IRB NUMBER: 211950030719

LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES DIVISION
MAYWOOD, ILLINOIS
DEPARTMENT OF PEDIATRICS

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE: Use of text messaging for positive reinforcement to help improve quality of life in pediatric obese patients

THE APPROVAL FOR THIS PROJECT EXPIRES ON 03/07/2020.

If you are a parent or guardian of a patient younger than 18 years old and have been asked to read and sign this form, the "you" in this document refers to the patient.

Participant Information

About this research study
Scientists do research to answer important questions which might help change or improve the way we do things in the future. You are being asked to participate in a research study.

Taking part in this research study is voluntary
You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Loyola University of Chicago and Loyola University Medical Center.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Overview and Key Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

1. **Why am I being asked to take part in this research study?**
   We are asking you to take part in this research study because you are between the ages of 13 and 18, you are overweight, you have a cell phone and because you are being seen by a Loyola University Medical Center physician who specializes in pediatric medicine.

2. **Why is this research being done?**

This purpose of this study is to see if text messaging with a positive message after achieving a goal can improve the quality of life of children who are overweight.

3. What will happen to me during the study?

If you agree to participate in this study, you will receive weekly text messages asking whether you have completed recommended exercises for a total of 6 months. If you complete the recommended exercises, you will receive a text message acknowledging your response or giving you a positive comment depending on which research group you are randomized to.

For more information, please see the Description and Explanation of Procedures section below.

4. How long will I participate?

Your participation in this study will last 6 months and include weekly text messages and two office visits. These office visits are standard of care and recommended by your primary care physician. There will be no additional doctors visits required to be a part of the study.

5. Will I benefit from the study?

We do not know if you will benefit from participating in this study. For more information, please see Benefit section below.

6. What are the risks?

This research is considered no more than minimal risk, which means that there is no more expected risk to you than what you might experience during a typical day or during a routine physical exam. There is a risk that by us sending you a text message using the contact information we have, you may get charged by your cell phone company based on what type of phone plan you have. For details and a list of risks you should know about, please see the Risks/Discomforts section below.

7. Do I have other options besides taking part in this study?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

8. Will I be paid to participate?

You will not receive any payment for taking part in this study.

9. Will it cost me anything to participate?

You will not be responsible for any costs related to the research; however, you or your insurance company will still be responsible for the cost of your normal medical care. For more information, please see the Financial Information section below.

End of Overview and Key Information

Please review the rest of this document for details about these topics and additional things

you should know before making a decision about whether to participate in this research.

PURPOSE OF RESEARCH: You are being asked to participate in this study because you are between the ages of 13 and 18, you are overweight, you have a cell phone and because you are being seen by a Loyola University Medical Center physician who specializes in pediatric medicine.

The purpose of this study is to see if text messaging with a positive message after achieving a goal can improve the quality of life of children who are overweight.

The study is being conducted by Dr. T Marsha Ma at Loyola University Medical Center in the Department of Pediatrics.

Approximately 40 people will participate in this research.

DESCRIPTION AND EXPLANATION OF PROCEDURES: If you agree to participate in this study, you will be asked to do the following things:

You will be randomized to either a control group or an intervention group. We will ask for your cell phone number and cell phone service provider in order to contact you via text message. Regardless of which group you are a part of, you will receive two text messages. These text messages will come from the research team via a text messaging application created by Loyola University.

You will receive a schedule for the full 6 months of different activities to do. The schedule tells you what to do each week. The weekly activities we will recommend for the subjects include:

1. Walking for 30 minutes 3 times a week
2. Speed walk for 30 minutes 3 times a week
3. Walk up and down stairs for 30 minutes 3 times a week
4. Jogging for 30 minutes 3 times a week
5. Jumping jacks for 30 minute 3 times a week

At our first meeting with you, you and your parent will be asked to fill out a brief survey. This survey should take 10 minutes or less to fill out.

We will collect from your clinical records (1) your height and weight, (2) and your seated blood pressure.

For the next 6 months, you will be asked to follow the schedule of recommended activities every week. On Monday evenings between 5pm and 6 pm, you will be sent a text message from the research team asking you if you completed the recommended activity. When you respond, if you are a part of the control group, you will be sent a text message back saying "Thank you for your response". If you are a part of the intervention group and you completed, the activity, you will be sent a response saying, “Great job! We’re so proud of you! Keep up the good work!”. If you did not complete the activity, you will receive a text message back saying, "Thank you for your response."

After 6 months, you will have a scheduled appointment with your primary care physician as a weight check that is standard of care. At that visit, you and your parent will be asked to fill out a second survey. This survey should take less than 10 minutes to fill out.
We will collect from your clinical records (1) your height and weight, and (2) your seated blood pressure.

Your chances of being assigned to either or any of the treatments are random.
Neither you nor your doctor will be able to choose which type of treatment you receive.

Your chances of being assigned to either or any of the treatments are 50/50.

If during your participation in the research project new information becomes available which would affect your being in the research project (such as better treatments or the side effects of the treatments), your doctor will discuss this new information with you and will help you make a decision about your continuing in the research.

RISKS/DISCOMFORTS: The treatment you are assigned to receive may not help.

The treatment you are assigned to receive may be associated with more problems or may be less effective than the other treatments in this study that you did not receive.

The loss of your privacy and/or confidentiality is a risk in this study. However, the research team is taking steps to minimize this risk. For example, we will code your data with a unique code to protect your identity. We will also use study bar codes, locked filing systems, and locked password protected computer files to ensure your confidentiality privacy is maintained. If we write a report or article about this study or, share the study data set with others, we will do so in such a way you cannot be directly identified.

<u>There is a risk that by us sending you a text message using the contact information we have, you may get charged by your cell phone company based on what type of phone plan you have. You understand this risk and are willing to pay for these costs.</u>

There should be no other risks associated with study since text messages do not have adverse side effects and no negative messages will be sent to you. We will send these text messages on Monday evenings from 5:00 pm -6:00 pm.

There may be other side effects that we cannot predict or are currently unknown.

BENEFITS: We do not know if you will benefit from participating in this study.

ALTERNATIVE TREATMENTS: You do not have to participate in this research project to receive care and treatment at Loyola University Medical Center.

Your doctor has discussed other options with you along with their risks and benefits.

FINANCIAL INFORMATION: Taking part in this study may or may not cost your insurance company more than the cost of getting treatment without being in this study. Some health plan insurers will not pay the costs for people taking part in studies. Check with your health plan insurer to find out what they will pay for. Depending on your health insurance coverage, there may be out-of-pocket costs for you like co-payment of the standard visits, co-insurance, or deductibles. You will be responsible for these expenses.

RESEARCH RELATED INJURY:
In the event that you are injured or have side effects as a result of participating in this research project, your doctor will take the necessary steps to treat the problem. There are no funds available from Loyola University Medical Center, Gottlieb Memorial Hospital, Loyola University Health System or Loyola University of Chicago to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems. By signing this form, you are not giving up any legal rights to seek to obtain compensation of injury.

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, your test results, and how you do from you and your Loyola University Medical Center medical records. The information will be collected by Dr. T Marsha Ma , the study physician(s), the research nurses, data administrators and secretaries.

Information about you will be provided to Loyola University of Chicago.

In this way, we will learn about the quality of life in pediatric patients who are overweight.

During your participation in this study, you may not be able to access your medical records. Once your participation has been completed, access to your medical record will be reinstated.

The information we will collect and send includes:

__X__ DEMOGRAPHIC INFORMATION (e.g., name, address, phone number)

__X__ MEDICAL RECORD (including, but not limited to, history and physical exam notes, progress notes, consultation reports, laboratory test results, AND/OR operative reports)

We will collect and provide this information about you for as long as you are in the study.

Once the information is disclosed outside of Loyola University Medical Center or Gottlieb Memorial Hospital, it may no longer be protected by federal privacy laws.

De-identified data from this study may be shared with others for research purposes. We will remove or code any personal information that could identify you before data are shared with other researchers to ensure that no one will be able to identify you from the information we share, however this cannot be guaranteed. Once identifying information is removed, the information and samples cannot be withdrawn from further use. You will not be asked to sign an additional consent for this use.

It is possible that the sponsor Dr. T Marsha Ma or research assistants, research nurses, data collection and/or study verification agencies, data administrators or staff, or the Food and Drug Administration will come to Loyola University Medical Center or Gottlieb Memorial Hospital and view the medical record (see above for description of content) and the research records. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information Loyola University of Chicago is sending to them.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUMC to use and disclose your medical information is required in order for you to participate in the study.

This authorization does not expire.

WITHDRAWAL OF CONSENT: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at Loyola University Medical Center or Gottlieb Memorial Hospital, as applicable, unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by Loyola University of Chicago and the sponsor.

If you withdraw from the study, we will ask that you sign the form attached to this consent and send it to Dr. T Marsha Ma or give it to the study staff. Your withdrawal from the study will not have any effect on any actions by Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago taken before the attached form is received by Loyola University of Chicago.

Your study doctor, the Institutional Review Board, the regulatory authorities, or the sponsor, Dr. T Marsha Ma, may terminate the study at any time with or without your consent.

CONSENT

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-327-9131.

_____Date:____/_____/____
Signature

Dr. T Marsha Ma, the principal investigator for this study, Alexandra Kieffer or Dr. Christina Senger will be available to answer any questions you may have and can be reached at708-327-9131.

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact either Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Division, at 708-216-2633 or Cynthia Tom-Klebba, MA, CIP, Director of the Human Research Subjects Protection Program at 708-216-4608.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

_____Date:____/_____/____
(Signature: Parent/Legal Guardian)

_____Date:____/_____/____
(Signature: Witness)

CHILD'S ASSENT TO CONSENT

I have been fully informed of the research project and what my part in the project will be. I have also been fully informed of any side effects that may occur during my participation. I give permission to be part of this study. I know that Dr. T Marsha Ma will be available to answer any questions I may have. I understand that I am free to withdraw this Assent to Consent and participation at any time. I have received a copy of this Child's Assent to Consent.

_____Date:____/_____/____
(Signature: Participant)

_____Date:____/_____/____
(Signature: Witness)

PROJECT TITLE: Use of text messaging for positive reinforcement to help improve quality of life in pediatric obese patients

REVOCATION OF AUTHORIZATION TO
RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the study titled, "Use of text messaging for positive reinforcement to help improve quality of life in pediatric obese patients", at Loyola University Medical Center ("LUMC"). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information to Dr. T. Marsha Ma as outlined on the consent form, which I signed on ____/_____/____ (INSERT DATE CONSENT WAS SIGNED ORIGINALLY). I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

_____Date:____/_____/____
Signature: Participant

Please return this form to:
Dr. T Marsha Ma
Loyola University Medical Center
2160 South First Avenue
Maywood, Illinois 60153