The Effects of Postural Education or Corrective Exercise Intervention on the Craniovertebral Angle in Young Adults with Forward Head Posture: A Randomized Controlled Trial

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Declarations of interest: The current study was part of the requirements for completion of a Ph.D. dissertation (Concordia University Chicago) written by Dr. David Titcomb. Conflicts of interest: none.

Funding: This work was supported by the National Academy of Sports Medicine and Liberty University Center for Research & Scholarship [grant number UR2201]. Funding sponsors had no involvement in study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the article for publication.

Document date: 07/19/2021

Consent Form

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Principal Investigator: David Titcomb, PT, DPT, EP-C, CES

Concordia University Chicago Study # 1775403-1 CUC IRB approval date __6/24/21_____

Liberty University Study # IRB-FY20-21-1073 LU IRB approval date _7/19/21_____

1. Explanation and Purpose

You are invited to participate in a research study investigating the effects of posture education and corrective exercise intervention on forward head posture (FHP). You were selected as a potential participant due to meeting the study's criteria: healthy young adult between the ages of 18-30 years with no acute musculoskeletal injury to the head, shoulders, or spine within the last six months; or having been diagnosed with pathology related to the cervical spine, thoracic spine, or upper extremities; as well as scoring at least a 3 on the Stages of Change questionnaire. You will be voluntarily participating in a research study in which your sitting and standing head and neck posture will be screened using photography. Based on the analysis of your posture, if it is determined that you have FHP, you may be randomly assigned to one of three intervention groups: posture education (PE), self-myofascial release-stretching (SMRS), or self-myofascial release-stretching-strengthening (SMRSS); or a control group. It is important that you understand that participation in this study is voluntary, and you may stop participating whenever you wish.

David Titcomb, a doctoral candidate at Concordia University Chicago, is conducting this study for his dissertation. He is also a full-time faculty member at Liberty University.

The purpose of this study is to examine the effects of postural education or corrective exercise intervention on the craniovertebral angle in young adults with FHP.

2. Participation Requirements/Procedures

a. Participants will complete a Pre-Intervention Demographics/SOC Self-Rating/Injury History questionnaire and the 2021 PARQ+ questionnaire (10 minutes).

b. A researcher will measure your height and weight using a medical scale (1 minute).

c. Your posture will be screened by taking photographs of you in sitting and standing positions (10 minutes).

d. After the posture screen and photograph assessment, if it is determined that you have FHP, you may be randomly placed into one of three intervention groups (PE, SMRS, SMRSS); or a control group. A research group leader will conduct a session lasting approximately 20 minutes to lead you through an assigned home program instruction based on group designation:

PE Group: you will be informed of the negative health risks associated with FHP, taught postural guidelines for using mobile electronic devices/computers, as well as rest break guidelines. You will be asked to adhere to these guidelines for 4 weeks and will receive weekly reminder emails over the course of the 4-week study. After the 4th week of the study, you will be asked to return back to the lab for follow-up posture assessment with photography. Participants will also be asked to complete a mid- and post-intervention questionnaire that will take approximately 2 minutes to complete.

SMRS Group: you will be instructed on how to apply self-myofascial release (SMR) to your sternocleidomastoid, upper trapezius, pectoralis minor, upper cervical extensor, and thoracic paraspinal musculature. In addition, you will be instructed on a home stretching program. You will be provided with a soft tissue mobilization tool and myofascial roller for home use. You will be able to keep the myofascial roller and resistive exercise band regardless of whether or not you complete the entire study. The soft tissue mobilization tool is property of Liberty University and is to be returned to the primary investigator at the end of the study. You will be asked to perform your home program 3 times per week for the first 2 weeks, progressing to 5 times per week during weeks 3-4. Bouts of corrective exercise will take approximately 10 minutes to complete. You will receive weekly reminder emails over the course of the 4-week study and will be asked to return back to the biomechanics lab on two additional occasions: Week 2- for review of your home program to ensure proper technique (10 minutes) and Week 5 (Post-study) for follow-up posture assessment with photography (12 minutes). Participants will also be asked to complete a mid- and post-intervention questionnaire that will take approximately 2 minutes to complete.

SMRSS Group: you will be instructed how to apply self-myofascial release (SMR) to your sternocleidomastoid, upper trapezius, pectoralis minor, upper cervical extensor, and thoracic paraspinal musculature. In addition, you will be instructed on a home program for muscle stretching and strengthening. You will be provided with a soft tissue mobilization tool, a myofascial roller, and a resistive exercise tubing for home use. You will be able to keep the myofascial roller and resistive exercise tubing

regardless of whether or not you complete the entire study. The soft tissue mobilization tool is property of Liberty University and is to be returned to the primary investigator at the end of the study. You will be asked to perform SMR and stretching 3 times per week for the first 2 weeks, progressing to 5 times per week during weeks 3-4. You will also be asked to perform strengthening exercises 3 times per week throughout this 4-week study. Bouts of corrective exercise will take approximately 10 minutes to complete. You will receive weekly reminder emails over the course of the study and will be asked to return back to the biomechanics lab on two additional occasions: Week 2- for review of your home program to ensure proper technique and Week 5 (Post-study) for follow-up posture assessment with photography (12 minutes). Participants will also be asked to complete a mid- and post-intervention questionnaire that will take approximately 2 minutes to complete.

Control Group: you will not be receiving intervention; however, you will be asked to return to the lab on the week after the end of the 4-week study to have your posture re-assessed using photography.

☐ I consent to being photographed for posture analysis and to participate in any one of the above groups I am randomly assigned to _____ (Initials)

☐ I will not start or stop any other exercise program that is not part of this study over the next 4 weeks, regardless of the group I am randomly assigned to _____(Initials)

☐ If assigned to the SMRS or SMRSS group, I will return the soft tissue mobilization tool that was provided to me back to the primary investigator at the end of the study, as this tool is the property of Liberty University. _____ (Initials)

3. Risks and Discomfort

The risks of this study are minimal, which means they are equal to the risks you would encounter in everyday life. If you are assigned to the SMRS or SMRSS group there is a possibility that you may feel mild intermittent muscle soreness as a result of performing self-myofascial release, stretching, or strengthening exercises. Every effort will be made to minimize risks through the instruction of a safe and proper implementation of your home program. One of the questionnaires used in this study (pre-intervention demographics) asks about your injury history and pathology history. For some individuals who have had a previous injury or pathology, this could result in experiencing negative or uncomfortable emotions, mild/transient sadness, or anxiety. If this occurs and you would like to seek mental health services, they are available on Liberty University's campus at Student Counseling Services, 1830 Green Hall, Phone: 434-582-2651.

4. Responsibilities of the Participant

Participants are responsible to be compliant with their assigned home program, as well as perform it safely using proper technique as prescribed. Participants are asked not to start or stop any other exercise program that is not part of the study over the next 4 weeks. If in the event you experience any painful symptoms during the study, it is essential to stop your home program and promptly contact the primary investigator. You are responsible for seeking professional medical assistance if necessary. If assigned to the SMRS or SMRSS group you will return the soft tissue mobilization tool (provided to you at no cost at the start of the study) back to the primary investigator at the end of the study, as this tool is property of Liberty University.

5. Benefits to be Expected

Direct benefits participants in the experimental groups may experience include, but are not limited to improvements in posture, flexibility, strength, and enhanced ability to perform activities of daily living and functional tasks. Compliance with your assigned home program may influence benefits received. Participants will not be compensated financially for participating in this study, however those assigned to the SMRS group will be provided with a soft tissue mobilization tool and myofascial roller at no cost. Participants assigned to the SMRSS group will be provided with a soft tissue mobilization tool, myofascial roller, and resistance tubing at no cost. Soft tissue mobilization tools are property of Liberty University and shall be returned back to the primary investigator at the end of the study. Participants may keep the myofascial roller and resistive tubing regardless of whether or not they complete the entire study. Participants in the control group should not expect to receive any direct benefits from participating in this study.

6. Confidentiality

All data collection forms, records, and digital photographs will become property of the researcher. Digital files will be kept private and stored securely in a password-locked computer only accessible by the primary investigator. Hard copy files will be kept in a locked filing cabinet only accessible by the primary investigator. You and the information you provide will remain confidential at all times. Each participant will be assigned a number to impede the ability to identify subject names. Participant responses will be kept confidential through the use of code numbers. Data collected from you may be shared for use in future research studies or with other researchers. If data collected from you is shared, any typewritten or handwritten information that could identify you will be

removed before the data is shared, however the digital image files containing your photo may be utilized in future studies. If the digital image files are used in a future study, the files will be named using code numbers and not your name. All data and electronic records will be kept securely for three years. After three years, records identifying subjects will be destroyed. If you choose to withdraw from the study, please contact the researcher at the email address/phone number included in the next paragraph. Should you choose to withdraw, digital image files of your posture taken at baseline will still be retained for data analysis. After three years, the image files will be destroyed.

7. Inquiries

This study has been approved by the Institutional Review Board (IRB) at Concordia University Chicago and the IRB at Liberty University. The primary investigator for this study is Dr. David Titcomb. If you have any questions at any time throughout the study, you are encouraged to contact him at 434-509-8741 or dtitcomb@liberty.edu. You may also contact the researcher's faculty supervisor, Dr. Bridget Melton, at bridget.melton@cuchicago.edu.

If you have any questions or concerns regarding this study or your rights as a participant and would like to talk to someone other than the researcher, you are encouraged to contact the Concordia University Chicago Institutional Review Board at IRB@CUChicago.edu or the Liberty University Institutional Review Board at 1971 University Blvd., Green Hall Ste. 2845, Lynchburg, VA 24515 or email at irb@liberty.edu.

Disclaimer: The Institutional Review Board (IRB) is tasked with ensuring that human subjects research will be conducted in an ethical manner as defined and required by federal regulations. The topics covered and viewpoints expressed or alluded to by student and faculty researchers are those of the researchers and do not necessarily reflect the official policies or positions of Liberty University.

8. Conflicts of Interest

The researcher serves as a professor in the Department of Allied Health Professions at Liberty University. Although the potential exists for study participants to be a current student in a course that is taught by the researcher, there will be no reciprocity, such as a grade received in the class based on participation or outcome measures in the study. To limit any potential or perceived conflicts, research assistants will be present during data collection and analysis. This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study. No action will be taken against an individual based on his or her decision to participate or not participate in this study.

9. Freedom of Consent

a. I hereby consent to voluntarily participate in this research study and to make every effort to be compliant with my prescribed home program if assigned to an intervention group. My permission is given voluntarily, and I understand that I am free to discontinue without penalty at any time if I choose to do so.

b. I consent to the release of the digital image files containing photos of my posture for future research.

c. If I choose to discontinue participation, I may do so at no penalty or loss of benefits to which I am otherwise entitled.

d. Should I choose to discontinue or refuse to participate, I will give prompt notice to the researcher upon doing so.

e. By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. You will be given a copy of this document for your records. The researcher will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I have read this form and agree to its policies. I understand the risks and discomforts. Knowing these risks and discomforts and having had the opportunity to ask questions that have been answered to my satisfaction, I consent to participate in this study.

_____	_____	_____
Printed Subject Name	Signature & Date	Participant #

_____	_____
Signature of Investigator	Date