Pain relief and functional improvement in U.S. knee osteoarthritis patients using a foot-worn gait-modifying therapy

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What is Known

Knee osteoarthritis is a leading cause of pain and disability worldwide. Non-surgical treatments, including gait-modifying footwear such as wedged insoles and pod-based devices, can reduce knee pain and improve function by altering lower-limb biomechanics, but available designs vary in complexity, availability, adaptability, and therapeutic scope.

What is New

This study demonstrates that a novel, adjustable single-piece plantar gait-modifying shoe produces clinically meaningful improvements in pain, patient-reported outcomes, and gait mechanics after 12 weeks of home use. The findings support its potential as a practical, non-invasive therapeutic option that may delay the need for surgical intervention.

Data Availability: The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing Interests: Authors Astley, Greenberg, Cole, Dougall, and Banks have an ownership interest in, and authors Gustke and Harman have an employment relationship with, Scientific Motion Technologies Inc, the company providing the technology reported in this manuscript.

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Abstract

Objective:

To determine whether an adjustable, single-piece plantar surface gait-modifying shoe improves pain, self-reported outcomes, and gait mechanics in individuals with symptomatic knee osteoarthritis after a 12-week home-based therapy program.

Design:

Prospective, multi-site observational cohort study with repeated measures. Thirty-two subjects (42 painful knees) with radiographic knee osteoarthritis completed a 12-week intervention using customized gait-modifying footwear worn at home for 30–60 minutes daily. Outcomes assessed at baseline and 12 weeks included numerical rating scale pain, Knee Injury and Osteoarthritis Outcome Score (KOOS), and spatiotemporal gait parameters. Paired one-tailed t-tests with Bonferroni correction were applied.

Results:

Significant improvements were observed after 12 weeks. Average knee pain, night pain, and nights with pain each decreased by approximately two points or nights ($p < 0.001$). KOOS overall and all subscales improved by 8–15 points ($p < 0.001$). Gait velocity increased by 12–13 cm/s, step length by 3–4 cm, and single-limb support by ~1% for both barefoot and shod walking ($p \leq 0.013$).

Conclusion:

A 12-week home-based program using a customizable single-piece gait-modifying shoe produced clinically meaningful improvements in pain, function, and gait mechanics in individuals with knee osteoarthritis, supporting its role as a non-invasive therapeutic option.

Keywords: *Osteoarthritis, Knee; Prospective Studies; Shoes; Gait*

Introduction

Severe knee pain due to osteoarthritis (OA) affects tens of millions of Americans and hundreds of millions worldwide[1], and accounts for very significant negative impacts on quality of life[2], availability for work and medical system costs[3–5]. Knee OA causation is a complicated combination of genetics[6,7], obesity[8], diet[9], socioeconomic[10] and other factors, making it a major healthcare challenge that defies solution using a single therapeutic approach. Indeed, recommended non-surgical treatment methods for knee OA include pharmacologic, visco-supplementation, bracing, exercise of various forms, footwear modifications and other methods, each with different profiles for costs, applicability and effectiveness[11–13].

A variety of knee OA treatment approaches have utilized footwear modifications to affect gait biomechanics, stability, pain relief, and to facilitate gait retraining. For example, wedged insoles have been used to alter the coronal plane knee adduction moment[14,15] with some reported positive clinical results[16–18]. Another approach utilizes plantar rocker surfaces to affect knee biomechanics in subjects with knee OA[19,20]. A third approach utilizes forefoot and hindfoot plantar surface gait modifying elements to alter sagittal and coronal plane biomechanics and stability to facilitate pain relief and gait retraining[21–23]. These methods have shown positive pain relief results in knee OA populations and can present a relatively low-cost, noninvasive therapeutic modality to be used alone or in combination with other modalities.

The demonstrated success of gait modifying footwear in altering knee biomechanics and, in some cases, reducing knee OA pain, and the variety of reported design approaches, led to the concept of creating a single-piece plantar surface gait modifying element that provided the ability to modify coronal, sagittal, stability and rocker dimensions as an extension of the previously reported approaches. It was hypothesized that this 1-piece multidimensional gait modifier approach could be used to relieve pain and produce therapeutic carryover effects in a knee OA cohort when utilized in a 12 week at home therapy program. Specifically, it was hypothesized that (1) study participants would demonstrate improved self-reported pain and function scores after 12 weeks therapy with the 1-piece gait modifying footwear, and that (2) study participants would exhibit improved gait parameters (velocity, step length and single limb support percent) after 12 weeks therapy with the 1-piece gait modifying footwear.

Methods

This observational cohort study was conducted with IRB approval and written informed consent at two sites in accordance with the Declaration of the World Medical Association (WCG Protocol #1385170, ClinicalTrials.gov: NCT06598696). Study cohort size was determined to detect a 2-point decrease in subject-reported pain, i.e., the value for being "much improved"[24] on the 11-point numerical rating system for pain, yielding a minimum cohort size of 16 subjects ($\beta = 0.9$; $\alpha = 0.050$). Because the protocol required a total of four laboratory visits over 12 weeks, a target of 30 subjects was chosen to account for potential study dropouts and/or subjects who did not follow the therapy protocol for device use and documentation. Study inclusion/exclusion criteria sought to select for subjects with significant osteoarthritis-related knee pain who lacked other back or lower extremity pain sources, who could safely perform household ambulatory activities wearing gait-modifying shoes, and who were not in active alternate treatment for their knee pain (Table 1). This study is reported in compliance with STROBE guidelines[25].

The study consisted of an initial laboratory visit for evaluation and gait modifying shoe prescription followed by three additional monthly visits over 12 weeks for evaluation and prescription adjustment. Laboratory evaluations consisted of height and weight measures; physical therapy evaluations to assess lower limb alignment, strength, joint range of motion and flexibility; and instrumented walking evaluations to assess gait velocity, step length and single limb support percent (StepScan, StepScan Technologies Inc. or OptoGait, Microgate USA). Knee pain was assessed using an 11-point numerical pain rating scale with anchors of 0, indicating no pain, and 10, indicating the worst pain possible[24,26]. Subjects were asked to assess their average knee pain over a 24-hour period ($NRS_{24HPain}$), their pain at night while resting ($NRS_{NightPain}$), and the number of nights per week they experienced pain while resting. The Knee Injury and Osteoarthritis Outcome Score (KOOS) was administered at each laboratory visit to assess each subject's self-reported pain, symptoms, activities of daily living, sports and recreation function, and knee-related quality of life[27].

At the initial laboratory visit, upon completion of physical evaluations and scores, the subjects' barefoot self-paced gait mechanics and pain were assessed. An investigator then measured the geometry of each foot and placed gait modifiers on the plantar surface of a high-top shoe in positions relating to anatomical landmarks (Figure 1). Subjects then walked shod, recording gait mechanics and pain level. Based upon their observations, the investigator then iteratively modified the position and orientation of the plantar surface gait modifiers using a 7 degree-of-freedom alignment device (Figure 2) and then reassessed instrumented walkway gait parameters and pain. Three-to-five iterations of modifier placement adjustments typically converged to an initial footwear prescription that provided knee pain relief and improved gait velocity, step length and single limb support percent. The subject was then sent home with the gait modifying shoes, instructions for their use, compliance data logging using a tracker, and scheduled for a subsequent laboratory visit. Follow-up visits at 4-week intervals consisted of physical exams, barefoot and shod walking assessments, and prescription adjustments were made as necessary to optimize pain perception and walking mechanics.

Subjects executed an at-home therapy program for the 12-week duration of the study. Subjects were instructed to don the gait modifying shoes and wear them at home during routine daily activities that included a mix of seated, walking and standing activities for 30–60 minutes per day. The subjects were explicitly instructed not to wear the gait modifying shoes outside the home, or for any kind of vigorous walking or sustained ambulatory activities. Subjects logged their footwear use and pain perceptions daily to demonstrate compliance with the therapy program. In addition, an electronic step counter was affixed to one shoe to monitor compliance and therapeutic input in accordance with the prescribed regimen.

Data analyses compared values recorded at the study initiation visit with those recorded at 12 weeks using paired, 1-tail t-tests. When multiple comparisons were performed, e.g., velocity, step length and single limb stance percent are three measures from a single walking trial, a Bonferroni correction was applied to the significance level.

Results

A total of 32 subjects with 42 painful knees who met the study inclusion/exclusion criteria and who completed the 12-week therapy program without major protocol deviations were available for reporting (Figure 3). Three subjects withdrew participation during the treatment program: two subjects with prior back pain whose back symptoms returned with increased physical activity, and one subject who withdrew without disclosing a reason. Three subjects completed the therapy program but were excluded from the analysis: two for major protocol deviations and one subject whose Kellgren-Lawrence knee osteoarthritis score[28] (K-L score = 1) was only determined after study participation was begun. The final study cohort had 18 females/14 males, averaged 69 ± 9 years of age, 171 ± 9 cm in height, 84 ± 19 kg in mass, 28 ± 6 kg/m^2 in body mass index, and a median Kellgren-Lawrence score of 3 (range 2–4) for their most painful knee.

Subjects reported significantly less knee pain, significantly lower night pain, and significantly fewer nights with pain after 12 weeks of gait modification therapy (Table 2). $NRS_{24HPain}$, $NRS_{NightPain}$, and NRS Pain # Nights each decreased by an average of 2 points or 2 nights after 12 weeks of gait modification therapy ($p << 0.001$ in each case).

Subjects' self-reported KOOS scores improved significantly overall and for each KOOS subscale (Table 3). Subjects' KOOS overall average score improved 11 points, while the KOOS subscales improved an average of 8 to 15 points after 12 weeks of gait modification therapy ($p < 0.0012$ in all cases).

Subjects demonstrated significantly improved barefoot and shod (using the gait-modifying shoes) walking mechanics, as measured by step length, single limb support percent, and velocity after 12 weeks of gait modification therapy (Table 4). Step length improved by an average of 4 cm and 3 cm for barefoot and shod walking, respectively ($p << 0.001$). Single limb support percent increased by 1% for both barefoot and shod walking ($p << 0.001$ and $p = 0.013$, respectively). Gait velocity increased by 13 cm/s and 12 cm/s for barefoot and shod walking, respectively ($p << 0.001$).

Discussion

Knee OA presents a global-scale disease burden with significant negative impacts affecting quality of life, productivity, and healthcare spending. The causes and progression of knee OA are multifaceted, thus therapies have evolved to include physical exercise, diet, device, pharmacologic, and surgical interventions. Inspiration for this study derived from longstanding efforts to provide mechanical and neuromuscular stimulus with footwear modifications to achieve pain relief and gait adaptions that confer lasting therapeutic effects. An exercise shoe was designed with a single-piece plantar surface gait-modifying element that could be adjusted to the subject to affect their sagittal, transverse and coronal joint loads and timing, while also providing a degree of instability to provoke an adaptive training response[29]. The study evaluated the effect of a 12-week gait therapy treatment in subjects with pain related to advanced knee OA, and found significant improvements in pain, self-reported outcomes and gait biomechanics.

Study subjects reported a 40% decrease in average pain, 50% decrease in night pain, and 40% fewer nights with pain after 12 weeks of gait modification therapy (Table 2). Using a variable stiffness lateral wedged shoe worn for an average of 7 hours per day, Erhart et al. observed a 37% reduction in pain scores in a 6-month study[18]. Elbaz et al. used forefoot & rearfoot pod-based gait modifying elements in a 12-week study of subjects with knee OA and found 21%–29% pain improvements[22]. Drexler et al., using the same pod-based gait modifying shoes in a 12-week study of subjects with knee OA found 30% pain improvements[22]. Dworkin et al.[24] suggested that a 30% improvement in pain represented "much improved" and a "moderate clinically important difference", indicating variable stiffness lateral wedged shoes, pod-based gait modifying shoes, and the novel 1-piece adjustable gait modifying shoes have the potential to provide similarly positive outcomes with 12-weeks or more therapy. Based upon these comparisons, it appears the novel 1-piece adjustable gait modifier achieves similar knee pain relief after a 12-week treatment program as the previously-reported insole or pod-based gait modifying approaches.

Many other therapeutic modalities have been reported for knee OA pain relief. For example, land-based physical therapy results in a standardized mean reduction in pain of 0.5 in a large meta-analysis[30], where the standardized mean reduction in this study is 0.67 for $NRS_{24HPain}$ and NRS Pain # Nights, and 1.0 for $NRS_{NightPain}$. Acetominophen, by contrast, provided a standardized mean reduction in OA pain of 0.13, considered of questionable significance, in a large meta-analysis[31]. Electrical stimulation using interferential current protocols was reported to have a standardized mean reduction in knee OA pain of 2.06 compared to controls in a systematic review and network meta-analysis[32]. High-intensity laser therapy was shown to produce a standardized mean knee OA pain reduction of 0.98 compared to conventional physical therapy modalities in another systematic review and meta-analysis[33]. Thus, gait modifying footwear therapies can provide pain relief of similar magnitude to other therapies and, interestingly, might be used in combination with other non-pharmaceutical & non-surgical modalities to achieve even greater pain relief effects.

Study subjects self-reported 24% improvements in their KOOS overall scores (Table 3), with 15%–49% improvements on the KOOS subscales, after 12 weeks therapy. Erhart et al. reported comparable 28% improvements in WOMAC scores[34] after 6-months therapy with variable stiffness lateral wedged shoes[18]. Similarly, Elbaz et al.[21] and Drexler et al.[22] reported 24% and 29% improvements in the WOMAC function score, respectively, and 15% and 10% improvements in the SF-36 function score[35], respectively, after 12 weeks therapy with pod-based gait modifying shoes. Singh et al.[36] estimated MCID ("somewhat better") and Moderate Improvement ("great deal better") thresholds for the KOOS Pain (PS) and Quality of Life (QoL) subscales as 2.2/15.0 points (PS) and 8.0/15.6 points (QoL). Study subjects reported average 12-point (PS) and 10-point (QoL) improvements after 12 weeks therapy with the novel 1-piece gait modifying shoes, indicating subjects achieved MCID in 69% (PS) and 53% (QoL) and Moderate Improvement in 41% (PS) and 31% (QoL). Again, the 1-piece gait modifying shoe appears to provide comparable outcomes benefit to the previously-reported gait modifying footwear approaches.

Study subjects, on average, had improvements of 13 cm/s in velocity, 4 cm in step length, and 1% for single limb stance % after 12 weeks therapy during barefoot gait, with 12 cm/s, 3 cm and 1% improvements for gait in the therapy shoes, respectively (Table 4). The observed mean differences between barefoot and shod gait parameters were consistent with some prior research[37]. Elbaz et al. reported average velocity changes of 10.5 cm/s, step length changes of 3.1 cm, and single limb stance % of 0.5% in barefoot knee OA subjects after 12 weeks therapy with pod-based gait modifying shoes[21]. Lubovsky et al.[38] used the same pod-based gait modifying shoes in a cohort of obese subjects with knee OA and found 9.9 cm/s, 3.1 cm, and 0.9% changes in velocity, step length and single limb support % comparing subjects' barefoot gait from pre-treatment to after 12 weeks of therapy. Bohannon et al.[39] evaluated MCID for gait speed across several pathologies and concluded changes of 10–20 cm/s may be clinically important, while Baudendistel et al.[40] determined MCIDs of 8.2 cm/s for velocity and 3.6 cm for step length in a Parkinsons population. Assuming these MCIDs are relevant for knee OA populations, the gait modifying shoe therapies appear to provide clinically important benefit for barefoot gait characteristics.

The strength of the current study is that it assessed a non-invasive therapy in a cohort of knee OA subjects who sought surgeon care for their knee pain in the United States, where access to surgery is high and waiting times are relatively low. If a non-invasive therapy can serve to delay or, in some cases replace, surgical interventions then patients have greater therapeutic options, less morbidity, and there may be reduced overall costs to the healthcare system[41,42]. The key limitation of this study was the lack of a contemporaneously recruited control group. However, there is abundant information on the natural progression of knee OA, indicating worsening disease in significant percentages of those affected if the disease is not treated[43]. A relative limitation of this study was therapy was limited to a 12-week program. Other footworn therapy approaches have studied longer duration programs and have shown additional benefit beyond the 12-week timepoint[23,44] with some evidence the ultimate benefit is achieved with 6 months of therapy[45].

Non-invasive biomechanical approaches for the treatment of symptomatic knee OA are attractive as being simple to implement, reversible, and able to be used in combination with other therapies. Inspired by previous work on gait modifying footwear for the treatment of knee OA, a novel 1-piece modifiable plantar surface element was designed to provide therapists with a wide gamut of potential treatment configurations. These gait modifying shoes were evaluated in 32 study subjects with 42 painful knees in a 12-week treatment program, and the subjects showed significant improvements in each pain, outcome and gait variable studied. This novel gait modifying therapy may provide a useful additional tool for clinicians to treat the pain and disability associated with knee OA.

Table 1. Study Inclusion/Exclusion Criteria

Category	Criteria
Inclusion	Male or female between 40 and 85 years of age at the time of consent
	Chronic, moderate, OA-related knee pain occurring with ambulation
	NRS Pain score reaches between 4/10 or greater 4+ days a week
	Kellgren and Lawrence score of 2, 3 or 4, as demonstrated by x-ray within the last 2 years
	Able to walk unassisted for at least 10 minutes at a time
	Wear a women's U.S. shoe size of 7 to 14 or a men's U.S. shoe size of 6 to 13
	Not currently enrolled in a supervised physical therapy program
	Has access and ability to use smart phone
Exclusion	Suffering from acute septic or inflammatory arthritis
	High fall risk (3+ falls in last year, TUG >21 seconds, TURN180 > 4 steps)
	Unstable cardiovascular, orthopedic, or neurological conditions, uncontrolled diabetes, or any condition that would preclude exercise in moderate duration, moderate workload trials
	Received a corticosteroid injection or invasive procedures within prior 3 months
	History of avascular necrosis in the knee
	Pathological osteoporotic fracture
	Severe symptomatic degenerative arthritis in lower limb joints other than the knees
	Severe back pain, prior spinal fusion, or spinal deformity that would affect gait
	Major cardiac or pulmonary conditions and any orthopedic limitation that precludes their ability to independently walk for 10 minutes or longer
	Any major injury to either knee within the prior 12 months
	Currently enrolled in a supervised physical therapy program
	Currently using any knee brace on a regular basis for the knee pain, with the exception of basic knee sleeves
	Previous partial or total knee joint replacement

Table 2. NRS Pain for 24 hours, night pain and number of nights per week

	Baseline	12 Weeks	Change	p-value	Significant
NRS 24H Pain	5 ± 2	3 ± 2	-2 ± 3	1.0E-06	Yes[1]
NRS Night Pain	4 ± 2	2 ± 3	-2 ± 2	1.4E-06	Yes[2]
NRS Pain # Nights	5 ± 2	3 ± 3	-2 ± 3	1.7E-06	Yes[2]

[1]p = 0.05; [2]p = 0.025 with Bonferroni correction for two comparisons

Table 3. KOOS score and subscales comparing baseline and 12 weeks

	Baseline	12 Weeks	Change	p-value	Significant*
KOOS Total	48 ± 12	59 ± 16	11 ± 14	3.8E-05	Yes
Symptoms	56 ± 17	64 ± 19	8 ± 14	1.2E-03	Yes
Pain	56 ± 12	68 ± 14	12 ± 15	5.7E-05	Yes
Living	63 ± 13	75 ± 15	12 ± 18	4.0E-04	Yes
Sport/Recreation	31 ± 16	46 ± 24	15 ± 17	1.2E-05	Yes
Life Quality	33 ± 15	43 ± 19	10 ± 17	8.8E-04	Yes

**p = 0.0083 with Bonferroni correction for six comparisons*

Table 4. Gait parameters at baseline and 12 weeks

Footwear	Parameter	Baseline	12 Weeks	Change	p-value	Sig.*
	Step Length (cm)	55 ± 7	59 ± 8	4 ± 5	2.3E-06	Yes
Barefoot	% Single Limb Support	32 ± 3	34 ± 3	1 ± 1	1.6E-06	Yes
	Velocity (cm/s)	98 ± 15	112 ± 18	13 ± 14	6.3E-08	Yes
	Step Length (cm)	60 ± 7	63 ± 8	3 ± 5	4.5E-04	Yes
Shod	% Single Limb Support	35 ± 4	36 ± 3	1 ± 2	1.3E-02	Yes
	Velocity (cm/s)	105 ± 16	116 ± 18	12 ± 13	2.3E-07	Yes

**p = 0.017 with Bonferroni correction for three comparisons*

Figures

Figure 1. The gait modifying footwear consists of (A) a high-top sneaker with a stiffened sole plate with (B) the single-piece gait modifying elements attached to the plantar surface of the shoe. The gait modifying elements used in the study offered variation in size/width, thickness, anterior to posterior slope and directional or omni-directional contact surfaces at heel-strike and toe-off.

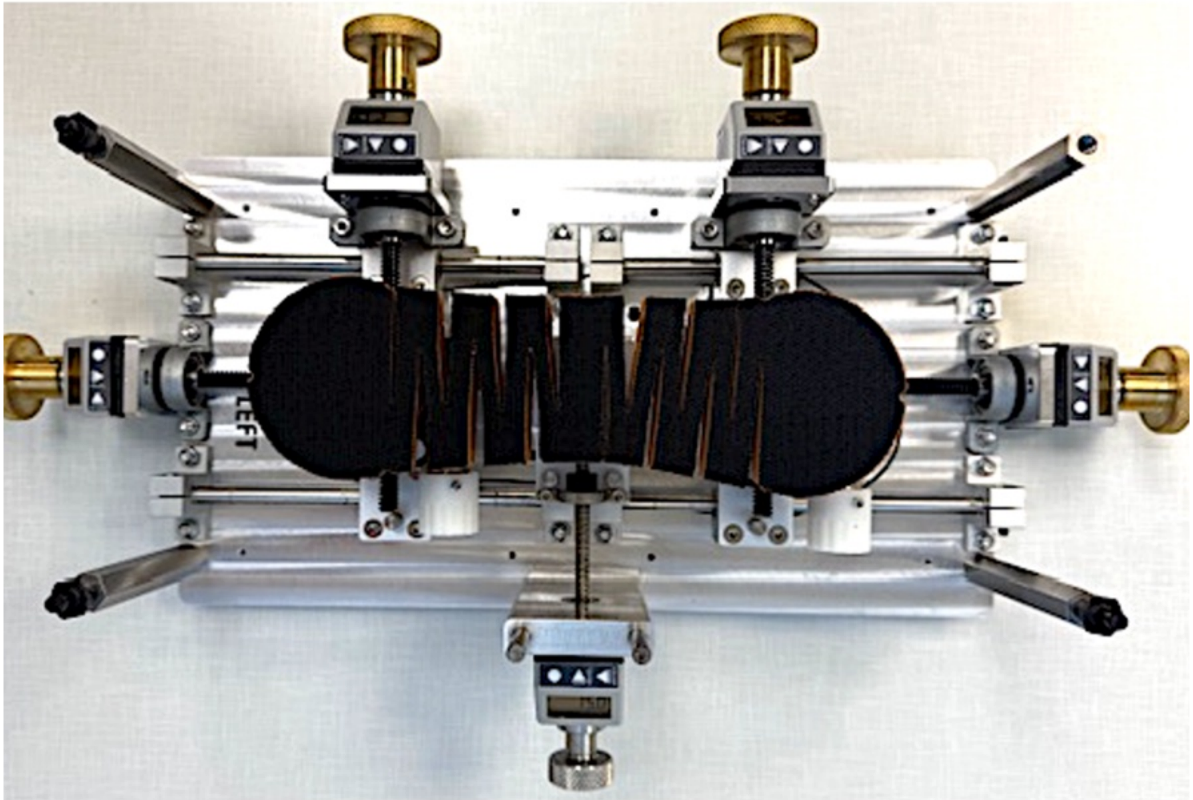

Figure 2. The gait modifying element is adjusted with 7 degrees of freedom to implement the therapy prescription. The single-piece gait modifier is attached to a platform that can independently adjust the fore/aft, medial/lateral and transverse rotation position of the forefoot and hindfoot sections, as well as adjust the medial/lateral location of the central portion before application to the shoe.

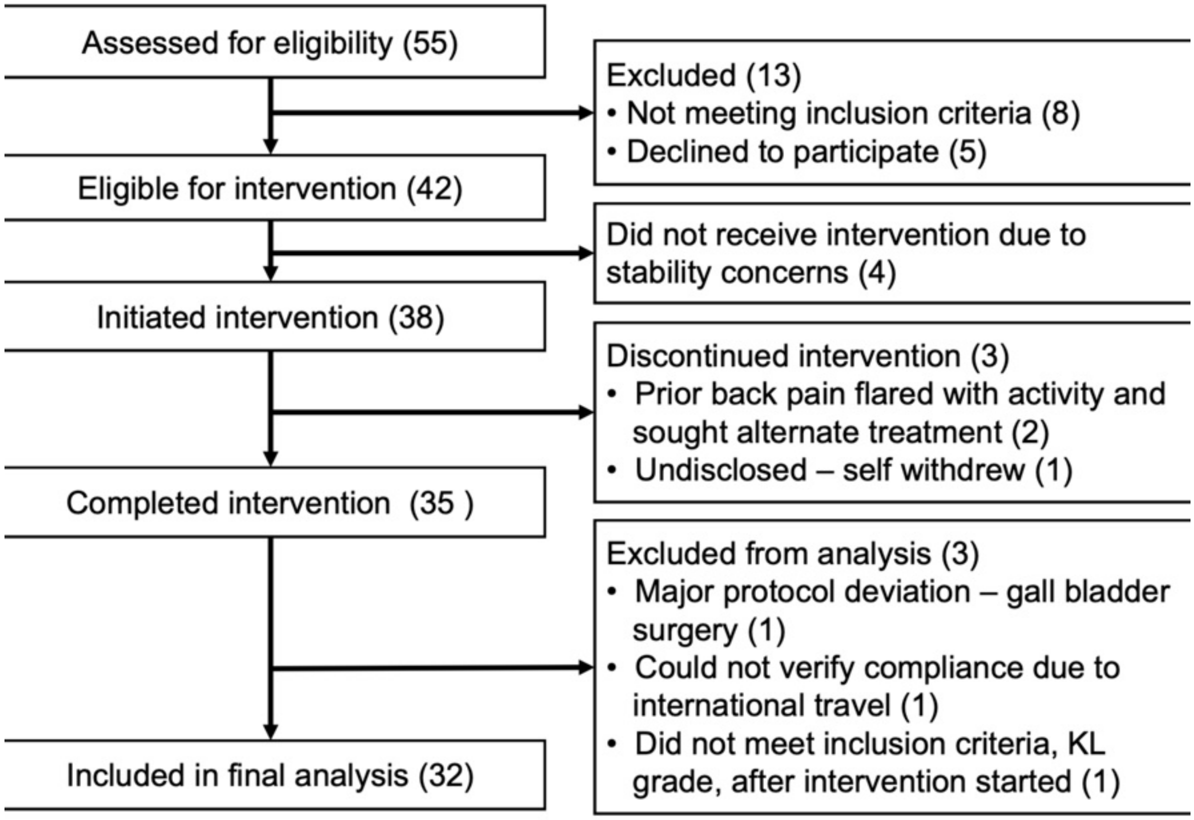

Figure 3. The flowchart shows the progression of the study, in terms of number of individual subjects involved (in parentheses), from initial recruitment through to study completion.

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