Official Title: Improving the outcomes of adolescents with ADHD via a pre-visit question prompt list/video intervention: a randomized controlled feasibility trial

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University of North Carolina-Chapel Hill
Consent to Participate in a Research Study-Parents

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IRB Study # 22-3288
Title of Study: Improving the outcomes of adolescents with ADHD via a pre-visit question prompt list/video intervention: a randomized controlled feasibility trial
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Funding Source and/or Sponsor: National Institute of Mental Health
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Concise Summary

The clinic is involved in a research project about services provided to children with ADHD. The goal of the project is to improve communication between providers, parents, and children/teens about ADHD. A quarter of the families will receive both a one-page sheet where the child and parent can check off questions about ADHD, they want to ask the provider and they will watch a short video on the importance of children/teens being involved during visits, another quarter will receive a one-page sheet, another quarter will just watch the video, and another quarter of the families will not receive anything before the visit. Families will be followed for 6 months and will be interviewed today and 3 and 6 months from now. Each visit will take about 30 minutes. There is a potential risk of breach of confidentially and embarrassment. You may not benefit personally from being in this research study.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.
Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.
Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The clinic is involved in a research project about services provided to children with ADHD. The goal of the project is to improve communication between providers, parents, and children/teens about ADHD.

How many people will take part in this study?

If you decide to be in this study, you will be one of approximately 140 parents/guardians of children with ADHD in this research study, which is being conducted in North Carolina.

How long will your part in this study last?
Your participation in this study will last for approximately 6 months. You will be interviewed today, in about three months, and in six months from now. Each visit will take about 30 minutes.

What will happen if you take part in the study?
During the course of this study, the following will occur today, in about 3 months, and in 6 months from now at your child's follow-up ADHD visits:

1. We will ask the children/teens a few questions before the medical visit.
2. We will **only** tape record today's visit and 3-month visit with your child's providers.
3. A quarter of the families will have the parent and child each receive a one-page sheet where the child can check off questions about ADHD they want to ask the provider and they will watch a short video on the importance of children/teens being involved during visits, another quarter will have the child and parent receive the one-page sheets, another quarter just the video, and another quarter of the families will not receive anything before the visit.
4. We will ask you to fill out a survey in a private area of the clinic that should take about 15 to 20 minutes to complete immediately following your child's visit. The questionnaire asks about your child's ADHD and the medical visit. At the same time, the research assistant will interview your child.
5. We will review your child's medical records to abstract information related to their ADHD and use of ADHD medications 6 months before and after they are enrolled in the study.
6. We will ask your child's teacher to complete the Vanderbilt ADHD teacher informant form for today's visit, 3 months, and 6 months visits.

Are there any reasons you should not participate?
You should **not** participate in this study if:

- Your child does not have ADHD.
- Your child is not between the ages of 11 and 17.
- Your child does not see a provider at the clinic who is participating in the study.
- Your child does not speak English.
- You do not want to have today's medical visit audio-recorded.
- You are under 18 years of age, do not speak and read English, and are not the legal guardian of the adolescent.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. You may not benefit personally from being in this research study. However, the findings of the study may help improve communication about ADHD during pediatric visits.

What are the possible risks or discomforts involved from being in this study?
This study might involve the following risks and/or discomforts to you and/or your child: some people may feel uncomfortable having their physician visits audio-tape recorded. If at any time during your visit you or your child would like to turn off the audio tape recorder, please tell your provider. Also, some people may feel uncomfortable filling out a survey. You do not have to answer any questions that make you feel uncomfortable. In addition, there may be uncommon or previously unrecognized risks that might occur. For example, there is a potential risk of breach of confidentially and embarrassment. However, we will take all necessary precautions to protect your information as stated below in this form. You should report any problems to the researcher.

If the team has any concerns about your child harming himself/herself or others, they will refer your child to the primary care provider and Rob Christian, MD (co-investigator) for assistance. The team will report concerns to the state to the extent required by North Carolina law. If you state any concerns about adverse events from ADHD medications, the team will advise you to alert the primary care provider immediately.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

How will information about you be protected?

You and your child will be assigned identification numbers when you agree to participate in the study. All data collected in this study will be recorded under your identification numbers, not your names. A list which links provider, parent, and child names to identification numbers will be kept in a locked filing cabinet that is separate from all study data. This list will be destroyed once all data is collected. No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-CH will take all steps allowable by law to protect the privacy of personal information.

Your de-identified data and your child's de-identified data may be used for future research without additional consent.

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your and your child's deidentified study data helps researchers learn new and important things about brain science more quickly than before.

Deidentified study data means that all personal information about you or your child (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to NDA.

You may decide now or later that you do not want your study data or your child's study data to be added to NDA. You and your child can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

The content of the audio-tape of the medical visits recorded during this study will be coded and summarized across all patients participating in the project. The audio-tape of you and your child's visits

will be transcribed into text by a research staff member, and any information that could identify you, your child, or your provider will not be transcribed. The written transcript will only have an identification number on it, to protect you and your child's confidentiality. The audio-tapes will be erased after they have been transcribed. Only the identification number on the transcripts will be entered into the computer data set. No information in this project will identify you or your child.

Check the line that best matches your choice:

_____ OK to record me during today's study visit and 3-month study visit

_____ Not OK to record me during today's study visit and 3-month study visit

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you 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.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. Investigators also have the right to stop your participation at any time. This could be because your child had an unexpected reaction or failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?

You will receive $25 for completing a questionnaire and allowing us to audio-tape the medical visit today. You will receive another $25 after completing participation at the 3-month follow-up visit, and another $25 after completing participation at the 6-month follow-up visit.

Will it cost you anything to be in this study?

There will be no costs for being in the study.

Who is sponsoring this study?

This research is funded by the National Institute of Mental Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.
The study team would like to message you by text messaging or e-mail; however, you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.
If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this consent form. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing my cell phone and/or e-mail to send me communications.
List -email address and/or cell phone #: _____

_____ No, I do not consent to receive un-protected communication from the study team.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent