

INFORMED CONSENT

Relax, Release, Relief (RRR) with Foot Posture Correction Study

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What the study is about

The purpose of this research is to determine effectiveness of Relax, Release, Relief technique in decreasing pain and increasing range of motion in effected joints. We will compare self reported medical history of painful diagnoses with the effects of RRR when combined with Foot Posture Correction. Using angles measured digitally from still photos, Longitudinal Arch Angle test (www.LAAngletest.com), Analog pain scale (1-10), looking at the duration of relief over one year. Data for fabrication of the orthotics will be gathered via three different techniques. Both the subjects and myself will be blind to which method is used to fabricate the orthotics. Subjects will evaluate the comfort of the orthotics and the role the orthotics have in retaining relief.

What we will ask you to do

On the first visit, I will ANSWER any questions you may have about the research and you will, if you decide to participate, sign Informed Consent to allow me to cast your feet in the three techniques, perform the LA Angle Test, video record every relaxation session, perform the gentle relaxation techniques which involve positioning your body, asking you to apply a gentle force against resistance while I apply a gentle for on a “relaxation point”. I also will be asked to evaluate both the level of pain and orthotic device in a brief email questionnaire monthly for the next year. Additionally, I will ask a few medical questions to determine what diagnoses your doctors have given you and what treatments you have received for the pain and how effective each treatment was. You may also be asked questions about how the pain is effecting your lifestyle and emotions.

Risks and discomforts

I do not anticipate any risks from participating in this research.

Benefits

Relax, Release, Relief may give you relief from all or part of your pain for period of time and possibly permanently. Restoring a corrective posture to your feet should make positive changes in all of your joints from head to toe. By releasing the tension on your ligaments, the changes in foot posture may significantly elongate the time period of pain relief.

Payment for participation

You will receive ONE pair of custom foot orthotics made from one of the casts taken on your first visit. The usual and customary cost for these orthotics is between \$375-\$800. Depending on the market

Audio/Video Recording

All sessions beginning immediately following the consent will be video taped and still photos taken. As releases are done, colored dots will indicate positional changes in range of motion of your joints which will then be measured from stills.

Additional medical info relevant to your pain will be added to your record from videos and evaluations you make of the results

may be shared on our website while concealing your identity. A full video release is a requirement for participation. Images may also be used, with your identity concealed, for scientific papers, publications, and testimonial purposes.

I am willing to have this interview video recorded:

Signed: _____ Date: _____

Privacy/Confidentiality

None of your personal data, medical or otherwise will be shared with any person or organization both private and public, other than the observers you bring or allow in the room during your research sessions. I will not report your results to any agency, or government entity unless so ordered by a Judge with rightful jurisdiction.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication/treatment, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

If you have question

Please ask any questions you have now. If you have questions later, you may contact Edward S. Glaser at rrrtved@gmail.com or at (615) 579-5846.

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

Your Signature _____ Date _____

Your Name (printed) _____

Signature of person obtaining consent _____ Date _____

Printed name of person obtaining consent: **Edward S. Glaser, DPM**

This consent form will be kept by the researcher for at least five years beyond the end of the study.