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ClinicalTrials.gov ID: [Not yet assigned]

Study Identification

Unique Protocol ID: 3/BN/UPB/2023

Brief Title: Active Break Intervention on Low Back Pain and Musculoskeletal Discomfort During Prolonged Sitting Among Young People

Official Title: The Effect of an Active Break Intervention on Nonspecific Low Back Pain and Musculoskeletal Discomfort During Prolonged Sitting Among Young People (SPINE-have&Care)

Secondary IDs:

Study Status

Record Verification: March 2023

Overall Status: Recruiting

Study Start: April 1, 2023 [Anticipated]

 **NOTE : Study Start Date should be updated and changed to Actual once the first participant is enrolled.**

Primary Completion: July 1, 2023 [Anticipated]

Study Completion: August 1, 2023 [Anticipated]

Sponsor/Collaborators

Sponsor: Józef Piłsudski University of Physical Education

Responsible Party: Principal Investigator

Investigator: Magdalena Plandowska [mplandowska]

Official Title: Jozef Pilsudski University of Physical Education in Warsaw

Affiliation: Józef Piłsudski University of Physical Education

Collaborators: University of Tehran

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved

Board Name: Ethics Committee of the AWF Warsaw

Board Affiliation: Jozef Pilsudski University of Physical Education in Warsaw

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 **ERROR : Approval Number is a required field.**

Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: The most recent evidence showed that the COVID-19 pandemic caused an increase in low back pain (LBP) prevalence and intensity among young people. This may be explained by the prolonged sitting time, next to a reduced level of physical activity. Young people spend most of their time in a sitting position while studying (in school class, during homework) and using electronic devices (using the computer, laptop, mobile phone, tablets, or watching TV), and now using e-learning methods. E-learning, and thus prolonged sitting, is a topic that returned to higher education at the beginning of the 2022-2023 academic year because of the current energy crisis. Re-education on sitting posture is a common aspect of LBP management. Physiotherapists recommend many different sitting positions to prevent and treat the negative effects of prolonged sitting. However, there is debate regarding what is an optimal sitting posture. Studies showed that sitting posture with the backrest on the chair induced minimal changes in lumbar lordosis and significantly lesser pain compared to other types of the chair. Even though the sitting posture will be followed by proper ergonomic principles, every position (lordotic or kyphotic) maintained for a prolonged time leads to discomfort and soft tissue symptoms. Studies showed that body perceived discomfort scores increased over time during sitting and after 30 min of sitting is significantly greater than those at baseline. Currently, breaks are recommended for mitigating the adverse of prolonged sitting, but more evidence is needed to verify effectiveness of breaks. The aim of this study is to evaluate the effect of active break on reduce LBP and perceived musculoskeletal discomfort during prolonged sitting in young people with LBP. Optimal combination of sitting and breaks will help to develop ergonomic recommendations for young people. Main research outcomes – exercise protocol and intervention – will be developed to match the needs of young people with LBP and the possibilities of the environment, in order to reduce LBP and musculoskeletal discomfort during prolonged sitting, and consequently, maintain health and quality of life. The intervention will address the social and health needs of a particular social group: young people, with the possibility of extending the recommendations to other groups.

Detailed Description: Background:

Young people tend to spend most of their time in sitting position while studying (in the school class, during homework) and using the electronic devices (using the computer, laptop, mobile phone, tablets or watching TV). Moreover, during the Covid-19 pandemic, many countries switched their teaching programs into e-learning, where students spend long hour using electronic devices. Now e-learning methods have been often used, not only during pandemic. The current energy crisis, exacerbated by the war in Ukraine, is causing e-learning back to educational institutions. However this change in learning methods is associated with musculoskeletal dysfunction including low back pain (LBP). Low back pain was one of the most common musculoskeletal disorders in prepandemic period and today it is known that the Covid-19 pandemic caused an additional increase in LBP prevalence and intensity. This may be explained by the prolonged sitting time, next to reduced level of physical activity. Most people sit for a long hours in a slumped sitting posture (thoraco-lumbar and lumbar angles

kyphosed approaching and of range). During 1 hour of sitting workers appeared to assume slumped sitting postures after just 20 minutes of sitting. Prolonged sitting causes changes in the passive structures of the spine and induces a low back compressive load significantly higher than that observed in standing. Physiotherapists recommend many different sitting positions to prevent and treat negative effects of prolonged sitting. However, there is debate regarding what is an optimal sitting posture. Periodic rest breaks have been identified as a way to reduce self-report discomfort at the low back and a standing breaks may be beneficial for the passive tissues of the spine. A combination of sitting and standing is beneficial for reducing musculoskeletal discomfort.

Research aim:

The aim of this study is to evaluate the effect of active break on reduce LBP and perceived musculoskeletal discomfort during prolonged sitting in young people with LBP.

Methods:

This will be a randomized controlled study with pre and post-intervention assessment. The participants will be recruited from students. Participants were randomly assigned to the intervention group consisting of an active break (n = 25) or the control group (n = 25). The group with an active break with postural change from sitting to standing will be recommended to take an active break for every 30 minutes of sitting. The primary outcome will be frequency of LBP (questionnaire), average pain intensity (Visual Analogue Scale, VAS), disability at 3 months measured using the Oswestry Disability Index and perceived musculoskeletal discomfort during prolonged sitting (Borg scale). Secondary outcomes will be patients' Global Perceived Effect of change (7-point Likert scale), Adherence to Active break Program (0-100%) at Completion of Initial 12 Week Intervention (questionnaire) and Satisfaction after the intervention (5-item self-completed questionnaire).

Expected outcomes:

Research outcomes – exercise protocol and intervention – will be developed to match the needs of young people with LBP and the possibilities of the environment, in order to reduce LBP and musculoskeletal discomfort during prolonged sitting, and consequently, maintain health and quality of life. The intervention will address the social and health needs of a particular social group: young people, with the possibility of extending the recommendations to other groups. Research outcomes will build evidence-based practice for students, teachers, health professionals, personal trainers, and family doctors.

Conditions

Conditions: Low Back Pain

Keywords: non-specific low back pain
young people
sitting position
break
active break

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Double (Participant, Outcomes Assessor)

Allocation: Randomized

Enrollment: 25 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Experimental group Participants assigned to the experimental group will receive recommendation to take an active break with the proposed lumbar and hip extension exercises for every 30 minutes of sitting.	Behavioral: Active break with the proposed lumbar and hip extension exercises Participants assigned to the experimental group will receive recommendation to take an active break with the proposed lumbar and hip extension exercises for every 30 minutes of sitting. In the experimental intervention, the exercise program include exercises and will be based on patient education. The participants will also explain the importance of regular training and receive a booklet with photographed and described exercises.
Active Comparator: Control group Participants assigned to the control group will receive an self-care recommendations book.	Behavioral: Self-care recommendations Participants assigned to the control group will receive an educational self-care book containing information on low back pain, anatomy of the spine and its relation to the muscular chain, care during daily life activities and the importance of regular physical exercises. The control group will perform their regular baseline activities.

Outcome Measures

Primary Outcome Measure:

1. Frequency of pain

The prevalence of LBP will be assessed with the questionnaire prepared by the authors.

[Time Frame: Change from Pre-Intervention (baseline) compared to Post-Intervention (12 weeks) and Follow-up (6 months)]

2. Pain Intensity

Pain will be measured through Visual Analogue Scale (VAS, in centimeters). 0 represents "no pain" and 10 "worst pain possible".

[Time Frame: Change from Pre-Intervention (baseline) compared to Post-Intervention (12 weeks) and Follow-up (6 months)]

3. Disability

Level of functional disabilities of participants resulting from LBP would be measured using Revised Oswestry Low Back Pain Disability Index

[Time Frame: Change from Pre-Intervention (baseline) compared to Post-Intervention (12 weeks) and Follow-up (6 months)]

Secondary Outcome Measure:

4. The Global Perceived Effect

Global perceived effect (GPE) will be assessed the satisfaction: a) unsatisfied: $GPE \leq 4$, symptoms will be not changed or worse; b) satisfied: $4 < GPE \leq 5$, symptoms will be improved; and c) very satisfied: $GPE \geq 6$, symptoms will be improved distinctly or patients recovered. Success will be defined as score ≥ 6 (6 or 7 on a 7-point Likert scale).

[Time Frame: Completion of 12 week intervention]

5. Adherence to Home Program (0-100%) at Completion of Initial 12 Week Intervention

This questionnaire is designed to provide information about how often a participant performs his treatment as it was prescribed. Scoring: Average adherence is calculated by averaging the participants' daily adherence. Scores range from 0-100%. Higher values indicate higher adherence to treatment.

[Time Frame: Completion of 12 week intervention]

6. Satisfaction - self-completed questionnaire

Participants will be provided with a 5-item self-completed questionnaire developed by our research team that will measure their satisfaction with the intervention they received and the study in general. The items will be presented in the form of statements to which patients will be asked to respond using a 1-5 Likert scale ("strongly agree", "agree", "not sure", "disagree", and strongly disagree").

[Time Frame: Completion of 12 week intervention]

Eligibility

Minimum Age: 18 Years

Maximum Age: 25 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- 18 to 25 years of age;
- participants with non-specific low back pain (defined as pain and discomfort) localized below the costal margin and above the inferior gluteal folds, pain of at least 3 months' duration, without radiation to legs;
- participants who did not have a surgical history due to spinal problems;
- participants who did not have radiculopathy or other injuries such as fractures, stenosis or tumors in the spine;
- participants who had not received any treatment related to low back within the last six months;
- participants who had not used medication for low back pain in the last three months.

Exclusion Criteria:

- spinal pathology (eg, tumor, infection, fracture, inflammatory disease),
- patients with disc herniation and leg length discrepancy;
- pregnancy,
- nerve root compromise,
- previous spinal surgery,
- major surgery scheduled during treatment or follow-up period,
- presence of any contraindication to exercise.

Contacts/Locations

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Central Contact Backup:

Study Officials:  **NOTE : Study Official is required by the WHO and ICMJE.**

Locations: **Poland**

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[Recruiting]

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IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information: