Subject Informed Consent Document and Research Authorization

COMPUTER-ASSISTED COGNITIVE-BEHAVIOR THERAPY FOR DEPRESSION IN PRIMARY CARE

Sponsor assigned number: R18 HS024047
Sponsor(s) name & address: National Institute of Health (Agency for Health Care Quality and Research), Washington, DC
Investigator(s) name & address:
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Jesse Owen, Ph.D., (Co-investigator, University of Denver, Denver Colorado)
Site(s) where study is to be conducted: University of Louisville Physicians at Family Practice Clinics, Department of Family and Geriatric Medicine, University of Louisville (Cardinal Station and Newburg offices in Louisville, KY and T.J. Samson Medical Center in Glasgow, KY) and Internal Medicine offices and clinics at UofL Health Sciences Center
Phone number for subjects to call for questions: 502-588-0678

Introduction and Background Information

You are invited to participate in a research study. The study is being conducted by Jesse H. Wright, M.D., Ph.D. and co-investigators (Becky Antle, Ph.D., Tracy Eells, Ph.D., Rangaraj Gopalraj, M.D., Laura Bishop, M.D., Brent Wright, M.D., and Jesse Owen, Ph.D). The study is sponsored by the National Institute of Health (Agency for Health Care Quality and Research) and the University of Louisville, Departments of Psychiatry and Behavioral Science and Family and Geriatric Medicine.

The study will take place at University of Louisville Physicians at Family Practice Clinics administered by the Department of Family and Geriatric Medicine, University of Louisville (Cardinal Station, Newburg offices in Louisville, KY and T.J. Samson Medical Center in Glasgow, KY) and the Department of Internal Medicine at the University of Louisville Health Sciences Center. Approximately 320 subjects will be invited to participate.

Purpose

The main purpose of this study is to determine whether adding computer-assisted cognitive behavior therapy to standard treatment improves outcome (patients get more relief from treatment if they have computer-assisted therapy added to standard treatment). Computer-assisted cognitive-behavior therapy (CCBT) has been studied in many other investigations and often has been found to be helpful. However, further studies are needed to learn more about how to provide this therapy to primary care patients and to determine cost benefits, if any, of using a computer program to assist in the delivery of treatment. Other purposes of the study include determining the **i**mpact of CCBT on satisfaction with treatment, quality of life, and overall health care costs. Finally, the study will explore possible effects of CCBT on brain chemistry that can be assessed by obtaining samples of saliva that will be analyzed for DNA and RNA (genetic information).

Procedures

In this study, you will be asked to complete several questionnaires before the study begins, and at 4 additional times (6 weeks, 12 weeks, 6 months, and 9 months later). The questionnaires will be used to assess levels of depression and anxiety, satisfaction with treatment, quality of life and wellbeing, and costs of treatment. The total amount of time required to completed these questionnaires will be about 30 minutes each time they are given

(total over 9 months will be 30 minutes times 5 administrations = 150 minutes). You may decline to answer any questions that make you uncomfortable.

In addition to questionnaires, you will be asked to provide a sample of your saliva before treatment, immediately after treatment ends, and 3 months after treatment ends. You will be supplied with saliva collection kits, instructions for collecting the saliva, and pre-paid envelopes to mail the samples to the investigators.

Patients with depression will be randomly assigned (like a coin toss) to receive treatment as usual from their primary care doctor (including any standard treatments for depression such as antidepressants and psychotherapy [counseling]) or treatment as usual plus computer-assisted cognitive-behavior therapy (CCBT). The treatment with CCBT will last 12 weeks and will include use of a computer program ("Good Days Ahead") that has been tested in other studies and found to be acceptable and helpful in treatment of depression. Patients assigned to CCBT will have access to the "Good Days Ahead" program which has 9 lessons (each usually takes about 30 minutes to complete) that they will use on their own over the 12 week treatment period. It is recommended that patients try to do one lesson per week over 9 weeks and then review program material if needed over the last 3 weeks. In addition to access to the "Good Days Ahead" program, patients assigned to CCBT will have a care coordinator who will contact them by phone and/or email (if available) once weekly for about 20 minutes to coach them on use of "Good Days Ahead" and to support their use of CCBT. Weekly sessions with the care coordinator will be audio recorded and these recordings will be reviewed by study investigators to assess coach's performance in delivering treatment. Patients assigned to treatment as usual without CCBT will not have the weekly calls or e-mails from the care coordinator because this is not part of standard treatment as usual.

For those patients assigned to treatment as usual, the total time to participate in the study will be about 150 minutes (2 and ½ hours) to complete the questionnaires. For those patients assigned to CCBT, the total time to participate in the study will be about 700 minutes (11 hours, 40 minutes [150 minutes to complete questionnaires + 270 minutes to complete the "Good Days Ahead" program + 240 minutes for weekly calls or e-mails with the care coordinator/coach]).

Potential Risks

There are no known risks associated with participation in CCBT. In previous studies no adverse effects have been observed. There are no known risks to saliva sample collection. Although there are no foreseeable risks, there may be unforeseen risks.

Research Involving Genetic information

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

1. Health insurance companies and group health plans may not request your genetic information that we get from this research or use your genetic information when making decisions regarding your eligibility or premiums.
2. Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

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Employers with 15 or more employees, health insurance companies, and group health plans must follow this law. This new law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Benefits

The possible benefits of this study include improved outcome for symptoms of depression and quality of life in those assigned to CCBT. There are also potential benefits to all participants in discovering information that will improve treatment of depression for other people. Although information collected may not benefit you directly, it may be helpful to others.

Compensation

You will be compensated for your time in completing questionnaires after the initial evaluation. You will be paid $25 by prepaid VISA card for completion of questionnaires at each of the following time points (6 weeks, 12 weeks, 6 months, and 9 months after beginning the study). The total compensation will be $100 for those who complete questionnaire at all time points).

Because you will be paid to be in this study the University of Louisville may collect your name, address, social security number, and keep records of how much you are paid. You may or may not be sent a Form 1099 by the University. This will only happen if you are paid $600 or more in one year by the University. This will not include payments you may receive as reimbursement, for example mileage reimbursement. We are required by the Internal Revenue Service to collect this information, and you may need to report the payment as income on your taxes. You can still be in the study even if you don't want to be paid.

HIPAA Research Authorization

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides federal safeguards for your protected health information (PHI). Examples of PHI are your name, address, and birth date together with your health information. PHI may also include your medical history, results of health exams and lab tests, drugs taken and results of this research study. Your PHI may not be used or shared without your agreement, unless it meets one of the HIPAA exceptions.

State and federal privacy laws protect your health information. In most cases, health information that identifies you can be used or shared by the research team only if you give your permission by signing this form.

If you sign this form your health information will be used and shared to answer the research questions described above and to make sure that the research was done correctly. The time period when information can be used or shared ends when all activities related to this study are completed.

Your access to your health information will not be limited during this study.

You do not have to sign this form. If you do not sign this form you may not participate in the study, and health information that identifies you will not be shared with the research team.

In our research, the research team will look at and may share information about you and your health. Federal law requires that health care providers and researchers protect the privacy and security of health information that identifies you.

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We may use or share your health information from the following sites: University of Louisville Physicians: Family Practice Clinics, Department of Family and Geriatric Medicine, University of Louisville (Cardinal Station and Newburg offices in Louisville, KY and T.J. Samson Medical Center in Glasgow, KY), Internal Medicine offices and clinics at UofL Health Sciences Center.

Protected health information (PHI) that will be used or shared for research:
Consultation reports, questionnaires, discharge summaries, history and physical exams, laboratory, x-ray, and other tests, records of your operation(s), medical progress notes, other cost-related information (such as costs of medications, office visits, and lab tests to determine total costs of your health care).

The information we may look at or gather for this research may also include:
The diagnosis and treatment of a mental health condition
Drug and Alcohol Use History

Revocation of Research Authorization
You may cancel the permission you have given to use and share your protected health information at any time. This means you can tell us to stop using and sharing your protected health information. If you cancel your permission:

- We will stop collecting information about you.
- You may not withdraw information that we had before you told us to stop.
    - We may already have used it or shared it.
    - We may need it to complete the research.
- Staff may ask your permission to follow-up with you if there is a medical reason to do so.

To cancel your permission, you will be requested to complete a written "Revocation of Research Authorization" form located at the end of this document. You may also obtain a copy from your study doctor, designated personnel or from the Human Subjects Protections Program Office website (http://louisville.edu/research/humansubjects/links-to-forms).

Confidentiality
Total privacy cannot be guaranteed. Your privacy will be protected to the extent permitted by law. If the results from this study are published, your name will not be made public. Once your information leaves our institution, we cannot promise that others will keep it private.

Your information may be shared with the following:
The sponsor and companies hired by the sponsor to oversee the study

- The University of Louisville Institutional Review Board, Human Subjects Protection Program Office, and Privacy Office, and others involved in research administration at the University,
- The local research team,
- Office for Human Research Protections (OHRP),
- Office of Civil Rights, and
- Empower Interactive (developers and distributors of "Good Days Ahead" computer program) (see below for details)

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The "Good Days Ahead" computer program used by those receiving CCBT records data such as your user name, password, mood ratings on levels of depression and anxiety, responses to questions, and text that you may enter on self-help exercises. This information is used to track your progress, provide feedback and guidance to you and your doctor and care coordinator, and for assessing outcome of treatment. Your data in this program is password protected and encrypted (extra level of security) to provide a very high level of security. However, total confidentiality cannot be guaranteed.

Conflict of Interest

This study involves a conflict of interest because the principal investigator (Jesse H. Wright, M.D., Ph.D.) is a stock holder in Empower Interactive (developers and distributors of "Good Days Ahead" computer program used for CCBT). This conflict of interest is managed by an agreement with the University of Louisville. Please ask the investigators how Dr. Wright may benefit by your participation in the study.

Security

In order to help protect confidentiality, data will be kept in a locked file cabinet and in password protected computers in a secured area.

Voluntary Participation

Taking part in this study is voluntary. You may choose not to take part at all. If you decide to be in this study you may stop taking part at any time. If you decide not to be in this study or if you stop taking part at any time, you will not lose any benefits for which you may qualify.

You will be told about any changes that may affect your decision to continue in the study.

Contact Persons, Research Subject's Rights, Questions, Concerns, and Complaints

If you have any concerns or complaints about the study or the study staff, you have three options. You may contact the principal investigator at 502-588-4886.

If you have any questions about your rights as a study subject, questions, concerns or complaints, you may call the Human Subjects Protection Program Office (HSPPO) (502) 852-5188. You may discuss any questions about your rights as a subject, in secret, with a member of the Institutional Review Board (IRB) or the HSPPO staff. The IRB is an independent committee composed of members of the University community, staff of the institutions, as well as lay members of the community not connected with these institutions. The IRB has reviewed this study.

If you want to speak to a person outside the University, you may call 1-877-852-1167. You will be given the chance to talk about any questions, concerns or complaints in secret. This is a 24 hour hot line answered by people who do not work at the University of Louisville.

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Acknowledgment and Signatures

This informed consent document is not a contract. This document tells you what will happen during the study if you choose to take part. Your signature indicates that this study has been explained to you, that your questions have been answered, and that you agree to take part in the study. You are not giving up any legal rights to which you are entitled by signing this informed consent document. You will be given a copy of this consent form to keep for your records.

Subject Name (Please Print)	Signature of Subject	Date Signed
Printed Name of Legal Representative (if applicable)	Signature of Legal Representative	Date Signed
Relationship of Legal Representative to Subject		
Printed Name of Person Explaining Consent	Signature of Person Explaining Consent Form (if other than investigator)	Date Signed
Printed Name of Investigator	Signature of Investigator	Date Signed

List of Investigators:	Phone Numbers:
Jesse H. Wright, MD, PhD	502-588-4886
Becky Antle, PhD	502-852-2917
Tracy Eells, PhD	502-852-6720
Laura Bishop, MD	502-852-2822
Brent Wright, MD	270-651-4865
Rangaraj Gopalraj, MD	502-588-4271
Jesse Owen, PhD	303-871-2482

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REVOCATION OF AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR HEALTH INFROMATION FOR RESEARCH

Return To:

Jesse H. Wright, MD, PhD 401 E. Chestnut Street, Suite 610 Louisville, KY 40202	OR	Institutional Review Board MedCenter One, Suite 200 501 E. Broadway Louisville, KY 40202

Do not sign this letter unless you are withdrawing from this research. You will be sent confirmation that this notice was received.

To Whom It May Concern:

I would like to discontinue my participation in the research study noted above. I understand that health information already collected will be continue to be used as discussed in the Authorization I signed when joining the study.

Your options are (***choose one***):

☐ **Withdraw from Study & Discontinue Authorization:**

Discontinue my authorization for the future use and disclosure of protected health information. In some instances, the research team may need to use your information even after you discontinue your authorization, for example, to notify you or government agencies of any health or safety concerns that were identified as part of your study participation.

☐ **Withdraw from Study, but Continue Authorization:**

Allow the research team to continue collecting information from me and my personal health information. This would be done only as needed to support the goals of the study and would not be used for purposes other than those already described in the research authorization.

Subject Name (Please Print)	Signature of Subject	Date Signed
Printed Name of Legal Representative (if applicable)	Signature of Legal Representative	Date Signed
Relationship of Legal Representative to Subject	Birthdate of Subject	
Subject's Address	Subject's Phone Number	

Optional:
I am ending my participation in this study because: