Adolescent assent, parental consent, and adult consent documents for NCT04190225: “Physical Activity Intervention for Adolescent Girls”

Approved January 18, 2022

University of California, San Diego
Assent to Act as a Research Subject

Chicas Fuertes

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study?
Dr. Britta Larsen and associates are conducting a research study to learn more about ways to help Latina girls be physically active. You have been asked to participate in this study because you are a Latina girl between the ages of 13 to 18. There will be approximately 200 participants in this study. The research is sponsored by the National Institute of Nursing Research.

Why is this study being done?
The purpose of this study is to test a 12-month physical activity intervention for young Latinas. The long term goal of this study is to provide valuable information on behavior change within Latino families, particularly adolescent Latina girls.

What will happen to you in this study and which procedures are standard of care and which are experimental?
This study is intervention-based, and all procedures involved are experimental. Your participation in the study will last 1 year (12 months). If you agree to participate in this study, you will be asked to do the following:

Come to an in-person, orientation session where a research staff member will tell you about the study. You will then be asked to read and sign an assent form approved by the university's institutional review board, and a parent will sign a consent form. If a parent/guardian is unable or would prefer not to attend the orientation session with you, s/he can read information about the study online, contact the study team with any questions, and then download and sign the permission form in advance. You will be required to bring the signed parent permission form to the orientation session if your parent/guardian does not attend with you. After you sign this assent form, you will fill out some questionnaires regarding health, health behaviors, such as being physically active, and your mood. **These questionnaires are only for research, and are not for diagnosing any physical or mental health problems. We may not tell you or your parents if your answers suggest you might have health problems, like depression.** This first session will last about one hour.

Afterwards, you will:

Wear a red activity monitor for 1 week. You will be asked to wear this monitor on your hip for seven days. It counts the number of "up and down" movements you make. You will record the days and time that you put the monitor on and take it off. After you are finished wearing the monitor, you will bring it with you to your next visit occurring the following week. There will be no cost to you in the case that the activity monitor is lost or stolen. To reduce the risk of losing the activity monitor, research staff will provide instructions on how to wear it for the 7 days.

Wear and Sync a FitBit activity tracker

- The Fitbit is a watch sized, wrist worn, physical activity tracker.
- You will wear the Fitbit for a week at the beginning of the study to get an idea of how active you usually are. During this week you won't be able to see anything on the Fitbit. Then you will wear it for the rest of the study, and you will be able to use all the Fitbit tools.
- **Wearing the FitBit:** You will be asked to wear the FitBit as many hours (day and night) as possible.
- **Synching the FitBit:** You will be provided instructions on syncing your FitBit using your smartphone or computer. You will be asked to sync your FitBit at least once a week.
- **Charging the FitBit:** You will be asked to keep your FitBit charged. The FitBit battery last for about 5 days and takes about 1-2 hours to charge.
- If the watch is uncomfortable, we can provide you with a clip to wear it on a belt or pocket instead.
- **Reminders from Study Staff:** If you are not wearing, synching, or charging your FitBit, you may be called by study staff to check in and remind you to please do so.

After this week, you will be assigned by chance to a study group. Your chance of being assigned to each group is 1 in 2. Neither you nor the researcher(s) can choose the group to which you will be assigned.

Attend a baseline study visit

- You will attend a baseline visit at the Center for Community Health in City Heights, or at the UCSD Altman Clinical & Translational Research Institute. You will return the activity monitor, and we will check to make sure you wore it long enough. If you didn't, you will need to wear it for another week and come back another time.
- We will measure your height and weight and blood pressure, take a 10-minute walk to show you what moderate intensity activity, and talk to you about your current exercise.
- You will randomly be assigned to either receive the individually tailored multimedia physical activity intervention, or to receive only a Fitbit.
- If you are assigned to the multimedia intervention, you will talk to a member of the research team about physical activity goals and discuss any problems or concerns you may have with being active. You will be given a username and password for the study website, and the research team will show you the features of the website. You will have a choice to be 'friends' with our study on Instagram, where we will post regular photos and videos about physical activity. **We will not look at your Instagram pictures or videos unless they are tagged with the study hashtag. We will NOT report the content of any pictures or videos to parents or anyone outside the study.**
- This session will last approximately one hour for those assigned to the multimedia intervention, and 30 minutes for those assigned to receive only a Fitbit.

Intervention

- If you are assigned to the multimedia intervention, during the next 12 months you will:

    - Fill out monthly surveys about your physical activity habits. These surveys take about 10-20 minutes to complete.
    - Receive regular text messages reminding you to access new features on the website, sync your Fitbit, and giving tips on physical activity
- We will call you on the phone one month after your first visit to see how you are doing and to answer any questions you may have at that point.

Follow Up Visits

- One week before your 6-month visit we will mail the red activity monitor to you, same as at the start of the study, along with some questionnaires. We will ask that you wear the monitor for 7 days and fill out the questionnaires. This will be repeated at 12 months.
- At 6 and 12 months, you will return to the Center for Community Health or UCSD ACTRI. We will measure your height, weight, and blood pressure again, and talk to you about your physical activity. Some of you will also be asked to tell us what you did and didn't like about the program.
- We may also ask if we can audio-record or monitor your in-person and telephone sessions with study staff. This is for training and quality control purposes and will not be used for any other purpose. Recordings will not contain any identifying information about you and will be labeled only with your study identification number. These recordings will be protected in the same manner that all study information is protected and will only be available to researchers and staff. These recordings will be maintained indefinitely. All audiotaping is optional. You have the right to request that the recording be stopped or erased in full or in part at any time.

    ____Yes, I agree to have the sessions recorded and understand my rights as described.
    ____No, I do not agree to have the sessions recorded.

    Subject Initials _____
    Staff Initials _____

How much time will each study procedure take, what is your total time commitment, and how long will the study last?

You will have four study visits: orientation (1 hour), baseline & randomization (30 minutes – 1 hour), and 6- and 12-month follow-up visits (30 minutes). Throughout the study, you should keep your Fitbit charged and synced. Charging takes 1-2 hours every 5 days, and syncing takes approximately 20 seconds at least once per week. The study will be running for approximately 4 years.

What risks are associated with this study?

Participation in this study may involve some added risks or discomforts. These include the following:

- Although increasing your physical activity can have great benefits, there is always some risk associated with exercise. You may find exercising uncomfortable. You may experience sprains or bone injuries. Heart attack and sudden death related to heart problems have been known to occur in people while they are exercising. However, this is very rare.
- You may experience some discomfort wearing the Fitbit wristband, including skin irritation

or rash if your skin is very sensitive. If the wristband is uncomfortable, you have the option of wearing the Fitbit on a clip instead.

- You may feel some embarrassment or discomfort sharing your Fitbit data with other participants in the study. However, your Fitbit account does not have to include your real name, and you can choose whether or not to participate in challenges that would show everyone your steps.
- There is also a potential risk of loss of confidentiality associated with this study. To minimize this risk, all paper study records are kept in locked filing cabinets in a locked file room. Only the principal investigator and key staff will have access to either the file room or the filing cabinets. All computerized study data is password protected and only accessible to study staff.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

What are the alternatives to participating in this study?
The alternatives to participation in this study are to participate in other health promotion programs in the community. You may also choose to learn more about exercise on your own.

What benefits can be reasonably expected?
There may or may not be any direct benefit to you. While we cannot guarantee any direct benefit from participating in this study, you may learn more about being active and become motivated to exercise more. The broader benefits are contributing to development of programs to help Latina girls become more physically active.

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. You decide whether or not you want to be in the study. If you decide to participate now, you can change your mind later and quit the study. If you decide that you no longer wish to continue in this study, it will not affect your current or future relationship with UCSD. You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your assent?
You may be withdrawn from the study for the following reasons:

1) If the researcher or your doctor feels it is best for you, they may choose to take you out of the study at any time before you complete the study.
2) You may also be withdrawn from the study if you do not follow the instructions given to you by the study personnel.

Will you be compensated for participating in this study?
All monetary compensation will be in the form of a gift card. You do not need to change your behavior (exercise more) to participate or receive the compensation. You will get $25 for completing baseline, and $50 for the 6 month, and 12 month visits, after you return the red activity monitor and complete the study visit. You will get a bonus ($25) for completing both 6

and 12 month visits, and, if you are in the control group, you will get $10 each month you keep your Fitbit synced at least weekly. You will also get to keep your Fitbit. If you are in the multimedia intervention group, you will receive $10 each month you complete your online questionnaires.

What are the costs? There will be no cost to you for participating in this study.

What if you are injured as a direct result of being in this study?
If you are injured or become ill as a direct result of this research study, you will be provided with medical care.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. All of your records from this study will be treated as confidential documents. All paper study records are kept in locked filing cabinets in a locked file room. Only the principal investigator and key staff will have access to either the file room or the filing cabinets. No information that identifies you will be collected online and data downloaded from online questionnaires will be stored in a secure study database. All computerized study data is password protected and only accessible to study staff. Research records may be reviewed by the UCSD Institutional Review Board, and the National Institute of Nursing Research (NINR).

Who can you call if you have questions? Dr. Britta Larsen and/or _____ has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Britta Larsen at 858-534-8426 or study staff at 619-416-1499.

Your Signature and Assent
You have received a copy of this assent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

_____ _____
Subject Signature Date

Human Research Protections Program
(858) 246-4777
(858) 246-3329 (FAX)

University of California, San Diego
9500 Gilman Drive, Mail Code 0052
La Jolla, CA 92093-0052

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The faculty and staff of the University of California, San Diego wish you to know:

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of a signed and dated written consent form when one is required.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

If you have questions regarding a research study, the researcher or his/her assistant will be glad to answer them. You may seek information from the Human Research Protections Program - established for the protection of volunteers in research projects - by calling (858) 246-4777 from 7:30 AM to 4:00 PM, Monday through Friday, or by writing to the above address.

University of California, San Diego
Parent Consent for Child to Act as a Research Subject

Chicas Fuertes

Who is conducting the study, why your child has been asked to participate, how she was selected, and what is the approximate number of participants in the study?
Dr. Britta Larsen and associates are conducting a research study to learn more about ways to help Latina girls be physically active. Your child has been asked to participate in this study because she is a Latina girl between the ages of 13 to 18. There will be approximately 200 participants in this study. The research is sponsored by the National Institute of Nursing Research.

Why is this study being done?
The purpose of this study is to test a 12-month physical activity intervention for young Latinas. The long term goal of this study is to provide valuable information on behavior change within Latino families, particularly adolescent Latina girls.

What will happen to her in this study and which procedures are standard of care and which are experimental?
This study is intervention-based, and all procedures involved are experimental. Her participation in the study will last 1 year (12 months). If she agrees to participate in this study, she will be asked to do the following:

Come to an in-person, orientation session where a research staff member will tell her about the study. She will then be asked to read and sign an assent form, and a parent will sign a consent form. If a parent/guardian is unable or would prefer not to attend the orientation session, s/he can read information about the study online, contact the study team with any questions, and then download and sign the permission form in advance. Your child will be required to bring the signed parent permission form if she attends the session without a parent or guardian. After she signs the assent form, she will fill out some questionnaires about health, health behaviors, such as being physically active, and her mood. **These questionnaires are only for research, and are not for diagnosing any physical or mental health problems. We may not tell her or you if her answers suggest she might have health problems, like depression.** This first session will last about one hour.

Afterwards, she will:

Wear a red activity monitor for 1 week. She will be asked to wear this monitor on her hip for seven days. It counts the number of "up and down" movements she makes. She will record the days and time that she puts the monitor on and takes it off. After she is finished wearing the monitor, she will bring it with her to her next visit occurring the following week. There will be no cost to her in the case that the activity monitor is lost or stolen. To reduce the risk of losing the activity monitor, research staff will provide instructions on how to wear it for the 7 days.

Wear and Sync a FitBit activity tracker

- The Fitbit is a watch sized, wrist worn, physical activity tracker.
- She will wear the Fitbit for a week at the beginning of the study to get an idea of how active she usually is. During this week she won't be able to see anything on the Fitbit. Then she will wear it for the rest of the study, and she will be able to use all the Fitbit tools.

- **Wearing the FitBit:** She will be asked to wear the FitBit as many hours (day and night) as possible.
- **Synching the FitBit:** She will be provided instructions on syncing her FitBit using her smartphone or computer. She will be asked to sync her FitBit at least once a week.
- **Charging the FitBit:** She will be asked to keep her FitBit charged. The FitBit battery last for about 5 days and takes about 1-2 hours to charge.
- If the watch is uncomfortable, we can provide her with a clip to wear it on a belt or pocket instead.
- **Reminders from Study Staff:** If she is not wearing, synching, or charging her FitBit, she may be called by study staff to check in and remind her to please do so.

After this week, your child will be assigned by chance to a study group. Your child's chance of being assigned to each group is 1 in 2. Neither you, your child, nor the researcher(s) can choose the group to which your child will be assigned.

Attend a baseline study visit

- She will attend a baseline visit at the Center for Community Health in City Heights, or at the UCSD Altman Clinical & Translational Research Institute. She will return the activity monitor, and we will check to make sure she wore it long enough. If she didn't, she will need to wear it for another week and come back another time.
- We will measure her height and weight and blood pressure, take a 10-minute walk to show her what moderate intensity activity, and talk to she about her current exercise.
- She will randomly be assigned to either receive the individually tailored multimedia physical activity intervention, or to receive only a Fitbit.
- If she is assigned to the multimedia intervention, she will talk to a member of the research team about physical activity goals and discuss any problems or concerns she may have with being active. She will be given a username and password for the study website, and the research team will show her the features of the website. She will have a choice to be 'friends' with our study on Instagram, where we will post regular photos and videos about physical activity. **We will not look at her Instagram pictures or videos unless they are tagged with the study hashtag. We will NOT report the content of any pictures or videos to parents or anyone outside the study.**
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Intervention

- If she is assigned to the multimedia intervention, during the next 12 months she will:
    - Fill out monthly surveys about her physical activity habits. These surveys take about 10-20 minutes to complete.

    - Receive regular text messages reminding her to access new features on the website, sync her Fitbit, and giving tips on physical activity
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Follow Up Visits

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- We may also ask if we can audio-record or monitor her in-person and telephone sessions with study staff. This is for training and quality control purposes and will not be used for any other purpose. Recordings will not contain any identifying information about her and will be labeled only with her study identification number. These recordings will be protected in the same manner that all study information is protected and will only be available to researchers and staff. These recordings will be kept indefinitely. All audiotaping is optional. You or your child have the right to request that the recording be stopped or erased in full or in part at any time.

    ____Yes, I agree to have the sessions recorded and understand my rights as described.
    ____No, I do not agree to have the sessions recorded.

    Subject Initials _____
    Staff Initials _____

How much time will each study procedure take, what is her total time commitment, and how long will the study last?

She will have four study visits: orientation (1 hour), baseline & randomization (30 minutes – 1 hour), and 6- and 12-month follow-up visits (30 minutes). Throughout the study, she should keep her Fitbit charged and synced. Charging takes 1-2 hours every 5 days, and syncing takes approximately 20 seconds at least once per week. The study will be running for approximately 4 years.

What risks are associated with this study?

Participation in this study may involve some added risks or discomforts. These include the following:

- Although increasing her physical activity can have great benefits, there is always some risk associated with exercise. She may find exercising uncomfortable. She may experience sprains or bone injuries. Heart attack and sudden death related to heart problems have been known to occur in people while they are exercising. However, this is very rare.
- She may experience some discomfort wearing the Fitbit wristband, including skin irritation or rash if her skin is very sensitive. If the wristband is uncomfortable, she can choose to wear the Fitbit on a clip instead.

- She may feel some embarrassment or discomfort sharing her Fitbit data with other participants in the study. However, her Fitbit account does not have to include her real name, and she can choose whether or not to participate in challenges that would show everyone her steps.

- There is also a potential risk of loss of confidentiality associated with this study. To minimize this risk, all paper study records are kept in locked filing cabinets in a locked file room. Only the principal investigator and key staff will have access to either the file room or the filing cabinets. All computerized study data is password protected and only accessible to study staff.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

What are the alternatives to participating in this study?
The alternative to participation in this study is to participate in other health promotion programs in the community. She may also choose to learn more about exercise on her own.

What benefits can be reasonably expected?
There may or may not be any direct benefit to her. While we cannot guarantee any direct benefit from participating in this study, she may learn more about being active and become motivated to exercise more. The broader benefits are contributing to development of programs to help Latina girls become more physically active.

Can she choose to not participate or withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. She decides whether or not she wants to be in the study. If she decides to participate now, she can change her mind later and quit the study. If she decides that she no longer wishes to continue in this study, it will not affect her current or future relationship with UCSD. She will be told if any important new information is found during the course of this study that may affect her wanting to continue.

Can she be withdrawn from the study without her assent?
She may be withdrawn from the study for the following reasons:

1) If the researcher or her doctor feels it is best for her, they may choose to take her out of the study at any time before she completes the study.
2) She may also be withdrawn from the study if she does not follow the instructions given to her by the study personnel.

Will she be compensated for participating in this study?
All monetary compensation will be in the form of a gift card. She does not need to change her behavior (exercise more) to participate or receive the compensation. She will get $25 for completing baseline, and $50 for the 6 month, and 12 month visits, after she returns the red activity monitor and completes the study visit. She will get a bonus ($25) for completing both 6 and 12 month visits, and, if she is in the control group, she will get $10 each month she keeps her

Fitbit synced at least weekly. She will also get to keep her Fitbit. If she is in the multimedia intervention group, she will receive $10 each month she completes her online questionnaires.

What are the costs? There will be no cost to her for participating in this study.

What if she is injured as a direct result of being in this study?
If your child is injured as a direct result of this research study, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if your child is injured. You or your child may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about her confidentiality?
Research records will be kept confidential to the extent allowed by law. All of her records from this study will be treated as confidential documents. All paper study records are kept in locked filing cabinets in a locked file room. Only the principal investigator and key staff will have access to either the file room or the filing cabinets. No information that identifies her will be collected online and data downloaded from online questionnaires will be stored in a secure study database. All computerized study data is password protected and only accessible to study staff. Research records may be reviewed by the UCSD Institutional Review Board, and the National Institute of Nursing Research (NINR).

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Your Signature and Assent
You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to allow your child to participate.

_____ _____
Parent/Guardian Signature Date

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University of California, San Diego
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- We will call you on the phone one month after your first visit to see how you are doing and to answer any questions you may have at that point.

Follow Up Visits

- One week before your 6-month visit we will mail the red activity monitor to you, same as at the start of the study, along with some questionnaires. We will ask that you wear the monitor for 7 days and fill out the questionnaires. This will be repeated at 12 months.
- At 6 and 12 months, you will return to the Center for Community Health or UCSD ACTRI. We will measure your height, weight, and blood pressure again, and talk to you about your physical activity. Some of you will also be asked to tell us what you did and didn't like about the program.
- We may also ask if we can audio-record or monitor your in-person and telephone sessions with study staff. This is for training and quality control purposes and will not be used for any other purpose. Recordings will not contain any identifying information about you and will be labeled only with your study identification number. These recordings will be protected in the same manner that all study information is protected and will only be available to researchers and staff. These recordings will be maintained indefinitely. All audiotaping is optional. You have the right to request that the recording be stopped or erased in full or in part at any time.

  ____Yes, I agree to have the sessions recorded and understand my rights as described.
  ____No, I do not agree to have the sessions recorded.

  Subject Initials _____
  Staff Initials _____

How much time will each study procedure take, what is your total time commitment, and how long will the study last?

You will have four study visits: orientation (1 hour), baseline & randomization (30 minutes – 1 hour), and 6- and 12-month follow-up visits (30 minutes). Throughout the study, you should keep your Fitbit charged and synced. Charging takes 1-2 hours every 5 days, and syncing takes approximately 20 seconds at least once per week. The study will be running for approximately 4 years.

What risks are associated with this study?

Participation in this study may involve some added risks or discomforts. These include the following:

- Although increasing your physical activity can have great benefits, there is always some risk associated with exercise. You may find exercising uncomfortable. You may experience sprains or bone injuries. Heart attack and sudden death related to heart problems have been known to occur in people while they are exercising. However, this is very rare.
- You may experience some discomfort wearing the Fitbit wristband, including skin irritation or rash if your skin is very sensitive. If the wristband is uncomfortable, you have the option of wearing the Fitbit on a clip instead.
- You may feel some embarrassment or discomfort sharing your Fitbit data with other participants in the study. However, your Fitbit account does not have to include your real name, and you can choose whether or not to participate in challenges that would show everyone your steps.
- There is also a potential risk of loss of confidentiality associated with this study. To

minimize this risk, all paper study records are kept in locked filing cabinets in a locked file room. Only the principal investigator and key staff will have access to either the file room or the filing cabinets. All computerized study data is password protected and only accessible to study staff.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

What are the alternatives to participating in this study?
The alternatives to participation in this study are to participate in other health promotion programs in the community. You may also choose to learn more about exercise on your own.

What benefits can be reasonably expected?
There may or may not be any direct benefit to you. While we cannot guarantee any direct benefit from participating in this study, you may learn more about being active and become motivated to exercise more. The broader benefits are contributing to development of programs to help Latina girls become more physically active.

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. You decide whether or not you want to be in the study. If you decide to participate now, you can change your mind later and quit the study. If you decide that you no longer wish to continue in this study, it will not affect your current or future relationship with UCSD. You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study for the following reasons:

1) If the researcher or your doctor feels it is best for you, they may choose to take you out of the study at any time before you complete the study.
2) You may also be withdrawn from the study if you do not follow the instructions given to you by the study personnel.

Will you be compensated for participating in this study?
All monetary compensation will be in the form of a gift card. You do not need to change your behavior (exercise more) to participate or receive the compensation. You will get $25 for completing baseline, and $50 for the 6 month, and 12 month visits, after you return the red activity monitor and complete the study visit. You will get a bonus ($25) for completing both 6 and 12 month visits, and, if you are in the control group, you will get $10 each month you keep your Fitbit synced at least weekly. You will also get to keep your Fitbit. If you are in the multimedia intervention group, you will receive $10 each month you complete your online questionnaires.

What are the costs? There will be no cost to you for participating in this study.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of this research study, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. All of your records from this study will be treated as confidential documents. All paper study records are kept in locked filing cabinets in a locked file room. Only the principal investigator and key staff will have access to either the file room or the filing cabinets. No information that identifies you will be collected online and data downloaded from online questionnaires will be stored in a secure study database. All computerized study data is password protected and only accessible to study staff. Research records may be reviewed by the UCSD Institutional Review Board, and the National Institute of Nursing Research (NINR).

Who can you call if you have questions? Dr. Britta Larsen and/or _____ has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Britta Larsen at 858-534-8426 or study staff at 619-416-1499.

Your Signature and Consent
You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

_____ _____
Subject Signature Date

Human Research Protections Program
(858) 246-4777
(858) 246-3329 (FAX)

University of California, San Diego
9500 Gilman Drive, Mail Code 0052
La Jolla, CA 92093-0052

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The faculty and staff of the University of California, San Diego wish you to know:

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of a signed and dated written consent form when one is required.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

If you have questions regarding a research study, the researcher or his/her assistant will be glad to answer them. You may seek information from the Human Research Protections Program - established for the protection of volunteers in research projects - by calling (858) 246-4777 from 7:30 AM to 4:00 PM, Monday through Friday, or by writing to the above address.