PROTOCOL NUMBER	VERSION	SUBMITTING UNIT	REVIEW BODY	DATE SUBMITTED
IRB-CHRON-2026-011	1.0	Department of Neurology	Institutional Review Board	June 11, 2026

Cognitive Load and Pain Catastrophizing in Adults with Chronic Low Back Pain: A Randomized Crossover Feasibility Study

HUMAN SUBJECTS RESEARCH DOSSIER / IRB REVIEW SYNOPSIS

1. PROTOCOL PURPOSE

This study evaluates whether acute cognitive load tasks modulate self-reported pain intensity and catastrophizing in adults with chronic low back pain, compared with passive rest and distraction control conditions.

Chronic low back pain affects approximately 20% of adults and is associated with significant disability, yet mechanisms linking cognitive engagement to pain modulation remain incompletely characterized. Cognitive load tasks may activate descending pain modulation pathways, but controlled comparisons with matched distraction and rest conditions have not been systematically performed.

2. PRIMARY QUESTIONS

1. Does an acute cognitive load task reduce self-reported pain intensity during the task window compared with passive rest?
2. Does cognitive load differentially affect pain catastrophizing scores compared with distraction and rest conditions?
3. Is the study design feasible and acceptable to adults with chronic low back pain?

3. STUDY THESIS

Acute cognitive load will produce measurable short-term reduction in self-reported pain intensity and catastrophizing relative to rest and distraction controls in adults with chronic low back pain.

A. PROTOCOL SYNOPSIS

Study class	Prospective, randomized, within-subject crossover feasibility study
Population	Adults ages 21-65 with chronic low back pain of at least 3 months duration; N = 36 enrolled; target completers >= 30
Design	Randomized, within-subject crossover
Study arms	Cognitive load task; Distraction control; Passive rest
Session duration	Approximately 60 minutes per visit: 10 minutes baseline, 15 minutes task, 15 minutes post-task observation, 20 minutes questionnaires and debrief.
Primary endpoint family	Change in numeric pain rating scale score from pre-task baseline to post-task; Change in Pain Catastrophizing Scale score from baseline to post-task
Risk level summary	Risks are minimal to low. The study involves questionnaires and computerized tasks with no physical intervention. Participants may experience mild exacerbation of existing pain from sitting. Direct benefit is not expected; knowledge benefit is characterization of cognitive-pain interaction.
Analysis framework	Linear mixed-effects models will evaluate condition, time window, and condition-by-time interaction with participant as random effect.

B. COMPARATOR / ARM LOGIC

Arm	Purpose
Cognitive load task	Tests cognitive engagement effect on pain and catastrophizing.
Distraction control	Controls for engagement and time without cognitive load.
Passive rest	Controls for expectancy and procedural attention.

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IRB Approval Criteria and Submission Map

IRB REVIEW DOSSIER / FULL PROTOCOL COMPILER

A. APPROVAL CRITERIA CROSSWALK

IRB Criterion	Protocol Location	Reviewer Evidence	Closure Test
Risks minimized	Risk closure matrix; procedures; device controls	Mitigations map to each participant exposure	No unmitigated exposure remains
Risk/benefit reasonable	Risk-benefit summary; endpoints	Knowledge value tied to defined outcomes	Risk level matches expected scientific yield
Equitable selection	Population and recruitment	Inclusion/exclusion criteria and recruitment sources	No unjustified targeting or exclusion
Informed consent adequate	Consent process and appendix language	Key information, risks, voluntariness, contacts	Consent covers actual procedures and risks
Data monitoring adequate	Safety monitoring; AE reporting	Monitoring roles, stopping criteria, reporting path	Action thresholds are explicit
Privacy and confidentiality protected	Data governance and HIPAA section	Identifiers, coding, access controls, sharing plan	Identifiable data are segregated and controlled
Vulnerable populations protected	Population exclusions and consent capacity	Special groups excluded or justified	Safeguards match enrolled population

B. REQUIRED PACKET ARTIFACTS

- Full protocol dossier
- Consent form or consent script
- Recruitment material
- Screening checklist
- Adverse event reporting plan
- Data security plan
- Delegation log and training plan

C. CONDITIONAL MODULES

- Device module: Disabled
- Biospecimen module: Disabled
- HIPAA module: HIPAA authorization or waiver will be obtained or documented according to institutional policy.
- Vulnerable population module: see population

D. SUBMISSION STATE

- Protocol version: 1.0
- Review body: Institutional Review Board
- Confidentiality: Investigator draft for IRB review. Not for clinical use.
- PI: [Principal Investigator Name], MD

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Study Design, Objectives, and Endpoint Logic

IRB REVIEW DOSSIER / FULL PROTOCOL COMPILER

1. SCIENTIFIC PREMISE

- Cognitive engagement may activate prefrontal descending modulation pathways that reduce pain salience during task performance.
- Pain catastrophizing amplifies pain experience through rumination and helplessness and may be differentially modulated by cognitive engagement compared with passive conditions.
- A within-subject crossover design allows direct comparison of cognitive load, distraction, and rest conditions while controlling for individual pain sensitivity.

2. DESIGN TYPE

Randomized, within-subject crossover. Washout: >= 48 hours between sessions. Session duration: Approximately 60 minutes per visit: 10 minutes baseline, 15 minutes task, 15 minutes post-task observation, 20 minutes questionnaires and debrief.

3. RANDOMIZATION AND BLINDING

Session order will be assigned by Latin-square counterbalancing. Randomization list generated by biostatistician.

Participants will be informed that the study tests several types of tasks but will not be told the hypothesis. Outcome assessors will use coded condition labels.

4. PARTICIPANT STOP RULE

Any participant may stop a session immediately for increased pain, distress, or request to stop.

A. ENDPOINT HIERARCHY

Tier	Endpoint(s)
Primary	**Change in numeric pain rating scale score from pre-task baseline to post-task** Primary pain intensity measure for within-subject crossover comparison. **Change in Pain Catastrophizing Scale score from baseline to post-task** Primary psychological outcome for within-subject comparison.
Secondary	• Task acceptability and completion rate • Session completion rate • Baseline-to-follow-up pain diary scores
Exploratory	• Correlation between cognitive task performance and pain rating change • Moderation by baseline catastrophizing score

B. ARM PURPOSE MATRIX

Condition	Description	Purpose
Cognitive load task	Validated dual n-back task at moderate difficulty, 15 minutes.	Tests cognitive engagement effect on pain and catastrophizing.
Distraction control	Passive video viewing matched for duration without cognitive demand.	Controls for engagement and time without cognitive load.
Passive rest	Quiet seated rest with no screen or task.	Controls for expectancy and procedural attention.

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Participants, Recruitment, and Consent

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1. TARGET POPULATION

Adults ages 21-65 with chronic low back pain of at least 3 months duration. Sample size: N = 36 enrolled; target completers >= 30.

Recruitment will seek balanced representation by sex and will not target economically or educationally vulnerable groups.

2. RECRUITMENT SOURCES

- Neurology and pain clinic patient panels
- IRB-approved flyers posted in clinic waiting areas
- Institutional volunteer registry

3. CONSENT PROCESS

Consent will be obtained in person in a private clinical area before any research procedures. Participants will receive the consent document, a verbal explanation, time for questions, and confirmation that participation is voluntary and will not affect clinical care.

4. COMPENSATION AND INJURY LANGUAGE

Compensation: $40 per completed session plus parking reimbursement if applicable.

Research injury: No physical procedures are involved. Emergency care will be provided as clinically indicated if distress occurs.

A. INCLUSION / EXCLUSION HIGHLIGHTS

Inclusion	Exclusion
Age 21-65 years	Active psychiatric hospitalization or psychosis
Chronic low back pain >= 3 months duration	Cognitive impairment precluding informed consent or task completion
Average pain intensity >= 3/10 on numeric rating scale in past week	Currently participating in a conflicting pain intervention study
Able to provide informed consent	Scheduled surgery or procedure within the study window
Able to complete computerized cognitive tasks	Inability to sit comfortably for 60-minute session

B. KEY INFORMATION AND COMPREHENSION

KEY INFORMATION

- This is a research study, not clinical treatment.
- Participation involves cognitive tasks, questionnaires, and self-report pain ratings.
- The study will not provide direct pain treatment or benefit.
- Participants can withdraw at any time without affecting their clinical care.

COMPREHENSION CHECKS

- Participant can describe study purpose in their own words.
- Participant can identify that withdrawal will not affect their clinical care.
- Participant understands they will complete three different task conditions.

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Study Procedures and Schedule of Events

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A. VISIT PROCEDURE MAP

Visit	Window	Activities
Screening	Day -14 to Day 0	• Informed consent • Medical history and pain history review • Eligibility confirmation • Baseline questionnaires
Session 1	Randomized condition	• Pre-session pain rating • Baseline questionnaires • Assigned task condition • Post-task pain rating • Post-task questionnaires • Adverse event assessment
Sessions 2-3	Crossover conditions	• Repeat session procedures with alternate conditions • Washout compliance confirmation

B. SCHEDULE OF ASSESSMENTS

Assessment	Screening	Baseline	Task	Post-Task	Follow-Up
Consent and eligibility	X	-	-	-	-
Pain intensity NRS	X	X	X	X	-
Pain Catastrophizing Scale	X	X	-	X	-
Cognitive task / control	-	-	X	-	-
Task acceptability rating	-	-	-	X	-
Adverse event review	X	X	X	X	X

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Participant Exposure and Risk Closure

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1. RISK / BENEFIT POSITION

Risks are minimal to low. The study involves questionnaires and computerized tasks with no physical intervention. Participants may experience mild exacerbation of existing pain from sitting. Direct benefit is not expected; knowledge benefit is characterization of cognitive-pain interaction.

2. ANTICIPATED ADVERSE EVENTS

- Transient pain exacerbation
- Mild fatigue
- Mild emotional discomfort from questionnaire content

3. STOPPING CRITERIA

- Participant requests to stop
- Significant pain exacerbation requiring clinical attention
- Participant distress requiring support intervention

A. EXPOSURE-TO-MITIGATION MATRIX

Exposure	Risk	Mitigation	Monitoring
Sustained seated posture during sessions	Mild transient pain exacerbation	Sessions limited to 60 minutes; participants may adjust position; sessions stopped on request	Pre- and post-session pain ratings; adverse event review
Pain-related questionnaire items	Mild emotional discomfort	Participants may skip items; support resources provided; withdrawal option emphasized	Distress check and participant report
Collection of identifiable health information	Loss of confidentiality	Coded participant IDs; separate storage of identifiers; encrypted research dataset	Data access audit

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Privacy, Confidentiality, and Data Governance

IRB REVIEW DOSSIER / FULL PROTOCOL COMPILER

1. IDENTIFIERS AND CODING

Participants will be assigned coded study IDs. Direct identifiers stored separately in restricted-access file.

- Name and contact information for scheduling
- Medical pain history
- Questionnaire responses linked to participant ID

2. STORAGE AND RETENTION

Storage: Research data stored on encrypted institutional systems with access restricted to approved study staff.

Retention: Data retained per institutional policy then archived or destroyed as approved.

3. SHARING AND HIPAA

De-identified aggregate results may be shared in publications. Identifiable data will not be shared without authorization.

HIPAA authorization or waiver will be obtained or documented according to institutional policy.

A. DATA LIFECYCLE

B. ACCESS CONTROL TABLE

Direct identifiers	Stored separately; restricted to approved personnel
Research dataset	Coded participant ID; no direct identifiers in analysis file
Device/session logs	Linked by study ID; reviewed for safety and signal integrity
Publication outputs	Aggregate or de-identified results only

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Safety Monitoring and Adverse Event Reporting

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1. MONITORING PLAN

The PI or delegated study clinician will review adverse events at each session and following any reported exacerbation.

2. UNANTICIPATED PROBLEMS

Unanticipated problems involving risks to participants will be reported to the IRB per institutional timelines.

3. MEDICAL MONITOR

The PI will serve as medical monitor. Serious events will be reviewed by the PI and department chair.

4. EMERGENCY PLAN

Sessions will be stopped immediately for significant distress or pain exacerbation. Standard clinical escalation procedures will apply.

A. REPORTING PATHWAY

Event Type	Immediate Action	Review / Report
Mild expected event	Document and monitor	Summarize at continuing review
Moderate or concerning event	Pause procedure; clinician review	PI and monitor review
Serious or unexpected related event	Stop study activity; clinical response	IRB report per institutional policy
Device malfunction or data incident	Quarantine / secure system	Deviation or incident report

B. SAFETY ROLE ACCOUNTABILITY

Role	Responsibility
Principal Investigator	Overall study conduct, eligibility review, medical oversight, IRB compliance.
Study Coordinator	Recruitment, consent administration, session scheduling, data collection.
Biostatistician	Randomization, analysis plan, primary statistical reporting.

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Statistical Analysis and Decision Rules

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1. ANALYSIS POPULATION

Participants with at least one completed cognitive load session and one comparator session will be included in primary within-subject analyses.

2. PRIMARY ANALYSIS

Linear mixed-effects models will evaluate condition, time window, and condition-by-time interaction with participant as random effect.

3. MULTIPLICITY AND MISSING DATA

Co-primary endpoints will be tested hierarchically. Exploratory analyses labeled as such.

Missing data documented by reason. Mixed-model analyses under missing-at-random assumptions with sensitivity analysis if missingness exceeds 15%.

A. GO / REVISE / STOP MATRIX

Domain	Advance	Revise	Stop
Feasibility	>= 80% session completion	65-79% session completion	< 65% session completion
Safety	No serious adverse events; no clinically significant pain exacerbation pattern	Manageable non-serious events; minor protocol modifications needed	Serious adverse event possibly related to study procedures
Signal	Detectable condition difference on primary pain endpoint	Directionally consistent but underpowered	No interpretable signal and no feasibility justification for larger study

B. INTERPRETABILITY STANDARD

The protocol advances only when safety remains acceptable and the primary signal is interpretable against the declared comparator structure. Otherwise the recommended output is revision, dose/procedure redesign, or study stop.

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Appendix A. Consent Form Core Language

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A. PARTICIPANT-FACING LANGUAGE

Purpose	You are being asked to take part in a research study about how different mental tasks affect pain and thoughts about pain in people with chronic low back pain.
Procedures	You will complete questionnaires and short computerized tasks during up to three study visits. Each visit takes about 60 minutes.
Risks	Possible risks include mild temporary increase in pain from sitting, mild emotional discomfort from pain-related questions, and a small risk to the confidentiality of your health information.
Benefits	You are not expected to receive direct medical benefit from participation.
Voluntary participation	Taking part is completely voluntary. You may stop at any time and it will not affect your medical care.

B. RECRUITMENT COPY

Adults with chronic low back pain are invited to participate in a paid research study about mental tasks and pain. Up to three clinic visits required. Compensation provided.

C. SCREENING CHECKLIST

- Age confirmation
- Pain duration and average intensity
- Cognitive task ability
- Conflicting study participation
- Upcoming procedures or surgery

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Appendix B. Logs, Forms, and Closeout Artifacts

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A. REQUIRED LOGS

- Eligibility and consent log
- Session attendance log
- Adverse event log
- Protocol deviation log
- Data access log

B. DEVIATION CLASSIFICATION

Class	Example	Action
Minor	Administrative correction without risk impact	Document in deviation log
Major	Procedure outside approved protocol	PI review; report per policy
Safety-relevant	Exposure outside safety limits or consent failure	Immediate pause and IRB notification as required

C. REFERENCE BASIS

- 45 CFR 46 Subpart A - Federal Policy for the Protection of Human Subjects
- OHRP informed consent guidance and FAQs
- Sullivan MJL et al. The Pain Catastrophizing Scale: Development and validation. Psychol Assess. 1995.
- Owen AM et al. N-back working memory paradigm: A meta-analysis. Psychon Bull Rev. 2005.

D. FINAL READINESS CHECK

- All participant-facing language reconciled with protocol procedures.
- All exposures mapped to risks, mitigations, and monitoring.
- All endpoints mapped to study questions.
- All data flows mapped to privacy controls.
- All conditional modules either completed or marked not applicable.