UTHealth Houston

Examining the feasibility and acceptability of a tailored version of a Mindfulness-Based Intervention (MBI) among Youth Experiencing Homelessness (YEH) aged 18-25 years old

NCT04950816

Version Date: 03/06/2023

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CONSENT TO TAKE PART IN RESEARCH PILOT

Simple Study Title: Mindfulness Based Intervention among Youth Experiencing Homelessness

Full Study Title: Examining the feasibility and acceptability of a tailored version of a Mindfulness-Based Intervention (MBI) among Youth Experiencing Homelessness (YEH) aged 18-25 years old

Study Sponsor: National Institute of Health

Principal Investigator: Diane Santa Maria, DrPH, RN

Study Contact: Jennifer Jones, Research Coordinator, [redacted].

The purpose of this study is to further tailor *.b* (pronounced dot-b) and conduct a feasibility pilot among sheltered homeless youth.

There are potential risks involved with this study that are described in this document. Some known risks include breach of confidentiality or discomfort with session topics. However, to mitigate such risks, we have figured out a plan to protect confidentiality. There may be potential benefits to your health and wellbeing. All participants will have ongoing access to mental healthcare services through the onsite health clinic located at Covenant House Texas Shelter.

The alternative to participating in this research study is to not to participate.

Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not affect the clinical care you receive at the University of Texas Health Science Center Houston or Covenant House.

If you are interested in participating, please continue to read below.

What is the purpose of this research study?
The purpose of this research study is testing a tailored Mindfulness Based Intervention and evaluating its overall health and wellness impact.

National Institute of Health (NIH) is paying UTHealth for their work on this study.

Who is being asked to take part in this study?
You are being asked to take part in this research study because you are a youth experiencing homelessness (YEH). This study is being conducted at UTHealth, Houston. About 90 people will take part in the study in Houston and will be recruited at Covenant House Texas (CHT).

What will happen if you take part in this study?
Once consented, you will take the baseline survey and receive a group assignment from the Research Coordinator. You will complete a baseline survey using an iPad using REDCap, a secure data collection system. You will enter response data directly into the tablet so your answers will be private. After the first survey, you will be randomized (similar to flipping a coin) to be placed in the .b group (case) or the Healthy Topics group (control). This will allow a careful comparison to study the impact of the intervention. There is a 50/50 chance you will be in either group.

1) If you are randomized to receive the intervention: You will receive the *.b* curriculum which includes 5 – 90 minute face-to-face sessions with other participants to introduce concepts such as paying attention, fostering curiosity, self-compassion , understanding rumination and catastrophizing, staying in the present, recognizing thoughts as separate from our minds/selves, responding instead of reacting, understanding stress and how it affects us, accepting negative and positive experiences, moving mindfully and using mindfulness in our everyday lives. These sessions will be audio recorded and reviewed by research staff and maybe reviewed by an external expert to ensure the quality of the sessions. Whatever you choose to share in these sessions will stay confidential, unless you disclose that you intend to hurt yourself or someone else. During the intervention, you will be asked to have your cell phone with you at all times to keep in touch with study staff and have access to an app to support your mindfulness practice.
2) If you are randomized to receive Healthy Topics (HT), you will receive general health information. You will attend 5 90-minute sessions to cover such topics like physical activity, nutrition, managing weight, understanding adolescence, personal care, avoiding tobacco, alcohol, and drugs. You will have access to housing, food and clothing needs, basic healthcare, mental health, and substance use treatment referrals that are usually available to you.
3) After the *.b* curriculum or Healthy Topics, you will then take 3 more follow up surveys: one immediately after receiving either the last intervention or usual care session, and then one at 3 months, 6 months. These surveys will be taken on an ipad, smartphone, computer or another device and will be similar to the baseline survey. You will be issued a password-protected cell phone to use for 6 months. The study phone will have food, housing, and healthcare resources programmed in the contacts and an app to allow for video calls with the study staff. The study phone will also have meditation apps installed on which data usage will be collected. For the remainder of the study, we will use the study-issued cell phone to contact you about study-related visits and updates. In the event that study staff can no longer reach you on the study cell phone, the phone line will be disconnected and study staff will attempt to contact you using the other methods of contact you provided. You may be asked to participate in an exit survey and may be asked to participate in a brief exit interview after completion of the study to learn more about your experience with the intervention. This exit interview would be audio recorded.

How long will you be in the study?
If you agree to take part, your participation will last for 6 months and will involve 7 visits.

What are the risks of taking part in this study?
There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

If you choose to take part in this study, there is a risk as there is with any research study. Mindfulness practices, surveys questions, and exit interviews might create awkwardness or discomfort. This study is considered to constitute minimal psychological and physical risk and no legal or social risks. The risks are minimal since educational interventions generally promote good health, not endanger it.
As a participant in this study, you will be asked to answer questions about private information that may have legal consequences. A breach of confidentiality is a possible risk. The means that people who are not part of this research study may find out that you are participating in this study.

What are the benefits to taking part in this study?
Potential benefits to study participation may include participants becoming more aware of how thoughts and feelings can affect one's behaviors and stress. Recent studies found significant effects and benefits on Youth Experiencing Homelessness with Mindfulness approaches, however, we do not know if this will happen in everyone taking part in this study. Finally, participants will have access to resources and contact information for services that will be pre-programmed into the study-issued smartphones provided to participants for the duration of the study. This study may help the study team learn things that could help others in the future.

Can you stop taking part in this study?
You may decide to stop taking part in the study at any time. To withdraw from the study, please contact Dr. Diane Santa Maria at [redacted] or Jennifer Jones at [redacted].

Dr. Santa Maria can stop the study at any time. Dr. Santa Maria may stop your participation in the study if the study is not in your best interest. If your participation in the study is stopped, the research team will discuss the reasons.

If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this study, the study team will notify you of new information that may become available and could affect your willingness to stay in the study.

What happens if you are injured during the study?
In the event of injury resulting from this research, UTHealth is not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You or your insurance company will be billed for any treatment.

You should report any such injury to Dr. Santa Maria at [redacted] and to the Committee for the Protection of Human Subjects at [redacted]. You will not give up any of your legal rights by signing this consent form.

What are the costs of taking part in this study?
There is no cost to you for taking part of this study. You will receive food, hygiene items, a $10 gift card for each session you attend. for attending the each of the sessions. You will receive $15 for completing the baseline and immediate post-interventions surveys and $20 for completing the 3 and 6-month follow up surveys. The total compensation you may be eligible to receive is $120.

How will your privacy and confidentiality be protected?
Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

Information that may identify you and information that you share with the study team will be kept confidential, however there is a potential risk of a breach of confidentiality. To minimize this risk, the information you share will be labeled with a code, so your identity cannot be easily discovered, and access to this information will be limited to study team members only.

All the specific details that could be used to identify you, like your name, will be removed from the private information (data) collected in this study. After we remove all the information that could identify you, the data may be used for future research or shared with other researchers without your additional informed consent.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Whom can you contact if you have questions about the study?
If you have questions at any time about this research study, please feel free to contact the Principal Investigator Dr. Santa Maria at [redacted], she will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at [redacted].

Are you interested in being contacted for future research studies?
Please add your initials to the appropriate line to indicate your preference. If you are interested in participating in future studies, the research team will keep information that will identify you, such as your name, phone number, and/or email address.

_____Yes, please contact me in person or by phone for future studies.

_____No, please do not contact me for future studies.

SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject	Signature of Subject	Date	Time

Printed Name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date	Time