

Lifespan Affiliate Site where research will be conducted Rhode Island Hospital The Miriam Hospital Bradley Hospital Newport Hospital Gateway Healthcare**Agreement to Participate in a Research Study
And Authorization for Use and Disclosure of Information**

002814

Committee #

Name of Study Volunteer

i-DOVE**(Text-message-based depression prevention for high-risk youth in the ED)
*Randomized Trial***

Your child is being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to allow your child to be in the study, you and the researcher will engage in the “informed consent” process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what your child will be expected to do if they participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for your child.

If you decide to allow your child to be in the study, you will be asked to sign an agreement which states that the study has been explained, that your questions have been answered, and that you agree to have your child participate. You will be given a copy of this form to keep.

Federal and Lifespan institution rules require that if your child is 8 years or older, the "assent" (agreement) of your child be obtained by the researcher before your child may participate in this study. Your child must sign the consent form as well. You will be given a copy of the signed consent form to keep.

1. Nature and Purpose of the Study

Your child is being asked to take part in a research project to develop and evaluate a text-message based intervention to help teens deal with stress and fights, and to prevent depression. In this part of the study, we will ask for your child’s participation in the program. We expect to enroll 120 subjects into this study. The study is sponsored by the National Institute of Mental Health.

2. Explanation of Procedures

Your child will be randomly assigned (like by the flip of a coin) by a computer to one of two groups. Neither you nor the researcher can decide which group you will be assigned to. For both groups, this study will involve your child's participation in a brief survey and in-person session here in the emergency department (ED), followed by text messages for 8 weeks.

The in-person session will be conducted right now, before you leave the ED, and will take about 20-30 minutes. In the session, we will go over with your child either the way that thoughts, emotions, and behavior work together (GROUP 1), or ways to improve their use of healthy behavior like seatbelts and nutrition (GROUP 2). For both groups, we will also go over the text messaging system. During the session with your child, we will ask you to step out of the room and you will be given some handouts to read. If your child is discharged from the emergency department before finishing the in-person session, we will move to a private treatment room to finish it. It should not take more than 20-30 minutes to finish.

The session will be digitally recorded for quality purposes. Recordings of the session will be kept confidential and will be stored in a locked file in a locked research office. All identifying information will be destroyed after the study is complete. The audio recordings will be destroyed 5 years after the close of the study. The purpose is to evaluate the performance of the study staff, not you.

GROUP 1 participants will receive daily text messages that will provide skills on managing stressful situations. Each day, GROUP 1 participants will be automatically sent one text-message question about their day, followed by a text message just for your child. The text messages will provide skills on managing stressful situations. Although no one will be monitoring the text messages, our program can send extra messages on certain topics ("MOOD" and "FIGHT") if your child needs them. GROUP 2 participants will receive regular text messages on topics related to diet and nutrition. Messages will be sent to your child's cell phone using an automated computerized system developed by an outside company, Reify Health. Only members of this research team will see your child's text messages and responses.

For both groups, we will contact your child to complete a follow-up survey and brief interview (over the phone, in person, or over the internet) at 8 weeks and again at 16 weeks (since the start of the study). We will also review the number of hospital visits that your child has had over the 6 months following enrollment in the study.

If at any time during the study there are signs that your child is very depressed, or very likely to hurt him/herself or someone else, we will let you know and will help your child get professional help. Additionally, if your child discloses that s/he is a victim of child abuse, we will let you know and will notify relevant authorities. Otherwise, all of your child's answers are confidential.

Compensation: Your child will be given a \$25 gift card today for completing the in-ED session, \$10 gift cards each month for two months for text-messaging plans, a \$40 gift card for the 8-week follow-up, and a \$50 gift card for completing the 16-week follow-up. In order for this project to have scientific value, we need to know whether our interventions were helpful. Therefore, we will make every effort to stay in touch, and we will compensate your child an additional \$5 gift card if you or your child lets us know about any changes in your/their contact information (for instance, their cellphone, your cellphone, your address, etc). Further, if your child completes the 8-week follow-up

survey before their follow-up date, your child will be given a \$5 gift card. If your child completes the 16-week follow-up survey before their follow-up date, they will be given a \$5 gift card. In total, your child may receive up to \$150 in gift cards.

Costs for participating in this study: Some of the services your child will receive are being performed only because they are participating in this research study. Examples of these ‘research only’ services include the in-ED session and 8 weeks of text messages. Those services will be paid for by the study and will not be billed to you or your health insurance company.

Other services your child will receive during this research study are considered "routine clinical services" that your child would have received even if they were not in the research study. Examples are the emergency department care your child will receive today for his/her illness or injury. These services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

Contact Information: The Principal Investigator for this study is Dr. Megan Ranney. She is available to answer any questions at (401) 444-2557.

3. Discomforts and Risks

The risks in this study are considered minimal. The types of text messages we are sending to your child are common in standard care and do not pose any greater risk than other teens may receive in the community. Your child may experience some emotional discomfort in taking part in this study, but most children do not. Your child does not need to reply to any text message that makes him/her uncomfortable. Also, we will make sure that your child’s participation in this study remains confidential.

It is very important that you understand that NO ONE is monitoring the text messages at any particular time. If your child needs immediate help at any time, please call 911, or one of the crisis numbers we will provide to you, or your child’s doctor.

4. Benefits

You and your child may not receive any benefit from participating in this study. However, by participating in the in-ED session and text messages, you and your child will have the opportunity to learn more about his/her mood. As a result of this program, your child *may* develop better skills to deal with and prevent stress. Additionally, your child’s participation in this study will help us to design a program to prevent stress for other teens.

5. Alternative Therapies

If you do not choose to participate in this study, we can provide you with the names of other resources that pertain to depression/stress and fights.

6. Refusal/Withdrawal

It is up to you whether you want your child to be in the study. You are not required to enroll your child or participate. If you decide you want your child to participate, you can always change your mind and remove them from the study at any time. If you decide not to have your child be in the study, or if you

remove them later, your child will still be able to get the health care services they would normally get. If you enroll your child but later on the researcher or your doctor feels being in the study is no longer good for your child, they may choose to take your child out of the study before it is over. If new information becomes available that might change your mind about whether you want your child to stay in the study the researcher will share this information with you as soon as possible.

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to have your child quit the study please tell the head researcher Dr. Megan Ranney at (401) 444-2557.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If your child is injured by a medical treatment or procedure they would have received even if they were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If your child does experience a research injury, Lifespan or the study doctor can arrange medical treatment for them. Such treatment will be paid for as described below.

If you have insurance and your child has a research injury that is not covered by the study, it is possible that some or all of the cost of treating your child could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you or your child have any complaints about your child's participation in this study, or would like more facts about the rules for research studies, or the rights of people who take part in those studies, you may contact Janice Muratori, anonymously if you wish, in the Lifespan Office of Research Administration, telephone number (401) 444-6246.

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information

Your child's research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies. In particular, we are required to get your permission to use or disclose (release your child's information to someone outside of Lifespan) their health information for research purposes. If you sign this form you agree to have your child be in this research study and you permit the use and disclosure of your child's health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date.

We will do everything we can to keep others from learning about your participation in this study. To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS).

With this Certificate, we cannot be forced (for example by court order or subpoena) to disclose information in the research records that may identify you in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information in the research records that would identify you or your child, except to prevent serious harm to you or others, and as explained below.

You should understand that a Certificate of Confidentiality does not prevent you, or a member of your family, from voluntarily releasing information about yourself, your child, or your involvement in this study.

If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Disclosure will be necessary, however, upon request of DHHS for the purpose of audit or evaluation, and is limited only to DHHS employees involved in the review.

You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor National Institute of Mental Health
- Doctors, nurses, laboratories and others who provide services to you in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights;
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when Lifespan needs to release your child's health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers protect the privacy of your child’s health care information. Other people and businesses/organizations might re-release your child’s information.

You have the right to refuse to sign this form and not allow your child to participate in the research. Your refusal would have no affect on your child’s treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, your child will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to have your child quit the study after signing this form (as described in Section 6) no new information will be collected about them unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you removed your child from the study to complete analysis and reports of this research.

For more detail about privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

SIGNATURE

I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED AND I GIVE PERMISSION FOR MY CHILD TO PARTICIPATE IN THIS RESEARCH STUDY.

**This informed consent document expires on _____.
DO NOT sign this document after this expiration date**

The Researcher is required to provide a copy of this consent to you.

Signature of parent/guardian*

Date and Time when signed

Signature of parent/guardian*

Date and Time when signed

