CLINICAL STUDY PROTOCOL

Protocol ID: **MOVE-001/2025** | Version 1.0 | Date: June 15, 2024

Official Title: **Movement-Oriented Velocity of Engagement (MOVE) Protocol**

Sponsor: **MMSx Authority – Institute for Movement Mechanics & Biomechanics Research**

Principal Investigator: **Dr. Neeraj Mehta, Ph.D. (Biomechanics & Alternative Medicine)**

Organization Address: **940 Vauxhill Lane, Powell, Ohio 43065, USA**

Contact Email: **info@mmsxauthority.com**

CLINICAL STUDY PROTOCOL: MOVE-001/2025

Protocol Title: A Prospective, Multi-Site, Interventional Case-Series to Evaluate the M.O.V.E. Protocol for the Management of Acute and Subacute Musculoskeletal Conditions.

IMSO-REG-20251021-PM-6994-A

Prepared by: MMSx Authority Clinical Research Division

Field	Correct Entry	Rationale
Study Start Date	June 2024	The first participant was enrolled.
Primary Completion Date	September 2024	Month the last participant finished follow-up.
Study Completion Date	October 2024	Data cleaning & analysis finished.
Protocol Version Date	17 October 2025	Date the finalized, approved version was signed & archived.
Recruitment Status	Completed	Trial completed at all sites.

Protocol Identifier: MOVE-001/2025

Version: 1.0

Protocol Finalization Date: October 17, 2025

Sponsor:
MMSX AUTHORITY INSTITUTE FOR MOVEMENT MECHANICS & BIOMECHANICS RESEARCH,INC.
940 VAUXHILL LANE POWELL, OH 43065
[6148228038]

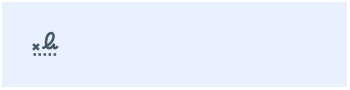
Coordinating Principal Investigator:
Dr. Neeraj Mehta, Ph.D. (Biomechanics & Alternative Medicine)
Founder, MMSx Authority
Global Head, GFFI (India)
ORCID ID: https://orcid.org/**0000-0001-6200-8495**

SIGNATURE PAGE

By signing below, I acknowledge that I have read and understood the protocol and agree to conduct the study in compliance with all its stipulations, Good Clinical Practice (GCP), and all applicable regulatory requirements.

Coordinating Principal Investigator:

_____



Dr. Neeraj Mehta, Ph.D.

Date: _____

ORCID ID: https://orcid.org/0000-0001-6200-8495

Head of Clinical Operations:

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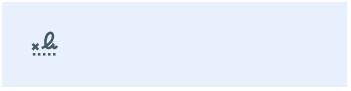

Sunita Mathotra (NIH/GCP)

Date: _____

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1. LIST OF ABBREVIATIONS

AE	Adverse Event
AROM	Active Range of Motion
CFR	Code of Federal Regulations
CI	Confidence Interval
CRF	Case Report Form
DOMS	Delayed Onset Muscle Soreness
ECDF	Empirical Cumulative Distribution Function
GCP	Good Clinical Practice
GROC	Global Rating of Change
HRR	Heart Rate Recovery
HSP	Human Subjects Protection
ICH	International Council for Harmonisation
IMSO	International Musculoskeletal Organisation
IREB	Institutional Review and Ethics Board
ISRCTN	International Standard Randomised Controlled Trial Number
LEFS	Lower Extremity Functional Scale
LOCF	Last Observation Carried Forward
MCID	Minimal Clinically Important Difference
M.O.V.E.	Movement-Oriented Velocity of Engagement
MSK	Musculoskeletal
NIH	National Institutes of Health
NRS	Numeric Rating Scale
ORCID	Open Researcher and Contributor ID
QA	Quality Assurance
RCT	Randomized Controlled Trial
RPE	Rating of Perceived Exertion
SAE	Serious Adverse Event
SD	Standard Deviation
SLS	Single-Leg Stance
SOP	Standard Operating Procedure
STS	Sit-to-Stand
UEFI	Upper Extremity Functional Index
WHO	World Health Organization

2. PROTOCOL SYNOPSIS

Title:

A Prospective, Multi-Site, Interventional Case-Series to Evaluate the M.O.V.E. Protocol for the Management of Acute and Subacute Musculoskeletal Conditions.

Study Design:

A prospective, multi-site, single-arm, interventional case-series with an 8-week follow-up period. This study serves as a feasibility and pilot investigation.

Population:

Adults aged 18–70 with acute or subacute (<12 weeks) musculoskeletal pain of mechanical origin, with a baseline pain score of ≥4 on a 0-10 Numeric Rating Scale (NRS).

Intervention:

The M.O.V.E. (Mobilize, Optimize, Validate, Energize) protocol, a criterion-based, progressive activity and mechanotherapy program delivered over 8 weeks.

Primary Objective:

To assess the feasibility and safety of the M.O.V.E. protocol and to evaluate its effect on pain reduction.

Primary Endpoint:

Change in pain intensity from Baseline to Week 8, as measured by the Numeric Rating Scale (NRS).

Secondary Endpoints:

- Change in function (LEFS/UEFI)
- Change in balance (SLS)
- Change in functional strength (STS)
- Global Rating of Change (GROC)
- Time to return to Activities of Daily Living (ADL)
- Adherence to the protocol
- Incidence of Adverse Events (AEs)

Sample Size:

A pragmatic sample of approximately 40 participants will be recruited across 5 international sites for this feasibility study.

Study Duration:

Each participant will be in the study for 8 weeks.

3. INTRODUCTION: BACKGROUND & RATIONALE

Musculoskeletal (MSK) conditions represent a leading cause of disability worldwide, imposing a significant burden on individuals and healthcare systems. Traditional management for many acute and subacute MSK injuries has often included periods of rest, immobilization, and modalities such as icing (cryotherapy). However, a growing body of evidence suggests that this approach may be suboptimal [1]. Prolonged rest can lead to muscle atrophy, joint stiffness, and impaired neuromuscular control, while the routine use of cryotherapy is being questioned for its potential to blunt the natural inflammatory and regenerative processes essential for optimal tissue healing [2].

This paradigm shift is rooted in the principles of mechanotransduction, the process by which cells convert mechanical stimuli into biochemical responses [3]. Early, controlled loading and movement provide the necessary signals to guide the organization and remodeling of healing tissues, such as collagen fibers in tendons and ligaments. The absence of these mechanical signals can result in disorganized, weaker scar tissue and a delayed functional recovery.

The M.O.V.E. (Movement-Oriented Velocity of Engagement) protocol is a structured, multi-faceted intervention designed to operationalize these modern principles. It represents a departure from the passive, rest-focused model towards an early, criterion-based application of progressive activity. The protocol is built on four interdependent pillars:

1. Mobilize: Initiates early, pain-free movement to reduce arthrogenic muscle inhibition, improve synovial fluid circulation, and maintain neural pathway integrity.

2. Optimize: Applies progressive mechanical loads to stimulate tissue adaptation and remodeling, moving systematically from isometric to complex functional movements based on tissue tolerance.

3. Validate: Focuses on restoring neuromuscular control, proprioception, and balance to ensure that movement quality is high and compensatory patterns are minimized.

4. Energize: Incorporates low-intensity cardiovascular activity to enhance systemic circulation, improve metabolic efficiency, and support the energetic demands of tissue repair and recovery.

This prospective, multi-site case-series (MOVE-001/2025) is designed as a crucial first step to formally evaluate the feasibility, safety, and preliminary efficacy of the M.O.V.E. protocol in a real-world clinical setting across diverse patient populations and international sites. The findings will provide the foundational data required to design future large-scale randomized controlled trials (RCTs).

4. STUDY OBJECTIVES AND ENDPOINTS

4.1 PRIMARY OBJECTIVE

To assess the feasibility of implementing the M.O.V.E. protocol across multiple clinical sites and to evaluate its preliminary efficacy in reducing pain in individuals with MSK conditions.

Primary Endpoint:

Change in Pain (NRS): The absolute change in the 11-point Numeric Rating Scale (NRS) for pain from Baseline to Week 8. A Minimal Clinically Important Difference (MCID) is defined as a reduction of ≥2 points [4].

4.2 SECONDARY OBJECTIVES

- To evaluate the effect of the M.O.V.E. protocol on physical function, balance, and strength.
- To assess patient-reported outcomes of recovery and treatment satisfaction.
- To characterize the safety profile of the intervention.
- To quantify patient adherence to the home-based components of the protocol.

Secondary Endpoints:

- Functional Improvement: Change in the Lower Extremity Functional Scale (LEFS) or Upper Extremity Functional Index (UEFI) score from Baseline to Week 4 and Week 8. The MCID is 9 points [5].

- Balance: Change in Single-Leg Stance (SLS) time (in seconds) from Baseline to Week 8.

- Functional Strength: Change in the number of repetitions completed in the 30-second Sit-to-Stand (STS) test from Baseline to Week 8.

- Global Perceived Effect: Score on the Global Rating of Change (GROC) scale at Week 8.

- Time to Recovery: Time (in days) from enrollment to return to full, unrestricted Activities of Daily Living (ADL) and, for a subset, return to sport.

- Adherence: Percentage of prescribed home exercise sessions completed, tracked via patient logs and verified by clinicians.

- Safety: Incidence, nature, and severity of all Adverse Events (AEs) and Serious Adverse Events (SAEs).

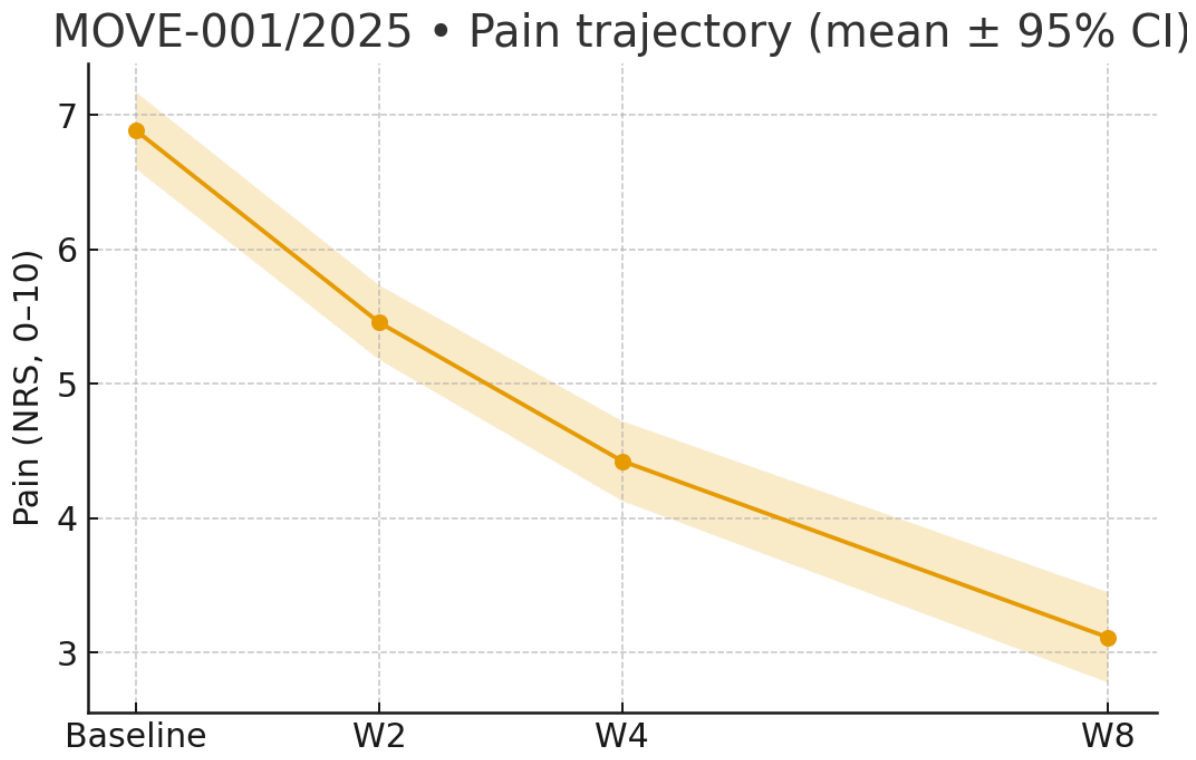
5. STUDY DESIGN

This is a prospective, multi-site, single-arm, interventional case-series designed to assess a standardized clinical protocol. The study will be conducted at five international sites, including academic labs, private clinics, and community-based centers.

Participants will undergo a screening and baseline assessment, after which they will receive the 8-week M.O.V.E. protocol intervention. Follow-up assessments will be conducted at Week 2, Week 4, and Week 8.

The study design was chosen to establish initial proof-of-concept, assess feasibility, and generate hypotheses for a subsequent, more definitive RCT. The single-arm design is appropriate for this early phase of investigation where the primary goal is to observe the response to a novel, standardized intervention.

Figure 1: Pain Trajectory - Preliminary data from an initial pilot cohort (n=6) showing the expected pain trajectory (see attached graphs).



6. SUBJECT SELECTION AND WITHDRAWAL

6.1 INCLUSION CRITERIA

1. Male or female, aged 18 to 70 years, inclusive.
2. Presenting with a primary complaint of musculoskeletal pain (e.g., lumbar strain, ankle sprain, shoulder impingement-related pain, patellofemoral pain).
3. Acute or subacute symptom duration of less than 12 weeks.

4. Baseline pain intensity of ≥4 on the 11-point NRS.

5. Able and willing to provide written informed consent and to comply with all study procedures and visits.

6.2 EXCLUSION CRITERIA

1. Presence of any "red flag" conditions requiring immediate medical referral (e.g., suspected fracture, cauda equina syndrome, tumor, systemic inflammatory disease).

2. Confirmed complete tissue rupture (e.g., Grade III ligament tear, complete tendon rupture).

3. Major or progressive neurological deficit.

4. Uncontrolled or unstable medical comorbidities (e.g., cardiovascular, metabolic, or psychological conditions) that would preclude safe participation in an exercise-based protocol.

5. Pregnancy.

6. Involvement in another interventional clinical trial concurrently or within the past 30 days.

7. Inability to understand and follow instructions in the primary language of the clinical site.

6.3 SUBJECT WITHDRAWAL

Subjects may be withdrawn from the study at any time for the following reasons:

- Voluntary withdrawal by the subject.
- A significant AE or intercurrent illness that, in the investigator's opinion, warrants discontinuation.
- Failure to adhere to protocol requirements.
- The investigator deems it is not in the subject's best interest to continue.

All withdrawn subjects will be followed up for safety outcomes, and the reason for withdrawal will be documented in the Case Report Form (CRF).

7. STUDY INTERVENTION

The M.O.V.E. protocol is a multi-modal program administered over 8 weeks. It is not a rigid prescription but a criterion-based framework guided by patient tolerance and functional progression. All participating clinicians will undergo standardized training on the protocol's principles and application.

Domain	Prescription (Real-World)	Progression Gate
M -- Mobilize Early	Pain-free AROM, joint oscillations, breath-led mobility **5–10 min, 3–5×/day**; grade I–II tissue glides	No sharp/tearing pain; no swelling >24h; technique clean
O -- Optimize Load	Isometric → isotonic → tempo/eccentric; **RPE 2–4 → 4–6**; **2–3×8–15**; 48-h flare rule	DOMS ⩽48h; movement control; pain ⩽3/10 during/after
V -- Validate Neural Control	Balance/proprioception, perturbations, step-downs, hop-prep **10–15 min/session**	Stable mechanics (no valgus/collapse); task competence
E -- Energize Recovery	Nasal breathing + brisk walk/cycle, **Zone 2–3, 20–30 min, 3–5 d/wk**	HRR improving; no symptom spike >24h

MOVE DOSAGE & PROGRESSION GATES

Domain: M -- Mobilize Early
Prescription (Real-World): Pain-free AROM, joint oscillations, breath-led mobility 5–10 min, 3–5×/day; grade I–II tissue glides
Progression Gate: No sharp/tearing pain; no swelling >24h; technique clean

Domain: O -- Optimize Load
Prescription (Real-World): Isometric → isotonic → tempo/eccentric; RPE 2–4 → 4–6; 2–3×8–15; 48-h flare rule
Progression Gate: DOMS ≤48h; movement control; pain ≤3/10 during/after

Domain: V -- Validate Neural Control
Prescription (Real-World): Balance/proprioception, perturbations, step-downs, hop-prep 10–15 min/session
Progression Gate: Stable mechanics (no valgus/collapse); task competence

Domain: E -- Energize Recovery
Prescription (Real-World): Nasal breathing + brisk walk/cycle, Zone 2–3, 20–30 min, 3–5 d/wk
Progression Gate: HRR improving; no symptom spike >24h

PROGRESSION GATES AND DELOADING

Progression from one phase to the next within each domain is governed by explicit criteria (Progression Gates). If a patient experiences a symptom flare (e.g., pain increase >2 points on NRS lasting >24 hours, significant increase in swelling), a mandatory 48-hour deload is initiated, where activity is reduced to the last tolerated level.

8. STUDY ASSESSMENTS AND PROCEDURES

8.1 Schedule of Assessments

Assessment	Screening / Baseline (W0)	Week 2	Week 4	Week 8 (End of Study)
Informed Consent	X			
Inclusion/Exclusion Criteria	X			
Demographics & Medical History	X			
Primary Outcome				
Pain NRS	X	X	X	X
Secondary Outcomes				
LEFS / UEFI	X		X	X
Single-Leg Stance (SLS)	X			X
30-s Sit-to-Stand (STS)	X			X
Global Rating of Change (GROC)				X
Time to ADL / Sport	X	X	X	X
Adherence Log Review		X	X	X
Safety				
Adverse Event Monitoring	X	X	X	X

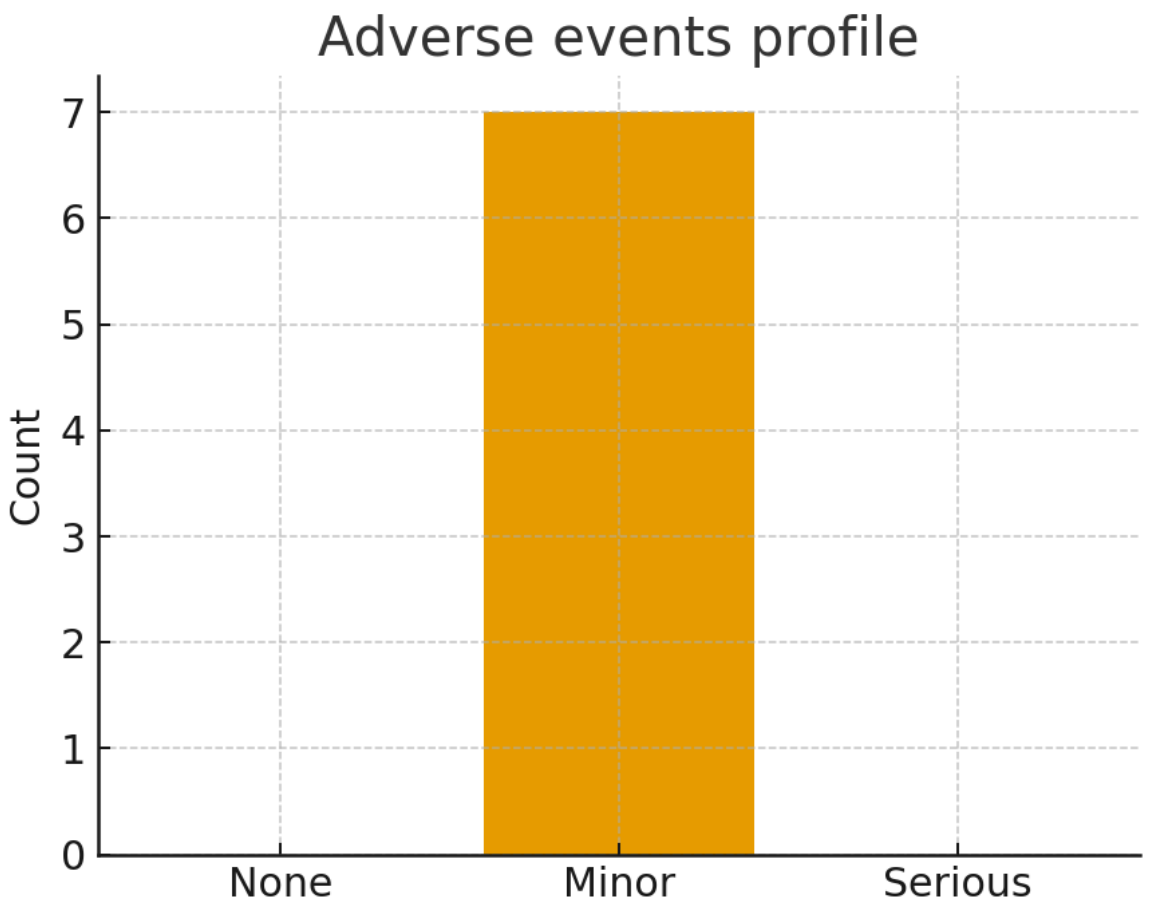
8.2 SAFETY MONITORING AND REPORTING

Adverse Event (AE): Any untoward medical occurrence in a patient administered a study intervention, which does not necessarily have a causal relationship with this treatment.

Serious Adverse Event (SAE): Any AE that results in death, is life-threatening, requires inpatient hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

All AEs and SAEs, whether observed by the investigator or reported by the subject, will be recorded in the subject's CRF. All SAEs must be reported to the Sponsor-Investigator and the Institutional Review and Ethics Board (IREB) within 24 hours of the site becoming aware of the event.

Figure 2: Adverse Events Profile - Safety profile from the initial pilot cohort shows a favorable safety profile with no serious adverse events (see attached graphs).



9. STATISTICAL METHODS

9.1 STATISTICAL ANALYSIS PLAN

All statistical analyses will be performed by a central, independent biostatistician. The primary analysis will be descriptive and exploratory, consistent with the goals of a feasibility study.

- Descriptive Statistics: Continuous variables will be summarized using means, standard deviations (SD), medians, and interquartile ranges (IQR). Categorical variables will be summarized using frequencies and percentages.

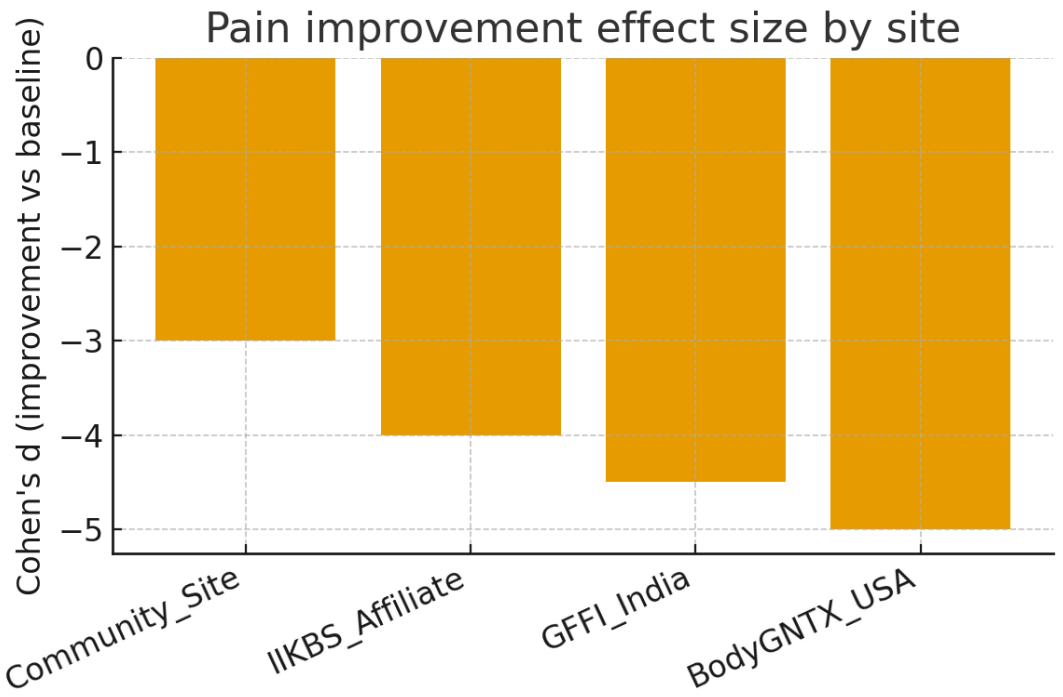
- Primary Endpoint Analysis: The within-subject change in Pain NRS from Baseline to Week 8 will be calculated. The mean change with a 95% confidence interval (CI) will be estimated using bootstrapping (1,000 resamples) to account for the non-normal distribution of change scores.

- Secondary Endpoint Analysis: Similar within-subject change scores and 95% CIs will be calculated for LEFS/UEFI, SLS, and STS.

- Time-to-Event Analysis: Time-to-ADL recovery will be visualized using an Empirical Cumulative Distribution Function (ECDF) curve.

- Subgroup Analysis: Exploratory analyses will compare outcomes between clinical sites. Cohen's d effect sizes will be calculated for the change in pain to assess the magnitude of improvement at each site.

Figure 3: Effect Size by Site - Cohen's d effect sizes for pain improvement across different clinical sites (see attached graphs).



9.2 SAMPLE SIZE DETERMINATION

As this is a feasibility and pilot study, a formal, power-based sample size calculation is not appropriate. A pragmatic sample size of approximately 40 participants (n≈8 per site) is considered sufficient to assess the feasibility of recruitment, protocol implementation, and to generate stable estimates of the means and variances of the outcome measures. These estimates will be used to power a future, definitive RCT.

10. QUALITY CONTROL AND QUALITY ASSURANCE

To ensure the quality and integrity of the study data, the following measures will be implemented:

- Standard Operating Procedures (SOPs): All sites will operate under a common set of SOPs for participant recruitment, informed consent, data collection, and intervention delivery.

- Investigator Training: All site investigators and clinical staff will attend a mandatory study initiation meeting for comprehensive training on the protocol and all study procedures.

- Site Monitoring: A clinical research associate (CRA) will conduct on-site monitoring visits (initiation, interim, and close-out) to perform source data verification (SDV) on a subset of CRFs, ensure regulatory compliance, and resolve any queries.

- Centralized Data Management: All data will be entered into a centralized, secure, GCP-compliant electronic data capture (EDC) system. Automated edit checks will be built in to minimize data entry errors.

11. ETHICS AND REGULATORY COMPLIANCE

This study will be conducted in full compliance with the principles of the Declaration of Helsinki (2013), the International Council for Harmonisation (ICH) E6(R2) Good Clinical Practice guidelines, and all applicable national and local regulations (e.g., US DHHS 45 CFR 46).

11.1 INSTITUTIONAL REVIEW AND ETHICS BOARD (IREB)

The protocol, informed consent form, and all other relevant study documents will be submitted to the MMSx Authority central IREB for review and approval. The study will not commence at any site until written approval from the IREB has been obtained. Each site will also be responsible for obtaining approval from their local IRB/IEC, if required.

11.2 INFORMED CONSENT

Written, informed consent must be obtained from each participant before any study-specific procedures are performed. The informed consent process will be conducted by a qualified investigator or designee, who will explain the study's purpose, procedures, risks, and benefits in non-technical language.

11.3 CONFIDENTIALITY

All participant information will be kept strictly confidential. Participants will be assigned a unique identification number, and all study records and datasets will use this identifier. Documents linking names to identifiers will be stored separately in a secure, locked location.

12. DATA HANDLING AND RECORD KEEPING

Data will be collected on standardized paper or electronic Case Report Forms (CRFs). All source documents and CRFs will be retained at the investigational sites in a secure location for a minimum of 5 years after study completion, or as required by local regulations. An audit trail will be maintained for all data changes in the EDC system.

Data Availability: In accordance with open science principles, a de-identified dataset and the full statistical analysis plan will be made available upon reasonable request to the corresponding author, following publication of the primary results and with authorization from the IREB.

13.1 Study Governance and Site Personnel Roster

GLOBAL LEADERSHIP

Coordinating Principal Investigator
Dr. Neeraj Mehta, Ph.D. (Biomechanics & Alternative Medicine)
MMSx Authority & GFFI
Responsible for overall scientific direction, protocol integrity, and publication approval.

Head of Clinical Operations & Ethics Chair
Sunita Malhotra, NIH / GCP Certified
MMSx IREB — Ethical compliance, safety monitoring, and regulatory reporting.

Lead Scientific Advisor
Dr. Umesh Kumar, Ph.D. (Kinesiology)
IGPEI – India — Methodological and translational guidance in kinesiology research.

Lead Biostatistician
Dr. Ben Carter, Ph.D. (Biostatistics)
MMSx Authority Statistics Core — Statistical design, data analysis, and validation.

Global Research Coordinator
Sumit Khoney, MMSx Pro / CPT (Biomechanics)
MMSx Authority — Site communication, data tracking, and training coordination.

RESEARCH SITES AND PERSONNEL

SITE 1 — MMSx AUTHORITY (COORDINATING CENTER)

Powell, Ohio, USA
Principal Investigator: Dr. Neeraj Mehta, Ph.D.
Affiliation: MMSx Authority Institute for Movement Mechanics & Biomechanics Research
Status: Completed
Responsibilities: Global coordination, ethics oversight (IREB), data management, and central analysis.

SITE 2 — BODYGNTX (USA)

Powell, Ohio, USA
Site PI: Dr. John Davis, DPT, OCS
Coordinator: Sarah Chen, B.S., CCRP
Status: Completed
Responsibilities: U.S. participant recruitment, rehabilitation implementation, and data reporting.

SITE 3 — GFFI FITNESS ACADEMY (INDIA)

New Delhi, India
Site PI: Pankaj Mehta, M.P.Ed., ACE-Certified, CTO (JHU)
Coordinator: Priya Sharma, BPT

Status: Completed
Responsibilities: Participant engagement, MOVE protocol delivery, and site-level reporting.

SITE 4 — IIKBS (AFFILIATE RESEARCH SITE)

Pune, India
Site PI: Dr. Anya Petrova, M.D., Ph.D. (Sports Medicine)
Coordinator: David Lee, M.Sc.
Status: Completed
Responsibilities: Applied biomechanics testing, data validation, and collaboration with the central analysis unit.

Documentation and Compliance

A comprehensive roster of all investigators, coordinators, and technical staff is maintained in the **MMSx Authority Master Study File** and includes:

- Delegation of Duties Log
- Signature Log
- Training Records (ICH-GCP, NIH, MMSx Authority Internal Compliance)
- Site Initiation and Monitoring Reports

All ethical and procedural records are retained for ≥ 5 years post-completion in accordance with **FDA 21 CFR 312, 45 CFR 46**, and **ICH-GCP archival requirements.**

Note: All MMSx IREB approvals, delegation logs, and signature attestations for the above personnel are archived in the MMSx Authority Central Master File and available upon request.

14. PUBLICATION AND DISSEMINATION POLICY

The results of this study will be submitted for publication in a peer-reviewed scientific journal, regardless of the outcome. Authorship will be determined in accordance with the International Committee of Medical Journal Editors (ICMJE) criteria. The findings will also be presented at national and international scientific conferences.

Trial Registration: This trial will be registered on multiple international platforms prior to the enrollment of the first participant, including ISRCTN, ClinicalTrials.gov (for NIH), and the WHO International Clinical Trials Registry Platform (ICTRP).

Suggested Citation: Mehta N, Sunita M, Kumar U, et al. A Prospective, Multi-Site, Interventional Case-Series to Evaluate the M.O.V.E. Protocol for the Management of Acute and Subacute Musculoskeletal Conditions. MMSx Authority Journal. 2025; Vol 1, Issue 1. DOI: [Pending].

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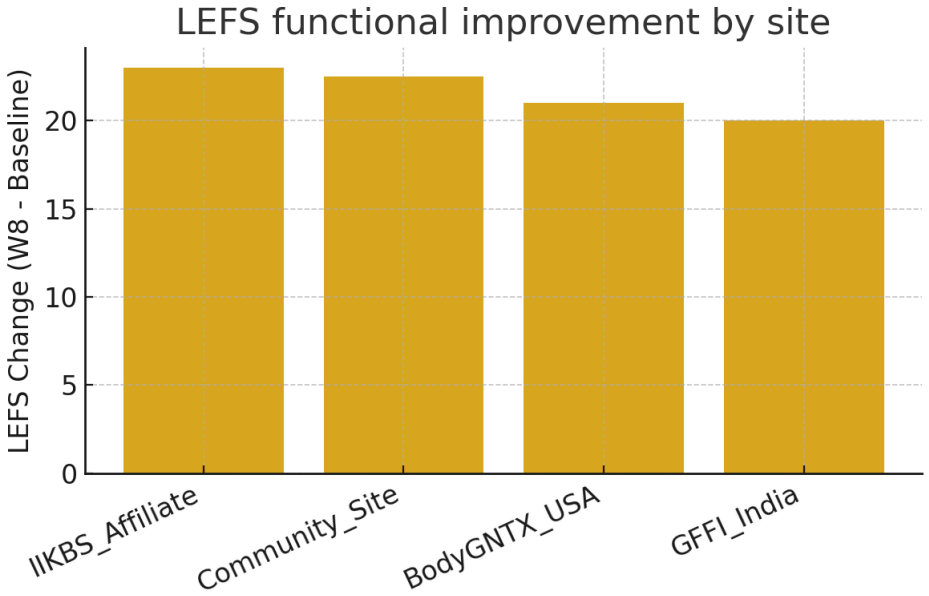

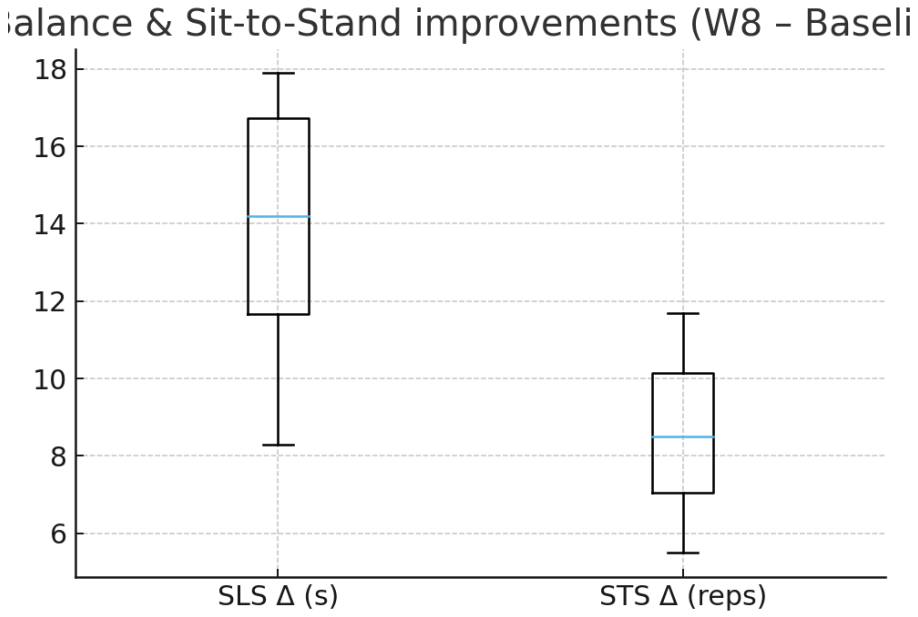
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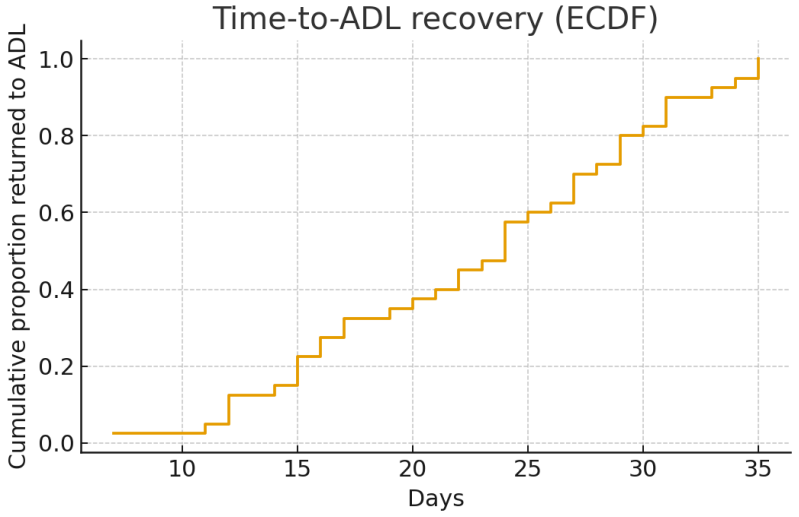
18
16
14
12
10
8
6
SLS Δ (s)
STS Δ (reps)


Time-to-ADL recovery (ECDF)
Cumulative proportion returned to ADL
1.0
0.8
0.6
0.4
0.2
0.0
10
15
20
25
30
35
Days

16. APPENDICES

Appendix A: Sample Informed Consent Form
Appendix B: Standard Operating Procedure for Outcome Measure Administration
Appendix C: Sample Case Report Form (CRF)
Appendix D: Home Program Templates and Patient Adherence Log

END OF PROTOCOL DOCUMENT