

Clinical HeartSync Study Information Sheet

Title of the Project: Clinical HeartSync Evidence-Based Research Project

Principal Investigator: Steve Fair, LMSW

Co-Investigator: Dr. David Jenkins PsyD – Department of Psychology, Liberty University, who is submitting the IRB proposal.

Consultant: Dr. Harold Koenig, MD

Key Information about the Research Study

You are invited to participate in a research study measuring the effectiveness of a counseling modality called “Clinical HeartSync”. To participate, you must be at least 18 years old, and have symptoms of depression that will be measured on a set of standardized tests. We would ask that anyone with current suicidal/homicidal thoughts or intent, or manic and/or psychotic features, not apply for this particular study. You must have not received formal HeartSync treatment or prayer ministry in the past and be willing to learn about this model through an introductory video.

Things you should know:

- The purpose of the study is to measure the effectiveness of what has been an Inner Healing Prayer Model, as a clinical application formatted to be used in a clinical counseling setting through a 10-session treatment program and giving pre, mid, and post testing (immediately following the program and 3 months afterwards) that measure if your depression symptoms decrease while being given these “Clinical HeartSync” sessions. If you choose to participate, you will be asked to learn about the “Clinical HeartSync” model through an introductory video, doing a clinical assessment and treatment plan session with a licensed counselor, and attend ten 50-minute “Clinical HeartSync” sessions. We ask that you would do some journaling and complete the daily homework that your counselor prescribes outside of the counseling office. Your involvement will take approximately 10 hours total of session time scheduled at your convenience within a 3-month period, and at least 20 minutes a day of homework exercises given to you by your counselor.
- Risks or discomforts from involvement in this research project are minimal, and emotionally the risks are no more intensive than would be expected from involvement in a normal clinical counseling session. The choice is yours whether you elect to talk about and address the root issues of your depressive symptoms and each session will be completed in full confidentiality between you, your counselor, and our small research team.
- HeartSync sessions have been said by a vast majority of those receiving this type of intervention to be a highly effective and efficient tool in addressing their depression

symptoms and that HeartSync has given them the tools they need to continue their ongoing recovery. It is our hope that participants will experience heart healing while they are entered in this research project. However, no guarantees can be made for the benefits that you will receive while in this study.

- We want to make sure all potential participants understand that taking part in this research project is completely voluntary. You do not have to participate, and you can stop at any time.

Please read this entire form and ask questions before deciding whether to participate in this research.

What is the study about and why is it being done?

The purpose of this study is to test the effectiveness of a counseling tool called “Clinical HeartSync” that has been adapted from what has been an inner healing prayer model called HeartSync Ministries that has been helping people since 2010. It is our hope to collect data from you by asking you to complete two standardized tests before you receive “Clinical HeartSync”, in the middle of the 10-sessions, after your 10 sessions, and then 3 months after you are done with the program. We will then tally and analyze this data to show the effectiveness of this modality, and are hypothesizing that “Clinical HeartSync” will be shown to be at least as effective as other traditional clinical counseling tools in treating depression and other mental health symptoms.

What will happen if you take part in this study?

If you agree to be in this study, I will ask you to do the following:

- I will ask you to submit an application and consent form that is listed on our website: **www.renewalcenter/heartsyncresearch.org**
- I will ask you to schedule with a licensed counselor who is also Qualified in HeartSync to be seen for 10 sessions within a 3-month period, starting with a Clinical Assessment and a Treatment Planning session with your counselor as is the norm in most clinical counseling settings.
- I will ask you to complete several short scales including the PHQ-9 and GAD-7 tests that measure depression and anxiety, before the counseling begins, during the counseling, immediately after the counseling, and then 3 months after it is finished.
- I will ask you to do the homework your counselor gives you in session which will include daily journaling between sessions, and a 15-minute daily HeartSync exercise.
- I will ask you to complete a questionnaire about your experience after the sessions are completed.

How could you or others benefit from this study?

The direct benefits participants should expect from participating in this study include experiencing the healing that many others have experienced from receiving “Clinical HeartSync” interventions, and learning tools that will help you stay out of depression in the future. The benefits of helping us to prove or disprove the effectiveness of this model could have more far-reaching rewards that extend well beyond our participants. Your help in this study could lead to the further acceptance of faith-based interventions such as “Clinical HeartSync” being accepted in the clinical world as an “evidence-based” intervention.

What risks might you experience from being in this study?

The expected risks from participating in this study are minimal, which means they are equal to or less than the risks you would encounter in everyday life. The inherent risk in starting any counseling relationship as you will be doing in this study, is that you may feel worse emotionally before you feel better, and it can be uncomfortable to open yourself to looking at the roots of your depression, and the past traumas that may be underlying. The risk for any breach of your confidence is also minimal, as your name will be kept confidential in accordance with all federal HIPPA regulations. During this study, if I receive information about child abuse, child neglect, elder abuse, elder neglect, or thoughts/intent to harm self or others, the clinician involved will be required to report it to the appropriate authorities.

How will personal information be protected?

The records of this study will be kept private. Published reports will not include any information that will make it possible to identify a subject. Research records will be stored securely, and only the researchers will have access to the records.

- Participant responses will be kept confidential by replacing names with numbers.
- Counseling sessions received while in this research program will be conducted in confidential and quiet settings when in person, and when on line will be conducted on HIPPA compliant technology.
- Data collected from you may be used in future research studies and/or shared with other researchers. If data collected from you is reused or shared, any information that could identify you, will be removed beforehand.
- Data will be stored on a password-locked computer. Only the researcher, the members of his research team, and your counselor, will have access to the data. After seven years all electronic records will be deleted and all hardcopy records will be shredded.
- Client sessions will be recorded for quality compliance purposes and these recordings will be stored on a password-locked computer. Only the researcher and the members of his research team will have access to the recordings. Once the researchers have reviewed and confirmed the fidelity of the interventions provided by listening to a random selection of the recordings, then the recordings will be deleted.

How will you be compensated for being part of the study?

Participants will not be compensated for participating in this study and will be asked to pay the normal fee of the counselor involved per their agency policies. However, after completing the 10 sessions and related standardized testing and questionnaire, participants will be offered free access to the Basic Training Videos of HeartSync Ministries valued at \$495 from which to learn more about the model of therapy that they received.

What are the costs to you to be part of the study?

To participate in this research project, you must agree to pay the standard fees for the counseling hours that you receive paid at the time that each service hour is rendered, per the policy of the agency you attend. Some scholarships may be available to participants from the participating professionals involved, and some health insurance companies may reimburse your costs for part or all of your counseling.

Is study participation voluntary?

Participation in this study is voluntary. Your decision whether to participate will not affect your current or future relations with any of the involved organizations including, HeartSync Ministries, your local counseling center providing the therapy, Liberty University's Institutional Review Board (IRB) whose ethics committee has overseen this study, or the research team involved. If you decide to participate, you are free not to answer any question or withdraw at any time without affecting those relationships.

What should you do if you decide to withdraw from the study?

If you choose to withdraw from the study, please contact the researchers at the email address/phone number included in the next paragraph. Should you withdraw, data collected from you will be destroyed immediately and not included in this study.

Whom do you contact if you have questions or concerns about the study?

The researcher conducting this study is Steve Fair, LMSW and the co-researcher is Dr. David Jenkins. The consultant on this project is Dr. Harold Koenig MD. You may ask any questions you have now and at any time. If you have questions later, **you are encouraged** to contact Steve Fair at sfair@renewalcenter.org.

Whom do you contact if you have questions about your rights as a research participant?

If you have any questions or concerns regarding this study and want to talk to someone other than the researchers, **you are encouraged** to contact the IRB. The physical address of the Liberty University IRB is Institutional Review Board, 1971 University Blvd., Green Hall Ste. 2845, Lynchburg, VA, 24515; the phone number is 434-592-5530, and the email address is irb@liberty.edu.

Disclaimer: The Institutional Review Board (IRB) ensures that human subjects research will be conducted ethically as defined and required by federal regulations. The topics covered and viewpoints expressed or alluded to by student and faculty researchers are those of the researchers and do not necessarily reflect the official policies or positions of Liberty University.