Title: Mobile Health Intervention to Promote Positive Infant Health Outcomes in Guatemala

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CHILDREN'S HOSPITAL LOS ANGELES
MAYA HEALTH ALLIANCE
INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

mHealth Smartphone Technology for Active Monitoring of Infant Development in Guatemala
Focus Groups

Subject's Name: _____

A person who takes part in a research study is called a research subject or research participant.

KEY INFORMATION

You are being asked to participate in a research study. This section describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide the details of the research.

What should I know about this research?

- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't want to take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask the research team questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

You will be asked to participate in one focus group. However, additional focus groups (up to 5 total) may be held. Each focus group will last between 1-2 hours.

Why is this research being done?

This research is being done to help us design a smart phone application. Involving users of the application such as yourself in the design will help us make the updates and improvements necessary to have a useful application.

What happens to me if I agree to take part in this research?

Study procedures for this research are:

- Participation in one or more focus groups.

Could being in the research hurt me?

The most important risks or discomforts that you may expect from taking part in the research are:

1. The time commitment may result in lost productivity.
2. You may feel uncomfortable answering some of the questions.

3. There is the risk that you may feel like you have to participate in the research project in order to receive care from Maya Health Alliance (MHA) or get a good performance review if you work at MHA. You are not under any obligation to participate in this research study.
4. There is the risk that you and other family members might disagree about whether to participate in the study which might cause conflict.

Please see the POSSIBLE RISKS AND DISCOMFORTS section below for a complete list of expected risks.

Will being in this research benefit me?
The most important benefit that you may expect from taking part in this research is understanding how to support better growth and development in infants.

What other choices do I have besides taking part in this research?
The alternative is not to participate in the study. Your decision will not affect you or your family's right to receive health care from MHA or your performance review if you are a staff member at MHA.

INTRODUCTION
You are invited to join a research study led by Beth Smith, PT, DPT, PhD, from the Division of Research on Children, Youth, and Families, from Children's Hospital Los Angeles (CHLA) and Peter Rohloff, MD, from Maya Health Alliance (MHA). This research is paid for by U.S. National Institutes of Health (NIH).

You are invited to join this study because you are a first-time caregiver, who owns a smartphone, has an infant 0-6 months old, and is receiving services from Maya Health Alliance Clinic or you are a staff member at Maya Health Alliance Clinic that works in early child development and nutrition programs. Participation in this study is voluntary. Please read the information below and ask questions about anything you do not understand before deciding whether or not to be in the study.

PURPOSE OF THE STUDY
The purpose of this research is to develop a smartphone application (app). The goal of the app is to promote positive infant-caregiver interaction and better growth and development in infants. The app will collect information from caregivers and provide information to them about infant growth and development. Involving users of apps such as yourself in the design, will help us make the updates and improvements necessary to have a useful app. The app might lead to the ability to intervene earlier when infants need extra help.

NUMBER OF PARTICIPANTS
We will be conducting focus groups with up to 20 caregivers with small children, and up to 20 Maya Health Alliance staff.

LENGTH OF PARTICIPATION
Each focus group will last between 1-2 hours.

PROCEDURES
If you volunteer to be in this study, we will ask you to do the following things:

- Participate in one focus group. Additional focus groups (up to 5 total) may be held as needed so that preference can be given to those who prefer the discussions in Spanish or Kaqchikel. Each focus group will last 1-2 hours.
- You will be asked about your opinions around your experience and comfort level with smartphone applications and perceived role of an mHealth application in supporting caregiving.
- You will be shown and will have the opportunity to interact with examples of existing parenting/caregiving applications.
- You will be asked to provide feedback on the usefulness of these existing applications.

POSSIBLE RISKS AND DISCOMFORTS

1. The time commitment may result in lost productivity.
2. You may feel uncomfortable answering some of the questions. You can skip or stop answering any questions that make you uncomfortable.
3. There is the risk that you may feel like you have to participate in the research project in order to receive care from MHA or get a good performance review if you work at MHA. You are not under any obligation to participate in this research study.
4. There is the risk that you and other family members might disagree about whether to participate in the study which might cause conflict.

As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality may occur. The researchers have procedures in place to lessen the possibility of this happening (see the CONFIDENTIALITY section below for details).

POSSIBLE BENEFITS TO SUBJECTS
You may not benefit from participating in this study. For caregivers, potential benefits may include improvements in developmental and growth outcomes, an enhanced knowledge of early child development and improved ability to care for your child. For MHA staff members, you may have a greater sense of empowerment and job satisfaction.

POSSIBLE BENEFITS TO SOCIETY
This project may help to improve implementation knowledge around mHealth and infant development interventions in Guatemala.

YOUR OPTIONS IF YOU CHOOSE NOT TO BE IN THIS STUDY
The alternative is not to participate in the study. Your decision will not affect you or your family's right to receive health care from Maya Health Alliance. If you are a Maya Health Alliance staff member, your decision to or not to participate in this study is separate from your job duties and will not affect your performance reviews.

COSTS TO YOU FOR BEING IN THIS STUDY
There are no additional costs to you for being in this study.

PAYMENT FOR PARTICIPATION

To recognize the time spent in the study, we will give caregiver participants a small care package of useful items for the home, such as toys for your baby and healthy foods like eggs and beans, each time you participate. Each care package will be worth around 40 quetzales. If you are a Maya Health Alliance staff member, you will not be paid for participation in this study.

CONFIDENTIALITY

The data collected as part of this study will be "coded." Coded means that the data collected for this study will be assigned a unique code or Study ID. Your research data will not include your name or any other identifying information about you. The code that could be linked back to your identifying information will be kept separate from your research data.

People on the research team will know that you are in this research. All results will be kept confidential. The data collected as part of this study will be sent to Children's Hospital Los Angeles in the United States.

Your information and data will be shared with individuals and organizations that oversee this research, including:

- Government agencies, such as the Department of Health and Human Services
- The CHLA Institutional Review Board (IRB) and authorized representatives of CHLA Maya Health Alliance (MHA) Institutional Review Board (IRB) that also reviewed this research, and authorized representatives of MHA

We will take steps to keep your personal information private, but we cannot guarantee complete secrecy. All identifiable information about you will be replaced with a unique code or study ID. A list linking the code and your identifiable information will be kept separate from the research data. All research data and records will be stored electronically on a secure network with encryption and password protection to help prevent unauthorized access to your personal information.

We will not release information about you to others not listed above, unless required or permitted by law. For instance:

- if we learn of child or elder abuse, harm to self or others, or
- if you have certain infectious diseases; or
- you are injured and need emergency care.

The results of the research may be presented or published. We will keep your name and other identifying information confidential.

FUTURE RESEARCH USE OF DATA AND/OR SPECIMENS

Once this research study is completed, the data collected as part of this study will be "de-identified" or "anonymized." This means that there will be no way to link the data back to you. Once your data have been de-identified it will be stored in the NIH Data and Specimen Hub (DASH) repository indefinitely (forever) and may be used by researchers for future research projects that are unrelated to the purpose of this study.

The future research may be done without consulting you or obtaining your consent (permission) for this additional use.

STUDY WITHDRAWAL
The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions. The researchers might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about/from you up to that point will remain part of the study and may not be removed from the study database.

QUESTIONS ABOUT THE STUDY
If you have questions, concerns, or complaints about the study, or think this research has harmed you, talk to the research team:

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call the Principal Investigator, Peter Rohloff, at +502 50005833.

This research is being overseen by the CHLA Institutional Review Board ("IRB") and the Maya Health Alliance (MHA) Institutional Review Board "IRB"). An IRB is a group of people who perform ethical review of research studies. You may talk to the CHLA IRB at (323) 361-2265, or hspp@chla.usc.edu or the (MHA) IRB at MHA IRB at 502 7840 3112 or Contact@wuqukawoq.org if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

ClinicalTrials.gov is a Web site that provides information about federally and privately supported clinical trials. 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.

RIGHTS OF RESEARCH SUBJECTS
You can agree to take part in this study and stop your participation in the study anytime. You should not participate in this study if you have any questions that have not been answered or if you are unclear about any information in this form.

Your participation in the study is entirely voluntary. If you choose not to take part in the study or decide to stop your participation in this study at any time, there will be no penalty or loss of benefits to which you are otherwise entitled. If you wish to leave the study after agreeing to participate, you should let the Principal Investigator know.

You will be told about any new information found during the course of the study that may affect your health, welfare, or choice to stay in the research. If this happens, you might be asked if you still want to participate in the study and may be given a new consent form.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive.
- If you decide not to take part, you can still receive medical care.
- You will be given a copy of this signed and dated consent form to keep.

DOCUMENTATION OF VERBAL CONSENT OF RESEARCH SUBJECT

To ensure that you are informed about this study and how to participate in it, we are asking you to read this consent (or have it read to you). This document may contain some words that are not well known to you, so please ask for explanation about anything you do not understand. If you consent, you are not waiving any rights that Guatemalan law gives you.

Consent

Do you want to participate in this study? YES NO

_____
Name of participant

_____
Name of the person who discussed this informed consent information

_____
Signature of the person who discussed this informed consent information

_____ _____
Date Time

CHILDREN'S HOSPITAL LOS ANGELES
MAYA HEALTH ALLIANCE
INFORMED CONSENT/PARENTAL PERMISSION TO PARTICIPATE IN A RESEARCH STUDY

mHealth Smartphone Technology for Active Monitoring of Infant Development in Guatemala
Two-arm Prospective, Longitudinal, 6-Month Pilot Intervention

Subject's Name: _____

A person who takes part in a research study is called a research subject or research participant. If you are reading this consent form as a parent/legal guardian "you" also refers to "your child" (the research participant) and/or the research participant, as applicable.

KEY INFORMATION

You are being asked to participate in a research study. This section describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide the details of the research.

What should I know about this research?

- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't want to take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask the research team questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

The study will last 6 months.

Why is this research being done?

This research is being done to help collect data on the usefulness of a smartphone application for caregivers to support infant growth and development.

What happens to me if I agree to take part in this research?

The procedures for this research are:

- Receive either printed caregiving materials or a smartphone application (app) on your smartphone.
- If you receive the smartphone app, you will complete a short survey in the app and receive some information about feeding, sleeping, and activities.
- Study staff will make monthly visits.
- Complete the Bayley Scale of Infant Development (BSID-4) survey.

Could being in the research hurt me?
The most important risks or discomforts that you may expect from taking part in the research are:

1. The time commitment may result in lost productivity.
2. You may feel uncomfortable answering some of the questions.
3. There is the risk that you and other family members might disagree about whether to participate in the study which might cause conflict.
4. There is the risk that your protected health information may be accidentally disclosed by the research team.
5. There is the risk that you may feel like you have to participate in the research project in order to receive care from Wuqu' Kawoq | Maya Health Alliance (Maya Health Alliance or MHA). You are not under any obligation to participate in this research study.

Please see the POSSIBLE RISKS AND DISCOMFORTS section below for a complete list of expected risks.

Will being in this research benefit me?
The most important benefit that you may expect from taking part in this research is understanding how to support better growth and development in infants.

What other choices do I have besides taking part in this research?
The alternative is not to participate in the study. Your decision will not affect you or your family's right to receive health care from Maya Health Alliance.

INTRODUCTION
You are invited to join a research study led by Beth Smith, PT, DPT, PhD, from the Division of Research on Children, Youth, and Families, from Children's Hospital Los Angeles (CHLA) and Peter Rohloff, MD, from Maya Health Alliance. This research is paid for by U.S. National Institutes of Health (NIH).

You are invited to join this study because you are a first-time caregiver, with an infant between 0-4 weeks old, with a full-term (>37 weeks) birth, and receiving services from Maya Health Alliance (MHA) Clinic. Participation in this study is voluntary. Please read the information below and ask questions about anything you do not understand before deciding whether or not to be in the study.

PURPOSE OF THE STUDY
The purpose of this research is to develop a smartphone application (app). The goal of the app is to promote positive infant-caregiver interaction and better growth and development in infants. The app will collect information from you and provide information to you about infant growth and development. We want to find out how the app works for you and determine whether it supports better growth and development in infants. This might lead to the ability to intervene earlier when infants need extra help.

NUMBER OF PARTICIPANTS
We aim to enroll 40 caregivers and infants.

LENGTH OF PARTICIPATION
The study will last 6 months

PROCEDURES
If you volunteer to be in this study, we will ask you to do the following things:

- You will be randomized to one of 2 groups (control or intervention). Randomization is a procedure used to assign research participants by chance to a study group in a clinical trial. In this study, you have a 50/50 chance of being assigned to one group or another, like with a flip of a coin.

- Control Group: The control group will receive printed caregiving materials and study staff will make monthly visits to ask you if there are questions about the printed caregiving materials.

- Intervention Group: The intervention group will receive the smartphone application (app). Study staff will visit your home to install the app on your smartphone and teach you how to use it. Study staff will also make monthly visits to make sure the app is working properly, and to answer questions. Three days per week, the app will ask you to complete a short survey (less than 1 minute) that asks about the baby's: 1) feeding, 2) sleeping, or 3) type of activity and interaction. Study staff will provide feedback to you (by phone/text) for problem areas. On the days when you don't complete a survey, the app will provide you with some information about feeding, sleeping, and activities. On the first and last visits, you will provide your opinions about the app's usefulness and how you liked using it. At the last visit, we will also ask you some questions to determine your interests, use, and thoughts about the app. In this last visit, we will audio record your responses to help better analyze them.

- Both groups: The Bayley Scale of Infant Development (BSID-4) survey will be completed, on infants, in two additional visits at the start and the end of the study. It will take about 1 hour to complete this survey. This may be done in a space provided by the institution or close to where you live, to ensure comfort for your baby and the psychologist doing the survey. We will discuss the results of this survey with you and will provide you with recommendations if needed.

- Both groups: There will be a total of 9 visits with study staff and each visit will last about 15 minutes to 1 hour.

- Both groups: During the home visits, research staff will also collect information such as: infant/caregiver demographics, infant's medical history, caregiver poverty scorecard, and your infant's height and weight. This information will be collected for research purposes only and will be come directly from the caregiver.

POSSIBLE RISKS AND DISCOMFORTS
1. The time commitment may result in lost productivity.

2. You may feel uncomfortable answering some of the questions. You can skip or stop answering any questions that make you uncomfortable.
3. There is the risk that you and other family members might disagree about whether to participate in the study which might cause conflict.
4. There is the risk that your protected health information may be accidentally disclosed by the research team.
5. There is the risk that you may feel like you have to participate in the research project in order to receive care from Wuqu' Kawoq | Maya Health Alliance (Maya Health Alliance or MHA). You are not under any obligation to participate in this research study.

As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality may occur. The researchers have procedures in place to lessen the possibility of this happening (see the CONFIDENTIALITY section below for details).

POSSIBLE BENEFITS TO SUBJECTS
You may not benefit from participating in this study. Potential benefits may include improvements in developmental and growth outcomes. For caregivers, benefits may include an enhanced knowledge of early child development and improved ability to care for their child. You may see improvement in some or all your child's symptoms.

POSSIBLE BENEFITS TO SOCIETY
This project may help to improve implementation knowledge around mHealth and infant development interventions in Guatemala.

YOUR OPTIONS IF YOU CHOOSE NOT TO BE IN THIS STUDY
The alternative is not to participate in the study. Your decision will not affect you or your family's right to receive health care from Maya Health Alliance.

COSTS TO YOU FOR BEING IN THIS STUDY
There are no additional costs to you for being in this study.

PAYMENT FOR PARTICIPATION
To recognize the time you spend in the study, we will give you a small care package of useful items for the home, such as toys for your baby and healthy foods like eggs and beans, at each visit. Each care package will be worth around 40 quetzales.

CONFIDENTIALITY
The data collected as part of this study will be "coded." Coded means that the data collected for this study will be assigned a unique code or Study ID. Your research data will not include your name or any other identifying information about you. The code that could be linked back to your identifying information will be kept separate from your research data.

People on the research team will know that you are in this research study. All results will be kept confidential. The data collected as part of this study will be sent to Children's Hospital Los Angeles in the United States.

Your private information, data and medical records will be shared with individuals and organizations that oversee this research, including:

- Government agencies, such as the Department of Health and Human Services.
- The CHLA Institutional Review Board (IRB) that reviewed this research, and authorized representatives of CHLA.
- Maya Health Alliance (MHA) Institutional Review Board (IRB) that reviewed this research, and authorized representatives of MHA.

We will take steps to keep your personal information private, but we cannot guarantee complete secrecy. All identifiable information about you will be replaced with a unique code or study ID. A list linking the code and your identifiable information will be kept separate from the research data. All research data and records will be stored electronically on a secure network with encryption and password protection to help prevent unauthorized access to your personal information.

The audio-recordings made of you during the interview will not be shared outside the study team. They will be destroyed after the audio-recordings are transcribed (i.e. your responses are written down).

We will not release information about you to others not listed above, unless required or permitted by law. For instance:

- if we learn of child or elder abuse, harm to self or others, or
- if you have certain infectious diseases; or
- you are injured and need emergency care.

The results of the research may be presented or published. We will keep your name and other identifying information confidential.

FUTURE RESEARCH USE OF DATA

Once this research study is completed, the data collected as part of this study will be "de-identified" or "anonymized." This means that there will be no way to link the data back to you. Once your data have been de-identified it will be stored in the NIH Data and Specimen Hub (DASH) repository indefinitely (forever) and may be used by researchers for future research projects that are unrelated to the purpose of this study. The future research may be done without consulting you or obtaining your consent (permission) for this additional use.

STUDY WITHDRAWAL

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions. The researchers might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about/from you up to that point will remain part of the study and may not be removed from the study database.

QUESTIONS ABOUT THE STUDY

If you have questions, concerns, or complaints about the study, or think this research has harmed you, talk to the research team:

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call the CHLA Principal Investigator, Peter Rohloff, at +502 50005833.

This research is being overseen by the CHLA Institutional Review Board ("IRB") and the Maya Health Alliance (MHA) Institutional Review Board "IRB"). An IRB is a group of people who perform ethical review of research studies. You may talk to the CHLA IRB at (323) 361-2265, or hspp@chla.usc.edu or the (MHA) IRB at MHA IRB at 502 7840 3112 or Contact@wuqukawoq.org. if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

ClinicalTrials.gov is a Web site that provides information about federally and privately supported clinical trials. 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.

RIGHTS OF RESEARCH SUBJECTS

You can agree to take part in this study and stop your participation in the study anytime. You should not participate in this study if you have any questions that have not been answered or if you are unclear about any information in this form.

Your participation in the study is entirely voluntary. If you choose not to take part in the study or decide to stop your participation in this study at any time, there will be no penalty or loss of benefits to which you are otherwise entitled. If you wish to leave the study after agreeing to participate, you should let the Principal Investigator know.

You will be told about any new information found during the course of the study that may affect your health, welfare, or choice to stay in the research. If this happens, you might be asked if you still want to participate in the study and may be given a new consent form.

- You have a right to have all of your questions answered before deciding whether to take part.

- Your decision will not affect the medical care you receive.
- If you decide not to take part, you can still receive medical care.
- You will be given a copy of this signed and dated consent to keep.

DOCUMENTATION OF VERBAL CONSENT OF RESEARCH SUBJECT

To ensure that you are informed about this study and how to participate in it, we are asking you to read this consent (or have it read to you). This document may contain some words that are not well known to you, so please ask for explanation about anything you do not understand. If you consent, you are not waiving any rights that Guatemalan law gives you.

Consent

Do you want to participate in this study? YES NO

_____
Name of infant participant

_____
Name of legal guardian providing consent

_____
Name of the person who discussed this informed consent information

_____
Signature of the person who discussed this informed consent information

_____ _____
Date Time

CHILDREN'S HOSPITAL LOS ANGELES
MAYA HEALTH ALLIANCE
CONSENTIMIENTO INFORMADO / PERMISO DE LOS PADRES PARA PARTICIPAR EN UN ESTUDIO DE INVESTIGACIÓN

Tecnología de teléfonos inteligentes Salud Móvil para el monitoreo activo del desarrollo infantil en Guatemala Intervención piloto prospectiva de dos brazos, longitudinal, de 6 meses

Nombre del Sujeto :

Una persona que participa en un estudio de investigación se denomina sujeto de investigación o participante de investigación. Si está leyendo este formulario de consentimiento como padre / tutor legal, "usted" también se refiere a "su hijo" (el participante de la investigación) y / o el participante de la investigación, según corresponda.

INFORMACIÓN CLAVE

Se le pide que participe en un estudio de investigación. Esta sección describe la información clave que creemos que la mayoría de las personas necesita para decidir si participar en esta investigación. Las secciones posteriores de este documento proporcionarán los detalles de la investigación.

¿Qué debería saber sobre esta investigación?

- La participación en esta investigación es voluntaria. Si participa depende de usted.
- Si no quiere participar, no lo tomarán en su contra.
- Puede participar ahora y luego abandonarlo, y no se lo tomará en cuenta.
- Si no comprende, haga preguntas al equipo de investigación.
- Haga todas las preguntas que desee antes de decidirse.

¿Cuánto tiempo estará en esta investigación?

La investigación durará 6 meses.

¿Por qué se está realizando esta investigación ?

Esta investigación se está realizando para ayudar a recopilar datos sobre la utilidad de una aplicación de teléfono inteligente para que los cuidadores apoyen el crecimiento y el desarrollo infantil.

¿Qué pasa si está de acuerdo en formar parte de este estudio?

Los procedimientos para esta investigación son:

- Recibir materiales impresos para el cuidado de niños o una aplicación para teléfonos inteligentes (app) en su teléfono inteligente.
- Si recibe la aplicación para teléfono inteligente, completará una breve encuesta en la aplicación y recibirá información sobre alimentación, sueño y actividades.

• El personal del estudio realizará visitas mensuales.
• Completar la encuesta de Bayley Scale of Infant Development (BSID-4)

¿Participar en la investigación puede lastimarle?
Los riesgos o molestias más importantes que puede esperar al participar en la investigación son:

1. El compromiso de tiempo puede resultar en una pérdida de productividad.
2. Puede sentirse incómodo al responder algunas de las preguntas.
3. Existe el riesgo de que usted y otros miembros de su familia no estén de acuerdo sobre si participar en el estudio, lo que podría causar un conflicto.
4. Existe el riesgo de que el equipo de investigación divulgue accidentalmente su información médica protegida.
5. Existe el riesgo de que sienta que tiene que participar en el proyecto de investigación para recibir atención de Wuqu ’Kawoq | Maya Health Alliance (Maya Health Alliance o MHA). No tiene ninguna obligación de participar en este estudio de investigación.

Consulte la sección POSIBLES RIESGOS Y MOLESTIAS a continuación para obtener una lista completa de los riesgos esperados.

¿Le beneficiará estar en esta investigación?
El beneficio más importante que puede esperar de participar en esta investigación es comprender cómo apoyar un mejor crecimiento y desarrollo en los bebés.

¿Qué otras opciones tiene además de participar en esta investigación?
La alternativa es no participar en el estudio. Su decisión no afectará su derecho ni el de su familia a recibir atención médica de Maya Health Alliance

INTRODUCCIÓN

Está invitado a unirse a un estudio de investigación dirigido por Beth Smith, PT, DPT, PhD, de la División de Investigación sobre Niños, Jóvenes y Familias, del Children's Hospital Los Angeles (CHLA) y Peter Rohloff, MD, de Maya Health Alliance . Esta investigación está financiada por los Institutos Nacionales de Salud de EE. UU. (NIH).

Usted está invitado a unirse a este estudio porque es un cuidador por primera vez, con un bebé de 0 a 4 semanas de edad, con un parto a término (> 37 semanas) y recibiendo servicios de la Clínica Maya Health Alliance (MHA). La participación en este estudio es voluntaria. Lea la información a continuación y haga preguntas sobre todo lo que no comprenda antes de decidir si participa o no en el estudio.

PROPÓSITO DEL ESTUDIO

El propósito de esta investigación es desarrollar una aplicación para teléfonos inteligentes (app). El objetivo de la aplicación es promover una interacción positiva entre el bebé y el cuidador y un mejor crecimiento y desarrollo en los bebés. La aplicación recopilará información sobre usted y le brindará información sobre el crecimiento y desarrollo infantil.

Queremos saber cómo funciona la aplicación para usted y determinar si apoya un mejor crecimiento y desarrollo en los bebés. Esto podría conducir a la capacidad de intervenir antes cuando los bebés necesitan ayuda adicional.

NÚMERO DE PARTICIPANTES

Nuestro objetivo es involucrar a 40 cuidadores de infantes.

DURACIÓN DE LA PARTICIPACIÓN

El estudio durará 6 meses.

PROCEDIMIENTOS

Si se ofrece como voluntario para participar en este estudio, le pediremos que haga lo siguiente:

• Se le asignará al azar a uno de 2 grupos (control o intervención). La aleatorización es un procedimiento que se utiliza para asignar al azar a los participantes de una investigación a un grupo de estudio en un ensayo clínico. En este estudio, tiene una probabilidad del 50/50 de ser asignado a un grupo u otro, como si se lanzara una moneda al aire.

• Grupo de control: el grupo de control recibirá materiales impresos para el cuidado y el personal del estudio hará visitas mensuales para preguntarle si hay preguntas sobre los materiales impresos para el cuidado. Habrá 7 visitas mensuales y cada visita durará entre 15 minutos y 1 hora.

• Grupo de intervención: El grupo de intervención recibirá la aplicación (app) del teléfono inteligente. El personal del estudio visitará su casa para instalar la aplicación en su teléfono inteligente y enseñarle cómo usarla. El personal del estudio también realizará visitas mensuales para asegurarse de que la aplicación funcione correctamente y para responder preguntas. Tres días a la semana, la aplicación le pedirá que complete una breve encuesta (menos de 1 minuto) que pregunta sobre los siguientes aspectos del bebé:
1) alimentarse, 2) dormir o 3) tipo de actividad e interacción. El personal del estudio le proporcionará comentarios (por teléfono / mensaje de texto) para las áreas problemáticas. Los días en que no complete una encuesta, la aplicación le proporcionará información sobre la alimentación, el sueño y las actividades. En la última visita, también le haremos algunas preguntas para determinar sus intereses, uso y pensamientos sobre la aplicación. A esta última, le pediremos grabar sus respuestas para ayudar mejor analizarlos. Habrá un total de 7 visitas domiciliarias y cada visita durará entre 15 minutos y 1 hora.

• Ambos grupos: La encuesta de Bayley Scale of Infant Development (BSID-4) se completará, en bebés, en dos visitas adicionales, una al iniciar y la otra a concluir. Le tomará aproximadamente 1 hora completar esta encuesta. Es posible que se haga en un espacio proporcionado por la institución, cerca de donde Usted vive, para que sea cómodo para su bebe y la psicóloga haciendo la encuesta. Discutiremos los resultados de esta encuesta y le proporcionaremos recomendaciones si es necesario.

• Ambos grupos: durante las visitas domiciliarias, el personal de investigación también recopilará información como: datos demográficos del bebé / cuidador, historial médico del bebé, tarjeta de puntuación de pobreza del cuidador, medidas del bebé (por ejemplo, longitud corporal y peso), y opiniones sobre la funcionalidad de la application. Esta información se recopilará solo con fines de investigación y vendrá directamente del cuidador.

POSIBLES RIESGOS E INCOMODIDADES

1. El compromiso de tiempo puede resultar en una pérdida de productividad.
2. Puede sentirse incómodo al responder algunas de las preguntas. Puede omitir o dejar de responder cualquier pregunta que le haga sentir incómodo.
3. Existe el riesgo de que usted y otros miembros de su familia no estén de acuerdo sobre si participar en el estudio, lo que podría causar un conflicto.

4. Existe el riesgo de que el equipo de investigación divulgue accidentalmente su información médica protegida.
5. Existe el riesgo de que sienta que tiene que participar en el proyecto de investigación para recibir atención de Wuqu ’Kawoq | Maya Health Alliance (Maya Health Alliance o MHA). No tiene ninguna obligación de participar en este estudio de investigación.

Dado que este estudio implica el uso de su información personal identificable, existe la posibilidad de que se pierda la confidencialidad. Los investigadores cuentan con procedimientos para disminuir la posibilidad de que esto suceda (consulte la sección CONFIDENCIALIDAD a continuación para obtener más detalles).

POSIBLES BENEFICIOS PARA SUJETOS

Es posible que no se beneficie de participar en este estudio. Los beneficios potenciales pueden incluir mejoras en los resultados de desarrollo y crecimiento. Para los cuidadores, los beneficios pueden incluir un mayor conocimiento del desarrollo infantil temprano y una mayor capacidad para cuidar a su hijo. Es posible que observe una mejora en algunos o todos los síntomas de su hijo.

POSIBLES BENEFICIOS PARA LA SOCIEDAD

Este proyecto puede ayudar a mejorar el conocimiento de la implementación en torno a las intervenciones de salud móvil y desarrollo infantil en Guatemala.

SUS OPCIONES SI ELIGE NO PARTICIPAR EN ESTE ESTUDIO

La alternativa es no participar en el estudio. Su decisión no afectará su derecho ni el de su familia a recibir atención médica de Maya Health Alliance.

COSTOS PARA USTED POR PARTICIPAR EN ESTE ESTUDIO

No hay costos adicionales para usted por participar en este estudio.

PAGO POR PARTICIPACIÓN

Para reconocer el tiempo que pasa en el estudio, en cada visita le entregaremos un pequeño paquete de artículos útiles para el hogar, como juguetes para su bebé y alimentos saludables como huevos y frijoles. Cada paquete de cuidados tendrá un valor de alrededor de 40 quetzales.

CONFIDENCIALIDAD

Los datos recopilados como parte de este estudio serán "codificados". Codificado significa que a los datos recopilados para este estudio se les asignará un código único o ID de estudio. Los datos de su investigación no incluirán su nombre ni ninguna otra información de identificación sobre usted. El código que podría estar vinculado a su información de identificación se mantendrá separado de los datos de su investigación.

Las personas del equipo de investigación sabrán que usted participa en este estudio de investigación. Todos los resultados se mantendrán confidenciales. Los datos recopilados como parte de este estudio se enviarán al Children's Hospital Los Angeles en los Estados Unidos.

Su información privada, datos y registros médicos se compartirán con las personas y organizaciones que supervisan esta investigación, que incluyen:

• Agencias gubernamentales, como el Departamento de Salud y Servicios Humanos.

• La Junta de Revisión Institucional (IRB) de la CHLA que revisó esta investigación y los representantes autorizados de la CHLA.

• Junta de Revisión Institucional (IRB) de Maya Health Alliance (MHA) que revisó esta investigación y representantes autorizados de MHA.

Tomaremos medidas para mantener la privacidad de su información personal, pero no podemos garantizar el total secreto. Toda la información identificable sobre usted será reemplazada por un código único o ID de estudio. Una lista que vincula el código y su información identificable se mantendrá separada de los datos de la investigación. Todos los datos y registros de la investigación se almacenarán electrónicamente en una red segura con cifrado y protección con contraseña para ayudar a evitar el acceso no autorizado a su información personal.

No divulgaremos información sobre usted a otras personas que no figuran en la lista anterior, a menos que lo exija o lo permita la ley. Por ejemplo:
• si nos enteramos de abuso de niños o ancianos, daño a sí mismo oa otros, o
• si tiene determinadas enfermedades infecciosas; o
• está lesionado y necesita atención de emergencia.

Los resultados de la investigación pueden presentarse o publicarse. Mantendremos su nombre y otra información de identificación confidencial.
• Agencias gubernamentales, como el Departamento de Salud y Servicios Humanos.
• La Junta de Revisión Institucional (IRB) de la CHLA que revisó esta investigación y los representantes autorizados de la CHLA.
• Junta de Revisión Institucional (IRB) de Maya Health Alliance (MHA) que revisó esta investigación y representantes autorizados de MHA.

Tomaremos medidas para mantener la privacidad de su información personal, pero no podemos garantizar el total secreto. Toda la información identificable sobre usted será reemplazada por un código único o ID de estudio. Una lista que vincula el código y su información identificable se mantendrá separada de los datos de la investigación. Todos los datos y registros de la investigación se almacenarán electrónicamente en una red segura con cifrado y protección con contraseña para ayudar a evitar el acceso no autorizado a su información personal.

No divulgaremos información sobre usted a otras personas que no figuran en la lista anterior, a menos que lo exija o lo permita la ley. Por ejemplo:
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• si tiene determinadas enfermedades infecciosas; o
• está lesionado y necesita atención de emergencia.

Los resultados de la investigación pueden presentarse o publicarse. Mantendremos su nombre y otra información de identificación confidencial.

USO DE DATOS EN INVESTIGACIONES FUTURAS

Una vez que se complete este estudio de investigación, los datos recopilados como parte de este estudio serán "desidentificados" o "anonimizados". Esto significa que no habrá forma de vincular los datos con usted. Una vez que sus datos hayan sido desidentificados, se almacenarán en el repositorio de NIH Data and Specimen Hub (DASH) de manera indefinida (para siempre) y los investigadores pueden usarlos para futuros proyectos de investigación que no estén relacionados con el propósito de este estudio. La investigación futura puede realizarse sin consultarlo ni obtener su consentimiento (permiso) para este uso adicional.

RETIRO DEL ESTUDIO

Los investigadores pueden finalizar su participación en este estudio por varias razones, como si su seguridad y bienestar están en riesgo, si no sigue las instrucciones. Los investigadores también podrían decidir detener el estudio en cualquier momento.

Si decide dejar de participar en el estudio, o lo eliminan del estudio, o el estudio se detiene, los datos recopilados sobre usted hasta ese momento seguirán siendo parte del estudio y es posible que no se eliminen de la base de datos del estudio.

PREGUNTAS SOBRE EL ESTUDIO

Si tiene preguntas, inquietudes o quejas sobre el estudio, o cree que esta investigación lo ha perjudicado, hable con el equipo de investigación:

Durante el día, de lunes a viernes, de 8:00 a. M. hasta las 4:30 P.M. puede llamar al investigador principal de CHLA, Peter Rohloff, al +502 50005833.

Esta investigación está siendo supervisada por la Junta de Revisión Institucional de CHLA ("IRB") y la Junta de Revisión Institucional de Maya Health Alliance (MHA) "IRB"). Un IRB es un grupo de personas que realizan una revisión ética de los estudios de investigación. Puede hablar con CHLA IRB al (323) 361-2265, o hspp@chla.usc.edu o el (MHA) IRB en MHA IRB al 502 7840 3112 o Contact@wuqukawoq.org. Si:

- Tiene preguntas, inquietudes o quejas que el equipo de investigación no responde.
- No obtiene respuestas del equipo de investigación.
- No puede comunicarse con el equipo de investigación.
- Quiere hablar con alguien más sobre la investigación.
- Tiene preguntas sobre sus derechos como sujeto de investigación.

ClinicalTrials.gov es un sitio web que proporciona información sobre ensayos clínicos con apoyo federal y privado. Una descripción de este ensayo clínico estará disponible en http://www.ClinicalTrials.gov, según lo exige la ley de EE. UU. Este sitio web no incluirá información que pueda identificarlo. Como máximo, el sitio web incluirá un resumen de los resultados. Puede buscar en este sitio web en cualquier momento.

DERECHOS DE LOS SUJETOS DE INVESTIGACIÓN

Puede aceptar participar en este estudio y dejar de participar en el estudio en cualquier momento. No debe participar en este estudio si tiene alguna pregunta que no haya sido respondida o si no tiene clara la información contenida en este formulario.Su participación en el estudio es completamente voluntaria. Si elige no participar en el estudio o decide detener su participación en este estudio en cualquier momento, no habrá penalización ni pérdida de los beneficios a los que tiene derecho. Si desea abandonar el estudio después de aceptar participar, debe informarle al investigador principal.

Se le informará sobre cualquier información nueva que se encuentre durante el transcurso del estudio que pueda afectar su salud, bienestar o elección de permanecer en la investigación. Si esto sucede, es posible que se le pregunte si aún desea participar en el estudio y es posible que se le proporcione un nuevo formulario de consentimiento.

- Tiene derecho a que se respondan todas sus preguntas antes de decidir si desea participar.
- Su decisión no afectará la atención médica que reciba.
- Si decide no participar, aún puede recibir atención médica.
- Se le dará una copia de este consentimiento firmado y fechado para que lo conserve.

DOCUMENTACIÓN DE CONSENTIMIENTO VERBAL DEL OBJETO DE INVESTIGACIÓN

Para asegurarse de que está informado sobre este estudio y cómo participar en él, le pedimos que lea este consentimiento (o que se lo lea). Este documento puede contener algunas palabras que no conoce bien, así que solicité una explicación sobre cualquier cosa que no comprenda. Si da su consentimiento, no está renunciando a ningún derecho que le otorgue la ley guatemalteca.

Consentimiento

¿Desea formar parte de esta investigación? SI NO

_____
Nombre del infante participante

_____
Nombre del tutor legal que da su consentimiento

_____
Nombre de la persona que discutió esta información de consentimiento informado

_____
Firma de la persona que discutió esta información de consentimiento informado

_____ _____
Fecha Hora