Statistical Analysis Plan for

Translation of Robotic Apparel for Alleviating Low Back Pain

NCT05736393

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STUDY DESIGN AND OBJECTIVES

Study Design

This is a single-arm controlled trial with individuals aged 18-70 with low back pain (LBP). This study investigates the effect(s) of augmenting physical therapy (PT) interventions with the use of an experimental wearable soft robotic device ('exosuit').

Participants will attend 12 study visits over 6 weeks. Study visits will include routine physical therapy care and exosuit-augmented physical therapy care (including functional movements probed during a structured biomechanical assessment on visits 1, 3, 6, 9 and 12). Participants will complete small surveys every visit to understand changes in pain, disability, and suit safety. On visits 1, 3, 6, and 12 the participant's biomechanical function will be apprised using a formal biomechanical assessment. Additional surveys will probe suit effects (effort, pain, and fear reductions) on these visits and exosuit usability. Before the participant's first study visit (1), discharge study visit (12), and one-month follow-up phone call (follow-up), participants will complete comprehensive surveys remotely at home to quantify pain, disability, catastrophizing, kinesiophobia, physical function, sleep quality, depression, and anxiety.

Study Objectives and Hypotheses

Primary: Evaluation of the feasibility, usability, and safety of using a back exosuit to augment routine physical therapy

Objective 1-A(a): *Determine whether back exosuit augmentation can objectively and perceptually improve the capacity to complete common bending and lifting activities within a single physical therapy session. We hypothesize that exosuits will enable individuals to: i) complete a standard task with less discomfort, concern, or effort. Or ii) increase task intensity, including completing more repetitions, lifting higher weights, and bending deeper.*

Hypothesis:

- 1-A(a)-i) Tasks performed with exosuit assistance will lower Perceived Task Discomfort (Primary Outcome Measure 4) and Task Effort (Primary Outcome Measure 6) compared to the slack condition.
- 1-A(a)-i) Participants will report lower PHODA scores (Primary Outcome Measure 5) when they rate their concern about performing tasks when envisioning themselves using the exosuit compared to envisioning themselves without the exosuit.
- 1-A(a)-i) Tasks performed with exosuit assistance will provide improved function compared to performance in the slack condition, particularly for primary outcome measures 7-10:
    - 7) Individuals will be able to flex further (higher range of motion)
    - 8) Individuals will generate higher back extensor moments and achieve higher "pull force" for the dynamometer pull task
    - 9) Individuals will complete more repetitions/levels in the progressive postural lifting task
    - 10) Individuals will complete more repetitions in the repetitive asymmetric endurance lifting task

Objective 1-A(b): Determine whether the effects (objective or perceptual) of back exosuit augmentation during common bending and lifting activities change longitudinally (over multiple PT sessions).

Hypothesis:

- All above outcomes will achieve better performance in the exosuit versus the slack condition. However, the relative difference (delta) between performances will narrow as individuals improve physical function and reach a floor or ceiling disability or function, respectively.

Objective 1-B: *Determine whether a participant's perception of back exosuit usability (i.e., ease of use, helpfulness or desire to use) changes longitudinally*.

Hypothesis:

- Device usability (primary outcome measure 1) will start high and will not change over time.
- Preferred device assistance levels will reduce over time as individuals have improved function.

Objective 1-C: *Determine the safety of back exosuit augmentation over the course of physical therapy (i.e., multiple physical therapy sessions).*

Hypothesis:

- Dependent on the outcome measure, we hypothesize:
    - Primary Outcome Measure 2: The biomechanical assessment (performed with the exosuit) does not significantly increase an individual's perceived pre-post changes in NRS pain by more than the clinically minimal detectable difference (2)
    - Primary Outcome Measure 3: Exosuit body map discomfort in all three regions will not exceed a clinically minimal detectable difference of 2.

Secondary: Evaluation of the efficacy of using a back exosuit to augment routine physical therapy

Objective 2-A: *Determine whether individuals who complete exosuit-augmented physical rehabilitation experience higher reductions in self-perceived pain and disability compared to a historical control group.*

Hypothesis:

- Dependent on the secondary outcome measure, we hypothesize:
    - Pre-assessment values of worse NRS in the last 24 hours will be comparable between groups. However, discharge values of NRS will be lower in the exosuit-augmented physical therapy group than in the conventional PT group.
    - Pre-assessment values of modified ODI will be comparable between groups. However, discharge values of ODI will be lower in the exosuit-augmented physical therapy group than in the conventional PT group.

Objective 2-B: *Determine whether a higher proportion of individuals who complete exosuit-augmented physical rehabilitation achieve clinically meaningful improvements in disability and pain compared to a historical control group.*

Hypothesis:

- Dependent on the outcome measure, we hypothesize:
    - A higher proportion of participants in the exosuit-augmented physical therapy group will achieve a 30% reduction in pain than in the conventional PT group.
    - A higher proportion of participants in the exosuit-augmented physical therapy group will achieve a 30% reduction in ODI scores than in the conventional PT group.

Tertiary: Identify interventional phenotypes, determine the relationship between changes in participants' symptoms and biomechanical function throughout exosuit-augmented physical therapy, and evaluate the ability of exosuit biomechanical data to verify clinical observations.

Objective 3-A: *Evaluate the comprehensive baseline and longitudinal dataset to elucidate interventional phenotypes of individuals with LBP compared to gold-standard clinical assessment using baseline patient-reported outcome measures, biomechanical data, physical therapy evaluation, and recovery trajectories. Identifying treatment responders and non-responders and which users are most likely to adhere to back exosuit-augmented PT.*

Hypothesis:

- There will be group clusters. However, we will not propose the directionality of these differences.

Objective 3-B: *Determine the relationship between changes in a participant's biomechanical function and their perceived pain, fear, and disability throughout 12 visits of physical therapy.*

Hypothesis:

- Changes in a participant's perceived level of pain, fear, and disability will be related to biomechanical function. However, PROs will improve before differences in function.

Objective 3-C: *Determine whether exosuit IMUs can accurately detect the type of physical therapy exercise a participant is involved in and / or confirm clinical classifications or observations*

Hypothesis:

- The level of accuracy will be specific to the type of PT exercises and clinical phenotype. Features will be considered accurate if they achieve moderate to high agreement between IMUs and the labeled movement type or clinical classification.

OUTCOME MEASURES

Primary Outcome Measures

1) Suit Usability: QUEST v2.0 [Time Frame: Visit (1, 3, 6, 9 and 12)]
    a) The QUEST is a standardized usability scale to determine a user's device satisfaction. Results range from 1 to 5 on a Likert Scale, with higher scores (5) corresponding to a very satisfied response.
2) Suit Safety: Patient-Reported Pain [Time Frame: Pre and Post Every Visit (1-12)]
    a) The Numerical Rating Scale of Pain will measure patient-reported levels of current pain intensity at the beginning and end of every study visit. Results range from 0 to 10, with higher scores indicating increased pain intensity.
3) Suit Safety: Patient-Reported Body Discomfort [Time Frame: Post Every Visit (1-12)]

a) The patient-reported level of current body discomfort will be appraised using a localized Numerical Rating Scale of Pain. At the end of every study visit, participants will rank their pain level in regions contacted by the exosuit, including the i) shoulders, chest, and upper back, ii) lower back, and iii) the thighs and lower legs. Results range from 0 to 10, with higher scores indicating increased pain intensity.

4) Suit Effect & Safety: Perceived Task Discomfort [Time Frame: Post Visit (1, 3, 6, 9 and 12)]
   a) The patient-reported level of task discomfort will be measured at the end of selected biomechanical assessment tasks (performed with the suit in a slack and active condition). Participants will rank task discomfort on a numerical rating scale of task discomfort. Results range from 0 to 10, with higher scores indicating higher total body difficulty.
5) Suit Effect: Concern of Movement [Time Frame: Post Visit (1, 3, 6, 9 and 12)]
   a) Patient-reported level of concern of movement will be measured at the end of each biomechanical visit. Four selected images from the Photo Series of Daily Activity will be ranked, with the participants envisioning themselves completing the task with or without the aid of the exosuit (Quirk et al., 2023). Results range from 0 to 10, with higher scores indicating higher concern with completing the task.
6) Suit Effect: Perceived Task Effort [Time Frame: Post Visit (1, 3, 6, 9 and 12)]
   a) Patient-reported level of task effort will be measured at the end of selected biomechanical assessment tasks (performed with the suit in a slack and active condition). Participants will rank task difficulty on a numerical rating scale of task difficulty. Results range from 0 to 10, with higher scores indicating higher task difficulty.
7) Biomechanical Suit Effect: Trunk range of motion, velocity, and coordination [Time Frame: Visit (1, 3, 6, 9 and 12)]:
   a) Inertial measurement units (IMUs) are positioned on the torso and each thigh. IMU biomechanics will be processed to determine the peak trunk range of motion, peak trunk velocity, and trunk coordination (phase–portrait smoothness and consistency). These measures will be calculated in all planes of motion. For selected biomechanical assessment tasks (performed with the suit in a slack and active condition) peak angles and velocity will quantify biomechanical effects.
8) Functional Suit Effect: Peak Deadlift Pull Force [Time Frame: Visit (1, 3, 6, 9 and 12)]:
   a) Measured during maximum voluntary isometric contractions (kg) will be measured using a stationary dynamometer. Peak full force will be measured for the slack and active suit condition.
9) Functional Suit Effect: Peak Dynamic Lifting Force [Time Frame: Visit (1, 3, 6, 9 and 12)]:
   a) Measured during dynamic 4 repetitions, progressive (5 pound incremental) floor-to-waist functional capacity lifting evaluation. The maximum mass lifted (repetitions performed) will compared between the slack and active suit conditions.
10) Functional Suit Effect: Repetitions during endurance lifting task [Time Frame: Visit (1, 3, 6, 9 and 12)]:
   a) Measured during dynamic 2.5 minute dynamic asymmetric lifting task. The maximum repetitions performed will compared between the slack and active suit conditions.
11) Preferred Suit Assistance Level : [Time Frame: Visit (1, 3, 6, 9 and 12)]
   a) The level of exosuit assistance (lifting and lowering) calculated through our preference learning approach on each biomechanical visit. Representing a metric of device usability.

Secondary Outcome Measures

1) Numerical Rating Scale of Pain (Pre-visit Worse in last 24 hours) [Time Frame: Baseline (Visit 1-12), and 1-month post (i.e., 30 days after discharge)].

a) Patient-reported levels of their worst pain intensity in the last 24 hours will be measured by the Numerical Rating Scale of Pain at the beginning and end of every study visit. Results range from 0 to 10, with higher scores indicating increased pain intensity.

2) Patient-Reported Disability Score [Time Frame: Every Visit (1-12), and 1-month post (i.e., 30 days after discharge)].
   a) Patient-reported pain intensity and interference is measured by the Modified Oswestry Disability Questionnaire (MDQ) scale. The MDQ is a series of 10 questions. Results range from 0 to 5, with higher scores indicating increased low-back related disability.

Tertiary Outcome Measures

1) Trunk Biomechanics: [Time Frame: Visit (1, 3, 6, 9 and 12)]:
   b) Inertial measurement units (IMUs) are positioned on the torso and each thigh. IMU biomechanics will be processed to determine the peak trunk range of motion, peak trunk velocity, and trunk coordination (phase–portrait smoothness and consistency). These measures will be calculated in all planes of motion. Peak angles and velocity will quantify biomechanics change over time for selected biomechanical assessment tasks (performed in Slack suit only).
2) Physical Function: [Time Frame: Visit (1, 3, 6, 9 and 12)]:
   a) Functional measures of maximum walking speed, time to complete a five-times sit-to-stand, and maximum functional reach distance will be used to understand how a participant's physical function changes over time.
3) Patient-Reported Pain Outcome Scales [Visit 1, 12, and 1-month follow up]:
   a) Participants' level of perceived pain, disability, catastrophizing, kinesiophiobia, physical function, sleep, depression, and anxiety will be measured using a battery of validated scales recommended by the BACPAC minimum dataset including BACPAC Minimum Pain Inventory, sleep duration, pain-catastrophizing scale (PCS-6), Generalized Anxiety Disorder (GAD-2), TAPS-1 Tool and the PROMIS: pain interference, physical function, sleep disturbance, depression, and anxiety scales. Additional validated scales will be collected, including OSPRO-YF and the Patient Specific Functional Scale.
4) Patient-Reported Outcome Scales [Visit 1-12, and 1-month post (i.e., 30 days after discharge)].
   a) Participants level of pain (PEG, NRS) and disability (ODI & PEG) will be measured using a variety of questionnaires. NRS and ODI are mentioned in Secondary Outcome Measures. The Pain, Enjoyment, of General Activities (PEG) scale is a series of 3 questions. Results range from 0 to 10, with higher scores indicating increased pain intensity.

STATISTICAL ANALYSIS PLAN AND SAMPLE SIZE CALCULATION

Statistical Analysis Plan

Primary Objective 1-A (a): whether back exosuit augmentation can objectively and perceptually improve capacity to complete common bending and lifting activities within a single physical therapy session

Only tasks that have both a slack and active suit condition will be considered with the following measures collected during or immediately following the completion of the task:

- Objective biomechanics (peak trunk angle, velocity, and coordination) will be monitored for the static flexion range of motion task, the progressive, dynamic postural lifting capacity evaluation, and the repetitive asymmetric endurance lifting task.

- Objective functional biomechanics will include task maxima such as peak pull force, maximum postural lifting capacity mass, and maximum repetitions in the asymmetric endurance lifting tasks.
- Perceptual task discomfort and difficulty measured during these tasks will be considered a scalar descriptive outcome that can be compared statistically.

Perception of task concern will be calculated as a summary metric at the end of the biomechanical assessment, consistent with Quirk et al, 2023. These questions will be answered with the participant rating their level of concern if they performed these tasks with and without the exosuit. These 10-point scale data will be considered a scalar descriptive outcome that can be compared statistically.

A paired t-test will demonstrate whether an exosuit can modify biomechanics, perceived task effort, discomfort, and concern. Change scores will be calculated between the participant's slack-suit and active-suit condition (for Objective 3), which can be compared using a one-sample t-test.

Primary Objective 1-A (b): whether back exosuit augmentation can objectively and perceptually improve capacity to complete common bending and lifting activities over multiple physical therapy sessions.

All of the above outcome measures will be collected on five occasions (Visit 1, 3, 6, 9, and 12). A two-factor (time (5) condition (2 [active-suit or slack-suit])) Linear Mixed Model (LMM) will demonstrate whether an exosuit can modify biomechanics, perceived task effort, discomfort, and concern between conditions over time.

Primary Objective 1-B: whether participant's perception of back exosuit usability changes over time

Likert Scale Questions from the QUEST survey will be considered as individual scalar data points. Data points will be transformed so that high scores represent the perception of high device usability. An average score will be calculated across all QUEST domains. A one-factor (time (5)) LMM will determine whether usability changes over time.

Exosuit assistance levels for both lifting and lowering preferred by participants will be compared over time in a two-factor (direction (2 lift and lower) by time (5)) LMM to determine how an indivdiuals desired level of exosuit assistance changes over time and with changes in function.

Primary Objective 1-C: whether it is safe to augment physical therapy with a back exosuit

The numerical rating scale of pain will be measured before (pre) and after (post) each study visit (12). To exosuit safety will be tested in two ways. First, a change score (post-pre) will be calculated for each study visit. The average and maximum change scores will be calculated across 12 visits, and these data will be compared using a one-sample t-test to a reference change value of 2. To understand changes over time, a LMM that contains at least 2 factors (measure (2 [pre or post]) time (12)) will be used.

The participants' perceived local exosuit discomfort level will be measured on a 10-point NRS scale at 3 body regions. Exosuit discomfort will be tested in two ways. First, the average and maximum level of NRS discomfort will be compared for each body region using a one-sample t-test to a reference change value of 2. A two-factor (region (3) and time (5)) LMM will determine whether exosuit discomfort changes over time.

Secondary Objectives:

Description of Historical Data Set:

For individuals seeking treatment for LBP, BUPTC regularly collects data regarding participants' demographics (Age and Sex), initial assessment (STarT BACK, Treatment Based Classification, and Chronic LBP category), and clinical outcomes (NRS Current and Worse Pain, ODI) for each treatment visit including discharge. De-identified HIPPA-coded data collected from adults (>18 years old) treated at BUPTC from 2016-July 2024 are approved to be coded by authorized BUPTC members and uploaded to a Two-factor protected BU SharePoint as a historical control dataset by BU IRB (6644X) under section 45 CRF 64.104(d)(4)(ii)&(iii). The historical control dataset will include de-identified data collected at intake and discharge, the number of visits from intake to discharge, average visit frequency, and clinical outcomes measured around visits 1, 3, 6, 9, and 12.

Propensity matching approach:

This study will match study participants with a historical dataset measured at BUPTC. Participants will be propensity-matched with the following criteria. 1) A categorical match with treatment based category (movement or motor control), sex (women, men, or other), and STarT BACK risk category (low, medium or high) and LBP chronicity (yes or no). 2) Tolerance match for baseline levels of pain (levels numerical rating pain scale within a 2-point tolerance) and baseline (modified Oswestry disability index within a 7-point tolerance). These numbers reflect minimal clinical differences. 3) Tolerance matched by age within a 5-year tolerance, number of PT visits within a 4-visit tolerance, and the number of visits per week within a one-visit-per-week tolerance. Multiple potential matches will be measured for each participant.

Objective 2-A: Whether exosuit augmented physical therapy leads to greater reductions in pain and disability than a historical control group.

NRS and ODI intensity measured by the historical control group and the exosuit augmented physical therapy participants at baseline, and discharge will be compared using a 2-factor (group(2) and time (5)) LMM, to demonstrate whether augmented physical therapy decreased pain and disability to a greater magnitude or more quickly than conventional therapy.

Objective 2-B: Whether exosuit augmented physical therapy leads to a greater proportion of individuals who achieve clinically meaningful improvements in pain and disability compared to a historical control group.

Individuals will be classified as meeting their pain or disability clinical goals if they achieve a 30% reduction in these measures at discharge compared to baseline. The portion of individuals who failed to progress will be calculated in both the control and exosuit augmented physical therapy group. These data will be compared using a chi-square approach with significance set to an exploratory alpha of 0.05.

Tertiary Objectives

Objective 3-A: Phenotyping of treatment categories, responders, and adherent users

Baseline: i) patient-reported outcome measures, ii) functional performance, iii) biomechanical function and iv) short term exosuit change scores will be entered into General Estimating Equation (GEE) models use to predict:

- A participants TBC (movement or control impairment)

- Ability to meet pain or disability clinical goals, described in Objective 2-B (pass or fail)
- Participants who were or were not successful in attending all exosuit augmented study visits (>10 visits with more than 20 minutes of exosuit usage).

Predictor variables in categories 1-4 will be entered separately and combined. Larger models will be developed to correct significant confounding variables. A GEE was selected as it allows for the inclusion of time-varying covariates and estimates in the presence of missing data without listwise deletion. The distribution and fit function for the GEE will be selected based on minimizing the information criteria (Akaike Information Criteria and Bayesian Information Criteria). Significance will be set with an exploratory alpha of 0.05.

Objective 3-B&C: Determine the relationships between changes in biomechanical function and PRO measures of pain, disability, and fear & prediction of physical therapy tasks.

Principal Component Analysis will determine highly related variables. However, various neural network and machine learning models will be developed to determine the strength and accuracy of models designed to predict relationships between biomechanics and PRO. These models will include factors that correct for systematic time lags, for example, PRO recovery occurring before biomechanical recovery. These forms of analysis are exploratory, and data analysis plans will evolve with iteration.

Inclusion of Confounding Baseline Data

Baseline confounders between TBCs, responders and non-responders, and adherent exosuit users will be determined using t-test, Wilcoxon, or Chi-square test for parametric, rank order, and categorical data. Factors that obtain an alpha of 0.05 will be entered as co-variates into larger LMM and GEE models described above to correct for group differences.

Significance and Model Assumptions:

<u>t-test and LMM</u>

Significance will be set with an exploratory alpha of 0.05. These models assume linearity and normality, which will be evaluated using Box-Cox and Shapiro-Wilk tests, respectively. Outliers and influential cases will be screened for and removed. Violations of the assumptions will be remedied using a robust standard error or recommended Johnson transformation using Minitab 19.

Analysis Plan Overview

Data from this single-arm mechanistic trial will be analyzed across the study population. All participants included in this study will be exposed to the exosuit while in their first study visit. Hence, their data can be used for Objective 1-A(a) and 1-C. Given the pragmatic design of this study, participants are in charge of scheduling the frequency of therapy visits. Some participants may miss study visits, drop out, or be removed from the study early (see MOP Section 5.3). Most participants have at least 1 follow-up assessment. Hence, in many cases, participants' data can be applied to Objectives 1-A(b), B, 2, and 3 once correcting for missing data.

Objectives 1-A(b) and 2 will be analyzed as a partial pure population. These objectives require at least 1 follow-up assessment to be included in our statistical models. Data from the initial, discharge, and follow-up surveys will code whether the participant completed the study 1) per

protocol, 2) with early discharge, and 3) with early withdrawal or termination. To understand whether differences exist amongst participants who do or do not complete therapy.

Data from protocol deviations

Data collected from our pragmatic design, including the duration of exosuit-augmented physical therapy, is inherently flexible. Participants have the ability to skip experimental tasks, which will be treated as missing data. However, protocol deviations may occur.

The most likely protocol deviation will arise from participant time constraints or technological problems that make it impossible for the research team to conduct the biomechanical assessment on the desired study visit (3,6,9). If this were to happen, the biomechanical assessment will be scheduled one visit before or after the intended biomechanical assessment visit. Otherwise, the visit data will not be collected (missed).

Missing Data

Mixed models and estimating equations use each participant's available information, enabling estimates and tests for significance in the presence of missing data.

Loss to Follow-Up Analysis

Enrolled participants' data will be defined as complete or lost to follow-up. Baseline characteristics between participants who were and were not lost to follow up will be compared using a t-test, Wilcoxon, or Chi-square test for parametric, rank order, and categorical data, respectively. Depending upon how much data there is for a participant lost to follow-up and the study objective, participants lost to follow-up might be included for statistical analysis. For example, objective 1-A(a) can be completed by any participant who completed the biomechanical assessment, and 1-A(b) can be developed with missing data. Objective 1-C can be tested. with all participants included in the study.

SAMPLE SIZE AND POWER CALCULATIONS

Primary Objective 1-A (a): whether back exosuit augmentation can objectively and perceptually improve capacity to complete common bending and lifting activities within a single physical therapy session

For aim 1-A(a), previous work (Quirk, 2023b) in our lab and others (Baltrusch 2020, Kozinc, 2021) have determined moderate biomechanical differences (lifts completed, EMG reductions, moment reductions) between exosuit and no-exosuit conditions (effect size, Cohen's d=0.5-0.55) can be detected with a sample size of 30 participants. For perception, back exosuits and exoskeletons have been shown to have moderate to large abilities to increase self-confidence (d=0.63), the concern of movement (d=1.4), task difficulty (d=0.42-1.3), and task-related back pain (d=0.30-0.97). Suggesting these measures will achieve significance with a similar sample size.

No literature exists to support Objectives 1-A (b), 1-B (testing a null hypothesis), and 1-C.

Primary Objective 2-A: **Whether exosuit augmented physical therapy leads to greater reductions in pain and disability than a historical control group**

No study demonstrates the in-field efficacy of an exosuit or exoskeleton to reduce levels of low back pain and disability. Studies exist evaluating the effect of knee exoskeletons on promoting recovery from total knee replacements (Kotani et al., 2020). For aim 2, the study will seek to confirm that

each TBC demonstrates a response with exosuit therapy. Exoskeletons have been shown to reduce knee pain and disability more than conventional therapy, with a large effect size (Cohen's d=0.70-1.1) over 10 visits. Therefore, each TBC will require an n=19 to detect a significant difference (α=0.05) with 80% power. To improve the statistical power of aim two, we will use propensity score matching (PSM), inflating the n to greater than or equal to 80-120, depending on the PSM technique selected.

Collective sample size calculation

Our study anticipates a 20% dropout of participants. The minimum number of participants needed to achieve objective 2-A is approximately 40. To demonstrate the effect of a back exosuit with each of our TBCs (objective 1-A(a)), the study will seek data from at least 60 participants. If this number is not achieved, objective 1-A(a) will remain powered by combining participants from both TBC. Therefore, the study will aim to enroll 48-72 participants to achieve these goals.

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