



Subject Name: _____ Date: _____

Title of Study: Feasibility and Acceptability of The Equus Effect: A Small Randomized Controlled Pilot Study of an Equine-facilitated Therapy

Principal Investigator: Steve Martino, Ph.D.

Version Date: 4/11/2022

RESEARCH SUMMARY

You are invited to be evaluated for and potentially take part in a research study involving equine-facilitated therapy. This study is sponsored and funded by the VA Office of Rehabilitation Research & Development. Before you decide to take part in the study, it is important for you to know why the research is being done and what it will involve. This initial summary is to give you key information to help you decide whether to participate. Detailed information follows this brief summary. Please ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn if working with horses, in an approach called equine-facilitated therapy, can help people improve their ability to socially interact with others and manage their emotions. Your participation in this research will last about four and a half days over approximately 20 weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Potential benefits of your participation in this research study are that you may feel more able to cope with interpersonal problems and uncomfortable emotions and this might help you improve your social functioning. For a complete description of benefits, refer to the Research Details.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You might not want to volunteer for this study because you could be asked to interact with horses and not want to do that. In addition, if you volunteer for this study, you will work with other Veterans in groups, which might make you feel uncomfortable talking about your interpersonal difficulties or problems managing emotions. We will also ask you questions about various psychiatric symptoms, which may also make you feel uncomfortable. For a complete description of risks, refer to the Research Details.

If you choose not to volunteer for this study, you can continue to work with your mental health clinician at VA Connecticut. For a complete description of alternate treatment/procedures, refer to the Research Details.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.



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RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research study, we hope to determine if it is possible to study an equine-facilitated therapy group intervention and compare it to an alternative group intervention to help Veterans learn how to better manage their emotions and relationships with others. We also hope to determine what some Veterans think about these group interventions and what, if any, changes they experience after participating in them.

HOW LONG WILL YOU BE IN THE STUDY?

Approximately forty Veterans will participate in this study. The entire research study is expected to take approximately two years to complete. Your individual participation in the project will take about four and a half days over about 20 weeks. Your time will be spent completing surveys and interviews before you start the group intervention and about four and 16 weeks later. You will also spend time traveling to and from the location where the group interventions will be conducted and participating in weekly groups over a 4-week period.

WHAT WILL HAPPEN IF YOU TAKE PART IN THE STUDY?

This study will evaluate if working with horses, in an approach called equine-facilitated therapy, can help Veterans improve their ability to socially interact with others and manage their emotions. This study will examine two types of group interventions, an equine-facilitated therapy called The Equus Effect and a group intervention that does not involve interactions with horses. Both interventions aim to help improve social and emotion management skills.

Here is what will happen if you take part in the study:

- Screening: You will first be asked to participate in a psychiatric interview and complete some questionnaires. This screening will take approximately 30-40 minutes. The purpose of the screening is to determine if you are experiencing issues appropriate for the group interventions and if you meet other study eligibility criteria. You will be free to skip any questions that you would prefer not to answer.
- Assessment: If you are found to be eligible to participate in the study, you will be asked to complete several questionnaires that collect descriptive information about you, your experiences, psychiatric symptoms, and functioning. This assessment will take about one hour. You will be free to skip any questions that you would prefer not to answer.
- Group intervention assignment: You will be assigned by chance to either the equine-facilitated therapy group intervention or the general group intervention. Because this study involves group interventions, we will first collect a large enough group of Veterans who are eligible and consent to participate before assigning Veterans by chance to one



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or the other group intervention. You will know your assignment before you begin either intervention.

- Group intervention visits: You will be asked to attend four sessions of the equine-facilitated therapy group intervention or general group intervention (described below). These sessions will occur once a week for 4 weeks. Each session is four hours long and will run from either 10 am – 2 pm or 10:30 am – 2:30 pm on a weekday. At each session, you will talk with the group leaders, their assistants, and other members of your group. You will continue to receive your general mental health services at VA Connecticut as you have arranged it prior to participating in the study.
 - *Equine-facilitated therapy intervention*: The equine-facilitated therapy intervention is called The Equus Effect. Each session focuses on teaching people mindfulness and emotion management and interpersonal skills and uses experiential activities with horses to give people opportunities to learn and apply these skills.
 - *General group intervention*: Each session focuses on teaching people mindfulness and emotion management and interpersonal skills and uses team building activities to give people opportunities to learn and apply these skills. This intervention does not involve any horses.
- Travel. Both group interventions will be conducted at a facility in Sharon, CT. Travel time to the facility from either VA Connecticut's West Haven or Newington campuses is about two hours. Free transportation by van to and from the groups will be provided by VACHS staff or the Disabled American Veterans. Therefore, on days in which you are scheduled to attend the groups, you will need approximately eight hours in total. If you prefer to make alternative transportation arrangements, you are permitted to do so.
- Follow-up. You will be asked to complete a 1-hour assessment at the end of the four week group intervention. In addition, if you participate in the equine-facilitated therapy group, you will be asked to complete a 20-30 minute interview about your experiences with this intervention. We also will ask your mental health clinician to complete a 20-30 minute interview about the effect of equine-facilitated therapy on your work together. Another 12 weeks later, you will be asked to complete a final 1-hour assessment. Once again, you will be free to skip any questions that you would prefer not to answer.
- Interactions: During the study, you will interact with several different people. A research assistant will do the screening, assessment and follow-up appointments with you at either the VA Connecticut West Haven or Newington campuses. In addition, another research staff member will interview you about your experience with equine-facilitated therapy, if you are assigned to that intervention. Group leaders and their assistants located at the Sharon, CT facility will conduct the group interventions in which you will participate.
- Safety monitoring: We will monitor any complaints you may have about the study procedures or the group interventions. We also will monitor your report to us of any serious events like a life-threatening experience or hospitalization. All complaints or serious events will be reported to Dr. Martino by the research staff. If any serious events are related to the study, they will be reported to the VA Connecticut Institutional Review



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Board (IRB) within five working days. In the event that you or someone else in the study is physically hurt while interacting with a horse in the equine-facilitated therapy group intervention, the study will be stopped and study procedures will be immediately reviewed by the New England Mental Illness, Research, Education, and Clinical Center's Data Safety and Monitoring Board (DSMB) for guidance.

- Audio recording. All group intervention sessions will be audio recorded on VA-approved recording devices. Dr. Martino and his research staff will use these recordings to determine if the group leaders conduct the sessions properly. In addition, if you are assigned to the equine-facilitated therapy group, we will audio record an interview with you about your experiences in this intervention. The recordings will not be entered into your medical record.
- COVID-19 risk reduction. The study includes COVID-19 risk reduction procedures consistent with current VA Connecticut guidelines. These procedures involve COVID-19 symptom screening before travel by van, wearing 2-ply masks during van transportation and group interventions, and allowance for remote screening and completion of study assessments.

WHAT IS EXPECTED OF YOU IF YOU TAKE PART IN THIS STUDY?

If you take part in the study, we expect the following things from you:

- Keep your study appointments. If you miss an appointment, please contact the research staff to reschedule as soon as you know you will miss the appointment.
- Complete your questionnaires and interviews as instructed to the best of your ability.
- Attend all scheduled weekly group sessions. Please arrive on time. If you cannot make a session, please let us know in advance.
- Follow the directions of the group leaders.
- Show up on time if you decide to use the DAV transportation to and from the facility in Sharon, CT.
- Report any changes in your health that could affect your participation in the study.
- Adhere to COVID-19 risk reduction procedures as dictated by current VA Connecticut guidelines.
- While participating in this research study, do not take part in any other research project without approval from Dr. Martino or his research staff.
- Sign an Authorization for Release of Information between VA Connecticut Healthcare and The Equus Effect program in Sharon, CT where the group interventions will take place. This will allow our research staff and your mental health clinicians to coordinate your care with the group leaders for this study, as needed.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT YOU HAVE IF YOU TAKE PART IN THIS STUDY?



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Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks listed.

- Completing questionnaires. Some people become uncomfortable when asked questions about their personal life or problems they have experienced, like psychiatric symptoms; if, for any reason, you wish not to answer specific questions or you wish to terminate a screening or assessment session, you will be able to do so.
- Interacting with horses. Interacting with horses carries with it some health and safety risks. You may not understand a horse's behaviors and how to interact around them; this lack of knowledge might cause you to act in a manner that risks your physical safety (e.g., moving suddenly toward the horse). You also might not wear appropriate clothing or footwear. In addition, you might be intimidated or anxious around a large animal such as a horse. To reduce these risks, there will be many protections in place, including:
 - o The group leaders are trained as Experiential Learning with Horses Instructors through the Epona Equestrian Services Program in Tucson, AZ – an internationally acclaimed equine educational program that trains people in EFT. Both group leaders are very experienced in conducting equine-facilitated therapy and handling horses.
 - o All activities with horses are unmounted (no riding). Risk of injury from horses increases substantially when riding them. Under no circumstances will you be allowed to ride horses at the facility.
 - o You will be eased into experiential equine activities and guided at your own pace and comfort level. If you experience discomfort, the group leaders and their assistants will help you address the discomfort through conversation and practice using some of the skills taught in the groups, like emotion management techniques.
 - o The horses used in the program are predictable in their behavior and accustomed to interactions with group participants and experiential equine activities used in The Equus Effect. The horses are well treated and healthy, with proper stalls, pastures, feeding, grooming, exercise, and daily handling. All the horses have appropriate veterinarian care, including annual checkups, vaccinations, dental work and regular hoof care.
 - o Given that a maximum of six Veterans will complete the program at one time, this means that only two Veterans will be assigned to each horse, further reducing risk for you by not overwhelming the horses with too many participants at once. In addition, horses always are kept one horse length apart from one another and move in the same direction in the ring as you interact with them, both strategies that reduce risk. When you are not working with a horse, you will be asked to remain at a safe distance or outside the ring.
 - o At the beginning of the equine-facilitated therapy group intervention, the group leaders will teach you about horses, their behavior, and how to safely interact with them.



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- o The group leaders will have assistants in the ring. The assistants have years of experience with horses and equine-facilitated therapy. They will always be prepared to take control when you are working with the horses.
- o You must wear appropriate footwear and clothing when interacting with horses. This means boots and long pants are required. If you do not have proper footwear, the facility in Sharon, CT has extra pairs of boots, as well as hats and sunscreen for those who need it. No loose articles of clothing are permitted that might get tangled or cause you to trip or fall during experiential equine activities.
- o
- Participating in group interventions. You will work within groups. It is possible that you may feel uncomfortable discussing your life or difficulties you are experiencing in a group setting. You will not be forced to talk about anything you choose not to share with others. The group leaders also will enforce respectful interactions among group participants to reduce your risk of discomfort.
- Mandated reporting. Research staff are mandated to disclose certain types of information such as abuse of a child or elderly person, or significant current danger to harm yourself or others. If any of these situations were to arise, the research staff and Dr. Martino will inform you of the need to disclose to appropriate authorities and help you get emergency services at VA Connecticut, a non-VA facility, or the police for a safety check.

Risks of the usual mental health care you receive at VA Connecticut are not risks of this study. Those risks are not included in this consent form. You should talk with your mental health care providers if you have any questions about the risks of your usual mental health care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There will be no direct benefits to you if, after the screening, you are found to be ineligible for the study and do not receive one of the group interventions. The potential benefit to you, if you participate in either the equine facilitated therapy group or the general group, is unknown and the reason we are researching the interventions. It is possible that you may not personally be helped by taking part in this study, but your participation may lead to knowledge that may help others.

WHAT OTHER CHOICES DO YOU HAVE IF YOU DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If this is your decision, there are other choices such as participating in group treatments available at VA Connecticut that help Veterans better manage their social and emotional problems (e.g., social skills training, dialectical behavior therapy, general psychotherapy)

HOW WILL YOUR PRIVATE INFORMATION BE PROTECTED?



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Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- Your research records will be kept as confidential as possible. Your research records will be identified with a code number rather than your name. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.). The master list linking names to code numbers will be kept separately from the research data.
- All questionnaire data will be collected using a program called VA REDCap. VA REDCap is a secure web application that will be used for direct data entry by research staff.
- Recordings of group sessions and from interviews will be stored on a secure server at the VA. Interviews will be transcribed by VA research staff. After interviews are transcribed, the transcriptions will be coded by study staff to understand themes from the interviews; transcriptions and coding will be stored on a secure server at the VA.
- All research non-electronic information will be secured in locked files. Your identity will not be revealed in any reports or publications resulting from this study. Only research staff and authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory agencies such as the Government Accountability Office (GAO), the Office for Human Research Protections (OHRP), Office of Research Oversight (ORO), and VA Connecticut Healthcare System Research Office.

There are times when we might have to show your records to other people. For example, our local Research and Development Committee, VA officials, other study monitors may request to audit this study and look at or copy portions of records that identify you. Anyone involved in these type of monitoring activities will maintain the confidentiality of your records.

Sometimes, clinical information may be shared with your clinician when it is in the interest of good clinical care as determined by the principal investigator, Dr. Steve Martino. Also, any information that is gathered during research procedures that could be helpful in your rehabilitation may be shared with the clinicians involved in your care. This may include observations about your experience with the interventions.

In addition, when you complete questionnaires, we will ask you about your symptoms. If, in the course of our study procedures, we have reason to be concerned for your safety or feel that you may be a threat to the safety of others, we will inform your VA clinician who may wish that you be evaluated in the Psychiatric Emergency Room at VA Connecticut Healthcare System. Your clinician or the psychiatrist on duty might decide to hospitalize you, even if you do not wish to be hospitalized. If we are unable to contact your clinician and have concerns about your safety, we may escort you to the psychiatric emergency room, where you will be evaluated, and a decision may be made to hospitalize you.

Storage and Future Use of Data or Specimens



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Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Medical Record

The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for Veteran and non-Veteran research subjects. Therefore, if you participate in this study, a medical record will be created if you do not already have one. Notes from your visits, procedures, and any laboratory tests may be included in this record. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulation that protect privacy of medical records will apply to your VA record.

Clinical Trial

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

WHAT ARE THE COSTS TO YOU IF YOU TAKE PART IN THIS STUDY?

There will be no charge for care received as part of your participation in this study. However, some Veterans are required to pay a co-payment for medical and other services provided by the VA Connecticut Healthcare System that are not part of the study. These co-payments will continue to apply to medical care and services provided by VA that are not part of this study..

IS THERE PAYMENT TO YOU IF YOU TAKE PART IN THIS STUDY?

We will compensate you for the time you spend doing study assessments. You will be paid \$10 for the screening that determines your eligibility for the study, \$30 for the assessment at the beginning of the study, \$40 for the assessment and interview that occurs after you complete the group intervention, and \$50 for the assessment that occurs 12 weeks later. You will not be paid for participating in the group sessions. Total payment for the study is up to \$130.

Payments will be made through electronic funds transfer. You will need to provide us with your banking information by completing a special payment form. If your banking information changes while you are still participating in the study, you will need to fill out the form again. It is your responsibility to notify us if your banking information changes. Alternatively, if you do not have a bank account, a check will be mailed to you instead. This check(s) will be mailed to the address you provide us.

Please note, study payments are subject to withholding for outstanding federal debts (i.e., defaulted student loans, interstate child support, back taxes etc.) without notification. In addition,



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you will receive an Internal Revenue Service Form 1099 regardless of amount you are paid; your SSN will be used for this purpose.

WHAT WILL HAPPEN IF YOU ARE INJURED BECAUSE OF YOUR BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you. Except in very limited circumstances, this medical treatment will be provided in a VA Medical facility. There are no plans to provide compensation for disability or other losses occurring over the long term or if an injury becomes apparent after your participation in the study has ended. However, by agreeing to participate in this research study, you are not waiving or giving up any legal rights to seek compensation.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

The VA Connecticut Research Coordinator at 203-932-5711- x3350

AFTER HOURS:

VA Connecticut Emergency Room at 203-932-5711 x4471 or x4472. _____

Emergency and ongoing medical treatment will be provided as needed.

WHO ELSE MAY YOU CONTACT IF YOU HAVE QUESTIONS?

If you have questions about your rights as a study subject, or you want to make sure this is a valid VA study, you may contact the Chairman of the Human Studies Subcommittee at 203-932-5711 x3350.

If you have questions, complaints or concerns about the study or if you would like to obtain information or offer input, you may call the VA Connecticut Research Coordinator at 203-932-5711 x3350 or Dr. Steve Martino at 203-932-5711 x7418.

DO YOU HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary. By choosing to not take part in this study, or withdrawing from the study, you will not incur any penalty or give up any benefits to which you are otherwise entitled.



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If you are a VA employee or student, refusing to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress.

You may stop being in this study at any time, without any penalty or loss of benefits.

If you choose to stop participating, we do not anticipate any negative consequences to your health. We may continue to review the data already collected for the study but will not collect further information about you.

RIGHT OF INVESTIGATOR TO TERMINATE YOUR PARTICIPATION

At any point in the study, you may be discharged if your behavior is too disruptive or if the PI determines that you are no longer appropriate for the study.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The research staff member has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent document, or it has been read to you. You will receive a copy of this consent document after you sign it.

I agree to participate in this research study as it has been explained in this document.

Subject's Name	Subject's Signature	Date

Person Obtaining Consent	Person Obtaining: Signature	Date