Informed Consent for the Spark Trial

Grant Title:	Optimizing self-monitoring in a digital health intervention for weight loss
Principal Investigator:	Michele L. Patel, PhD (michele.patel@stanford.edu)
Sponsor:	Stanford University
Trial Registration:	ClinicalTrials.gov Identifier NCT05249465
IRB eProtocol Number:	64716
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Current Version Date:	July 2, 2024

CONSENT TO PARTICIPATE IN A RESEARCH STUDY
STANFORD UNIVERSITY

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FOR QUESTIONS ABOUT THE STUDY, CONTACT: Protocol Director, Michele Patel, PhD: 650-549-7047; 3180 Porter Drive, Palo Alto, CA 94304-1334.

Alternative Contact: Abby King, PhD: [redacted]

SUMMARY: The proposed research is testing ways to improve behavioral weight loss interventions for adults with overweight or obesity. Your consent is being sought for research and your participation is voluntary. The research will last 6 months and is entirely remote. Some individuals will be asked to track their dietary intake, steps, and/or body weight. All participants will receive weekly lessons and action plans. While there is no guarantee of benefit, all participants will receive evidence-based behavioral strategies that have been associated with weight loss. The research procedures are not invasive and pose minimal risk to participants. Promoting weight loss through behavioral intervention strategies for adults with overweight/obesity is consistent with recommendations put forth by the U.S. Preventive Services Task Force.

PURPOSE OF RESEARCH

You are invited to participate in a research study on developing a new weight loss program for adults. The goal of the study is to find the best strategies for tracking your behaviors. The program seeks to help people lose weight and improve health through changes in diet and physical activity. The study is entirely remote, meaning we will never ask you to come in-person for study visits.

The research study is looking for 176 adults (18+ years) with overweight or obesity, who live in the United States.

If you decide to terminate your participation in this study, you should notify Dr. Michele Patel at michele.patel@stanford.edu or 650-549-7047.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 6 months.

PROCEDURES

If you are eligible and decide to participate in this study, you will be asked to:

- Participate for 6 months in the research study.
- Provide your contact information – including telephone number, email address, and home/mailing address – as well as that of a close friend, relative, or other contact person in case we have difficulty reaching you.
- Complete 4 remote assessments during the study: at the beginning ("baseline"), at 1 month, at 3 months, and at 6 months. At each assessment, we will ask you to weigh yourself. We will provide a scale for doing so. We will also email or text you online surveys to be completed. One survey will ask questions such as about your health, beliefs, mood, and background (e.g., age, gender). A separate set of dietary recall surveys will ask about your eating habits.
- After completing the baseline assessment, you will be randomly placed (i.e., like flipping a coin) to test up to three strategies for tracking strategies for weight loss: (1) your dietary intake, which involves tracking everything you eat and drink during the day via the Fitbit app, (2) your steps, which involves tracking your steps every day via a Fitbit activity monitor, and/or (3) your body weight, which involves tracking your weight every day via a Fitbit or Withings "smart scale." If you are assigned to

track your steps, we will mail you an activity monitor. You will have a 12.5 percent chance of being assigned to each group.

- Install the Fitbit and Withings (when applicable) apps on your smartphone that sync with devices we give you so that we can track your progress along the way. We will provide instruction on how to get the apps (they are free). We will create a new account for each of these apps and request that you let us know if any changes are made to the account username or password. These devices will generate, access, and store your data. The data will be synced with Fitabase, which is a web platform that will collect and share these data with the research team.

- To participate in the study, you must accept Fitbit's and Withings' Privacy Policy and Terms of Service (which are standard when downloading any commercial app on your smartphone); you can view these documents on your smartphone, by going to the "Account" page in the Fitbit app, under the "License and Legal" section. On the Withings app, you can go to Settings, then go to the Help section. They also can be viewed on www.Fitbit.com or www.Withings.com.

- Review (a) weekly lessons on diet and physical activity and (b) weekly feedback on your progress. These will be emailed to you.

- Complete a brief online survey each week to create an action plan for how to achieve your goals.

- A subset of participants will be randomly chosen to engage in a remote orientation session prior to enrolling in the weight loss study. This session will last approximately 20 minutes.

- A subset of participants will be randomly chosen to participate in a 1:1 telephone- or Zoom -based interview to provide feedback about the weight loss program. The interview will last 30-45 minutes in length.

    - **Audiotaping:** The interview will be audio-taped to make sure the research staff correctly transcribe the conversation. After the study ends and the recordings are transcribed, we will destroy the audio recordings. If you do not wish to be audiotaped, you will not be eligible to participate in the interview.

The audiotape can be studied by the research team for use in the research project.

TIME INVOLVEMENT: Your participation in this research study will last up to 6 months. The baseline assessment will last approximately 60-90 minutes; the 1-month assessment will last approximately 5-10 minutes. The 3- and 6- month assessments will last approximately 30-60 minutes. For those assigned to view the orientation video, it will last approximately 20-25 minutes. For those participating in the telephone interview at the end of the study, the interview will last 30-45 minutes in length. During the weight loss intervention, daily tracking of behaviors is expected to take up to 20 minutes per day, and weekly review of lessons and feedback and completion of action plan surveys is expected to take 20-30 minutes per week.

Future Use of Private Information

Research using private information is an important way to try to understand human health and disease. You are being given this information because the investigators want to save private information for future research. Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Optional Procedure

Fitbit (owned by Google), Withings, and Fitabase are third-party companies that have their own Privacy Policies and Terms of Service. Participating in this optional part of the study may involve agreeing to these companies' Privacy Polices and Terms of Service; if you agree, we recommend that you review these documents before deciding to agree to participate in this portion of the research. We will provide the documents for you to review.

By checking the box below, you agree to participate in this optional portion of the study using Fitbit (owned by Google), Withings, and Fitabase:

___ Yes, agree

Please Initial: _____

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Complete all questionnaires and weight assessments.
- Keep your remote study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any adverse events that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Michele Patel at 650-549-7047.

Please note that if you withdraw from the study you have not withdrawn from Fitbit's or Withings' Privacy Policy or Terms of Service.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. In general, there will be low potential risk involved as a participant in this study. The Protocol Director and study staff have conducted similar studies over the past 20 years.

- There is a remote risk that persons completing questionnaires or interviews may feel uncomfortable. You have the right to refuse to take part in any part of the study, including answering particular questions.
- The physical risks in our study are consistent with typical risks associated with research participation in behavioral weight loss studies and are expected to be minimal. The strategies are in line with widely-disseminated guidelines that are directed to the general population. There are no invasive procedures planned. There is a small risk of injury consistent with initiation of a new physical activity program. Such injuries are usually temporary and minor (i.e., muscle fatigue and soreness). These risks are minimized by encouraging adults to gradually increase the frequency and intensity of physical activity, and engage in proper warm-up and cool-down before and after exercising. There is the possibility of adverse events ranging from minor musculoskeletal problems to, in very rare case cardiovascular events. Occasionally study participants experience minor orthopedic problems, but most are self-correcting with rest and standard first aid.
- If you become pregnant, we will ask you to leave the study. Changes in health behaviors and weight may not be healthy for a baby during pregnancy.
- If the study team think you should not continue in the study for health reasons, we will ask you to leave the study.
- Like most research studies, there is a risk of breach of confidentiality, such as when completing online questionnaires, using e-mail, using commercial products (such as an activity monitor), or using apps on your smartphone. The Fitbit app, Withings app, Fitbit activity monitor, Fitbit (owned by Google) or Withings smart scale, and Fitabase software will have access to your data, including intake of foods and drinks consumed, physical activity, and body weight. Information collected by the Fitbit mobile app and Withings mobile app are subject to the terms of use.

Many apps make claims that they are secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded/installed carries potential security risks, and Stanford cannot guarantee that the mobile app is free of risk. We encourage you to limit personal identifiers entered into the app to only those that they wish to voluntarily share with others. Fitabase has been used in over 1,100 research studies around the world, including those at Stanford. This web-based platform implements robust industry standards to maintain secure databases and keep data private.

- It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile app from your device.

- To minimize risks of breach of confidentiality, we will assign a Participant ID number (rather than writing your name on documents) and store all individual data in password-protect files and in encrypted data servers at Stanford. Only trained study staff will have access to the individual data. When we interview you, we will speak to you in a private location. Participants will not be identified by name in any reports or publications, nor will data be presented in such a way that the identity of individual participants can be inferred.

- You should talk with study staff if you have any questions.

POTENTIAL BENEFITS

Participants will receive tested behavioral program components that have been associated with weight loss. The direct benefits of participating in this intervention may include improvement in lifestyle behaviors and weight loss. Participation in the study helps us learn more about ways to develop effective treatments for individuals seeking to lose weight through behavior change strategies. We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

The alternative is not to participate.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your willingness to continue participation in this study.

ClinicalTrials.gov

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

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or specimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or specimens

protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Diabetes and Digestive and Kidney Diseases which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

This study seeks to develop a new, remote weight loss program for adults. The goal of the study is to find the best strategy for tracking your behaviors. The program seeks to help people lose weight and improve health through changes in diet and physical activity. The study is entirely remote, meaning we will never ask you to come in-person for study visits.

All participant information collected in the context of this study will be considered confidential and only be used by the research study team. Information about the study will be sent in reports to the NIH/NIDDK in a de-identified way. Participants will not be identified by name in any reports or publications, nor will data be presented in such a way that the identity of individual participants can be inferred.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study.

Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Michele Patel, 3180 Porter Drive, Palo Alto, CA 94304-1334.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, weight, height, physical activity (e.g., # of steps), dietary information, health insurance status, and presence/absence of select health conditions and related medications (e.g., prediabetes, type 2 diabetes, hypertension, cardiovascular event, pregnancy/ breastfeeding status, eating disorder, schizophrenia, cancer, end stage renal disease, physical limitation preventing engaging in moderate forms of physical activity).

HIPAA identifiers collected will include: Name; Telephone number(s); street address, city, zip code; birth date; Electronic mail addresses; voice (for qualitative interviews that are recorded). Other identifiers (e.g., Social Security number and driver's license) may be requested if needed for participant reimbursement purposes.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Michele Patel, PhD

- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- Fitbit (including via their mobile app, activity monitor, and smart scale), Withings (including the smart scale), RAZR Storefront (for ordering Fitbit devices), and Fitabase software
- Home Row, Inc (a professional transcription service)
- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Institutes of Health/NIDDK

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2050 or when the research project ends, whichever is earlier.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

FINANCIAL CONSIDERATIONS

Payment

- If you participate in the weight loss study, you will receive $20 at your 3-month assessment and $30 at your 6-month assessment.
- You will receive an additional $10 if you complete 4 dietary recall measures.
- If you participate in the phone interview, you will receive $25 for your time.
- In total, you could receive up to $85 for participating in the study.
- You will receive an electronic gift card for these payments.
- You will be provided with a smart scale (and may receive a Fitbit activity monitor) if you choose to participate in the study. You will not be responsible for any loss or damages done to the devices during the study; however, we ask that you treat the devices carefully given our inability to replace them if lost or damaged.

Sponsor

- NIH/NIDDK is providing financial support and/or material for this study.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist

you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Michele Patel, PhD at 650-549-7047. You should also contact her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Protocol Director, please contact Abby King, PhD at [redacted]

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;

- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- 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.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant