SOVA Pilot Trial Parent Consent

COVER PAGE:

TITLE: Supporting Our Valued Adolescents Pilot Randomized Controlled Trial (SOVA)

ClinicalTrials.gov Identifier: NCT03318666

5.3.2019

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Now I am going to ask for your permission for yourself and for your child to be involved in this study. I am required to give you this information but if something doesn't make sense to you, please ask. I will also email you this information as a document and you are free to look over it first before you make your decision.

Study information:
This study is called the Stress and Worry study. The main person in charge of it or principal investigator is Dr. Ana Radovic, who is a physician at the Center for Adolescent and Young Adult Health or CAYAH who does research in adolescent mental health. If Dr. Radovic is one of the providers who saw your child in clinic, please know that you are not under any obligation to participate in this study because she is your child's provider – you can feel free to ask any other provider in our clinic what they think about you and your child participating in this study. Whether or not you and your child participate will not affect the care your child gets in our clinic or any other UPMC facility. Dr. Radovic can be reached by calling the Children's Hospital and asking for her to be paged, her email is ana.radovic@chp.edu. The main person organizing the study is the research assistant who is a research social worker. In order to reach the research assistant, you can email socialmediastudy@chp.edu or call 412.540.5384. You may contact Dr. Radovic or the research assistant with any questions about the study.

We are doing this research study to understand how to better help adolescents and young adults get the help they need with stress and worry. Also this is a smaller version of a larger study and the information we gather will help us to plan it. We are asking you and your child to participate because your child's provider at CAYAH recognized that they have some problems with stress and worry. We are recruiting 150 patient and parent pairs to the study for a total of 3 months. We are also asking 20 of the patient and parent pairs to participate in a follow up interview after this part of the study is over.

Your and your child's participation in this study is entirely voluntary. Please ask us if you have any questions now or at any time.

Research Activities:
This study involves taking an online survey (one for you and one for your child) now which may take you about 20-30 minutes, a similar survey in 6 weeks, and a shorter 5-minute survey in 3 months. The surveys will ask you and your child questions about your thoughts and beliefs about depression and anxiety, how much social support you feel, and how you communicate with your child. Everyone in the study will receive care from CAYAH, the adolescent clinic, the same way they would if they were not in the study. This includes getting put in touch with the clinic social worker if your child needs help with resources or getting a therapy appointment. Also, we will send everyone an extra email with some information about stress and worry. After you (and your child/parent) take the first online survey, the computer will randomly select by chance whether or not you both receive an additional online intervention. This online intervention is access to a website for you and a separate website for your child. On these websites you will get a chance to interact with other parents – and your child with other adolescents their age – in a moderated and anonymous space. This website has been ongoing for the past 2 and a half years without any safety concerns, but if there are comments posted which are found to be offensive or hurtful, they will be removed immediately by our moderators. We will give you instructions on how to get onto the intervention and do a follow-up phone call to make sure you didn't have any technical problems. If you are randomized to the online intervention, it is important for you to know that any blogging or commenting content you add to the research website is intellectual property of the University of Pittsburgh. In the future, we may

not have the resources to continue to maintain this website as a research study. At that point, the website may be sold, patented, or licensed by the investigators and the University of Pittsburgh for commercial use (for example, an insurance company may maintain the site instead). If this were to happen, you would not share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

If you get access to the websites, we will remind you once a week for 6 weeks about new content on the intervention. After 6 weeks, everyone will take a survey. At that time, we will ask you if you are also interested in a follow-up interview – if you are, we will give you more information about that at that time.

We do not think you will experience any risk from participating in the study except an infrequent risk of a privacy breach. Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study. We will do our best to protect your privacy – if you are enrolled in the online intervention, the only available information on the websites will be your email – and that will only be visible by our team. Otherwise, all the data we collect from you is stored on a secure online survey platform called RedCAP which the University of Pittsburgh has used for many years. And the data we extract from that online survey platform will be stored on a secure UPMC server. We may share data without any information that can trace the data back to you or your child (identifiers) with other researchers in the future. For this study, our research team will also ask your permission to access your child's medical record to get information about what your child's provider recommended for treatment and whether or not they receive treatment. Dr. Radovic already has access to these records for clinical purposes, and her research team has received the appropriate privacy training to not share your information for any other purpose. The medical record information we obtain for this study may be shared with other groups such as the National Institutes of Health, Children's Hospital of Pittsburgh of UPMC, and the University of Pittsburgh Research Conduct and Compliance Office. Per University of Pittsburgh policy, we must keep all research records for 7 years after final publication of the project and for children, until they are age 28.

Some benefits you may receive by participating in the study include getting more help with information about stress and worry and what to do about it.

You and your child will be compensated for your participation. You will receive $10 on a prepaid debit card for every survey you take. There are a total of 3 surveys for you and 3 surveys for your child.

Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed to meet the requirements of the federal Food and Drug

Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect or harm to self or others.

Withdrawal
You and your child can withdraw from this study at any time. It is possible for you to be removed from this study if you or your child experience a safety concern (e.g. your child is involved in constantly bullying others on the website). We have not had any of these types of safety concerns during our prior studies. Your child will also be withdrawn if he or she is actively suicidal – meaning that they have thoughts of suicide with an intent to act on them. Your authorization for the research team to review medical records can be withdrawn by written request made to Dr. Radovic. Withdrawing that authorization means no further participation in the study but information up to that point may still be used.

This research is being funded by the federal government by the National Institute of Mental Health and by the Children's Hospital of Pittsburgh of UPMC and by the University of Pittsburgh. If you have any questions about your rights as a research subject or wish to talk to someone other than the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by US Law. This website – clinicaltrials.gov - will not include information that can identify you or your child. At most, the website will include a summary of the results. You can search this website – clinicaltrials.gov - at any time.

Neither you, nor your insurance provider will be charged for the costs performed only for the purposes of this research study. You will be charged in the usual manner for any procedures performed as part of your standard medical care (care you would receive even if you were not participating in this research study).

Do you consent for yourself to participate in this study?

Do you give your child permission to participate in this study and provide authorization for access to medical records for your child?

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(for research team only)

RedCAP form documentation for research team member administering consent will include:

Did participant consent for themselves? (yes/no)

Did participant consent for their child? (yes/no)

Time/date conversation initiated: (date/time)

Time/date conversation stopped: (date/time)

Questions answered: (free text)

Phone consent obtained by: (staff member name)

Phone consent obtained at: (date/time)