Trial Outcomes for Massage: Care Ally-Assisted vs. Therapist-Treated (TOMCATT)
NCT 03100539
JUNE 27, 2022

Subject Name:		**Date:**	
Title of Study:	**T**rial **O**utcomes for **M**assage**: C**are **Ally- A**ssisted vs. **T**herapist-**T**reated **(TOMCATT)** Study # **1604689005**		
Sponsor:	US Dept of Veteran's Affairs		
Principal Investigator:	Dr. Matthew Bair	**VAMC:**	Roudebush VA Indianapolis

Purpose *of study and how long it will last*:
You are invited to participate in a research study called **T**rial **O**utcomes for **M**assage**: C**are **A**lly**-A**ssisted vs. **T**herapist-**T**reated **(TOMCATT)** because you are a Veteran who has neck pain. The purpose of this study is to compare the effects of wait list control vs. therapist-treated massage on severity of neck pain. The intervention will be 12 weeks long and your participation in this study will last approximately 3 months.

Study Summary
This study has two groups: a control group which receives no other treatment besides what you would otherwise receive if you were not part of the study, and a massage group in which you receive 24 massages over a 12-week period. You are randomly placed into one of these groups. Regardless of group, there are three research interviews: one after consent, then one month and three months after your initial appointment. All interviews can be done in person or virtually. The only risks of this study are feeling uncomfortable answering questions and loss of confidentiality. You may withdraw from the study at any time without penalty to VA benefits or refuse to consent during our discussion today.

Description *of the study including procedures to be used*:
If you agree to participate, you will be one of **308** Veterans randomized in the TT-M (therapist-treated massage) or WL-C (waitlist control) group participating in this study. There was previously an additional group we randomized 102 Veterans and their Care Allies to, but we are no longer randomizing into this group.

If you agree to be in the study, you will do the following things:

If you agree to take part in this study, you will have a 1 in 2 chance of being assigned to either the TT-M group or the WL-C group. This group assignment will be determined by a table of random numbers created by our statistician. Your participation in this study will last approximately 3 months. The 2 study groups are described below.

<u>TT-M treatment group:</u>

You will receive up to 24 massage therapy sessions performed by a licensed massage therapist. These sessions will be up to twice a week for 12 weeks and last approximately 60 minutes each. Sessions will be held at the RLVAMC or on IUPUI campus, at the health science building. The session with the therapist will involve :1) hands-on assessment; 2) massage techniques applied

directly to the neck and associated trigger points; 3) identification and treatment of related muscles; and 4) reestablish the feeling of being unified in the body after intensive, isolated massage.
A random sample of participants will be observed by a study team member. This observation is done to help ensure the study is being done correctly.

WL-C group:

If you are placed in the waitlist control you will be instructed to continue your medical care as normal and to not begin any massage treatment during the 3 months of the study. At your final visit, you will have the option to complete a massage therapy training session.

Research Interviews

Regardless of the group in which you are placed, you will be interviewed 3 times during the next 3 months – today, 1 and 3 months after the date of your first intervention session, approximately. These interviews are in addition to the treatment sessions described above and will be conducted by a trained research assistant who is a different person from the massage therapist. The interviews can be conducted either in person or virtually.

Upon study conclusion, participants will be randomly selected and contacted to voluntarily participate in a one-time qualitative interview. If you are chosen, the interviews will last 45-60 minutes and you will be asked about your role in the study. These interviews will be audio-recorded and transcribed.

Risks:

While in the study, the risks are that you may feel uncomfortable answering some of the questions and there is a minimal risk of loss of confidentiality regarding the information that you may share. The study team will follow VA policy and regulations to minimize these risks.

In order to protect your confidentiality, all documents that contain your individually identifiable information will be locked and secured in file cabinets only accessible to authorized study personnel. Study data collected will be kept in a secure database and in secure files. You will also be assigned a unique study ID number which will be used to link you to your data.

Potential risks are minimal and may include the following: temporary pain or discomfort, swelling, skin irritation, sensitivity to massage oils, anxiety while talking on the phone, and feeling uncomfortable while answering the survey questions.

Your participation is voluntary and you can stop participation at any time.

Benefits:

The benefits to participation are as follows: Whether in the TT-M or WL-C group, you may experience some improvement in your neck pain. However, none of these benefits are guaranteed. Even if you do not benefit directly from this study, the knowledge gained may benefit future veterans with chronic neck pain.

Alternate Courses of Action or treatment:

Instead of being in the study, you have these options: 1) you do not have to participate. Your participation is completely voluntary. 2) You can continue to receive all currently approved treatments for your symptoms from your regular doctor without participating in the study.

Statement of Use of Research Results:
The results of this study may be published, but your records or identity will not be revealed unless required by law.

Will I Receive My Results?
We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. A short summary of the results will be mailed to you upon study completion. These results will include whether we found massage to be effective for neck pain and a summary of our interpretation of the results.

Audio/Video Recording
If selected, your one-time qualitative interview will be audio and/or video recorded. At any time you may tell the researcher that you feel uncomfortable or do not wish to continue. The audio files will be stored on a password-protected computer at Roudebush VA Medical Center. The VA policy is that no audio can be stored on the devices. Therefore, all recordings collected during the study will be immediately uploaded to the VA secure server. Once the files have been uploaded to the secure server the files remaining on the device will be immediately deleted from the audio recorder.

The investigator may add additional protections such as identified by a code.

Confidentiality:
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the VA Research and Development Committee's designees, and federal agencies, including but not limited to the Office for Human Research Protections (OHRP), the Office of Research Oversight (ORO), VA Office of the Inspector General (OIG).

Use of Your Information in Future Research:
Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

Retention of Research Records:
Research records will be maintained by the investigator in accordance with the VHA Records Control Schedule.

Research Subject Costs:

1. There will be no costs to you for any of the treatment or testing done as part of this research study. Eligibility for medical care at a VA Medical Center is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.
2. The study is sponsored by the Veterans Administration.
3. You will not be required to pay for medical care or services received as a participant in a VA research project except as follows:

    Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

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Compensation & Treatment for Injury:

1. You will receive payment for taking part in this study. You will receive a $25 store gift card for each of the 3 research interviews. Thus, if you complete all 3 interviews, you will receive a total of $75 in compensation. If you only complete some interviews, you will receive $25 in compensation for each interview completed. You will be paid after each interview.
2. The VA medical facilities shall provide necessary medical treatment to a research subject injured as a result of participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This does not apply to: (1) treatment for injuries due to noncompliance by a subject with study procedures; or (2) research conducted for VA under a contract with an individual or a non-VA institution.
3. Financial compensation for research-related injuries is not available. However, by signing this form, you do not give up your legal rights to seek such compensation through the courts.

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RESEARCH SUBJECT'S RIGHTS:

Participation in this study is entirely voluntary. You may refuse to participate. Refusal to participate will involve no penalty or loss of rights to which individuals are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits. You will receive a copy of this signed consent form.

In case there are medical problems or questions, Dr. Bair can be called at 317-988-2058 during the day and (317) 287-9469 after hours. If any medical problems occur in connection with this study, the VA will provide emergency care.

Please direct questions about the consent process and the rights of research subjects to the VA Customer Service Office at (317) 988-2602. For questions about your rights as a research participant or complaints about a research study, contact the Indiana University Human Subjects Office at 317/278-3458 or 800/696-2949. If you have any questions about the research study or want to check the validity, discuss problems, concerns or obtain information or offer input, please call the Research Office at 317-988-3032.

The study has been explained to me and all of my questions have been answered. The risks or discomforts and possible benefits of the study have been described. Other choices of available treatment have been explained.

_____	_____	_____
Subject's Signature	Printed Name of Subject	Date

_____	_____	_____
Signature of Person Obtaining Consent	Printed Name of Person Obtaining Consent	Date