This consent form is not valid without a TTUHSC IRB stamp in the lower left corner of each page.

CONSENT TO TAKE PART IN A RESEARCH STUDY

This is a research study for people who voluntarily choose to take part. Please take your time to make a decision, and discuss the study with your personal doctor, family and friends if you wish.

STUDY TITLE: IMMEDIATE EFFECT OF STANDING TRUNK EXTENSION POSTURES ON SPINAL HEIGHT AND CLINICAL OUTCOME MEASURES IN LOW BACK PAIN: A RANDOMIZED CLINICAL TRIAL

INVESTIGATOR(s):

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CONTACT TELEPHONE NUMBERS: (830)997-2001
(You may contact the investigator(s) at the number(s) listed above during normal business hours) if you develop any of the conditions listed in Question # 7 of this form or if you have any unexpected complications).

INSTITUTION: Lubbock TTUHSC

1. **Why is this study being done?** This study is being conducted in order to better understand the effect of back extension postures on your height, low back health and pain.

2. **How many people will take part in this study?** 100

3. **Why am I being asked to take part in this research study?** Because you have low back pain and we would like to know if your low back pain improves with some postures and if these postures help you grow in height.

4. **What will happen during this study? What will be done that is different from my usual care?**
   If you have low back pain and are between the ages of 18 and 80 years old and can attend two physical therapy sessions within a 2-week period, you will be asked if you are interested participate in the study free of charge.
   1. You will report to Sports Medicine Physical Therapy in Fredericksburg, Texas.
   2. You will be asked to completed a pre-screening questionnaire about you.
   3. You will view a presentation on a computer that explains and demonstrates what you will be doing during the study. A study investigator will answer questions.
   4. You will be given a consent form to complete. You will choose whether you want to participate in the study. If you do, you will sign the consent form. You will complete a questionnaire that will include information on your medical history.

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5. Your height and weight will be measured. You will be asked to wear shorts and socks without shoes and a t-shirt. However, men will be allowed to go without a shirt and women to wear a sports bra.
6. The two physical therapy sessions will each last approximately 60-minute.
7. **For session 1**, the investigator will test specific directions of trunk movements or postures that alleviate your back pain.
8. You will complete questionnaires about your low back pain.
9. You will complete a familiarization procedure to determine if you can reposition yourself in the apparatus that measures your height.
10. You will then lie on your back for 10 minutes and your height will be measured
11. You will then sit five-minute with 10 lb bag on each shoulder and 5 additional minutes without weight on the shoulders and your height will be measured.
12. You will then be assigned to one of two interventions:(1) standing repetitive back bends; or (2) standing sustained back bends.
13. Your height will then be measured on the apparatus that measures your height and you will score your pain.
14. A sheet including home exercise instructions will be given to you.
15. **For session 2**, you will complete the same questionnaires and sequence of postures as in session 1 and will then score your pain.

5. **How much of my time will this study take? How long will I be in the study?** Each of the two sessions will take approximately one hour. The length of the study will be approximately 2 weeks in duration.

6. **Are there any benefits to <u>me</u> if I take part in this study?** Participation in this study may help reduce your back pain and help improve your back health.

7. **What are the risks and/or discomforts to me if I join this study?** There are no known risks to participating in this study. You may experience increased soreness to your back or legs during the study.

8. **Will there be any added risks to me from this study if I am a female?** There are no known risks to participating in this study for men and women.

9. **What other choices do I have if I do not take part in the research study?** You do not have to take part in this study.

10. **What about confidentiality and the privacy of my records?**

    We will keep your involvement in this research study confidential to the extent permitted by law. In addition to the staff carrying out this study, others may learn that you are in the study. This might include federal regulatory agencies such as the Food and Drug Administration (FDA) and the Office for Human Research Protection (OHRP), Texas Tech University Health Sciences Center (TTUHSC) representatives, representatives from any hospital or site where the research takes place, and the TTUHSC Institutional Review Board (a committee that reviews and approves research). These people may review and copy records involving your participation in this research. A copy of this document may be placed in your medical record.

    Study results that are used in publications or presentations will not use your name.

11. Who is funding this study?
Texas Tech University Health Sciences Center, Department of Rehabilitation Sciences is providing design and is overseeing this study. No one on the research staff will receive anything of value from other agencies, organizations, or companies to carry out this research.

12. Will it cost me anything to take part in this research study? No.

13. Will I receive anything for taking part in this research study? You will receive a one-month free membership to Hill Country Memorial Wellness Center in Fredericksburg, Texas.

14. Does anyone on the research staff have a personal financial interest in this study? No

15. What if I am hurt by participating in this study?
Texas Tech University Health Sciences Center, Sports Medicine & Physical Therapy of Fredericksburg, Texas do not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness unless specifically stated.
If you have a research related illness or injury, care will be available to you as usual, but you and/or your medical or hospital insurance company will be responsible for the cost of treatment. Before entering this study, you should check whether your insurance company might limit your insurance coverage if you take part in a research study.

16. What are my rights as a voluntary participant?
Taking part in this study is your choice. If you sign this form, it means that you choose to be in the study.

You may also choose not to be in this study. If you decide not to be in the study, it will not affect any medical care, benefits or rights to which you are entitled.

If new information becomes available during the study that may affect your willingness to take part in the study, you will be told.

17. Can I stop being in the study?
You may leave the study at any time. If you leave the study, we cannot remove any information we have collected to that point.
If you decide to leave the study, discuss it with the investigator who will help you do so in the safest way. If you leave the study, your right to standard medical care will continue.

18. Can someone else end my participation in the study?
Under certain circumstances, the investigators, TTUHSC, or the study sponsor may decide to end your participation in this research study earlier than planned. This might happen because your back and/or leg pain worsen.

19. What if I have questions?
For questions about this study, contact the Investigator, Jean-Michel Brismée at (806)743-3243 or Jeremy Harrison at (432)208-0688.
If you would like to speak to someone who is not involved in the study about your rights as a participant, research-related injuries, or any other matter related to the study, you can call the TTUHSC EthicsPoint Hotline: 1-866-294-9352.

Or, you can file an EthicsPoint report online: https://secure.ethicspoint.com/domain/media/en/gui/12958/index.html. Please choose the "Regulatory Compliance" option when making an online report.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/ , as required by U.S. Law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

Your signature indicates that:

- **this research study has been explained to you;**
- **you have been given the opportunity to ask questions and have received answers;**
- **you accept your responsibility to follow the instructions given to you by the research team regarding study participation and, if applicable, research medication;**
- **you agree to take part in this study.**

You will be given a signed copy of this form.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date Time

_____ _____
Signature of Parent/Guardian or Authorized Representative Date Time

I have discussed this research study with the subject and his or her authorized representative, using language that is understandable and appropriate. I believe I have fully informed the subject of the possible risks and benefits, and I believe the subject understands this explanation. I have given a copy of this form to the subject.

_____ _____
Signature of authorized research personnel who conducted the informed consent discussion Date Time