ALETHA

ALETHA HEALTH: REVOLUTIONIZING THERAPEUTIC STRATEGIES FOR BACK PAIN AND PHYSICAL PERFORMANCE

A randomized control trial investigating the effects of a novel therapeutic program on lower back pain, mobility, physical function, and physiological metrics

White Paper by Susie Reiner, PhD, ACSM-EP, CSCS

CASE STUDY

Presents research that validates Aletha's products, highlighting key consumer insights and market trends.

CONTACT FOR DETAILS

Aletha Health

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The Highlights

This white paper presents the findings of an external validation study investigating Aletha Health's "Mark" device, designed to target deep hip flexors (specifically the psoas and iliacus muscles) to alleviate chronic lower back pain, improve mobility, and enhance physical function. Conducted in collaboration with Evolve Well Research Partners and Biostrap, the study demonstrated significant benefits in both acute and chronic outcomes when compared to traditional stretching exercises.

KEY FINDINGS

Acute Pain

After just one use of the Mark, participants experienced a 27% reduction in pain and a 24% reduction in muscle tension. 71% noticed a reduction in muscle tension. This improvement was observed following a single 90-second session, highlighting the immediate impact of the device.

Chronic Pain

With consistent use of the Mark three times per week over a period of four weeks, participants saw a 29% improvement in sleep duration, a 19% reduction in pain, and notable improvements in physical function. This sustained usage demonstrated the long-term benefits of the device for managing chronic low back pain and enhancing overall mobility.

Overall Impact

The Mark users maintained their physical activity levels while the Control group showed declines. The Intervention group also demonstrated improved sleep quality and a trend toward enhanced strength.

This study reinforces the potential of targeted therapeutic devices like the Mark for effectively managing low back pain and improving overall well-being.

Real Relief. Lasting Results.

Chronic lower back pain (LBP) is a significant global health issue, with up to 84% of adults experiencing it at some point in their lives (1). Despite its widespread prevalence, effective treatment for LBP remains a challenge, as conventional interventions, including physical therapy, pharmacotherapy, and stretching, often produce inconsistent results. A promising focus in recent research is the role of deep hip flexor dysfunction—specifically the iliacus and psoas muscles—in contributing to chronic LBP. Addressing imbalances or dysfunctions in these muscles may offer an effective solution for pain management and improved physical function (2, 3).

In response to this growing body of research, Aletha Health developed the Mark, an innovative therapeutic device designed to target the psoas and iliacus muscles to alleviate pain, improve mobility, and enhance overall physical function. This external validation study, conducted in collaboration with Evolve Well Research Partners and Biostrap, investigates the efficacy of the Mark compared to traditional stretching exercises. The study evaluates both acute (short-term) and chronic (long-term) effects on LBP management, sleep, mobility, and physical function through a randomized controlled trial.

Why We Did This: The Science Behind the Study

The primary objective of the study was to assess the acute and chronic benefits of the Mark in comparison to conventional stretching exercises. The acute effects were measured after a single use of the Mark, while the chronic effects were evaluated following consistent use over four weeks. The study aimed to determine if the Mark could provide measurable improvements in pain relief, sleep quality, physical activity, and overall well-being.

This study builds upon prior research suggesting that targeted interventions on the iliopsoas muscles can significantly reduce pain and improve physical function (2, 3). By comparing the results of the Mark to traditional stretching methods, the study offers valuable insights into the potential of new, targeted therapies for managing chronic LBP and improving quality of life for individuals affected by this condition.

Hypotheses

01 **Primary Hypothesis**

The Mark will result in significant improvements in pain, mobility, and physical function compared to traditional stretching exercises.

02 **Secondary Hypothesis**

The Mark will lead to improvements in sleep quality and reductions in ANS activity (e.g., increased heart rate variability, reduced resting heart rate).

Study Design

PARTICIPANTS

The study involved 25 adults (aged 25-55) from the U.S. with chronic LBP. Participants were divided into two groups:

The Intervention Group (n = 15): Used the Mark device three times per week for 90 seconds per session.
Control Group (n = 10): Performed standard hip flexor stretches three times per week for 90 seconds.

Exclusion criteria included recent surgeries, pregnancy, or certain medical conditions (e.g., neurological, cardiometabolic diseases).

OUTCOMES MEASURED

Pain: Daily self-reported pain levels using a Numeric Pain Rating Scale (NPRS) (4)
Mobility & Physical Function: Functional tests assessed via Zoom by an Exercise Physiologist (e.g., 30-second chair stand, hip rotation/flexion tests)
Sleep Quality: Measured with Pittsburgh Sleep Quality Index (PSQI) (5)
Heart Rate Variability (HRV) & Resting Heart Rate (RHR): Collected passively via Biostrap devices, focusing on nightly recovery scores
ANS Activity: Assessed through heart rate and HRV during sleep and intervention sessions
Immediate Effects: In the Intervention group. Participants rated pain, muscle tension, and mobility before and after each session

STUDY PHASES

Baseline (2 Weeks): Monitoring pain, function, and sleep quality.
Intervention (4 Weeks): Participants used the Mark or performed stretching exercises.
Washout (2 Weeks): No intervention, with follow-up assessments of pain, function, and other measures.

METHODS

Data were analyzed using paired t-tests and ANCOVAs to compare baseline, intervention, and washout phase results. Physiological and self-report data were examined for significant changes, and statistical analyses accounted for covariates like HRV and sleep quality.

The Impact

PHYSICAL ACTIVITY AND STRENGTH

Overall physical activity significantly decreased for the Control group from baseline (M = 72.17, SD = 26.65) to the intervention phase (M = 64.45, SD = 34.92), t(8) = -2.63, p = .030, Cohen's d = -0.88, 95% CI [-1.63, 0.08], but did not significantly change for the Intervention group from baseline (M = 70.59, SD = 17.06) to the intervention phase (M = 69.45, SD = 18.73), t(14) = -0.47, p = .646, Cohen's d = -0.12, 95% CI [-0.63, 0.39].

Daily steps significantly decreased from baseline (M = 11171.0, SD = 5911.4) to the intervention phase for the Control group (M = 9622.4, SD = 6092.3), t(8) = -3.17, p = .013, Cohen's d = -1.06, 95% CI [-1.86, -0.21], but did not significantly change from baseline (M = 10017.7, SD = 5470.5) to the intervention phase for the Intervention group (M = 9649.7, SD = 4597.0), t(14) = -0.50, p = .627, Cohen's d = -0.12, 95% CI [-0.63, 0.39].

Duration of activity significantly decreased from baseline (M = 10402.6, SD = 5551.6) to the intervention phase for the Control group (M = 8708.4, SD = 6113.9), t(8) = -2.55, p = .034, Cohen's d = -0.85, 95% CI [-1.60, -0.06], but did not significantly change from baseline (M = 8839.4, SD = 4644.0) to the intervention phase for the Intervention group (M = 8538.40, SD = 3934.22), t(14) = -0.57, p = .580, Cohen's d = -0.15, 95% CI [-0.65, 0.37].

Strength improved in the Intervention group; the number of chair stands performed increased from pre-intervention (M = 10.38, SD = 2.57) to post-intervention (M = 11.69, SD = 2.63), with the results approaching, but not reaching, significance t(12) = 1.97, p = .072, Cohen's d = 0.55, 95% CI [-0.05, 1.12]. For the Control group, the number of chair stands performed did not significantly change from pre-intervention (M = 14.0, SD = 5.2) to post-intervention (M = 14.5, SD = 5.3), t(7) = 0.53, p = .613, Cohen's d = 0.19, 95% CI [-0.52 0.88]. When examining one-sided p-values, the increase in number of chair stands for the Intervention group from pre-intervention to post-intervention reached significance, p = .036.

These findings suggest that using the Mark may help stabilize physical activity patterns and improve muscular strength during a back pain intervention, preventing the declines seen in the Control group.

LOCUS OF CONTROL

For the Intervention group, there was a statistically significant increase in overall internal locus of control from before (M = 3.6, SD = 0.6) to after (M = 2.9, SD = 0.6) the intervention, t(12) = 2.71, p = .019, Cohen's d = 0.75, 95% CI [0.12, 1.36]. For the Control group, the difference (baseline M = 3.6, SD = 0.8, post-intervention M = 3.7, SD = 0.8) was not statistically significant, t(8) = −0.13,p = .900, Cohen's d = .04, 95% CI [-0.61, 0.70]. When specifically examining the internal subscale, there was a statistically significant increase in internal locus of control from baseline (M = 4.5, SD = 0.9) to after (M = 4.8, SD = 0.8) the intervention for the Intervention group, t(12) = 2.38, p = .035, Cohen's d = 0.66, 95% CI [0.05, 1.25]. It was not statistically significant for the Control group, (baseline M = 4.7, SD = 1.0, post-intervention M = 4.6, SD = 1.2, t(8) = 0.13, p = .900, Cohen's d = -0.23, 95% CI [-0.89, 0.44].

Participants feel more empowered and in control of their LBP when using the Mark for four weeks when no changes were observed in locus of control in the Control group.

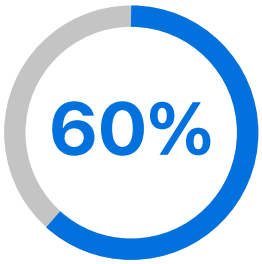
ACUTE PAIN

The Intervention group on average, reported there was a significant decrease in pain levels from before (M=2.6, SD=1.6) to after a single use of the Mark (M=1.9, SD=1.2), T(13)=-2.62, P=0.021, Cohen's d=-0.70, 95% CI [-1.28,-0.10]

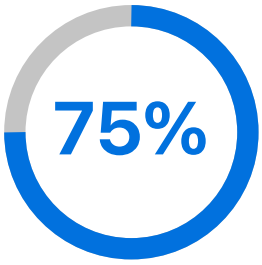
Acute Muscle Tension

The Intervention group on average, reported there was a significant decrease in pain levels from before (M=4.1, SD=2.02) to after a single use of the Mark (M=3.1, SD=2.23), T(13)=-3.89, P=0.002, Cohen's d=-1.04, 95% CI [-1.69,-0.37]

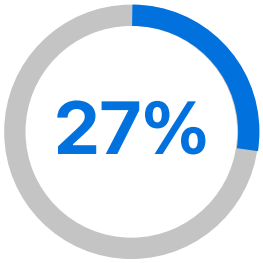
One of the standout findings was that after just one session, participants using the "Mark" experienced a 27% reduction in pain and a 24% reduction in muscle tension. While the Control group saw a reduction in these measures, they did not reach statistical significance. These immediate benefits highlight the device's ability to quickly target areas of discomfort, offering rapid relief from muscle tightness and pain commonly associated with lower back issues.



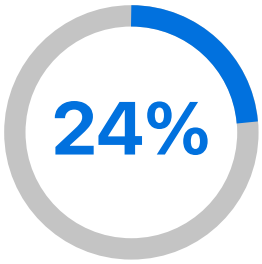
of participants experienced less pain after one use of the Mark



of participants experienced less muscle tension after one use of the Mark



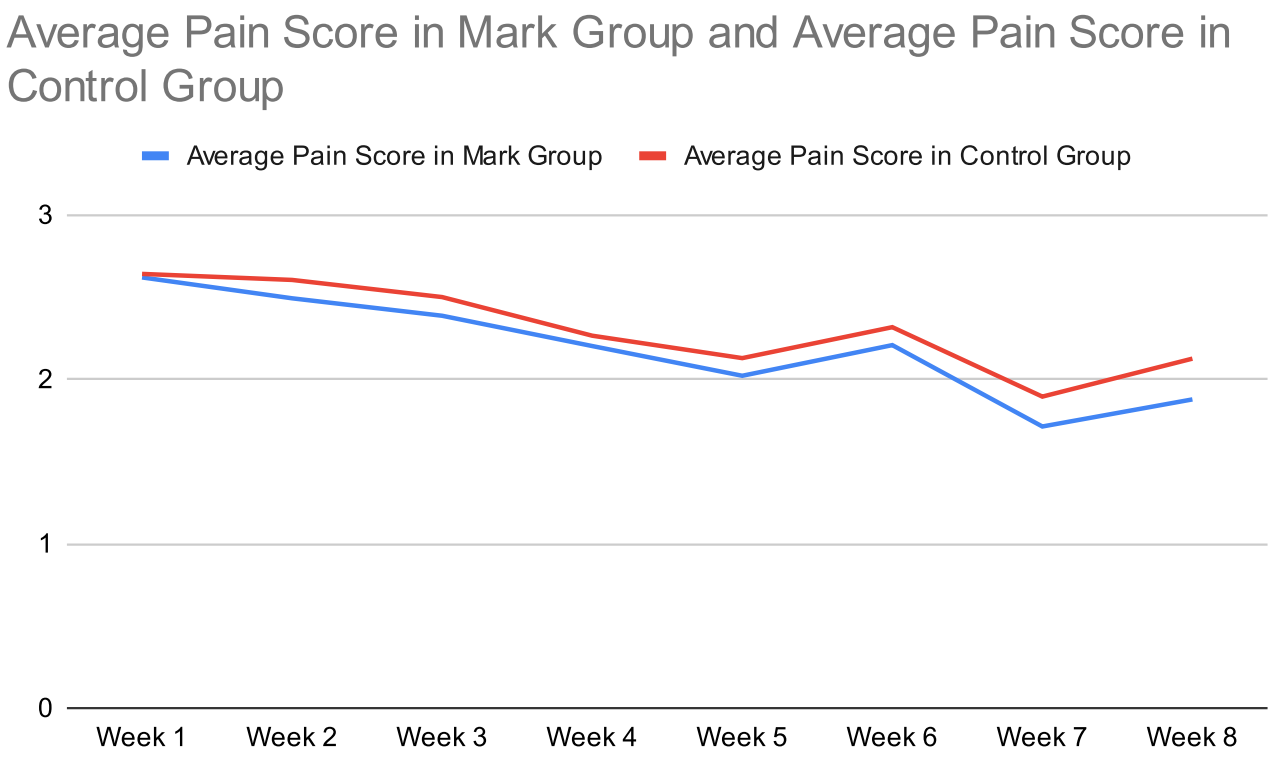
pain reduction after one use



reduction in muscle tension after one use

CHRONIC PAIN

For the Intervention group, there was a statistically significant reduction in average pain levels when comparing baseline (M = 2.6, SD = 1.5) and intervention phases (M = 2.1, SD = 1.8), t(13) = -2.21, p = .046, Cohen's d = -0.59, 95% CI [-1.15, -0.01]. Although average daily pain increased back to baseline levels in the washout phase on average (intervention M = 2.4, SD = 2.0, washout M = 2.6, SD = 2.0), the difference was not statistically significant, t(11) = 0.54, p = .598, Cohen's d = 0.16, 95% CI [-0.42, 0.72]. For the Control group, there was no statistically significant difference in average pain levels from baseline (M = 2.9, SD = 1.8) to during the intervention (M = 2.7, SD = 1.4) , t(8) = -0.54, p = .602, Cohen's d = -0.18, 95% CI [-0.83, 0.48].



Pain relief lasted for up to two weeks after the study ended, with participants continuing to feel less discomfort in their lower back even when they stopped using the device. The Control group did not experience this sustained effect.

Insights and Implications

This external validation study demonstrated that the Mark is effective in reducing pain, alleviating muscle tension, and improving sleep quality in individuals with chronic LBP. These findings align with a growing body of literature that highlights the benefits of targeted interventions for musculoskeletal health and functional improvements in people with LBP.

Pain Reduction and Muscle Tension Relief

The significant reduction in pain and muscle tension observed after both acute and chronic use of the Mark aligns with studies emphasizing the role of targeted myofascial release and hip flexor interventions in LBP management. Tightness in the psoas and iliacus muscles is often linked to lumbar pain, and tools targeting these muscles can improve spinal alignment, reduce pain, and enhance physical function.

Sleep Quality Improvements

The improvements in sleep duration and efficiency align with research showing that pain reduction leads to better sleep. Chronic pain disrupts sleep, creating a harmful cycle. By easing pain and tension, the Mark may have helped participants achieve more restorative sleep, similar to other interventions that support physical recovery and autonomic balance.

Physical Activity Maintenance

Participants using the Mark maintained their baseline physical activity levels throughout the study, unlike the Control group, which showed declines. This finding supports previous research indicating that pain relief and improved mobility help prevent the deconditioning associated with chronic pain. Continued physical activity is key to preventing functional decline in individuals with LBP.

Holistic Approach to LBP Management

The improvements in pain, muscle function, and sleep quality highlight the importance of addressing both physical and biopsychosocial factors in LBP management. The Mark offers a patient-centered approach, providing targeted mechanical interventions that empower individuals to manage their symptoms independently.

In conclusion, the Mark presents a promising, evidence-based solution for managing chronic LBP. By addressing pain, tension, sleep quality, and physical activity, it supports a holistic approach to improving quality of life in individuals with LBP.

Study Limitations

Sample Size and Generalization
The relatively small sample size (n = 25) limits the generalization of the results. Larger studies are needed to confirm these findings and explore subgroup variations in pain severity, age, and gender.

Study Duration
The six-week study duration, including a two-week washout phase, may have been too short to observe long-term changes in autonomic nervous system (ANS) activity. Longer follow-up periods are needed to assess sustained physiological and subjective effects.

Intervention Protocol
The protocol of 90-second sessions, three times per week, may not represent the optimal frequency or duration for maximum benefits. Future research should test different treatment parameters for faster or more significant improvements.

Limited Population Scope
This study focused on individuals with chronic LBP, limiting understanding of the Mark's effects on asymptomatic or healthy populations. Future studies should include these groups to explore its broader applications, such as injury prevention or athletic performance.

Measurement of ANS Activity
While ANS metrics were measured, changes in heart rate variability (HRV) may require longer interventions to manifest. More focused and extended monitoring of ANS activity is needed to better capture these effects.

Potential Bias in Self-Reported Measures
Self-reported outcomes, such as pain and sleep quality, could be subject to participant bias. Future studies should incorporate more objective pain assessments to improve reliability.

Participant Demographics
The study's sample was homogeneous in age and location, which limits its applicability to more diverse populations. Expanding the demographic range would help determine if the Mark has different effects based on age, ethnicity, or socioeconomic factors.

Despite these limitations, this study provides a solid foundation for the Mark as a potential treatment for chronic LBP. Future research with larger, more diverse samples and varied protocols will help clarify its broader clinical benefits.

The Bottom Line

In conclusion, the Mark presents a promising, evidence-based solution for managing chronic LBP by providing targeted relief and enhancing mobility, sleep, and physical function. By addressing both physical and psychological factors, it supports a holistic approach to LBP treatment that improves quality of life for individuals affected by this condition. Its ability to alleviate pain, reduce muscle tension, improve sleep, and maintain physical activity underscores its potential as a comprehensive tool for managing chronic LBP and promoting long-term well-being.

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