Team-Based Connected Health to Improve Clinical Outcomes and Access in Atopic Dermatitis

National Clinical Trial (NCT) Identified Number: NCT03981926

Document Date: November 12, 2019

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ADULT INFORMED CONSENT/YOUTH ASSENT/ PARENTAL PERMISSION

TITLE: Team-Based Connected Health (TCH) to Improve Clinical Outcomes and Access in Atopic Dermatitis

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DEPARTMENT: Dermatology

If you are reading this form as the parent of a participant, "you" also refers to "your child".

KEY INFORMATION

We invite you to take part in a research study. Participation in this study is voluntary. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your personal doctor. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form.

This research study is sponsored by the National Institutes of Health (NIH). NIH provides funding to cover the costs of conducting this study.

The purpose of this study is to compare the effectiveness of using an online model versus in-person office visits for delivering follow-up care for patients with atopic dermatitis.

If you take part in the study you will be randomly assigned to receive either online care via the team-based connected health (TCH) model or in-person care from your doctor (as you would normally receive). You will have an equal chance of being in either group.

The study will last 12 months. You will complete questionnaires at a baseline visit and then at months 3, 6, 9, and 12.

The possible risks and discomforts you could experience during this study could include receiving incomplete or inadequate care if you are assigned to the online group; However, we will do everything we can to ensure quality care online and you can supplement online care with face-to-face care if you feel this is necessary.

Possible benefits of participating in the study include reduction or elimination of travel time and expense if are randomized to the online group.

An alternative would be not to take part in this study and continue with your current care. You may have the option to receive online care regardless of your participation in the study. Your doctor can provide you with more information.

DETAILED INFORMATION

WHY IS THIS STUDY BEING DONE?

This study is about comparing the effectiveness of using an online model versus in-person office visits for delivering follow-up care for patients with atopic dermatitis. We hope to learn if and how patients' atopic dermatitis outcomes, quality of life, and access to care differ between these groups. You are invited as a possible participant because you have atopic dermatitis.

WHAT IS INVOLVED IN THE STUDY?

If you decide to take part, this is what will happen:

1. Before you begin this study, we will look at your skin and ask you some questions about your medical history to see if you qualify for the study. We will also check to make sure you have access to a computer and a digital camera and are able to complete the tasks associated with using the online model.

2. The study doctor will tell you whether you will receive care via the team-based connected health (TCH) model or in-person after you are enrolled.

3. If you are able to take part in the study, you will have a baseline visit. At this visit, you will be randomly assigned to receive either online care via the team-based connected health (TCH) model or in-person care from your doctor (as you would normally receive). Details of the TCH model are described below. Whether you are assigned to receive care using the TCH model or continue to receive care in-person will be determined by chance, much like flipping a coin. You will have an equal chance of being in either group.

4. You and your doctor will work together to determine how often you will need to visit, whether online or in person. You will be in the study for 12 months.

TCH (Online) Group

If you are in the online TCH group, you will first be trained on how to take and share digital pictures of skin lesions, and communicate with your dermatologist online through the secure study website. All training materials will be sent to you electronically and in hardcopies; they are accessible online at any time.

After the training, you will log on to the study website and conduct follow-up visits for your atopic dermatitis as scheduled between you and your doctor. You will answer questions about your atopic dermatitis, the medications you take, and symptoms you are experiencing. You will also upload digital photos of your atopic dermatitis lesions to the study website. If the image quality of the photos you take is poor, the online dermatologist will ask you to re-submit adequate images for clinical assessment.

A trained and qualified dermatologist will use the information and photos you provide to diagnose and make recommendations for your atopic dermatitis. Both you and your primary care doctor will receive a copy of the consultation report each time the online study dermatologist reviews and assesses a visit. If you or your primary doctor has follow-up questions for the dermatologist, you can communicate with the dermatologist online or by phone.

In-Person Group

If you are in the in-person group, you will continue to receive care for your atopic dermatitis as you normally would. The frequency of your in-person follow-up visits will be determined by you and your doctor. You will not receive any special training.

Health Assessment Questionnaires

Whether you are in the online or in-person group, you will be asked to fill out health assessment questionnaires at different time points. The questionnaires will ask about your overall well-being and if you are able to take part in normal daily activities while you are in the study. There will also be questions about your quality of life, your skin's appearance, your pain level, and how you are responding to any therapy you were prescribed by the doctor. You will complete the questionnaires at the baseline visit and then at months 3, 6, 9, and 12. All questionnaires will be available both online and in paper hardcopies.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Possible risks and discomforts you could experience during this study include:

- For participants assigned to receive online care, there is a risk of receiving incomplete or inadequate care. Although we will do everything we can to ensure quality care online, you can supplement online care with face-to-face care if you feel this is necessary.
- There is a small chance that people not connected with this study will learn your identity or personal information. We will do our best to keep all study data confidential.

- You may experience a loss of privacy if you use a public computer, such as in the library or at work/school.
- Some of the questions may make you feel uneasy or embarrassed. You can choose to skip or stop answering any questions that make you uncomfortable.

WILL YOUR INFORMATION BE KEPT PRIVATE?

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. The University of Southern California's Institutional Review Board (IRB) may review your records. If you are participating in this study at Children's Hospital Los Angeles (CHLA), the CHLA Institutional Review Board may review records. The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

If you disclose thoughts of self-harm, we will ask you additional questions to determine your risk of hurting yourself. We may require you to obtain psychiatric care depending on your responses.

Individual responses to survey questionnaires will be accessible to the research team and these will be destroyed five years after the data are analyzed if you are participating in this study at USC or they will be destroyed six years after closure of the study if you are participating in this study at CHLA.. Personally identifying information will be removed from any data that are analyzed and published.

Pictures that are uploaded will be accessible to the research team only and will be destroyed immediately after study participation concludes. You have the right to view and/or edit the images.

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

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

Possible benefits of participating in the study include reduction or elimination of travel time and expense if you are randomized to the online group. While not everyone may receive direct benefit from the study, your participation in this study will help us learn whether quality and timely specialist care for atopic dermatitis patients can be done in a more efficient, convenient way via telemedicine.

Your participation in this study will also help us learn whether this online model improves difficulties accessing specialty care, patient care, and patient outcomes.

WHAT OTHER OPTIONS ARE THERE?

An alternative would be not to take part in this study and continue with your current care. You may have the option to receive online care regardless of your participation in the study. Your doctor can provide you with more information.

ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

You will be compensated up to $250 for participation in the study. All participants will receive compensation for each set of assessments completed according to the following schedule:

Baseline: $30
Month 3: $40
Month 6: $50
Month 9: $60
Month 12: $70

Participants will receive payment in the form of a reloadable gift card, which will be provided to the participant after the baseline visit is completed. Participants will only receive compensation for completed assessments.

WHAT ARE THE COSTS?

Access to the study website will be provided by the sponsor free of charge while you are participating in this study. However, any test ordered or medications prescribed through the study website will be your and / or your health plan/insurance's responsibility. Some tests and procedures are done for your routine health care, and you would receive them even if you were not participating in this study. You and/or your health plan/insurance will be billed for the tests and procedures you need for routine health care while you are in this study. Your insurer or you will be billed for these medically necessary evaluations, medications, and labs in the same way as if you were not in a study. You will be responsible for any co-payments and deductibles required by your insurance. Some health plans/insurance companies will not pay these costs for people taking part in studies. Check with your health plan/insurance company to find out what they will pay for. If you have any questions about which tests or procedures will be billed to you and/or your health plan/insurance, ask the study doctor.

Participants who see a dermatologist or primary care provider in-person will be responsible for the cost of the in-person visit. You and/or your health plan/insurance will be billed for the in-person visit and any tests and procedures your provider feels is necessary for your health care while you are in this study. You will be responsible for any co-payments and deductibles required by your insurance.

WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?

If you think you have been hurt by taking part in this study, tell the study doctor immediately. The research doctor's name and phone number are listed in this consent form. USC and CHLA will offer you the care needed to treat injuries directly resulting from taking part in this research. You and/or your health plan/insurance will be billed for this treatment. You will be responsible for deductibles and co-payments, or any costs not paid by your insurer. The study sponsor will not pay for this treatment.

There are no plans to offer any type of payment for injury. However, by signing this form you have not given up any of your legal rights.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this study is voluntary. Your decision whether or not to take part will not affect your current or future care at this institution. You are not giving up any legal claims or rights. If you do decide to take part in this study, you are free to change your mind and stop being in the study at any time.

If you decide to leave the study early, we will ask you to the complete a final set of questionnaires.

CAN YOU BE REMOVED FROM THE STUDY?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. A possible reason for removal includes the sponsor closing the trial. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

You may contact April Armstrong, MD, MPH at (323) 865-3641 with any questions, concerns, or complaints about the research or your participation in this study. If you feel you have been hurt by taking part in this study, please contact April Armstrong, MD, MPH at (323) 865-3641.

If you are a CHLA participant, you may contact Minnelly Luu, MD at (323) 442-7417 with any questions, concerns, or complaints about the research or your participation in the study. If you are a CHLA participant and you feel you have been hurt by taking part in this study, please contact Minnelly Luu, MD at (323) 442-7417.

If you have questions, concerns, or complaints about the research and are unable to contact the research team, contact the Institutional Review Board (IRB) Office at 323-

442-0114 between the hours of 8:00 AM and 4:00 PM, Monday to Friday. (Fax: 323-224-8389 or email at irb@usc.edu).

If you have any questions about your rights as a research participant or want to talk to someone independent of the research team, you may contact the Institutional Review Board Office at the numbers above or write to the Health Sciences Institutional Review Board at 1640 Marengo Street, Suite 700, Los Angeles, CA 90033-9236.

If you have questions, concerns, or complaints about the research or questions about your rights as a research subject you may also call Children's Hospital Los Angeles, Human Subjects Protection Program office at (323) 361-2265.

An electronic copy of the consent form will be available to you. If you prefer, you will be given a paper copy of this consent form.

AGREEMENT:

Adult Research Participant:

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Name of Adult Research Participant	Signature	Date Signed (and Time)

Youth Assent and Parental Permission:

If your child agrees to participate, have your child sign here.

Name of Child	Child's Signature	Date Signed (and Time)

Name of Parent (or Legal Guardian)	Signature	Date Signed (and Time)

Name of Second Parent	Signature	Date Signed (and Time)

I have personally explained the research to the research participant and answered all questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed (and Time)

A witness is required when: (1) the participant cannot see, read, write, or physically sign the consent form, or (2) the Short Form method is used to obtain consent. In these situations, the witness must sign and date the consent form. If no witness is needed, leave this signature line blank.

Name of Witness	Signature	Date Signed

University of Southern California
Children's Hospital Los Angeles
Department of Dermatology

ASSENT TO BE IN RESEARCH

Team-Based Connected Health (TCH) to Improve Clinical Outcomes and Access in Atopic Dermatitis

1. My name is _____.

2. We invite you to take part in a research study. We are trying to learn more if caring for skin problems online is the same as caring for skin problems in-person.

3. If you decide to be in this study, you will fill out questionnaires about your eczema and other health topics every 3 months for one year.

   You will also be put into one of two groups: online or in-person. If you are in the online group, instead of going to the doctor's office for skin check-ups, you will log on to an online website to answer questions about how your skin is doing. You will also take pictures of your skin and upload them to the website. A doctor will be able to look at your pictures and give you advice and medications to help your skin.

   If you are in the in-person group, you will continue to go to your doctor's office for your skin check-ups like you normally do.

4. Sometimes things happen in research studies. Some of the bad things that could happen are: you could feel embarrassed or uncomfortable answering some of the questions on the questionnaire, and if you are assigned to the online group, you may feel like you are not getting all the skin care you need. Some of these things might happen to you or they might not. Or things might happen that we don't know about yet.

5. People also have good things happen to them when they are in research studies. The good things may be less travel time to your doctor's office and easier follow-up visits if you are assigned to the online group.

6. You will receive payment for each quarterly questionnaire you complete according to the following schedule:
   Baseline: $30
   Month 3: $40

Month 6: $50
Month 9: $60
Month 12: $70

If you complete all 5 questionnaires, you could get a total of $250 for participating in this study.

7. Please talk this over with your parents before you decide whether or not to take part in this study. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes" you can still decide not to do this.

8. If you don't want to be in this study, you don't have to. You may stop being in this study any time. Remember, being in this study is up to you and no one will be upset if you don't want to take part in this study or even if you change your mind later and want to stop. If you are assigned to the online group, you always have the option of also seeing your doctor in-person.

9. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me at 323-865-3641 or ask me next time.

10. Putting your name at the bottom means that you have decided to be in this study. You and your parents will be given a copy of this form after you have signed it.

_____
Name of Participant

_____ _____
(Please put your name here ↑) Date

_____
Name of Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date (must be same as Participant's)