Upright Back Posture Device Study

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Research Question(s)/Hypothesis(es):

The purpose of the this study is to determine if patients with back pain who use a device that provides a proprioceptive reminder regarding posture (UPRIGHT device) demonstrate improved pain control and self perception of posture over those who receive a brief instruction on posture and an ergonomic handout.

Hypothesis: There will be no difference in back pain score or self perception of posture between those using the UPRIGHT device and those receiving posture/ergonomic instruction alone.

Scientific Abstract:

Back pain is one of the most common conditions among the adult population (1). There is evidence that individuals with back pain have impaired motor control of trunk muscles and delayed neuromuscular recruitment (2,3). Poor posture has been associated with spinal extensor weakness, back pain, and lower quality of life scores (4). Those who spend prolonged time sitting in poor posture often develop muscular imbalances leading to tight chest muscles and weakness in back muscles. Back pain is commonly treated with flexibility and strengthening and exercises as well and a health education regarding proper posture (5). The purpose of the this study is to determine if patients with back pain who use a device that provides a proprioceptive reminder regarding posture (UPRIGHT device) demonstrate improved pain control and self perception of posture over those who receive a brief instruction on posture and an ergonomic handout.

Hypothesis: There will be no difference in back pain score or self perception of posture between those using the UPRIGHT device and those receiving posture/ergonomic instruction alone. This is a randomized controlled study to determine if patients between the ages of 18-50, with posture related low back pain, who use the UPRIGHT device demonstrate improved pain control and self perception of posture compared to those given standard ergonomic instruction. Subjects will complete a baseline history, physical exam and questionnaire to assess current pain level.

Subjects will be randomized into two groups. One group will receive the UPRIGHT device and a 15 minute tutorial on using the device. Subjects will complete a 4 week training program using the device. The control group will receive a 15 minute instruction on proper posture and an ergonomic handout explaining how to sit and stand with proper posture. At the end of 4 weeks subjects will be contacted via telephone to complete a questionnaire to assess their current pain level, perception of posture, and satisfaction with the device.

References:

1. Hoy D, Bain C, Williams G, et al. A systematic review of the global prevalence of low back pain. Arthritis Rheum. 2012 ; 64:2028-2037.

2. Hodges PW, Richardson CA. Inefficient muscular stabilization of the lumbar spine associated with low back pain. A motor control evaluation of transverse abdominis. Spine (Phila Pa 1976) 21(22):2640-2650.

3. Brumagne S. Cordo P, Lysens R, Verschueren S, Swinnen S (2000). The role of paraspinal muscle spindles in lumbrosacral position sense in individuals with and without low back pain. Spine (Phila PA 1976) 25 (8):989-994.

4 . Dunk NM, Callaghan JP. Lumbar spine movement patterns during prolonged sitting differentiate low back pain developers from matched asymptomatic controls. Work. 2010;35(1):3–14. doi:10.3233/wor-2010-0953

5. Zhang Y, Wan L, Wang X (2014). The effect of health education in patients with chronic low back pain. Journal of international medical research. 2014; Vol 42(3) 815-820.

Study Population:

A total of up to 45 participants will be enrolled into this study with a target accrual of 35 participants treated.

This study consists of two groups:
1. Upright posture device x 4 weeks.
2. Ergonomic instruction (15-20 min) and handout.

The Inclusion Criteria is as follows:
1. Ages 18-50
2. Postural related back pain

The Exclusion Criteria is as follows:

1. A diagnosis of significant scoliosis, herniated/bulging disc, lumbar spondylolysis, radiculitis, facet arthrosis, fibromyalgia, rheumatoid arthritis, seronegative spondyloarthropathy
2. Neurologic deficits on exam
3. Currently in PT

The participants will fall in either one of the following Intervention /exposure groups: Group 1- Upright device training x 4 weeks Group 2- Ergonomic training 30 min, ergonomic handout. The control group will get the upright device if they still have pain.

Randomization will be done by research member not in contact with participant using www.randomization.com and will use 3 blocks of 10 for randomization. At the end of 4 weeks patient will be reassessed with visual analog pain scale, and self preception posture scale. Patients receiving the upright device will have a brief training on the use of the device and proper posture. They will use a training protocol (attached). The control group will have a 15-20 minute instruction on proper posture and an ergonomic handout.

Patients will be identified by a physician at student health and enrolled by the research team. Informed consent will be obtained.

Study Procedures:

Subjects with complaints of back pain will be recruited from Columbia University Student Health and from Columbia Doctors Physical Medicine and Rehabilitation practice. Subjects will be consented and randomized to either the UPRIGHT device group or control group. The UPRIGHT group will get a brief training on how to use the device. This will involve downloading the app on subjects phone. We will set

up a separate de-identified gmail account which will be used collect data from the device. They will be instructed on how and where to attach the device to their back. The subject will be asked to sit with proper posture in a chair without leaning against the back rest with both feet flat on the ground. The training is once daily and each day the time increase according to the provided training protocol. The subjects will wear the device once per day for 4 weeks.

The subject needs to use a new adhesive (which will be provided) each time they put the device on. The device will be calibrated to detect changes in posture. A detailed physical exam as well as medical history, family history will be conducted on all participants. Subjects will then be given a 4 week training protocol through the app. The control group will have a 15 minute instruction on proper posture and an ergonomic handout explaining how to sit and stand with proper posture.

At the end of 4 weeks subjects will be contacted via telephone to complete a questionnaire to assess their current pain level, perception of posture, and satisfaction with the device. At the end of 4 weeks participants in the control group will be given an UPRIGHT device if they continue to have pain.

Prior to recruitment we will pilot the use of this device with 5 healthy controls. The purpose of the pilot study is to assess for any difficulties we may encounter with the device and while training with the device.

Recruitment:

Patients will be identified by a physician at student health or by a Columbia Doctors PM&R physician who will first introduce the study to the patients and enrolled by the research team. Informed consent will be obtained. Subjects who presents to the Columbia Health Clinic or Columbia Doctors Rehabilitation Medicine with complaints of back pain who meet the criteria will be asked to participate in our study. Information about the study will be provided and if they choose to participate they will be consented by our research coordinator. They will then be scheduled for study assessments. This study is completely voluntary. None of residents, students, fellows or employees within our Rehabilitation Department will be asked to participate in this study. Recruitment flyers will also be placed in the Department of Rehab at CUMC as well as displayed at student health at Columbia University.

An electronic flyer (attached) will be sent to the graduate school of arts and sciences communication department for them to attach to their monthly newsletter sent to the graduate students on our behalf. The communication department will not give us their list serve at any time. Graduate students are added to this list serve when registered for graduate classes at Columbia University and the communications department is the sole owner of this list. An individual who wants to participate in the study will contact Adam Blanchard directly and no one from the communication department will ever see this information.

Alex Gomberg, an employee of Upright, will send out the attached email (Upright_email script) to individuals who have purchased an Upright device in the past on our behalf. We will never have access to these individuals' contact information or listserve. When someone purchases an Upright device they are added onto their mailing listserve and agree to receive emails from Upright. Alex and Upright will be sending the email referencing our study and provide our contact information. An individual who wants to participate in the study will contact Adam Blanchard directly and no one from Upright will ever see this information.

Study Product:

UPRIGHT Go App, manufactured by Upright Technologies Ltd., is an app that connects to the device and tracks data and provides feedback from the device.

The Upright Pro is a wearable biofeedback posture trainer.

Statistical Plan:

No power analysis will be done, as only one other study has been published using this device. We'll be using 30 participants, as this study had 30 subjects participating in study.

For within subjects, data will be analyzed using paired T-test analysis. For between subjects data will be analyzed using ANOVA. Currently there are no similar studies to determine the sample size, we plan to analyze the outcomes.