

INFORMED CONSENT


NOVA
Institutional Review Board
Approval Date: JUN 26 2015
Continuing Review Date: JUN 25 2016



**Consent Form for Participation in the Research Study Entitled The Efficacy of Kinesio Taping as an Adjunct Intervention to Traditional Physical Therapy in the Treatment of Nonspecific Acute Low Back Pain:
A Prospective Randomized Controlled Trial**

Funding Source: None
IRB protocol #: 05291519Exp

Principal investigator

Hossameldien Elkholy, PT, MSc, CKTP
255 East 98th street,
Brooklyn, NY 11212
347-302-1604
Hossamel@nova.edu

Research Assistant

Haitham Sallam, PT, MSc, DPT
255 East 98th street,
New York, NY 11212
718-666-0267
hysallam@yahoo.com

Co-investigators

Dr. Madeleine Hellman, PT, MHM, EdD
Physical Therapy Program
Nova Southeastern University
3200 S. University Drive
Ft. Lauderdale, FL 33328
954-262-1282
Hellman@nova.edu

Dr. Lance Cherry, PT, Ed.D., OCS
Hybrid Entry Level DPT Program
Nova Southeastern University, Tampa
3632 Queen Palm Dr., Tampa, FL 33619
813-574-5327
lcherry@nova.edu

Dr. Mahmoud Ibrahim, PT, MSc, DSc,
PhD, FACCWS
Health Check Center
380 88th street, Brooklyn,
NY 11209
718-414-4382
Mst78@aol.com

For questions/concerns about your research rights, contact:
Human Research Oversight Board (Institutional Review Board or IRB)
Nova Southeastern University
(954) 262-5369/Toll Free: 866-499-0790
IRB@nsu.nova.edu

Site Information

Quick Docs Medical Center
255 East 98th street
Brooklyn, NY 11212
718-240-2644

Initials: _____ Date: _____

What is the study about?

We are asking you to participate in a research study. The purpose of this consent form is to give you information you will need to help you decide whether to be in the study or not. Please read the consent form very carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this consent form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent". The purpose of this study is to determine the efficacy of Kinesio Taping as an adjunct intervention to traditional physical therapy in the treatment of nonspecific acute low back pain. Participants who agree to participate in this study will be assigned a case number to protect their identity obtained from a computer random number generator. These random numbers which will be given to each participant will be used to assign each one in either an experimental group which will receive traditional physical therapy plus Kinesio taping or a control group which will receive traditional physical therapy only. You may be assigned to either one of these two groups based on that process. Such random allocation or assignment is outside the control of the researcher, you may be assigned to either one of these two groups. This process is called randomization and it will be performed to determine your group assignment.

Kinesio Taping is a form of adhesive tape that could be placed on almost any area of the body. It is made of 100% cotton and its adhesive is a medical grade acrylic so allergic reaction to this kind of taping is extremely low. However, an allergy test will be performed during your initial visit by the principal investigator to determine if you have such an allergic reaction and if so you will not be participating in the study. The tape will be placed on the lower back area and left in place for 72 hours every week for a total of four weeks. You can practice your ordinary activities including taking a shower. Manipulation of the lower back are movements of very small magnitude applied on certain parts of your lower back by the principal investigator in certain positions to reduce pain and improve function. You will be also getting therapeutic exercises which will be described to you by the principal investigator as a part of your treatment.

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Why are you asking me?

The study is conducted by Hossameldien Elkholy, a licensed physical therapist with around 20 years of experience. We are asking you to volunteer to participate in this study because your physician determined that you have an acute low back pain and this study is about examining the effect of a modality called Kinesio Taping in such conditions. However, not all participants will receive Kinesio taping. This will be based on your group assignment. If you will be assigned to the experimental group, you will receive traditional physical therapy plus Kinesio taping. If you will be assigned to the control group, you will receive traditional physical therapy only.

What will I be doing if I agree to be in the study?

If you agree to participate, you will be asked to see the physical therapist at Quick Docs Medical Center, Brooklyn NY for assessment. During your first visit, the physical therapist will conduct a routine physical examination and an allergy test for Kinesio Taping. The physical therapist will then inform you about your visit schedule. You will be expected to attend two times per week for four weeks. If you are assigned to the experimental group, you will receive traditional physical therapy plus Kinesio taping on your lower back. If you are assigned to the control group, you will receive traditional physical therapy only. Participants in both groups will receive spinal manipulative therapy and therapeutic exercises as part of their traditional physical therapy, whether they are in the control or the experimental group. The taping will be placed on your lower back for 72 hours every week if you are assigned to the experimental group. All subjects will be scheduled to see the principal investigator with all treatment sessions being conducted and performed by the principal investigator. Manipulation is a term used to describe movements of the spine induced by the therapist's hands in different directions and in different positions in order to reduce pain and improve function. Therapeutic exercises are bodily movements that will be instructed to you by your physical therapists in order to reduce pain and improve function. You will be given a hand out of these exercises to practice at home. The study will take around four weeks to be completed. At that time your participation in the study will be completed. Although your time in the study will be completed you will continue to receive standard physical therapy care if you are still unable to do activities of daily living. None of the procedures used in this study is experimental in nature.

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All procedures in this study are routine physical therapy procedures used by physical therapists in every day's clinical practice.

What are the dangers to me?

None of the procedures in this study is considered to be an experimental procedure. The only experimental aspect of the study is the gathering of information for the purpose of analysis. Participation in this study may be associated with risks such as skin irritation and breach of confidentiality. If you will be assigned to the experimental group, an allergy test will be conducted to determine your skin reaction to this taping. If you have any reaction to the taping and the test is positive, you will be excluded from the study. The likelihood of allergic reaction to Kinesio taping is extremely low because the tape is made of 100% cotton. Skin irritation due to prolonged taping will be minimized by using a tension level of less than 50%. Skin irritation is very unlikely to occur with such low tension level. Your confidentiality will be protected by the use of proper data storage and restricting access to only authorized personnel.

If you have any questions about the research, your research rights, or have a research-related injury, please contact Hossameldien Elkholy or Dr. Madeleine Hellman. You may also contact the IRB at the numbers indicated above with questions as to your research rights.

Are there any benefits for taking part in this research study?

There are potential benefits to you and future recipients from the information gained from this study including faster and less painful recovery. We cannot guarantee, however, that you will receive any benefits from participating in this study.

If you choose not to participate in this study, you will be receiving your prescribed physical therapy procedures.

Will I get paid for being in the study? Will it cost me anything?

You will not get paid for your participation in this study and your participation will not cost you anything beyond what you would normally have for your doctor visits and physical therapy.

How will you keep my information private?

All patients' data and records pertaining to this research study and any relevant information will be stored in a locked file cabinet at the facility in which the study will be conducted. A case number will be used to indicate patient's identity on these records.

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This information will be only accessible to the principal investigator, the independent physical therapist, and other research study staff involved in conducting this research study. All assessment data will be kept in a separate locked file cabinet which will be accessed only by the independent physical therapist. No confidential information such as the patient's name, address, phone number, or/and other information that might possibly be used to link the data back to the patient will be transmitted or shared. All questionnaires, daily logs, and measurement data to be used in computer analysis will have number codes rather than your name. Your name will not be recorded on the information or reported in papers. A master list of code numbers will be kept confidential by the researchers and will be stored a locked file cabinet. Data that will be used for computer analyses will be kept on diskette and only researchers involved in the study and representatives of the Nova Southeastern University Institutional Review Board will have access to the records and information about the study. These measures will be used to ensure the maintenance of patient confidentiality. All information obtained in this study is strictly confidential unless disclosure is required by law. The IRB, regulatory agencies, and the dissertation chair may review research records.

What if I do not want to participate or I want to leave the study?

If you do decide to leave or you decide not to participate, you will not experience any penalty or loss of services you have a right to receive.

If you choose to withdraw, any information collected about you before the date you leave the study will be kept in the research records for 36 months from the conclusion of the study.

Other Considerations:

If significant new information relating to the study becomes available, which may relate to your willingness to continue to participate, this information will be provided to you by the investigators.

Questions about This Study: If you have any questions about this study, please ask. If you have questions later about this study, you may contact Hossameldien Elkholy at (347) 302-1604.

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Voluntary Consent by Participant:

By signing below, you indicate that

- This study has been explained to you
- You have read this document or it has been read to you
- Your questions about this research study have been answered
- You have been told that you may ask the researchers any study related questions in the future or contact them in the event of a research-related injury
- You have been told that you may ask Institutional Review Board (IRB) personnel questions about your study rights
- You are entitled to a copy of this form after you have read and signed it
- You voluntarily agree to participate in the study entitled "The efficacy of Kinesio Taping as an Adjunct Intervention to Traditional Physical Therapy in the Treatment of Nonspecific Acute Low Back Pain: A Prospective Randomized Controlled Trial".

Participant's Signature: _____ Date: _____

Participant's Name: _____ Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Initials: _____ Date: _____