizontal gluteal fold) (24), and report pain of a moderate intensity (rating of ≥ 3 on a numeric rating scale ranging from 0-10) occurring on at least half of the days in the past 6 months. Pain must moderately interfere with their daily activities (rating of ≥ 3 on a numeric rating scale ranging from 0-10). In order to generalize results more broadly, study entry will not be restricted to low back pain although participants must identify low back pain as their primary pain condition. Exclusion criteria are as follows: 1) current participation in another psychological treatment; 2) severe psychiatric illness not adequately controlled by medication (e.g., schizophrenia, bipolar disorder) or other conditions anticipated to impair intervention engagement (e.g., substance abuse/dependence); 3) presence of chronic, malignant pain (e.g., HIV, cancer) or systemic inflammatory disease (e.g., rheumatoid arthritis, ankylosing spondylitis, systemic lupus erythematosus, etc.); 4) significant cognitive impairment on the Montreal Cognitive Assessment (25); 5) inability to read and write English; and 6) if currently taking prescription analgesic or psychotropic medication, must be stabilized on these treatments for ≥ 4 weeks prior to the baseline assessment. Participants are also encouraged to refrain from starting any new treatments for pain while participating in the study. These include, but are not limited to, seeing a new chiropractor, physical therapist, massage therapist, psychiatrist, or counselor, taking new opioid medications for pain or receiving epidural or cortisone injections, or using medical marijuana or CBD oil. If a participant begins a new pain treatment during study participation, the study PI will evaluate and decide whether or not it is cause for exclusion. All participants will be required to wear Personal Protective Equipment (PPE) during in-person visits. PPE (masks) will be provided by study staff upon participant arrival or participants may bring their own. If intervention sessions are conducted through PHI Zoom, study staff will ensure participants have access to Zoom as well as a stable internet connection. During Zoom intervention sessions, participants must have access to a working camera and microphone and have them both turned on in order to participate. Study staff will also ask participants if they have access to a space that will provide confidentiality (e.g. not conducting Zoom call where other people may overhear, inform other household members about confidentiality expectations, ensure no identifying information is visible through camera). Zoom tutorials will be provided during the Baseline Session.

Participant payments will be made according to the following schedule: Baseline Assessment (\$60), Intervention Sessions 1-6 (\$20), Intervention Session 7 (\$60), and an additional \$15 for completion of the 3-month follow-up assessment (total max payment=\$255). This is comparable to subject remuneration for studies of similar time commitment and invasiveness at our institution. Participants will receive partial payment if they do not complete the entire study. In addition, for participants traveling more than 25 miles
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each way to complete study visits, we will reimburse some travel expenses at up to the federal mileage rate (total max travel reimbursement=\$300). Payments for participation will occur after completion of each study session and will be handled through the University of Florida's Human Subject Payment Program.

Session 1 (Baseline):

Demographic and Medical History Questionnaire. All participants will complete a through demographic and medical history form. We will assess self-reported duration of back pain, comorbid conditions, and current medication use. This medical history information will be reviewed with the participant by the study PI or other training study staff to ensure eligibility and that items are completed accurately. Health status will also be reviewed with each participant during subsequent study sessions to ensure eligibility.

Vitals/Physical Measurements. Height will be assessed to the nearest cm using a wall stadiometer and body weight to the nearest 0.1 kg using a digital scale. Calculation of BMI will be determined by weight in kilograms divided by height in meters squared. Blood pressure will also be recorded for all participants.

Cognitive Testing. The Montreal Cognitive Assessment (MoCA) (25) is a widely used screening assessment for detecting cognitive impairment. It was validated in the setting of mild cognitive impairment and has subsequently been adopted in numerous other settings clinically. Participants with scores <26 will be excluded from participation as this could interfere with completion of the study intervention. The alternative/Equivalent version of the MoCA (Version 7.2) will be used to decrease possible learning effects when the MoCA (Version 7.1) has been administered within the past 3 months of study participation. This will serve as a safeguard for test-retest effects for participants who may have recently participated in studies requiring the administration of this instrument.

Physical Performance Battery. The Back Performance Scale (BPS) (26) consists of five tests (i.e., sock test, pick-up test, roll-up test, fingertip-to-floor test, lift test) to assess mobility-related activities in individuals with back pain. Each test is scored from 0 to 3, and a total summed score ranging from 0 to 15 is computed (higher scores equal worse functioning).

Sessions 2-8 (Intervention Delivery):

Intervention Procedure. All sessions will be administered by the PI, Co-I, and/or interventionist (masters/PhD level psychologists). Due to COVID-19, intervention sessions (Week 1 – Introduction and Background through Week 7 – Review of Skills and Wrap-Up) may be delivered online through PHI Zoom. To standardize the application of the intervention and ensure treatment fidelity, the resilience intervention is manualized and includes interventionist and client workbooks with materials and handouts for discussion. Client workbooks are written at the 6th grade reading level as measured by Flesh-Kinkaid Grade Level estimates. These intervention workbooks have been reviewed in an earlier phase of this trial (ARIAA 2A), whereby we conducted semi-structured focus groups and key informant interviews with approximately 47 older adults with cLBP to provide feedback on the treatment manual (IRB201802729). Interventionists will be provided with a checklist of procedures specific to each session, and each checklist will be reviewed to ensure treatment adherence. Participants who miss a group visit will be allowed to complete an individual make-up session, with the stipulation that only two missed sessions will be permitted.

Intervention Content. All activities were adapted from the positive psychology literature and selected due to their strong empirical evidence (27-30), ease of completion, and applicability to the targeted resilience constructs. Each session will follow the same format including a review of the previous week's content (i.e., homework review), an overview and discussion of the session objectives including didactic
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in-session activities, and assignment of homework. The intervention will be comprised of the following activities. **Week 1: Introduction and Background.** Participants will be provided with instruction on group therapy guidelines (e.g., confidentiality, respect, privacy), an overview of the purpose and structure of the program, and rationale for the use of resilience-enhancing activities for the management of cLBP. Participants will also be given education on cLBP etiology and symptoms and provided the opportunity to discuss their own personal experiences associated with chronic pain. As a home exercise, participants will be asked to complete a character strengths survey. **Week 2: Pleasant Activities.** During the second session, participants will be given instruction on how to increase the number of pleasant events in their life and will be provided with a list of pleasant activities to choose from (31). For their home practice, participants will be encouraged to engage in three pleasant activities over the week and to record things they are grateful for. **Week 3: Pain Acceptance.** Participants will receive instruction on valued activity, psychological flexibility, and mindfulness-based exercises for enhancing pain acceptance and awareness. A values assessment will be administered to assist participants in identifying important values in their life (32). **Week 4: Hope and Goal-Setting.** Based on Snyder's theory of hope (27), participants will focus on their personal strengths and learn ways in which to create attainable goals through the development of pathways and agency thinking. Participants will be asked to develop a goal that they would like to achieve over the course of the intervention to facilitate hopeful thinking and goal-directed behavior, and to identify areas in their life that inspire hope (33). **Week 5: Positive Events and Reappraisal.** To increase attentional focus on positive events, participants will be taught ways in which to minimize the impact of adverse events and to downregulate negative emotions and thoughts through positive reappraisal (34). As a home-based activity, participants will be encouraged to record, at minimum, one positive event that occurred every day, as well as negative events in which they had to practice positive reappraisal (35). **Week 6: Pain Self-Efficacy.** While it is anticipated that self-efficacy will gradually be fostered throughout the course of the intervention (i.e., skills mastery experiences, feedback on progress, social persuasion through group support), this session will complement ongoing training by targeting problem-solving skills and confidence building, as well as empowering participants to promote adaptive pain management behaviors. Participants will be asked to engage in diaphragmatic breathing as a form of relaxation and to note areas of accomplishment over the course of the intervention (36, 37). **Week 7: Review of Skills and Wrap-Up:** Skills learned in the previous sessions will be reviewed and specific plans for maintenance of resilience activities will be discussed. Participants will also complete post-treatment outcome questionnaires and provide feedback on the intervention program.

3-Month Follow-Up Assessment

Questionnaires will be administered via REDCap approximately 12 weeks after completion of the intervention to be completed online at home. These questionnaires will assess pain intensity and interference, mood, quality of life, and use of intervention materials and skills since the conclusion of the group sessions.

Study Questionnaires:

Several questionnaires will be administered to assess general health, pain-related symptoms, and psychological functioning. In order to distribute participant burden, some of the questionnaires administered during Visit 1 and Visit 8 will be dispensed either during the session or at home between sessions (either via our secure internet-based data collection system [i.e., REDCap] or on paper, depending on the participant's preference).

Measures of Treatment Acceptability. Treatment credibility questions (38) were adapted for the current study as a treatment expectancy measure and will be administered during Visit 1 and Visit 2 consisting of the following items: 1) reasonableness of treatment, 2) willingness to undergo treatment, 3) confidence in recommending the treatment to others, 4) confidence that the treatment will help with pain coping, 5)

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confidence that the treatment will decrease pain, 6) confidence that the treatment will eliminate pain, and 7) expectation for improvement.

The 8-item Client Satisfaction Questionnaire (CSQ-8) (39) will be administered after the intervention as an assessment of treatment satisfaction. Items are rated on a 4-point Likert scale and measure aspects related to the quality of treatment, willingness to recommend the treatment, and general satisfaction with the treatment.

As a treatment evaluation and to better understand their perceptions of the intervention, participants will be queried at posttreatment on their satisfaction with the intervention components, contentment with the structure of the intervention, and recommendations for intervention improvement. Participants will also be asked to indicate the usefulness of each intervention session module and home activity on a 5-point Likert scale ranging from 0 ("not at all") to 4 ("extremely").

Treatment engagement questions were adapted for the current study (40) to assess the participants' effort exerted during group activities, completion of homework, and engagement in group discussions. This questionnaire will be completed by the study therapist upon the completion of every group session for each attendee. A modified version of this scale will also be completed by each participant at the end of every session to assess their perceptions of engagement and interest in the session content. At the beginning of each group session (starting with Visit 3), participants will also be administered a 7-item questionnaire assessing ease and quantity of home activity completion.

Measures of Treatment Fidelity. Therapist adherence to the treatment protocol, appropriateness of the therapist's behavior, and quality of treatment delivery will be assessed using an adapted CT Adherence and Competence Scale (CTACS) (41). Adherence will be evaluated for a randomized selection of 50% of the sessions conducted and reviewed by the study PI and Co-I. Fidelity indicators are measured on a 0 ("poor") to 4 ("excellent") scale, with higher ratings indicative of greater adherence, appropriateness, and quality of treatment delivery.

Psychosocial and Pain Questionnaires. Several measures from the PROMIS short form (24, 42, 43) will be administered to assess self-reported pain intensity, pain interference, physical function, sleep impairment, and emotion (e.g., depression, anxiety). The World Health Organization Quality of Life–Brief (WHOQol-Bref) (44) scale consists of 26 items assessing quality of life over the past week in four domains: physical health, psychological health, social relationships, and environment. The Roland-Morris Disability Questionnaire (RMDQ) (45) is a 24-item self-report measure that assesses health status and disability related to low back pain. Respondents are instructed to indicate which of the statements (e.g., "I stay at home most of the time because of my back") describe their current experience. The 13-item Pain Catastrophizing Scale (PCS) (46) assesses patient report of catastrophic thinking about pain, with scores ranging from 0 (not at all) to 4 (all the time). The Brief Resilience Scale (BRS) is a 6-item questionnaire (47) that examines the ability to bounce back and recover from stress. Items are rated on a 5-point scale (1=strongly disagree, 5=strongly agree), with higher scores indicating greater levels of resilience. The 14-item Pain Resilience Scale (PRS) (48) is a pain-specific measure assessing perceived ability to regulate emotions and cognitions, as well as behavioral and motivational tenacity in the face of intense or prolonged pain. Items are rated on a 5-point scale (0=not at all, 4=all the time). The Modified Differential Emotions Scale (mDES) (49) is a 20-item scale that measures the extent to which positive and negative emotions have been experienced within the past few days. Items are rated on a 5-point scale ranging from 0 (not at all) to 4 (extremely). The Multidimensional Scale of Perceived Social Support (MSPSS) (50) is a 12-item scale with 4 items for each source of support (i.e., family, friends, and a significant other). Each item is rated on a 7-point scale ranging from "very strongly disagree" to "very strongly agree." The Perceived Stress Scale (PSS) (51, 52) is a 10-item measure examining the degree to which situations in one's life are appraised as stressful, with scores ranging from 0=never to 4=very often. The Graded Chronic Pain

Scale (GCPS) is a 7-item measure assessing pain intensity and pain-related disability (53). The Life Orientation Test-Revised (LOT-R) is a 10-item scale measuring positive and negative thoughts about the future (54).

Treatment Target Measures. To assess whether the intervention engages the proposed resilience targets (i.e., hope, self-efficacy, positive affect, pain acceptance), the following questionnaires will be administered. The Adult State Hope Scale (ASHS) (55) taps into state levels of hope. Two subscale scores assessing agency (i.e., sustained movement towards goals) and pathways (i.e., generation of workable routes to goals) thinking are derived, as well as a total score consisting of a sum of these two scales. Pain-related self-efficacy will be examined with the 10-item Pain Self-Efficacy Questionnaire (PSEQ) (56). Scores range from 0 (not at all confident) to 6 (completely confident to undertake an activity), and higher scores indicate a greater level of self-efficacy in the midst of chronic pain. The Positive and Negative Affect Schedule (PANAS) (57) is a 20-item scale assessing positive affect (PA) and negative affect (NA). Items are rated on a 5-point scale ranging from 1 (very slightly or not at all) to 5 (extremely) resulting in scale scores for PA and NA. The Chronic Pain Acceptance Questionnaire (CPAQ) (58) is comprised of 20 items measuring acceptance of pain. This measure has two subscales: activity engagement (i.e., pursuit of life activities regardless of pain) and pain willingness (i.e., disengaging from pain avoidance and control). Items are rated on a 7-point scale (0=never true, 6=always true).

Statistical Methods. The goal of the study will be to target 50 participants for the pilot intervention. Accounting for a conservative 20% attrition rate, we will recruit an additional 10 participants (Total $N=60$). This sample size is feasible and will provide stable estimates of dropout rates, feasibility, and acceptability of the intervention protocol. We anticipate screening an additional 70 participants who may not meet eligibility criteria (i.e., screen failures). **Data Analysis: Specific Aim 1.** The analysis of feasibility, tolerability, and acceptability outcomes will be predominantly conducted with descriptive statistics, with means and standard deviations reported. To assess feasibility, we will calculate a ratio between participants enrolled versus the number of participants commencing treatment. Tolerability will be examined by measuring completion rates (i.e., participants completing all seven sessions of the intervention). Participant acceptability of the intervention will be assessed through treatment credibility ratings and satisfaction with the program (59). Chi-square tests and between-group t -tests will be used to compare group differences in baseline characteristics between completers and participant dropouts. **Specific Aim 2.** To assess change in primary study outcomes (i.e., pain severity, pain interference, negative affect, quality of life), mean differences from pre- to post-intervention will be calculated using paired samples t -tests. Clinical significance of treatment changes will be determined by identifying participants whose raw change score for each outcome variable is greater than one-half of a standard deviation from their baseline score (60, 61). Using residualized change scores (i.e., difference between the post-intervention value with the pre-intervention score covaried out), Pearson correlations will be computed to examine associations between outcome and treatment target change scores.

Data and Safety Monitoring. Because this is not a formal clinical trial, a data and safety monitoring board (DSMB) will not be required. In order to ensure data integrity and safety of human subjects, adverse events reported by participants to staff members or the PI will be recorded on the "Adverse Event and Unanticipated Problems form" developed by the University of Florida's Institutional Review Board. This form requires a description of the event, the course of action taken, and specification regarding whether or not the event was: 1) serious (e.g., life threatening, requiring or prolonging hospitalization, resulting in significant disability/incapacity or death); 2) unexpected (e.g., consistent with anticipated potential risks outlined in the study protocol/informed consent); or 3) causally related to the study interventions/procedures. All serious and unexpected adverse events are to be reported to the University of Florida IRB (within 5 working days) and the study's sponsor. Other types of adverse events will be monitored and reported to the University of Florida IRB in the study's annual progress review.

The investigators will review the reported adverse events on a weekly basis to minimize the risk to the study subjects.

Confidentiality. All trained personnel assisting with the study will be instructed on the importance of protecting participants' confidentiality and will have successfully completed the required education on protection of human research participants. All paper and computer records will be identified only by subject number rather than by name. All study records will be stored in locked file cabinets and will only be available to the PI or other project staff. Computer data files (without subject identifiers) will be stored on computer servers with secure passwords and electronic storage devices will be encrypted. All study records will be stored in locked file cabinets and will only be available to the PI or other project staff. Study staff will be instructed to not record any information (e.g., responses to back pain criteria) obtained during the phone screen. Each intervention group will be audio-recorded (and video-recorded via Zoom) for the evaluation of therapist adherence to the protocol, and a random selection of 50% of all sessions conducted will be reviewed by the study PI and Co-I. No identifying information will be transcribed as the purpose of this digital recording is to assess treatment integrity. Once the audio recordings are reviewed and adherence is discussed with the study therapist, the recordings will be destroyed. Prior to destruction, the recordings will be kept in a locked filing cabinet in the laboratory of the PI. Video recordings via Zoom will only be used to extract an audio file, and video files will be promptly destroyed after each intervention visit.

8. Possible Discomforts and Risks: The risks for this study are minimal and appropriate safeguards are planned and in place to handle risks in a timely and appropriate manner.

Protection against potential risks:

Physical Performance Exam. The back performance test may cause participant discomfort as a result of the exam. The examiner will monitor the response of participants in order to gauge the need to discontinue the exam. Participants may stop at any time.

Questionnaires. Participants will fill out several questionnaires about themselves. While these generally carry no associated risks, it is possible that participants might experience some feelings of discomfort or unease when reading or responding to survey questions that are personal. Throughout each questionnaire, participants will be reminded that participation is completely voluntary, and they can refuse to answer any question or can stop at any time. The PI, Co-I, and study interventionists are psychologists and are trained to deal with depression. Any participants whose responses during the group sessions or on the PROMIS Depression Short Form (raw score ≥ 33) indicate severe psychological distress (such as severe depression) will be interviewed by the site PI, Co-I, or other appropriately trained professionals for suicide risk and risk of harm to self and others. Participants will be assisted to the emergency room if danger is imminent or referred to either their physician or a mental health professional if necessary.

Intervention Integrity. To protect participants and maintain treatment integrity, the PI will thoroughly train research assistants/interventionists on the intervention protocol. The intervention will be manualized to augment treatment fidelity and the study PI will be available for consultation/supervision during intervention sessions and will hold weekly supervision meetings with interventionists to review the protocol and ensure treatment compliance. In addition, the Co-I (Kimberly Sibille) is a licensed clinical psychologist who will be available for consultation/supervision during the intervention sessions.

9. Possible Benefits: While persistent pain is common in older adults, chronic low back pain is the leading cause of disability in this population and results in significant impairments in psychosocial and physical functioning. Participation in this research will provide the participant with a first-hand look at pain research and provide them with the opportunity to participate in a new self-management treatment

for chronic low back pain. Participants who complete the resilience intervention are expected to show improvement in pain severity, interference, negative affect, and quality of life. Overall, it is believed that the data will provide important insight into the effects of resilience-based interventions on clinical pain and functioning. Ultimately, such knowledge may enhance quality of life and reduce pain in the targeted population, as well as lead to advances in the treatment of pain in older adults.

Importance of the Knowledge to Be Gained. Chronic low back pain results in significant impairment in older adults, as well as tremendous individual and societal burden. The data obtained from the current study has the potential to advance treatment strategies for the management of chronic low back pain in older adults and may have broader implications for other medical populations likely to suffer from chronic pain. Moreover, our findings will enhance the understanding of underlying mechanisms contributing to treatment-related effects in our proposed pain and psychological outcomes.

Inclusion of Women and Minorities. Both male and female subjects will be recruited with the goal of equal gender distribution. It is planned that adult minorities (50+ years) will be included in the study sample in proportion to census levels in the Gainesville, Florida community including: 20% African-American, 6% Asian, 5% Hispanic or Latino, and 3.6% More than One Race. To ensure that the study sample includes census levels of minorities, we will assess their representation periodically over the course of the study and adjust recruitment or over-sample as needed.

10. Conflict of Interest: There is no conflict of interest involved with this study beyond the professional benefit from academic publication or presentation of the results.

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