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STUDY PROTOCOL

Effect of Passive Versus Active Aquatic Therapy Over Conventional Physiotherapy in Patients With Chronic Low Back Pain: A Randomized Crossover Trial — Study Protocol

[version 1; peer review: 1 not approved]

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Abstract

Background

Chronic low back pain (CLBP) is a highly prevalent musculoskeletal disorder worldwide, often associated with long-term disability and reduced quality of life.[1,2] Conventional physiotherapy continues to be the cornerstone of management; however, alternative approaches such as aquatic therapy have gained increasing attention in recent years due to their surging therapeutic benefits.[3,4] Within aquatic rehabilitation, various methods including passive aquatic therapy (Watsu) and active aquatic therapy are being implemented.[5,6] Despite their growing use, comparative evidence evaluating the relative effectiveness of these two approaches especially against conventional land-based physiotherapy remains limited.[7,5]

Objectives

To compare the effectiveness of active aquatic therapy, passive aquatic therapy (Watsu), and conventional physiotherapy in reducing pain, improving lumbar range of motion (ROM), and enhancing functional ability in individuals with CLBP.

Methods

A single-center, randomized crossover trial will be conducted involving 12 participants diagnosed with CLBP. Each participant will undergo three interventions i.e active aquatic therapy, passive aquatic therapy

Open Peer Review

Approval Status ✗

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Any reports and responses or comments on the article can be found at the end of the article.

(Watsu), and conventional physiotherapy in a randomized sequence. Each intervention will be administered for 4 weeks, with a one-week washout between interventions to minimize carryover effects. Clinical outcomes will be collected at baseline and after each intervention phase by a blinded assessor.

Statistical analysis

Data will be analyzed using repeated-measures ANOVA to compare within-subject differences across the three interventions for pain (VAS), functional disability (ODI), and lumbar ROM. Post-hoc pairwise comparisons with appropriate corrections (Bonferroni) will be performed when significant main effects are observed. A significance level of $p < 0.05$ will be considered statistically significant. Missing data procedures are pre-specified (see Statistical Methods section).[8]

Discussion

This randomized crossover trial is to be conducted in a single-center setting with 12 participants. Extending each intervention to 4 weeks allows for meaningful improvements in pain, lumbar ROM, and functional ability, while the crossover design minimizes between-subject variability. It is anticipated that active aquatic therapy will most improve ROM and function, passive aquatic therapy (Watsu) will be most effective for pain relief, and conventional physiotherapy will provide moderate benefits.[7,5] Access to an in-house hydrotherapy pool in Thumbay rehabilitation centre ensures consistent intervention delivery and enhances feasibility. A structured follow up and motivation sessions will be arranged to prevent any retention and facilitate active participation of patient without affecting the compliance.

Keywords
Hydrotherapy, WATSU, Relaxation, Flotation, Spatherapy, Warm water, Thermoneutral

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Introduction (SPIRIT Items 9–10)

Background and rationale (SPIRIT item 9a–9b)

Low back pain (LBP), also referred to as low back ache, is among the most prevalent musculoskeletal disorders worldwide. Lifetime prevalence ranges from 60% to 84% in high-income populations, with variation across regions, occupations, and lifestyle factors.[1] Approximately 73% of patients experience at least one recurrence within 12 months. Although individuals with acute LBP and disability often show rapid improvement within weeks, pain and functional limitations frequently persist, and recurrences are common.[9] LBP is a leading cause of disability in adults and carries substantial socioeconomic consequences.[2,10]

Chronic low back pain (CLBP) is defined as pain localized below the costal margin and above the inferior gluteal folds persisting for more than 12 weeks. Conservative management remains the primary approach and includes modalities such as electrotherapy, heat therapy, therapeutic exercise, manual therapy, and stabilization exercises.[11] However, the long term efficacy of existing treatments remains uncertain due to heterogeneity in sample sizes and methodological limitations of existing studies, and evidence synthesis shows analgesic effects are often modest across non-surgical, non-interventional options.[12,13]

It is a known fact that not all patients respond optimally to land-based rehabilitation particularly those with fear of movement, reduced load-bearing tolerance, obesity, or heightened pain sensitivity.[14] Aquatic therapy has recently gained recognition as a supportive alternative, providing an environment where patients may perform therapeutic movement with reduced mechanical stress and improved tolerance.[3] A systematic review reported significant benefits of aquatic physical therapy in CLBP,[7] and a randomized clinical trial demonstrated therapeutic aquatic exercise improved pain, function, quality of life, sleep quality, and mental well-being more than standard physical therapy modalities.[4]

Aquatic therapy is generally delivered in two main forms: active and passive. Active aquatic therapy uses structured patient-performed exercises in warm water to improve strength and mobility using water resistance and buoyancy.[7] Passive aquatic therapy such as Watsu (Water Shiatsu) involves therapist-guided stretches, rotations, and rhythmic passive movement while the patient is supported in warm water.[5] Watsu is frequently associated with pain relief, and practitioner surveys report consistent clinical use for LBP management.[6,15] Despite these findings, direct comparisons between active aquatic therapy, passive aquatic therapy (Watsu), and conventional physiotherapy remain scarce, limiting decisions on which method offers superior benefit in different outcome of the target patients.

Therefore, this study will directly compare these three approaches in a randomized crossover design. This allows each participant to experience all interventions, minimizing between-subject variability and increasing internal validity. The protocol follows SPIRIT guidelines.

Objectives (SPIRIT item 10)

Primary Objective: To compare the effectiveness of active aquatic therapy, passive aquatic therapy (Watsu), and conventional physiotherapy in reducing pain, improving lumbar ROM, and enhancing functional ability in individuals with CLBP.

Methods: Patient and Public involvement, trial design (SPIRIT items 11–12)

Patient and public involvement (SPIRIT item 11)

Patients and the public were not formally involved in the design, conduct, or reporting of this protocol. Participant preference and comfort will be solicited at the final study visit (see Feasibility outcomes) and will be used to inform the design of any future, adequately powered trial.

Trial design (SPIRIT item 12)

This is a single-center, prospective, randomized crossover clinical trial. Each of the 12 participants will complete three 4-week intervention phases (active aquatic therapy, passive aquatic therapy, conventional physiotherapy), separated by one-week washout periods.

- **Framework:** Superiority (comparative effectiveness).
- **Unit of randomization:** Individual participant.
- **Allocation ratio:** Balanced allocation to sequences (see Randomization section).
- **Masking:** Single (outcome assessor). Participants and therapists cannot be blinded due to treatment nature.

- **Note on duration:** Each participant will be followed through all phases (approximately 14 weeks total participation time), consistent with three 4-week interventions plus washouts and assessments.

Methods: Participants, interventions, and outcomes (SPIRIT Items 13–20)

Study setting (SPIRIT item 13)

The study will be conducted at Gulf Medical University physiotherapy outpatient clinic and hydrotherapy pool facility (Ajman, UAE). Recruitment will occur through institutional clinical pathways and physiotherapy referrals.

Eligibility criteria (SPIRIT item 14a)

Inclusion criteria:

- Adults aged 18–65 years.
- Diagnosed with nonspecific CLBP (>3 months).
- Able to attend sessions and provide written informed consent.

Exclusion criteria:

- Acute low back pain or red flags (fracture, malignancy, infection).
- Recent spinal surgery (<6 months).
- Neurological disorders affecting balance or gait.
- Cardiopulmonary contraindications to immersion.
- Patient with injury to back
- Pregnancy.

Interventions and comparator (SPIRIT item 15a–15d)

All interventions will be delivered/supervised by licensed physiotherapists. Aquatic interventions will be administered by physiotherapists trained in hydrotherapy; Watsu sessions will be delivered by a physiotherapist trained in Watsu techniques. Standardization sessions will be conducted before recruitment to ensure consistent delivery and documentation.

A. Active aquatic therapy.

Active aquatic therapy involves structured, therapist-guided exercises performed by the participant in warm water using buoyancy, hydrostatic pressure, and resistance to reduce joint loading and facilitate movement.[3,7]

Setting: Heated hydrotherapy pool (clinical center); water temperature 32–34 °C; supervision by a licensed physiotherapist; intensity monitored via Borg RPE (target moderate intensity).[16,17] Water immersion depth: xiphoid process-to-chest level (~T7–T10, approximately 1.2–1.35 m, adjusted to participant height) for standing and weight-bearing exercises, unloading roughly 50–60% of body weight while preserving trunk and postural control; shoulder-depth water is used only for the supported-floating component of cool-down.[18]

Dose: 45–60 minutes/session, 3 sessions/week, 4 weeks (12 sessions).

Session structure:

- Warm-up (10 min): water marching, arm swings, trunk rotations, hip circles.
- Main exercises (30–35 min): side flexion, hip abduction/leg lifts, back extensions with floatation aids, aqua walking (multi-direction), balance training, core activation, wall-supported strengthening.
- Cool-down (5–10 min): floating, deep breathing, gentle walking, passive stretching.

Stepwise progression criteria (Active Aquatic Therapy):

- **Stage 1 – Acclimatization (Sessions 1–3, Week 1):** Chest-depth water; low intensity (Borg RPE 9–11); bilateral hand support at pool rail/wall; focus on warm-up movements, water marching, gentle trunk rotation, and orientation to buoyancy and hydrostatic pressure.

- **Stage 2 – Controlled loading (Sessions 4–6, Week 2):** Chest-depth water maintained; progress from Stage 1 only if post-session VAS increase is ≤2 points from pre-session baseline, Borg RPE remains ≤13, and exercises are completed with correct form per therapist checklist. Introduce unilateral leg lifts, hip abduction, and reduced hand support at the wall.

- **Stage 3 – Resisted/dynamic training (Sessions 7–9, Week 3):** Progress only if full trunk/hip ROM is achieved without compensatory pattern and RPE 12–14 is tolerated without adverse response. Add buoyancy cuffs or webbed gloves for resistance, multidirectional aqua walking, and back extensions with flotation aids; hand support at the wall is used only for balance safety, not weight-bearing.

- **Stage 4 – Functional integration (Sessions 10–12, Week 4):** Progress only if Stage 3 exercises are tolerated at target moderate intensity (RPE 13–15) across consecutive sessions with no adverse events. Combine core activation, dynamic balance tasks, and wall-supported strengthening with added resistance; water depth may be reduced toward waist level for selected standing-strength tasks if balance and pain criteria continue to be met.

- **Advancement rule:** A participant advances to the next stage only when all of the following are met at the end of the preceding session: VAS increase ≤2 points from pre-session baseline; Borg RPE within the target moderate range for that stage; no adverse event (increased pain, dizziness, instability); exercise performed with correct form per the therapist fidelity checklist.

- **Regression rule:** If any criterion above is not met, the participant repeats the current stage at the same or reduced intensity (e.g., increased wall support, reduced repetitions, shallower excursion) for one additional session before re-attempting progression; the treating physiotherapist documents the decision on the session checklist.

Fidelity monitoring: Therapist checklist documenting that core components were completed each session.

B. Passive aquatic therapy (Watsu).

Watsu is a therapist-guided passive aquatic technique integrating stretching, mobilization, massage, rhythmic movement, and acupressure in warm water.[5,6]

Setting: Warm hydrotherapy pool (35 °C); continuous therapist support and guidance; floatation supports (neck, knee noodle if needed).[5] Water immersion depth: therapist stands in chest-to-shoulder-depth water (~1.2–1.4 m) to allow full range of movement while manoeuvring the participant; the participant floats supine near the surface, torso and limbs submerged, with the head and neck kept clear of the water at all times and supported by a neck float/therapist's arm.[18]

Dose: 45–60 minutes/session, 3 sessions/week, 4 weeks (12 sessions).

Session structure:

- Preparation and supported floating.

- Cradling and rhythmic passive movement.

- Passive stretching and mobilization.

- Acupressure/soft tissue release.

- Final relaxation and breathing techniques.

Stepwise progression criteria (Passive Aquatic Therapy – Watsu):

- **Stage 1 – Acclimatization and supported floating (Sessions 1–3, Week 1):** Participant is fully supported in a near-horizontal supine float with neck float in place; therapist introduces gentle rocking and cradling only; minimal-range passive movement; goal is water confidence and muscular relaxation before any stretch is applied.[19]

- **Stage 2 – Gentle passive mobilization (Sessions 4–6, Week 2):** Progress from Stage 1 only if the participant tolerates the full session without anxiety or increased muscle guarding, VAS is not worse than pre-session baseline, and comfort is rated acceptable on the end-of-session checklist. Introduce slow rotational movement and gentle spinal elongation within a small range.

- **Stage 3 – Extended stretch and mobilization (Sessions 7–9, Week 3):** Progress only if no adverse reaction has occurred and observable muscle guarding has decreased. Introduce longer-lever passive stretches, wider-excursion rhythmic movement, and acupressure/soft tissue release.

- **Stage 4 – Full protocol (Sessions 10–12, Week 4):** Progress only if Stage 3 techniques are tolerated with sustained relaxation and no adverse events across consecutive sessions. Deliver the complete sequence cradling, passive stretching/mobilization, acupressure, and final relaxation/breathing at full intended duration.[6,19]

- **Advancement/regression rule:** Advancement to the next stage requires: no increase in pain or anxiety during or after the session; an acceptable participant comfort rating; no adverse event. If any criterion is not met, the therapist regresses to the previous stage's techniques (shorter lever arms, smaller range, more support) for the next session and documents the decision on the Watsu component checklist.

Fidelity monitoring: Watsu component checklist plus notes on participant comfort and tolerance.

C. Conventional physiotherapy (Land-based).

Conventional physiotherapy includes heat, electrotherapy, and structured exercise for mobility and core stability, consistent with conservative rehabilitation approaches.[11,13]

Setting: Land-based physiotherapy treatment room/gym (GMU outpatient clinic); plinth and floor-mat exercise area with standard heat and electrotherapy equipment; supervision by a licensed physiotherapist throughout, consistent with guideline-based conservative management of chronic low back pain.[9,13]

Dose: 45 minutes/session, 3 sessions/week, 4 weeks (12 sessions).

Session structure:

- Warm-up (5–10 min): general mobility exercises, gentle active range-of-motion, light aerobic activity.

- Heat/electrotherapy modality (10 min): superficial heat and/or electrotherapy applied to the lumbar region to reduce pain and facilitate subsequent exercise, consistent with conservative management approaches.[11,13]

- Main exercise component (20–25 min): core-strengthening and intensive dynamic back exercises (abdominal bracing, dynamic stabilization, back extensor/flexor strengthening) progressed according to the stages below.[11]

- Cool-down (5 min): stretching and relaxation.

Stepwise progression criteria (Conventional Physiotherapy):

- **Stage 1 – Foundational mobility and stabilization (Sessions 1–3, Week 1):** Low-load abdominal bracing, pelvic tilts, and basic dynamic stabilization exercises performed in supported positions (supine/quadruped); heat/electrotherapy applied before exercise; goal is correct movement pattern and pain-free baseline tolerance before progressing.[11]

- **Stage 2 – Progressive core strengthening (Sessions 4–6, Week 2):** Progress from Stage 1 only if post-session VAS increase is $\leq$2 points from pre-session baseline and exercises are completed with correct form per therapist

checklist. Introduce intensive dynamic back exercises (extended plank variations, bridging, bird-dog) with increased repetitions.[11]

- **Stage 3 – Functional strengthening (Sessions 7–9, Week 3):** Progress only if core endurance and pain criteria from Stage 2 are met without compensatory movement. Add resistance (theraband, light free weights) and multi-plane trunk exercises, with exercise dose and progression informed by prescription variables associated with pain reduction in chronic low back pain.[13,17]

- **Stage 4 – Functional integration (Sessions 10–12, Week 4):** Progress only if Stage 3 exercises are tolerated at target intensity across consecutive sessions with no adverse events. Combine strengthening, stabilization, and functional/occupational movement patterns at full intended dose.[13]

- **Advancement rule:** A participant advances to the next stage only when all of the following are met at the end of the preceding session: VAS increase ≤2 points from pre-session baseline; no adverse event (increased pain, dizziness, muscle strain); exercise performed with correct form per the therapist fidelity checklist.

- **Regression rule:** If any criterion above is not met, the participant repeats the current stage at the same or reduced load/repetitions for one additional session before re-attempting progression; the treating physiotherapist documents the decision on the session checklist.

Fidelity monitoring: Land-based session checklist.

Washout period

A one-week washout separates phases. Participants will not receive trial-delivered physiotherapy during washout. Any usual care/analgesic changes will be recorded.

Outcomes (SPIRIT item 16)

Primary outcome: Pain intensity measured by the Visual Analog Scale (VAS).[20]

- **Variable:** VAS score (0–10 cm).

- **Metric:** Change from baseline to end of each phase; end-of-phase absolute value.

- **Aggregation:** Mean (SD) per intervention.

- **Timepoints:** Baseline and end of each 4-week phase.

Secondary outcomes:

- **Functional disability:**Oswestry Disability Index (ODI).[21] Variable: ODI total score (%); Metric: change from baseline to end of each phase; Psychometric properties: Cronbach's α 0.82–0.90, ICC 0.90–0.96, MCID ~10–12 points.

- **Lumbar ROM (flexion and extension)**: measured with double inclinometer.[22] Variable: degrees flexion/extension (average of repeated trials); Metric: change from baseline to end of each phase; Timepoints: baseline and end of each 4-week phase.

Feasibility outcomes:

- Recruitment rate.

- Retention/completion (all phases + assessments).

- Adherence per phase (% sessions attended).

- Participant feedback on preference/comfort at final visit.

Participant timeline (SPIRIT item 18)

The schedule of enrolment, interventions, and assessments is presented in Table 1. Following screening and baseline assessment, each participant completes three consecutive 4-week intervention phases in the randomly allocated sequence, separated by two 1-week washout periods, giving approximately 14 weeks of total participation. Outcome assessments (VAS, ODI, and lumbar ROM) are performed at baseline and at the end of each intervention phase, while adverse events and concomitant care are reviewed at every study timepoint. Participant flow through screening, randomisation, the three intervention phases, and analysis is summarised in Figure 1.

Sample size (SPIRIT item 19)

This is a pilot/feasibility trial with a target of 12 participants. Formal power calculation is not the primary basis for this sample size, consistent with recommendations for pilot crossover trials, where the purpose is to establish feasibility (recruitment, adherence, retention) and to estimate within-person variability (e.g., standard deviation of within-subject differences) needed to power a future, adequately sized definitive trial.[8] A sample of approximately 12 participants in a three-period crossover design is broadly consistent with common pilot-study guidance (e.g., ≥10–12 per arm/sequence group for feasibility estimation) and matches the number registered with ClinicalTrials.gov. No inferential power claim is made for the primary comparative analysis at this sample size; effect estimates will be reported with 95% confidence intervals to support planning of a future trial.

Recruitment (SPIRIT item 20)

Participants will be recruited from GMU clinical services and physiotherapy referrals in Ajman, UAE, beginning around the anticipated start date (February 20, 2027) until 12 participants complete baseline and are randomized.

Table 1. Schedule of enrollment, interventions, and assessments (SPIRIT-style table).

	Screening (−t1 to 0)	Baseline/ Random. (0)	t1 (End Ph.1)	t2 (End Wash. 1)	t3 (End Ph.2)	t4 (End Wash. 2)	t5 (End Ph.3/Close-out)
Eligibility screening	X						
Informed consent	X						
Demographics/ clinical history	X						
Randomization (sequence)		X					
Active aquatic therapy (A)	delivered in one of the three phases, per allocated sequence						
Passive aquatic therapy Watsu (B)	delivered in one of the three phases, per allocated sequence						
Conventional physiotherapy (C)	delivered in one of the three phases, per allocated sequence						
Washout (no trial therapy)				◄─ 1 wk ─►		◄─ 1 wk ─►	
VAS pain[20]		X	X		X		X
ODI disability[21]		X	X		X		X
Lumbar ROM[22]		X	X		X		X
Adverse events review		X	X	X	X	X	X
Concomitant care/ medication changes		X	X	X	X	X	X
Participant preference/ feedback							X

(The "as per randomized sequence" entries indicate that each participant receives all three interventions, in the order determined by their randomly allocated sequence.)



Figure 1. Participant flow diagram.

Methods: Assignment of interventions (SPIRIT Items 21–24)

Sequence generation (item 21a)

Six possible sequences (ABC, ACB, BAC, BCA, CAB, CBA); computer-generated by a team member not involved in outcome assessment.

Allocation concealment (item 22)

Sequentially numbered, opaque, sealed envelopes prepared in advance.

Implementation (item 23)
Enrollment is performed by the study team; after baseline assessment and consent, the next envelope is opened. The randomization list is stored securely and inaccessible to outcome assessors.

Blinding (item 24a–24b)
Participants and therapists cannot be blinded due to intervention nature. The outcome assessor is blinded to sequence, supported by separating scheduling/intervention records from assessment forms.

Emergency unblinding (item 24c)
Given that only the outcome assessor is blinded (participants and treating therapists are aware of allocation by necessity), there is no scenario requiring emergency unblinding of a blinded party for safety reasons. No unblinding procedure is therefore required; if an urgent clinical need arose to know a participant's current-phase assignment, this information is already available to the treating team and PI at all times.

Methods: Data collection, management, and analysis (SPIRIT Items 25–27)
Data collection (item 25a)
Outcomes will be assessed by a blinded assessor using standardized instructions for VAS/ODI; ROM via repeated measures with averaging; a training session will be held for the assessor and intervention physiotherapists; completeness checks will be performed after each assessment.

Data management (item 26)
Participant IDs will be used in datasets; identifiable information will be stored separately and securely; password-protected electronic files will be accessible only to investigators; data will be retained 5 years post-completion; range checks will be applied (VAS 0–10; ODI 0–100; ROM plausibility bounds); de-identified data will be used for analysis/sharing.

Statistical methods (item 27a)
Main analysis (item 27a).

A linear mixed-effects model (or repeated-measures ANOVA with period effects) will compare VAS, ODI, and lumbar ROM across the three interventions within participants. Fixed effects: treatment, period,[1–3] sequence, first-order carryover. Random intercept for participant; unstructured covariance. Bonferroni-corrected post-hoc comparisons will be used where the overall treatment effect is significant. $\alpha = 0.05$ (two-sided). Marginal means, mean differences, and effect sizes (Cohen's d or partial η^2) with 95% CIs will be reported. Treatment-by-period interaction will be formally tested; if significant, period-specific effects will be presented.

Analysis population (item 27b).

Primary modified intention-to-treat (all randomized participants contributing ≥1 post-baseline assessment). Sensitivity per-protocol (≥75% of scheduled sessions per phase, no major deviations affecting the primary outcome).

Missing data (item 27c).

Primary approach mixed-effects models under missing-at-random.[8] Sensitivity analyses: (a) last observation carried forward; (b) multiple imputation (if >10% missing for any primary outcome) via chained equations, 20 imputations, incorporating baseline values, treatment, period, and key covariates.

Carryover/period sensitivity (item 27d).

Explicit first-order carryover terms will be included in the primary model; a sensitivity analysis restricted to periods 2–3 only will be conducted; models with and without carryover terms will be compared; high home-exercise adherence during washout (if collected) and baseline-phase covariate adjustment will be explored.

Interim analyses (item 28b).

No interim analysis is planned, and no stopping rule applies, given the short overall trial duration, small pilot sample, and low-risk nature of all three interventions. The single planned analysis will occur after all participants complete all phases.

Exploratory analyses
Baseline pain severity or other characteristics may be explored as moderators, without formal subgroup testing or multiplicity adjustment given n = 12. Feasibility outcomes will be summarized descriptively with 95% CIs.

Software
SPSS v25.0 (or R/Stata for advanced mixed models).

Methods: Monitoring (SPIRIT Items 17, 28–29)
Data monitoring committee (item 28a)
No independent Data Monitoring Committee is planned the interventions are low-risk and non-invasive, the sample is small, and risk is monitored on a session-by-session basis. Internal PI oversight is provided, with safety reporting to the GMU IRB.

Harms (item 17)
Harms are defined as any undesirable medical occurrence (increased pain requiring modification, dizziness, falls, skin irritation, muscle strain), regardless of causality. Active surveillance will occur at every session, with an end-of-phase review by the blinded assessor. Severity will be graded mild/moderate/severe, and causality classified as related/possibly related/unrelated. Serious adverse events will be reported to the GMU IRB within 48 hours.

Trial monitoring (item 29)
No formal external auditing is planned. Internal monitoring of adherence logs, assessment completeness, protocol deviations, and adverse-event reports will be performed periodically by the PI, with documented deviations and corrective actions.

Ethics and dissemination (SPIRIT Items 30–34)
Research ethics approval (item 30)
Gulf Medical University Institutional Review Board (GMU IRB), approval IRB-COHS-STD-122-APR-2024.

Protocol amendments (item 31)
Substantive changes will be submitted to the GMU IRB before implementation; the trial registry will be updated; version history will be maintained.

Consent or assent (item 32a–32b)
Written informed consent will be obtained by the PI or trained/supervised personnel before any study procedures. No biological specimens or ancillary studies are involved.

Confidentiality (item 33)
Coded participant IDs will be used; contact details will be stored separately from outcome data; only de-identified data will be shared externally.

Declaration of interests (item 7b)
None declared.

Access to data (item 26)
Investigators and authorized personnel will have access to the final dataset; de-identified data will be available on reasonable request after publication, subject to IRB/consent conditions.

Ancillary and post-trial care (item 34)
Usual care continues during and after the trial; no financial compensation is provided; trial-related harms will be managed per GMU clinical/IRB procedures.

Dissemination policy (item 8)
Peer-reviewed publication and conference presentation are planned; the ClinicalTrials.gov record will be updated; a plain-language summary will be offered on request; authorship will follow ICMJE criteria.

Discussion

CLBP is a prevalent, disabling condition affecting daily activities, psychological health, and quality of life.[1,2] Conventional physiotherapy remains central to conservative management, but relief is often incomplete, and average analgesic effects across non-surgical options are modest.[12,13] Although surgical treatment provides modest clinical benefits, these should be carefully weighed against its approximately 16% early complication rate, highlighting the importance of judicious patient selection and shared decision-making.[14]

Upon the recent surging of evidence in support of aquatic therapy in rehabilitation of patient with CLBP, this present study is the first to compare the effectiveness of active aquatic therapy, passive aquatic therapy (Watsu), and conventional physiotherapy in reducing pain, improving lumbar range of motion (ROM), and enhancing functional ability in individuals with CLBP. Aquatic therapy is reported to reduce axial loading via buoyancy and may reduce muscle guarding through warmth and hydrostatic pressure,[3,7] facilitating movement for patients who struggle with land-based rehabilitation. Active and passive aquatic approaches may operate through different mechanisms and suit different patient profiles: active aquatic therapy targets strengthening, mobility, and stabilization,[7] while Watsu emphasizes relaxation and passive mobilization that may influence pain perception and guarding.[5,6]

The crossover design strengthens internal validity by having each participant serve as their own control. One-week washouts minimize carryover, though residual effects (e.g., strength gains from active therapy) cannot be fully excluded; the analysis plan addresses this via explicit carryover terms, period-effect testing, and multiple sensitivity analyses.[8] The limitations of this study such as the inability to blind participants/therapists, a limiting power to detect carryover, and burden from extended multi-phase participation, may be overcome through assessor blinding, standardized measurement, adherence strategies, and feasibility tracking.

This trial is expected to generate practical comparative insight and the variability estimates needed to power a future, adequately sized definitive trial.

Timeline

Recruitment (~2 weeks) → Phase 1 (4 weeks) → Washout 1 (1 week) → Phase 2 (4 weeks) → Washout 2 (1 week) → Phase 3 (4 weeks) → Analysis & reporting (3–4 weeks).

Administrative information

This protocol has been prepared in accordance with the SPIRIT 2025 (Standard Protocol Items: Recommendations for Interventional Trials) guidelines.

Title (SPIRIT item 1a)

Effect of Passive Versus Active Aquatic Therapy Over Conventional Physiotherapy in Patients With Chronic Low Back Pain: A Randomized Crossover Trial — Study Protocol.

Trial registration (SPIRIT item 4).

This trial has been registered with ClinicalTrials.gov (registration number: NCT07196826), a publicly accessible primary clinical trial registry, in line with World Health Organization Trial Registration Data Set requirements.

Primary Registry: ClinicalTrials.gov

Trial ID: NCT07196826

Public title: Effect of Passive Versus Active Aquatic Therapy Compared With Conventional Physiotherapy for Chronic Low Back Pain (AQUA-LBP).

Official title: Effect of Passive Versus Active Aquatic Therapy Over Conventional Physiotherapy in Patients With Chronic Low Back Pain — A Randomized Crossover Trial.

Registration/PRS receipt release date: December 10, 2025.

Secondary ID/Unique protocol ID: IRB-COHS-STD-122-APR-2024.

Overall status: Not yet recruiting.

Anticipated start date: February 20, 2027.

Anticipated primary completion: August10, 2027.

Anticipated study completion: Dec 10, 2027.

Country: United Arab Emirates.

Masking: Single (outcomes assessor).

Allocation: Randomized.

Arms: 3.

Enrollment: 12 (anticipated).

Protocol version (SPIRIT item 2)

Protocol Version 1.0 (7 December 2025). Any subsequent amendments will be version-controlled and dated, and substantive changes will be reported to the registry and the ethics committee.

Funding and conflicts of interest (SPIRIT item 7a)

This study received no external funding and is conducted as part of institutional research at Gulf Medical University, Ajman, United Arab Emirates.

Roles and responsibilities (SPIRIT item 3a–3d)

Role	Name/Affiliation/Contact
Principal Investigator — study concept & design, oversight, ethics & registry, supervision of intervention fidelity, adverse event reporting, data interpretation, dissemination decisions	Ammar Mohamed, Department of Physiotherapy, Gulf Medical University, Ajman, UAE
Co-investigator — intervention operational planning, scheduling coordination, recruitment support, data collection coordination, manuscript drafting and revision	Dr. D.R. Watson Arulsingh, Department of Physiotherapy, Associate Professor, Gulf Medical University, Ajman, UAE (dr.watson@gmu.ac.ae, +971 50 570 8763)
Co-investigator	Dr. Praveen Kumar Kandakurti Dean, College of Health Sciences Gulf Medical University, Al Jurf, Ajman, UAE
Co-investigator	Dr. Ramprasad Muthukrishnan, Professor, College of Health Sciences, Gulf Medical University, Al Jurf, Ajman, UAE
Sponsor	Gulf Medical University, Ajman, United Arab Emirates (Department of Physiotherapy). The sponsor provides institutional facilities (clinic and hydrotherapy pool) but has no role in outcome selection, analysis decisions, interpretation, manuscript content, or publication decisions.
Oversight	No independent Data Monitoring Committee is planned (low-risk rehabilitation interventions, small sample size, short duration). Internal oversight is provided by the Principal Investigator with safety reporting to the GMU IRB.

Open science, access, and dissemination (SPIRIT Items 4–8)

Trial registration details

As above: ClinicalTrials.gov NCT07196826, PRS receipt release date December 10, 2025.

Protocol and statistical analysis plan access

This protocol will be accessible through the intended journal publication and/or institutional repository, and core registration details are available via ClinicalTrials.gov. The statistical analysis plan is included within this protocol (Statistical Methods section).

Data sharing

ClinicalTrials.gov IPD sharing was listed as "Undecided." For this protocol, the investigators plan the following.

- **What will be shared:** De-identified participant outcomes (VAS, ODI, lumbar ROM), data dictionary, and statistical code used for primary analyses.
- **When:** After publication of primary results (or after study completion if publication is delayed).
- **How:** Available upon reasonable request to the corresponding author, subject to IRB approval/conditions and participant consent language.
- **Safeguards:** Only de-identified data will be shared; direct identifiers will never be shared.

Funding and conflicts of interest (SPIRIT item 7a–7b)

- **Funding:** No external funding; institutional facilities are used.
- **Competing interests:** None declared.
- **Declaration of interests:** The authors declare that they have no competing interests.

Dissemination policy (SPIRIT item 8)

Results will be disseminated via peer-reviewed publication and conference presentations (regional physiotherapy/rehabilitation conferences). Results will also be updated on the ClinicalTrials.gov record. Participants will be offered a brief plain-language summary of results on request after study completion. Authorship will follow ICMJE criteria.

Data availability

No underlying data are associated with this article, as this manuscript reports a study protocol only; the trial status is "Not yet recruiting" (ClinicalTrials.gov NCT07196826) and data collection has not yet commenced. Once the trial is completed, the de-identified dataset underlying the results (participant-level VAS, ODI, and lumbar ROM values, the data dictionary, and the statistical code used for the primary analyses) is deposited in an open-access repository under a CC0 licence, and this statement is updated with the repository name, dataset DOI, and a description of the shared variables (age, sex, occupation, and other demographic and clinical variables), consistent with the data-sharing plan described in the Open Science, Access, and Dissemination section above.[23]

Reporting guidelines

A completed SPIRIT 2025 checklist for this protocol (reproduced in the Appendix, Table 1) has been deposited in the Figshare data repository, under a CC0 licence. It can be accessed at https://doi.org/10.6084/m9.figshare.33253920.[23]

Extended data

The same repository (Figshare, https://doi.org/10.6084/m9.figshare.33253920) also hosts the extended data for this protocol, including the participant information sheet, informed consent form template, and Visual Analogue Scale (VAS) pain questionnaire, alongside the SPIRIT checklist described above.

This project contains the following extended data: participant information sheet; informed consent form template; VAS pain questionnaire; participant flow diagram (Figure 1). Extended data are available under a CC0 licence at https://doi.org/10.6084/m9.figshare.33253920. The Oswestry Disability Index (ODI) is not included, as it is a copyrighted instrument (Fairbank & Pynsent, 2000) and is not deposited by the authors; the source is available from the original publisher/copyright holder.[23]

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This study protocol describes a single-center, randomized, three-period crossover trial comparing active aquatic therapy, passive aquatic therapy using Watsu, and conventional physiotherapy in adults with chronic nonspecific low back pain. Twelve participants will receive all three interventions in randomized order. Each intervention lasts four weeks and consists of three sessions per week, with one-week washout periods. The primary outcome is pain measured using a visual analogue scale. Secondary outcomes are disability measured using the Oswestry Disability Index and lumbar flexion and extension measured using inclinometers. Outcomes will be collected by a blinded assessor.
The clinical question is relevant, and the manuscript has several strengths. These include prospective registration, assessor blinding, use of all six possible treatment sequences, monitoring of adherence and adverse events, and an attempt to standardize intervention progression. The authors also acknowledge that the study is a pilot and that the sample cannot support definitive efficacy conclusions.
However, substantial revisions are required before the protocol can be considered scientifically sound. The principal concerns are the mismatch between the stated effectiveness objective and pilot sample size, the suitability of the crossover design for interventions with potentially persistent effects, the absence of measurements at the beginning of each treatment period, and an analysis plan that is too complex for 12 participants.

1. Rationale and objectives: **Partly**
The clinical rationale is generally understandable. The authors explain the burden of chronic low back pain, the potential advantages of aquatic rehabilitation, and the distinction between active aquatic therapy and Watsu. The three interventions and intended outcomes are also clearly identified.
The primary objective, however, is not consistent with the sample-size justification. The study is described as a superiority trial intended to compare effectiveness, while the sample-size section states that it is an unpowered pilot intended to assess feasibility and estimate variability. With only 12 participants, the study cannot provide a reliable determination of comparative effectiveness. This must be resolved in one of two ways:

1. Reframe the study as a randomized pilot feasibility trial. Feasibility outcomes should then become the primary outcomes, with explicit progression criteria for a future definitive trial. Treatment effects on VAS, ODI, and ROM should be described as exploratory estimates with confidence intervals, without claims of superiority.
2. If comparative effectiveness remains the primary objective, provide an appropriate power calculation and recruit a substantially larger sample.

The statement that 12 participants are consistent with guidance of "10–12 per arm/sequence group" is internally inconsistent. Twelve participants divided among six sequences provides approximately two participants per sequence, not 10–12. This passage must be corrected.
Claims that this is the first study to make the three-way comparison should also be appropriately referenced or presented more cautiously. The predicted superiority of particular treatments should either be formulated as prespecified hypotheses with supporting evidence or removed.

2. Appropriateness of study design: **Partly**
A crossover design can reduce between-person variation, but its suitability here is uncertain. Exercise, motor learning, strengthening, increased confidence in movement, and changes in pain behavior may persist considerably longer than one week. Consequently, the effect of active aquatic or land-based exercise could influence outcomes in subsequent periods. The manuscript acknowledges this possibility but does not provide evidence that a one-week washout is adequate.
The protocol currently includes assessments at the original baseline and after each intervention, but not immediately before periods 2 and 3. Therefore, it will not be possible to determine whether participants returned to a stable condition after each washout or to calculate a clearly defined within-period change.
The following revisions are essential:

- Provide a clinical and empirical justification for the one-week washout. A parallel-group pilot should be considered if persistent treatment effects are likely.
- If the crossover design is retained, collect VAS, ODI, and ROM immediately before and after every treatment period, including after each washout.
- Define the treatment effect being estimated, including whether it is the post-period value adjusted for the corresponding pre-period value or the within-period change.
- Prespecify and standardize concomitant medication, home exercise, and nontrial physiotherapy throughout the entire study, not only during washouts.
- Replace the proposed sensitivity analysis restricted to periods 2 and 3. If carryover is suspected, period 1 is the only carryover-free period, although a first-period analysis would be severely underpowered with this sample.
- Recognize that testing for carryover does not solve the problem because such a test will have extremely low power with 12 participants.

Differences in water temperature, treatment duration, therapist contact, and nonspecific attention may also confound the comparison between active aquatic therapy and Watsu. The authors should state whether the intention is to compare complete treatment packages or isolate the effects of active versus passive movement. If the latter is intended, these contextual elements should be standardized where possible.

3. Replicability of methods: **Partly**
The manuscript gives useful information about treatment frequency, general session structure, water depth, temperature, and staged progression. Nevertheless, several important details are insufficient for independent replication.
For active aquatic therapy, the authors should specify the exercises delivered at each stage,

including sets, repetitions, duration, movement speed, resistance, rest periods, and permitted modifications. Terms such as “full ROM,” “correct form,” and “target intensity” require operational definitions.

The Watsu protocol needs a reproducible sequence of techniques, positions, durations, repetitions, range limits, and decision rules. The required therapist certification or minimum training and experience should be stated.

The conventional physiotherapy comparator is particularly variable. “Heat and/or electrotherapy” allows different participants or periods to receive different treatments. The exact heat and electrotherapy modalities, settings, duration, indications, and rules for choosing between them must be defined. Exercise dosage and progression also need greater detail. Intervention manuals and fidelity checklists should be included as supplementary material.

Additional methodological clarifications are required:

- Define how nonspecific chronic low back pain will be diagnosed and by whom.
- Clarify the vague exclusion criterion “patient with injury to back.”
- State whether radicular symptoms and other specific spinal disorders are excluded.
- Provide complete aquatic safety and contraindication criteria.
- Define intervention discontinuation and participant withdrawal criteria.
- Describe how missed sessions will be handled and whether sessions may be rescheduled.
- State the number of therapists involved and how therapist-specific effects and treatment contamination will be minimized.
- Define recruitment rate, retention, adherence, and participant acceptability, including feasibility success thresholds.

Outcome measurement also requires more detail. The VAS anchors, recall period, administration method, and exact scoring procedure should be provided. “0–10 cm” should be checked for consistency. The ODI version, language, scoring rules, and handling of missing items should be stated. For inclinometer measurements, specify anatomical landmarks, patient position, device calibration, number of trials, averaging procedure, allowable differences between trials, and whether flexion and extension will be analyzed separately. The interval between the final treatment session and outcome assessment should be standardized.

4. Statistical analysis

The analysis section requires major revision. The abstract specifies repeated-measures ANOVA, whereas the main text proposes a mixed-effects model “or” repeated-measures ANOVA. One primary method must be selected in advance.

A model containing treatment, period, sequence, first-order carryover, treatment-by-period interaction, a participant random effect, and an unstructured covariance matrix is not credible with 12 participants and only approximately two participants per sequence. Multiple imputation with 20 datasets will also be unstable in such a small sample, and last observation carried forward should not be used.

For a pilot study, the analysis should emphasize:

- Recruitment, adherence, retention, missingness, safety, and acceptability with clearly defined denominators and confidence intervals.
- Exploratory treatment-specific means and within-person differences with confidence intervals.
- Estimation of variability needed to design a future trial.
- A simple, fully specified mixed model if exploratory adjusted comparisons are retained.

- Transparent reporting of missing-data amounts and reasons, without LOCF.

The modified intention-to-treat definition excludes randomized participants without a post-baseline assessment and is therefore not a full intention-to-treat approach. The analysis population and estimand should be revised and justified. Methods for calculating within-person standardized effect sizes should also be specified.

5. Data accessibility: **Not applicable**
No participant dataset currently exists because this is a study protocol and recruitment has not begun. “Not applicable” is therefore the appropriate response.
The future data-sharing statements nevertheless require correction. One section states that data will be available upon reasonable request, while another promises deposition in an open-access repository under a CC0 licence. These are different access models. The authors should adopt one clear, prospective policy and ensure that it agrees with participant consent, ethics approval, and the trial registry. The wording that the future dataset “is deposited” should be changed to “will be deposited.”

6. References, registration, and ethics
The reference list requires a complete audit. Reference 11 appears to be an editorial placeholder rather than a valid bibliographic citation. Some in-text citations also do not support the statements to which they are attached. For example, references cited for Borg RPE and Watsu progression appear to correspond to unrelated publications in the reference list. These errors must be corrected before indexing.
The authors should also confirm that the detailed protocol version dated December 2025, including the crossover schedule and intervention procedures, is covered by the ethics approval identified as April 2024. Any subsequent amendments should be identified with approval dates.
The manuscript, registry, ethics documentation, and consent materials should contain consistent information on design, sample size, outcomes, intervention duration, and data sharing.
The recruitment timeline of approximately two weeks appears unrealistic and does not align clearly with the stated completion dates. A consistent and feasible schedule should be provided.

Essential revisions for scientific soundness
Before the article can be considered scientifically sound, the authors must:

1. Align the objectives, trial framework, sample size, and conclusions by either reframing the study as a feasibility pilot or adequately powering an effectiveness trial.
2. Justify the crossover design and washout duration, and add pre-period measurements after both washouts.
3. Replace the current overparameterized and internally inconsistent statistical analysis plan.
4. Provide sufficiently detailed and standardized intervention protocols, particularly for Watsu and conventional physiotherapy.
5. Fully specify outcome administration and measurement procedures.
6. Correct the reference list and audit every in-text citation.
7. Reconcile the data-sharing statements and confirm consistency among the manuscript, registry, ethics approval, and consent documents.

Overall, this is a worthwhile clinical question and the protocol contains several useful design elements, but major revision is required before the planned study can produce interpretable and reproducible evidence.

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Is the rationale for, and objectives of, the study clearly described?
Partly

Is the study design appropriate for the research question?
Partly

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: exercise science

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

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