

TITLE OF RESEARCH: Food Allergy Symptom Self-Management with Technology for Caregivers (FAST): An mHealth Intervention to Address Psychosocial Outcomes in Caregivers of Children with Newly Diagnosed Food Allergy (Phase 2)

Principal Investigator: Brandle Broome

NCT04512924

**Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT**

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Concise Summary

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to evaluate use of a mobile application (also commonly referred to as an app) designed to support caregivers of children with newly diagnosed food allergy. This study has 2 phases. In Phase 1, the researchers obtained feedback regarding use of mobile apps from caregivers who have been managing their child's food allergy for one year or more. The researchers then used this feedback to build a mobile app for caregivers of children with newly diagnosed food allergy. In Phase 2, the researchers will evaluate the mobile app during a 4-week evaluation period with a group of caregivers of children newly diagnosed with food allergy. You are being asked to participate in Phase 2 because you are the caregiver of a child who has been newly diagnosed with food allergy within the last 120 days.

If you chose to participate, you will be asked to participate in a 4-week evaluation period of a mobile app designed to support caregivers of children newly diagnosed with food allergy. There will be two groups participating in Phase 2. The first group will evaluate a mobile app that offers education and support related to food allergy, daily tracking of symptoms caregivers of children with food allergy may experience (such as feeling tired or feeling anxious), and ways to help make those symptoms better. The second group will evaluate a mobile app that offers only education and support related to food allergy. The group you are in will be randomly decided, like flipping a coin. If you decide to participate, you will complete a questionnaire and 6 surveys at the beginning of the 4-week evaluation period. The questionnaire will ask you some basic questions about yourself, e.g. your age, gender, marital status, highest level of education achieved, family income, race/ethnicity, employment status, family members living in home, length of time since child's food allergy diagnosis, gender and age of child with food allergy, number of serious reactions where child was given epinephrine, and number of identified food allergens. The surveys will ask you questions related to feeling tired, sleep disturbances, depression, anxiety, quality of life, and your confidence as a caregiver. You will complete the 6 surveys again at the end of the 4-week evaluation period and 3-months after the 4-week evaluation period. As well, the researchers may ask you to participate in an interview after the 4-week evaluation period so that you can give them more feedback about the mobile app. You will be provided with a \$50 gift card each time you complete the 6 surveys (\$150 total) and an additional \$50 gift card if you complete the interview after the 4-week evaluation period.

There is no direct benefit to you for participating in this study. However, the data obtained from this study will hopefully benefit caregivers like you in the future. The alternative is to not participate.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand.

You are being asked to participate in this study because you are the parent and/or caregiver of a child diagnosed with food allergy. This study is being conducted to evaluate use of a mobile application designed for caregivers of children newly diagnosed with food allergy. The study is being done at 1 location. Approximately 40 people overall will take part in this study; 10 participants in Phase 1 and 30 participants in Phase 2.

In the United States, many children are affected by food allergies. Most of the time informal caregivers, and/or parents, handle the daily management and needs of children. While caregiving is a normal part of being the parent of a young child, being a caregiver of a child newly diagnosed with food allergy might be overwhelming for caregivers. This research study is to determine if use of a mobile application designed specifically to support caregivers of children newly diagnosed with food allergy will improve the caregiver's overall well-being.

The study is considered a pilot study. A pilot research study is a small study that helps researchers understand more about an area of research where little is known. Because very little information is known about the use of mobile applications designed for caregivers of children newly diagnosed with food allergy, it is hoped the information found in this study will lead to future studies and outcomes that will help caregivers.

The study is sponsored by the College of Nursing at the Medical University of South Carolina. The investigator in charge of this study at MUSC is Dr. Brantlee Broome.

B. PROCEDURES

Your medical chart will be reviewed to collect diagnoses and determine eligibility for participation. If eligible and you agree to be in this study, the following will happen:

You will be randomly assigned (like flipping a coin) into either group 1 or group 2. Group 1 will download an enhanced mobile app that will include education and support resources related to food allergy and its management. Group 2 will download an enhanced mobile app that will include education and support resources related to food allergy and its management, a symptom monitoring and tracking system that allows mobile app users to log symptoms they may experience as caregivers of children newly diagnosed with food allergy, e.g. fatigue and anxiety, and symptom based interventions (recommendations) that may improve a caregiver's ability to self-manage experienced symptoms. Whether you are in Group 1 or Group 2, the researcher will deliver detailed

verbal instructions to you regarding the use of the mobile app and any available features such as the daily symptom tracker. You will also receive written instructions and a contact number for technical assistance, if needed. At this time, you will also be asked to complete a questionnaire and 6 surveys. The total time to complete the questionnaire and surveys is approximately 30-45 minutes. The questionnaire will ask you some basic questions about yourself, e.g. your age, gender, marital status, highest level of education achieved, family income, race/ethnicity, employment status, family members living in home, length of time since child's food allergy diagnosis, gender and age of child with food allergy, number of serious reactions where child was given epinephrine, and number of identified food allergens. The surveys will ask you questions related to feeling tired, sleep disturbances, depression, anxiety, quality of life, and your confidence as a caregiver. You will complete the 6 surveys again at the end of the 4-week evaluation period and 3-months after the 4-week evaluation period.

Participants will participate in the intervention over a 4-week-period. At the end of the 4-week period, the PI will conduct a post-intervention meeting with each individual caregiver participant during which measures will be collected. The research team will randomly select 5 participants from each arm of the study and invite them to participate in a 60-minute post-intervention interview. These interviews will be audio recorded and be sent to transcriptionhub.com, a company outside of the Medical University of South Carolina, to be recorded in writing.

C. DURATION

Participation in the study will take place over 4 months. Participants will initially be invited to complete a questionnaire and 6 surveys. Participants will then participate in the 4-week intervention. At the end of the 4-week period, participants will again complete the 6 surveys and once more 3-months after the end of the 4-week period for a total of 3 separate times. The research team will randomly select 5 participants from each arm of the study and invite them to participate in a 60-minute post-intervention interview.

D. RISKS AND DISCOMFORTS

Loss of privacy: There is a risk of loss of confidentiality of your information that is used in this study; however, measures have been put into place to protect your privacy and research data. Audio recorded interviews will be sent to transcriptionhub.com, a company outside of the Medical University of South Carolina to be recorded in writing. There is a risk of loss of information you provide during the interview; however, measures will be taken to avoid loss of information and to protect your privacy.

Emotional distress: Some of the questions asked may be upsetting to participants or make them feel uncomfortable answering them. Participants will be instructed that if they do not wish to answer a question, they can skip it and go to the next question.

Physical fatigue: Participating in a research study in addition to normal daily demands may be tiring to some participants. Participants may take breaks as necessary throughout the entire process.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Information about your study participation will not be in your MUSC medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

You will be randomly assigned (like flipping a coin) into either group 1 or group 2. Group 1 will download an enhanced mobile app that will include education and support resources related to food allergy and its management. Group 2 will download an enhanced mobile app that will include education and support resources related to food allergy and its management, a symptom monitoring and tracking system that allows mobile app users to log symptoms they may experience as caregivers of children newly diagnosed with food allergy, e.g. fatigue and anxiety, and symptom based interventions (recommendations) that may improve a caregiver's ability to self-manage experienced symptoms. The potential benefit to you is that the treatment received by participants in Group 2 may prove to be more effective than the other study treatment or than other available treatments, although this cannot be guaranteed.

If you are in Group 2 and receive the study intervention, you may benefit from participating in the study; however, this cannot be guaranteed.

G. COSTS

Potential costs related to participation in this study include mobile device data charges related to download and use of the FASST mobile application.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid a \$50 gift card after completing each of the 3 data collection points (\$150 total). If selected to participate in the post-intervention interview, you will receive an additional \$50 gift card.

Payments that you receive from MUSC for participating in a research study are considered taxable income per the IRS regulations. Payment types may include, but are not limited to checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds \$600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative is to not participate in this study.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

Results of the proposed study will not be made available to study participants.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:
 - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

M. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

N. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

O. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below for paper consents, or scroll down to the bottom of the screen and select your choice electronically:

☐ Yes, I agree to be contacted

☐ No, I do not agree to be contacted

P. CLINICAL TRIALS.GOV

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

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact **Dr. Brantlee Broome at 843-792-3370**. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. Please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.

Signature of Person Obtaining Consent Date *Name of Participant

Signature of Participant Date



NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." **We collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

- 1. For treatment.** Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.
- 2. To obtain payment.** We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.
- 3. For health care operations.** We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.
- 4. For public health activities.** We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.
- 5. Victims of abuse, neglect, domestic violence.** Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.
- 6. Health oversight activities.** We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.
- 7. Judicial and administrative proceedings.** Your PHI may be released in response to a subpoena or court order.
- 8. Law enforcement or national security purposes.** Your PHI may be released as part of an investigation by law enforcement.
- 9. Uses and disclosures about patients who have died.** We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.
- 10. For purposes of organ donation.** As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.
- 11. Research.** We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.

14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your health.

15. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.

16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

2. Information shared with family, friends or others. Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.

3. Health plan. You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.

2. Psychotherapy notes.

3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date.

B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in

certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.

E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTICE

We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: <http://www.musc.edu/privacy>.

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003.
Revised September 2013.