NCT04010747

Motivational Interviewing for Loved Ones (MILO)

Informed Consent Form

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RESEARCH CONSENT FORM

Basic Information

Title of Project: Motivational Interviewing for Loved Ones

IRB Number: H-41305

Sponsor: National Institute of Mental Health

Principal Investigator: Emily Kline
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Study Phone Number: (401) 206-0586

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you have a loved one with a recent onset of psychosis or psychosis symptoms that you want to connect to treatment. We are doing the research to teach parents or other loved ones of those suffering from recent onset psychosis some communication skills based in Motivational Interviewing. If you agree, you will participate in surveys, an over-the-phone exercise, and meet with a study trainer to learn communication skills and receive consultation of treatment options. You will be in the study for approximately 4-6 months if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are feeling inconvenienced of the time required to participate in the study and possible feelings of frustration or anxiety while learning new communication skills. You will find more information about risks later in this form.

You might benefit from being in the study because you will receive communication skills training and consultation on treatment options for you or your loved one. You will find more information about benefits later in this form.

You could get these benefits without being in the study by participating in a National Alliance on Mental Illness (NAMI) support group or receiving communication training from another source. You will find more information about alternatives later in this form.

Your child or loved one's doctor may also be an investigator in this research study. Being an investigator means your doctor is interested in both your child or loved one and the study. Your child or loved one's

doctor's goal as an investigator is to collect information to answer the scientific questions asked in this research study, in order to help future patients. This is different from their role as your child or loved one's doctor, where their goal is to treat them as a patient. You may want to get another opinion about being in the study from a doctor who is not an investigator in this study. You can do so now or at any time during the study. You do not have to agree to be in this study even though it is offered by your child or loved one's doctor.

Purpose

The goal of this study is to test a new intervention called "Motivational interviewing for loved one" ("MILO"). The intervention teaches skills that are derived from a communication style called motivational interviewing. Motivational Interviewing is used by health professionals as a way to talk with people about making healthy changes in their lives, like reducing how much alcohol they drink. The researchers have adapted motivational interviewing to make it relevant for loved one of teens and young adults who are experiencing a psychotic disorder. The researchers are interested in studying whether the MILO skills improve the relationships between the young person and their caregiver, and whether it helps the young person feel more ready to participate in treatment and take medications

What Will Happen in This Research Study

If you agree to participate in our research study, we will begin by asking you to complete an online survey that will take around 20 minutes to complete. Due to COVID19, we are conducting our operations remotely, but if you do not have access to a computer or smart device, you have the option to wait until you can come in person to complete the survey in our office. This initial survey will ask some questions about your demographic information, your stress level, and questions about your relationship to the individual with psychosis. After you complete the first survey, we will ask you to participate in a real play exercise over the phone with study staff. A real play exercise is a roleplay conversation where study staff discuss a problem they are experiencing. You will speak with them about their problem using your MILO skills. This exercise will take ten minutes to complete. The exercise will be audio recorded.

Once the baseline survey and real play exercise is complete, we will randomize you into one of the two versions of our program. Randomization means that you are randomly placed in one of two versions of our program. The first version is "Immediate MILO", which means you can start your training sessions with one of our MILO trainers. The second version is a "Waitlist Condition," which means you will be placed on a 6 week wait list and asked to complete another online survey and real play exercise with study staff. Whether you are placed in the Immediate MILO or Waitlist Condition will not affect your ability to receive the communications training. All participants will be offered the training in full.

Once you are placed in Immediate MILO or complete your Waitlist time period, you will start your MILO training. Our MILO training consists of 4-5 60 minute meetings with a MILO trainer. The MILO trainer will discuss communication skills and consultation of treatment options for your loved one experiencing psychosis. These meetings can be scheduled at times that are convenient for you. Meetings will occur either virtually over Zoom, or in person following COVID19 guidelines and safety precautions if you do not have access to technology necessary for virtual meetings.

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After your 4-5 training sessions with a MILO trainer, we will ask you to complete a survey after your training sessions and the last real play exercise. We will also ask you to complete additional surveys at 8 and 12 weeks after your training sessions.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

We will make an audio recording of the real play conversations that take place at the pre-training, waitlist, and post-training period.

You will be one of approximately 100 subjects who will be asked to be in the study.

Risks and Discomforts

Potential risks to participants include:
1) You may at times feel inconvenienced by the time required to complete the sessions and/or research assessments.
2) You may experience frustration or anxiety in learning to use the motivational interviewing communication skills.
3) You may experience sadness or discomfort when discussing personal problems. Discussing experiences with your loved one's psychiatric problems may also be upsetting to you.
4) Although there are measures in place to protect your privacy, you may feel uncomfortable if someone were to find out you were participating in the study.

There may be unknown risks or discomforts involved.

Potential Benefits

The benefits of being in this study may be receiving communication skills training and consultation of treatment options for you or your loved one. The communication skills may increase the chance that your loved on engages in care. However, you may not receive any benefit. The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in the study may help the investigators learn if parents and other loved ones are interested and committed to the training, if parents and other loved ones have less stress after completing the training, and if the individual experiencing psychosis adheres to mental health treatment due to the loved one participating in the training.

Alternatives

The following alternative procedures or treatments are available if you choose not to be in this study: The National Alliance on Mental Illness (NAMI) offers support groups and education for friends and family members of individuals with mental illnesses; you may wish to participate in a NAMI support program instead. We would be happy to give you the information about a NAMI chapter in your area that might be able to help.

Costs

There are no costs to you for being in this research study. If you choose to participate in person, there might be costs related to travel and/or parking.

Payment

You will receive $25 for each survey you complete. If you are placed in the immediate MILO version of our program, there are 4 surveys total. Therefore if you complete all four that is $100 total compensation. If you are placed in the waitlist version of our program, there is a total of 5 surveys total. Therefore if you complete all five surveys that is $125 total.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC**.** The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health and the National Institute of Mental Health.
- Any people who you give us separate permission to share your information.

You should know that we are required to report certain information that we might learn in this study to state or other agencies. The information includes child abuse or neglect; elder abuse; harm to others.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.

- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

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

Use and Sharing of Your Health Information

The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or shared during this research includes:

- Information that is in your hospital or office health records. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.
- The health information specifically includes:
  - Mental health communications (with a psychiatrist, psychologist, clinical nurse specialist, marriage-, family-, rehabilitation-, or mental-health-counselor, or educational psychologist)
  - Social work communications

The reasons that your health information might be used or shared with others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information. As we explained above, we also have to share any information from you about child abuse or neglect; elder abuse; harm to others.

The people and groups that may use or share your health information are:

- Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
- Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study
- The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research

- Public health and safety authorities who receive our reports child abuse or neglect; elder abuse; harm to others.

We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your health information:

- The time period is not known, because research is an ongoing process. We cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and share your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.
- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at Boston Medical Center at DG-privacyofficer@bmc.org.

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes_____No You may contact me again to ask for additional information related to this study

____Yes_____No You may contact me again to let me know about a different research study

Optional Activities:

Additionally, we are asking for your permission to store the audio recordings of the real plays for future use. The recordings may be used as research or training purposes. For example, we might use your audio file to train new study staff or might use it as an example at a future presentation. All identifying information will be removed from the recordings. If we do NOT have your permission to utilize your audio recordings, we will destroy them at the end of the study. You can always change your mind and

ask us to stop using the recordings for training purposes at any time point and we will destroy the files. Would you rather us store your recordings or delete them?
{ } YES, you may keep the audio recordings for future training or research presentation purposes.
{ } NO, you must destroy the audio recordings once the study is complete.

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get. You will only be paid for the study activities that you complete before withdrawing.

During this study, we may find out something that might make you not want to stay in the study. If this happens, we will tell you as soon as possible. You should also tell us if you ever have concerns about being in the study.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Dr. Emily Kline at Emily.kline@bmc.org. Also call (401) 206-0586 if you need to report an injury while being in this research

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and sharing of information that may identify you as described

_____ _____
Signature of subject Date

Researcher: _____
Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date

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