AALBORG UNIVERSITY

Statistical analysis plan for the EXO4MMH trial – a randomized controlled trial for the effectiveness of an occupational passive back-exoskeleton on the biomechanical load of warehouse workers

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Section 1: Administrative Information

Item 1a: Descriptive title

Statistical analysis plan for the EXO4MMH trial – a randomized controlled trial for the effectiveness of an occupational passive back-exoskeleton on the biomechanical load of warehouse workers

Item 1b: Trial registration number

Trial registration: ClinicalTrials.gov: NCT05890300 (registered 27.04.2023)

Version

Item 2: Statistical analysis plan (SAP) version number with dates

Statistical analysis plan version 1.2. Date: May 15, 2024

Protocol version

Item 3:

The SAP is based on the protocol approved by the North Denmark Region Committee on Health Research Ethics (LBK nr. 1083) and the study protocol which was published on the 27.04.2023. The SAP was made publicly available before commencing any statistical analysis of the outcomes.

SAP revisions

Item 4a/b/c

No revisions have been made.

Roles and responsibilities

Item 5: Roles, affiliations, and SAP contributors

Principal investigator:

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Item 6a: Signature of person writing the SAP

PhD student Lasse Schrøder Jakobsen Date: 06.05.2024

Item 6b: Signature of senior statistician responsible

Dr Afshin Samani Date: 09.05.2023

Item 6c: Signature of chief investigator

PhD student Lasse Schrøder Jakobsen Date: 06.05.2024

Section 2: Introduction

Background and rationale

Item 7:

The product-line of logistics wholesale companies are characterized by a low level of automation due to the big variety of goods, making them highly dependent on manual handling of materials (Danko & Straka, 2022). This is accompanied by strenuous tasks comprising heavy workloads, awkward postures, and repetitive movements (Glock et al., 2021; Skals et al., 2020). These tasks are considered as risk factors contributing to work-related musculoskeletal disorders (WMSDs) (Govaerts et al., 2021; Katz, 2006). Exoskeletons have been proving beneficial in terms of decreasing the muscular activity of target areas of the body during physical activity (Nussbaum et al., 2020; Theurel & Desbrosses, 2019). Thus, occupational exoskeletons represent potential benefits in terms of reducing the musculoskeletal loads during manual materials handling, and thereby reducing the risk of WMSDs. In a previous study, we report a 13-20% reduction in peak back muscle activity when wearing a back-supporting exoskeleton during similar work tasks (Schrøder Jakobsen et al., 2024).

However, literature still claims a lack studies investigating the long-term effects of wearing an exoskeleton on the biomechanics of the user (Crea et al., 2021; Howard et al., 2020; Kranenborg et al., 2023; Theurel & Desbrosses, 2019). Thus, this randomized controlled trial investigated the biomechanical changes after a 24-week period of using a back-supporting exoskeleton (BSE) for manual order picking tasks. Furthermore, it included data on the changes in musculoskeletal discomfort, acceptance of the exoskeleton, and perceived effort and work intensity of warehouse workers.

Objectives

Item 8: Description of objectives and hypothesis

The primary objective was to examine alterations in biomechanical parameters after 24 weeks of practical application of a back support exoskeleton (BSE). Furthermore, secondary aims encompassed the

investigation of changes in user acceptance, exoskeleton comfort levels, perceived exertion during tasks, and incidences of musculoskeletal discomfort following prolonged utilization of the exoskeleton device.

Hypothesis:

Based on established literature, we hypothesized that a duration of 24 weeks employing the BSE will yield positive impact on user biomechanics characterized by diminished back muscle activity and decreased knee flexion indicating a more stoop lifting technique (Diamond-Ouellette et al., 2022; Poggensee & Collins, 2021; Schrøder Jakobsen et al., 2024). Furthermore, we hypothesized that prolonged utilization of the BSE will increase exoskeleton comfort and acceptance among users, concomitant with a reduction in perceived work intensity and occurrences of musculoskeletal discomfort, due to the anticipated mitigation of biomechanical load (Kazerooni et al., 2019; Schrøder Jakobsen et al., 2024).

Section 3: Trial methods

Trial design

Item 9: Description of trial design

This trial was designed as a randomized controlled parallel intervention trial. Exoskeleton usage was allocated to the participating workers in a 1:1 ratio. The workers were randomized to intervention and controls. The intervention group was allocated a BSE for a 24-week period to perform their work tasks, while the control group performed their work tasks as normal for the same period. The primary endpoint was at the 24-week post-test.

Randomization

Item 10: Randomization details

The randomization was performed by an external blinded researcher not involved in data collection or assessments. After informed consent and baseline assessments had been conducted, the participants were randomly assigned to either intervention or control group using stratified randomization. Sex, work experience, and previous experience issues of low back-pain were used as strata.

Sample size

Item 11: Full details of sample size calculations

A priori sample size calculation for a repeated measure, within-between interaction design was conducted to estimate the required sample size to achieve a power of 80%. The calculation was based on effect sizes previously reported on training effects of the present BSE on muscular activity from SEMG erector spinae measurements ($\eta^2 \geq .370$) (Schrøder Jakobsen et al., 2024). A two-sided significance level at .05 was set and revealed that a total minimum of 18 workers was required resulting in an actual power of .838. To account for a 10% drop-out, a total of 20 workers (10 per group) were enrolled.

Framework

Item 12: Description and hypothesis testing framework

Primary outcomes (biomechanical measurements) were evaluated in a within-between interaction framework, hypothesizing that the workers would experience a reduction in muscular activity and changed kinematics when using the BSE, and further that the reduction will increase from baseline to post-test in line with previously reported training effects (Diamond-Ouellette et al., 2022; Poggensee & Collins, 2021;

Schrøder Jakobsen et al., 2024). Secondary outcomes, were evaluated in a superiority framework, hypothesizing that workers using the BSE would witness a reduction in musculoskeletal discomfort and perceived work intensity, and increased acceptance of comfort in relation to BSE usage. A significance level of .05 will set.

Statistical interim analysis and stopping guidance

Item 13:

No interim analysis was planned, and no adjustment of significance level was made. No stopping rules was defined a priory.

Timing of final analysis

Item 14:

The analysis of primary, secondary, and other outcomes was conducted collectively when all workers had completed the test session post the 24-week intervention/control period. The 24-week intervention was expected to finish in April 2024. Biomechanical data from baseline and post-test, and questionnaire data from all the data points (baseline + 4-, 8-, 12-, 16-, 20-weeks, and post-test) were be included in the analysis.

The analysis of the primary, pre-specified secondary, and other outcomes (item 26) will be reported in the primary publication. The remaining outcomes will be reported in the secondary publication.

Timing of outcome assessment

Item 15:

Biomechanical outcomes (surface electromyography (SEMG) and kinematics) and perceived effort will be evaluated at baseline and post-tests. The questionnaire assessed outcomes (perceived work intensity, exoskeleton comfort and acceptance, and musculoskeletal pain) will be evaluated continuously during the intervention period at four-week intervals ending at post-test. Further details can be found at the published study protocol (NCT05890300).

Section 4: Statistical principles

Confidence intervals and p-values

Item 16: Level of statistical significance

All conducted statistical tests will be two-sided and evaluated by a significance level of 5% (i.e., p =.05).

Item 17: Description of planned adjustment for multiplicity

To take precaution for multiplicity, multivariate statistical tests will be conducted to reduce the number of analyses ran, and thus the family-wise error rate. Additionally, Bonferroni corrections will be conducted to reveal significant differences when more repeated measures are occurring, which is considered a conservative approach in terms of reducing family-wise errors (Robert, 2020).

Item 18: Confidence intervals

The presented confidence intervals will be 95% and be two-sided.

Adherence and protocol deviation

Item 19a: Definition of adherence to interventions

Adherence will be defined as the workers of the intervention group compliance to BSE usage during the 24-week period. The protocol consists of a 5-weeks familiarization period consisting of progressive usage of the BSE (Schrøder Jakobsen et al., 2023), followed by 19 weeks of minimum 18-hours of BSE usage per week. Adherence is self-registered day-by-day by the individual worker and monitored by the principal researcher.

Item 19b: Description of how adherence to intervention will be presented

Adherence to the intervention will be reported as weekly reported hours of BSE usage during the full 24-week period. Weekly hours of BSE usage will be reported at both individual and group level.

Item 19c & 19d: Definition of protocol violation for the trial and how they will be presented

It is specified as an exclusion criterion if workers resigns / get laid off during the intervention period.

Analysis populations

Item 20: Definition of analysis populations

The analysed population corresponded to the workforce of a specific department at a Danish logistics company. The department consists of a total workforce of approx. 70 fulltime employees. Only fulltime workers were included in the trial. Workers who should resign during the intervention period will be excluded from the analysis.

Section 5: Trial population

Screening data

Item 21: Reporting of screening data

The recruitment period will be showcased from start to end alongside the total number of workers screened for eligibility.

Eligibility

Item 22: Summary of eligibility criteria

Workers were eligible to participate in the trial if they fulfilled the inclusion criteria:

- Full-time employed at the department handling fruits and vegetables at Dagrofa Logistics A/S
- No major injuries affecting their daily work tasks
- No plans of retiring before the end of the intervention period

Study exclusion criteria were:

- Body compositions unable to fit the exoskeleton (bad fit)
- Part-time employment
- Previous low-back injuries

Recruitment

Item 23 & 24: Information to be included in CONSORT flow diagram

A CONSORT flow diagram will be displayed, including the following information:

- Number of workers assessed for eligibility throughout the recruitment period
- Number of workers not meeting the inclusion criteria’s or not consenting to participate

- Number of workers eligible for inclusion
- Number of workers randomized to both arms of intervention (intervention & control)
- Number of workers included in baseline and post-test sessions
- Number of workers included in 4-, 8-, 12-, 16-, and 20-week questionnaire assessments
- Number of excluded workers and withdrawals throughout the intervention period

Baseline worker characteristics

Item 25a: List of baseline characteristics to be summarized

The workers will be described with baseline, demographic characteristics which include sex, age, height, body mass, BMI, work experience, and previously experienced low back-pain rated using a simplified version of the Nordic questionnaire (Kuorinka et al., 1987).

Item 25b: Details on how baseline characteristics will be descriptively summarized

Table 1 illustrates how the baseline characteristics will be interpreted. Continuous data will be presented as mean ± SD if data is normally distributed and as median and range if data is non-normally distributed. Categorical data will be presented as numbers and percentages. No test for statistical significance for the baseline characteristics will be conducted in line with the recommendations by the CONSORT statement (Moher et al., 2010).

Table 1: Baseline characteristics of the workers

Characteristics	Intervention group	Control group
Age (years), mean ± SD		
Sex (men/women), n & %		
Height (cm), mean ± SD		
Body mass (kg), mean ± SD		
Body mass index (kg/m^2), mean ± SD		
Work experience (years), mean ± SD		
Previously experienced low back-pain (0-10 index), mean ± SD		

Section 6: Analysis

Outcome definitions

Item 26: Specifications of outcome and timings

Table 2 specifies the measured outcomes, the timing of assessment, and the analysis methods. Further detailed descriptions can be found in the open access protocol (NCT05890300).

Table 2: Overview of primary, secondary, and other outcomes.

	Instrument for assessment	Timing for assessment	Analysis method
Primary outcome – reported in primary publication			
Changes in muscular activity of the back i) with/without BSE,	Surface electromyography (SEMG) analysis of erector spinae longissimus and	Baseline and 24-week post-test	Two-way Repeated measures multivariate analysis of variance

and ii) pre/post the 24-week intervention. Based on standardized work tasks performed during test sessions.	lower trapezius, including normalization to maximum isometric voluntary contraction. The analysis will include the 10^{th}, 50^{th} and 90^{th} percentile of the SEMG amplitude.		(2RM-MANOVA)
Changes in kinematical pattern of the back and knee joints i) with/without BSE, and ii) pre/post the 24-week intervention. Based on standardized work tasks performed during test sessions.	Inertial measurement unit based, full-body motion capture analysis. The analysis will include the 10^{th}, 50^{th} and 90^{th} percentile of the back forward bending and rotation (cumulative T8-S1) and knee flexion/extension joint angles.	Baseline and 24-week post-test	2RM-MANOVA
Secondary outcome – reported in primary publication			
Changes in perceived effort i) with/without BSE, and ii) pre/post the 24-week intervention. Based on standardized work tasks performed during test sessions.	Assessed using Borg Category-Ratio (CR) scale (0 = no effort, 10 = maximum effort).	Baseline and 24-week post-test	2RM-MANOVA
Changes in BSE comfort and performance	Assessed using a questionnaire including questions on fit and (thermal) comfort, balance, range-of-motion, safety, and perceived job performance. All questions are answered using a 10-point Likert-scale (e.g., 0 = no discomfort, 10 = most discomfort) (Kim et al., 2022).	Baseline, 4-, 8-, 12-, 16-, 20-weeks, and post-test	One-way Repeated measures multivariate analysis of variance (1RM-MANOVA)
Changes in liking of the BSE	Assessed using open-ended questions on liking: Q1: “What do you most like about the exoskeleton?", Q2: "What do you least like about the exoskeleton?", Q3: "If you could change anything about the exoskeleton, what would you change?" (Kim et al., 2022).	Baseline, 4-, 8-, 12-, 16-, 20-weeks, and post-test	1RM-MANOVA

Changes in perceived work intensity	Assessed using a questionnaire including questions on work intensity. All questions are answered using a 10-point likert-scale (0 = strongly agree, 10 = strongly disagree) (Kim et al., 2021).	Baseline, 4-, 8-, 12-, 16-, 20-weeks, and post-test	1RM-MANOVA
Changes in musculoskeletal discomfort	Assessed using the Cornell Musculoskeletal Discomfort Questionnaire (Hedge et al., 1999).	Baseline, 4-, 8-, 12-, 16-, 20-weeks, and post-test	1RM-MANOVA
Other outcomes – reported in primary publication			
BSE usage of the workers in the intervention group	Self-reported by the individual worker on daily basis.	Day-by-day assessment during the 24-week intervention	No statistical analysis
Secondary outcomes – reported in secondary publication			
Changes in productivity of the workers when using the BSE	Monitored by the company as a key performance indicator of the employees. Tracking of boxes handled / orders conducted during a workday.	Weekly assessment during the 24-week intervention	Regression analyses

BSE: Back support exoskeleton

Analysis methods

Item 27:

All statistical analyses will be performed by the principal investigator (LSJ). The principal senior statistician (AS) will take a supervisory role, and thereby take the responsibility of overseeing the SAP and the analyses performed.

The primary publication of the 24-week RCT will include the primary, pre-specified secondary, and other outcomes presented in table 2. The remaining secondary outcomes will be reported in the subsequent, secondary publications regarding changes in productivity of the workers due to BSE usage.

The primary outcomes will be the biomechanical changes (SEMG and kinematics) of i) BSE usage (with/without) and ii) intervention (baseline/post-test). Statistical test will be dependent on data distribution. Validation of normality and sphericity of the data will be conducted using Shapiro-Wilk tests of normality and Mauchly's sphericity tests, respectively. For continuous measurements we expect normality, thus will be using a two-way repeated measures multivariate analysis of variance (2RM-MANOVA) with BSE usage and baseline/post-test as independent factors, and the biomechanical outcomes as dependent variables. Effects of BSE usage, the intervention, and the interactional effect of the two will be included in the analysis. The perceived effort (from the secondary outcomes) will also be included in this analysis.

The remaining secondary outcomes will be assessed for normality and sphericity using an approach similar to the primary outcomes. However, a different statistical analysis will be conducted due to the difference in factors. A one-way repeated measures multivariate analysis of variance (1RM-MANOVA) with timepoints (baseline, 4-, 8-, 12-, 16- , 20-weeks, and post-test) as the independent factor and comfort, performance,

liking, work intensity, and musculoskeletal discomfort as dependent outcomes will be used for assessment. If any significant change is detected, an additional post hoc (Bonferroni) analysis will be performed.

The primary outcomes (including perceived effort) will be reported in figures including with /without BSE usage measures from baseline and post-test. In this case mean and individual values from both groups will be reported. The remaining secondary outcomes will be reported in figures including data from all time points (baseline, 4-, 8-, 12-, 16- , 20-weeks, and post-test). Similarly, mean, and individual values from both groups will be reported.

The individual BSE usage will be depicted in a graph for the workers included in the intervention group. This will include week-to-week reporting of individual BSE usage and group mean. The BSE usage will not be statistically analysed.

The secondary publication will focus on the potential changes in productivity of the worker when using the BSE. It will include a regression analysis between individual productivity of the worker, and the hours using the BSE. Additional outcomes will also be included in the publication, i.e., monitoring of temporal changes in musculoskeletal discomfort during the intervention period. The coherence between productivity and BSE usage will be depicted in scatter plots.

Missing data:

Item 28: Reporting and assumptions/statistical methods to handle missing data (e.g., multiple imputation)

If any worker was excluded from the trial initial to the post-test (i.e., due to resignation), none of the excluded worker's data will be included in the analysis. Number of data points available in each group at any timepoint will be displayed in the primary publication. Workers violating the protocol by using the BSE less than intended, will not be excluded from the analysis. However, the effect of this potential issue will be handled in additional analyses (see below).

Additional analyses

Item 29:

The following additional analyses may be added:

- Correlations between demographics and BSE usage to analyse the potential effects of demographics on exoskeleton acceptance.
- Cluster analysis of the effect of BSE usage on primary outcomes to analyse potential differences between workers in the intervention group with high and low adherence to BSE usage.

Harms

Item 30: Sufficient detail provided on summarizing harms

This study is designed to identify any harms or adverse events that may occur during the intervention. Self-reported changes in musculoskeletal discomfort and perceived work intensity will be monitored during the trial (see table 2). Additionally, the workers will at each timepoint be able to pass their individual feedback on the BSE, in term of what they 'least like', 'most like', and if they would change anything about the exoskeleton, in an open-ended questionnaire. Adverse events will be descriptively summarized for both groups and reported in the primary publication.

Statistical Software

Item 31: Details of statistical package used for the analysis

The statistical package IBM Corp. 2022. IBM SPSS Statistics for windows, Version 27.0. Armonk, NY: IBM Corp. was used for data management and analysis.

References

Item 32: Data Management

All the data will be stored in accordance with the Danish Personal Data Protection Act and other relevant Danish legislation. Biomechanical data is recorded in the original software file format (Noraxon and mvnx, respectively) and later exported to Matlab (MAT) format. Questionnaire data is recorded in hard copy during the outcome assessments and later noted in Excel spreadsheets. The main data set will not contain any personal information. Additionally, no personal information of the participants will be shared by the principal investigator and will be stored securely for his eyes only.

As mentioned, the analyses described in the present SAP will be performed by the principal investigator and be the basis of all primary and secondary outcomes. However, to avoid the risk of misleading interpretation, a blinded interpretation will be performed by the members of the research team (all but LSJ). The principal investigator will code the randomized groups as “group A” and “group B” before passing the statistical results to the blinded member. Thereby, the interpretation of the results will be blinded to allocation of BSE usage. The blinded members will then decide on two different interpretations of the results: one in which group A refers to the intervention group and group B to the control group, and one vice versa. The interpretations will be registered in a document titled “EXO4MMH trial: Blinded data analyses interpretation statement”. After registration of the different interpretation, the randomization will be broken, and the correct interpretation will be chosen as prescript to the primary publication (Järvinen et al., 2014).

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