A Behavior Change Technique (BCT) intervention to develop an hourly activity habit among caregivers for persons with Alzheimer's Disease (AD) or Alzheimer's Disease Related Dementias (ADRD)

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Northwell Health

Consent for Participation in a Research Study

Study Title: A Behavior Change Technique (BCT) intervention to develop an hourly activity habit among caregivers for persons with Alzheimer's Disease (AD) or Alzheimer's Disease Related Dementias (ADRD)

Principal Investigator: Ashley Goodwin, PhD

Sponsor: National Institute of Aging

Important information about this research
You are being asked to participate (take part) in a research study.

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

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. The purpose of a research study is to answer important scientific questions. These questions might change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study. You may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits you are entitled to. This study may enroll employees/affiliates of Northwell Health. Employee participation or non-participation will not affect an employee's position at Northwell Health or their ability to receive medical care.
Why is this research study being done?	The purpose of this study is to test how text message behavior change techniques (BCTs) can help people develop an hourly walking habit for 4 hours each day. This research will enroll caregivers of individuals with Alzheimer's Disease or related dementias.
What will happen to me during the study?	For the first two weeks we will learn about your usual activity. You will be asked to complete 2 surveys and wear a Fitbit activity tracker each day for at least 10 hours per day. If you are eligible to continue the study, you will continue with weekly surveys and Fitbit wear. You will receive 4 daily behavior change techniques (BCTs) delivered by text message for the next 10 weeks. This is to see if BCTs help you create an hourly walking habit. The hourly walking habit is increasing the number of steps you usually take each hour by 250 steps, during a 4-hour time period that you choose. At the end of the study, we will send you a survey about caregiving and your experience in the trial.

How long will I participate?	If you choose to take part in this study, the study procedures will last for 12 weeks (~3 months).
Will taking part expose me to risks?	Risks (possibility of injury or harm) of participating in this study are minimal (slight). This means they are no greater than risks you may experience in everyday life. Risks you may experience include: • muscle soreness or fatigue from increasing your daily walking, • mild skin irritation (rash) on the wrist from wearing the Fitbit • A loss of privacy, or having your personal information shared with someone who is not on the study team The study team's plans for keeping your information private are described in the sections below.
Are there any benefits to participation?	This study may or may not benefit you. You may potentially develop a walking habit that may be beneficial to your overall health and wellbeing.
What are my alternatives to participation?	You do not need to participate in this study to try BCTs to create a walking habit. You easily can access information about BCTs and use them yourself.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Introduction
You are being asked to join a research study. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Why is this research study being done?
The purpose of this research study is to test how text message behavior change techniques (BCTs) can help develop an hourly walking habit. A BCT is a set of activities designed to change human behavior patterns. This research will enroll caregivers of individuals with Alzheimer's Disease or related dementias.

How many people will take part in this study?
This research study hopes to enroll 100 participants.

How long will you be in this study?
If you choose to take part in this study, the study procedures will last for 12 weeks (~3 months).

What will happen in this research study?

Study Period	What You Will Be Asked to Do
Getting Set Up ("Onboarding")	Complete survey questions about caregiving, stress, mood, and health
	Share how and when you prefer to be contacted by the study team
	Set up a Fitbit activity tracker we will ship to your home using detailed instructions. This includes downloading the Fitbit app to your smartphone and using or creating a Google account to log into the Fitbit app
	Wear a Fitbit activity tracker each day for at least 10 hours per day

<table>
<tr><td>First 2 Weeks (“Baseline Period”)</td><td>Complete weekly surveys</td></tr>
<tr><td colspan="2">To be eligible for the “intervention period” you must:
1. Wear the Fitbit for at least 10 hours per day for at least 12 days of the 14-day baseline period
2. Complete at least 1 of the 2 weekly survey measures
If you are unable to do this, you will not be eligible to continue the study. You will be withdrawn (removed).

Before the intervention period begins, you will complete a survey confirming your understanding of upcoming study activities. You will select a 4-hour block of time to walk 250 more steps per hour each day of the “intervention” period of the study.</td></tr>
<tr><td rowspan="4">Next 10 Weeks (“Intervention Period”)</td><td>View 7 text messages daily with BCTs. The BCT messages may ask you to:
1. Set a goal for your walking time,
2. Make a plan for your walking time,
3. Prompt you to walk during your chosen walking time (each hour during your chosen 4-hour block), and
4. Monitor your walking progress</td></tr>
<tr><td>Wear a Fitbit activity tracker each day for at least 10 hours per day</td></tr>
<tr><td>Complete a weekly survey</td></tr>
<tr><td>Receive reminder text messages, like about the weekly random lottery and to sync the Fitbit to your phone</td></tr>
<tr><td rowspan="2">End of Study</td><td>Complete survey questions about caregiving, stress, mood ,and health</td></tr>
<tr><td>Complete questions about your satisfaction and experience with the study</td></tr>
</table>

You will have the option of pausing your study if you experience an unexpected circumstance that prevents you from completing study activities (illness, injury, death in the family, etc.). You can resume your study once the circumstance has been resolved.

What are the risks of the research study? What could go wrong?
Although this is a minimal risk study, there are some potential risks to participating.

Side Effects from Increased Walking:
It is not expected that increased low-intensity walking by healthy people will pose risks greater than those in everyday life. It is possible that you may feel tired, or experience muscle soreness related to increased walking. If you are concerned about any of these side effects or any others you may experience, you should immediately stop walking and contact a member of the study team. You may still be able to continue with the study or you may be asked to end your participation in the study.

Fitbit Activity Tracker:

Participants may experience mild skin irritation (red rash) on the wrist from wearing an activity tracker. This usually resolves by removing the tracker for a few days and keeping the wristband dry.

Loss of Confidentiality or Privacy

One risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. We will only share necessary information about you (see "Who else will see your information?" section below). Any information collected during this study that can identify you by name will be kept confidential. We will separate your personal information (name, address, cell phone number) from all the information you provide us (this is called giving a "code" to your data). The key to your identifiable information will be stored in a secure, password-protected, HIPAA compliant database. Your questionnaire responses will be obtained by a text message link from a secure web application used to collect survey data. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised.

Questionnaires

Some of the questions we will ask you are personal. You may feel embarrassed or stressed. You may ask to see the questions before deciding whether to take part in this study.

What are the benefits of this research study?

This study may or may not benefit you directly. You may or may not experience any change in your walking behavior in response to the interventions. Increased walking may or may not benefit your overall health. We cannot promise direct benefits to others if you participate. A possible benefit to others includes learning how BCTs can help people create walking habits.

Will I receive my results?

You will not receive any individual study results. You will have access to your activity data through the Fitbit app on your phone.

If you do not want to take part in this research study, what are your other choices?

You do not need to participate in this study to try BCTs to create a walking habit. You easily can access information about BCTs and use them yourself.

Are there any costs for being in this research study?

This research study is funded by the National Institute for Aging (NIA), part of the National Institute for Health (NIH). The Fitbit activity tracker will be provided to you for no cost.

This study uses text messaging to deliver notifications, reminders, and surveys. Standard message and data rates from your wireless phone carrier may apply. You will not be paid back for any costs related to data usage or sending or receiving text messages by the study or by members of the study team.

Will you receive any payments for participating in this research study?
You will be able to keep the Fitbit (valued at about $160) as a "thank you" for your participation. You will be paid a $200 ClinCard for taking part in this study. A ClinCard is a card that can be used like a credit or debit card, including online. Payment will be made at the end of the study after completion of the final survey.

Every week during your intervention period you will be entered in a random (by chance) lottery. If you are selected, you will receive a $150 Clincard if you:

- Wore your Fitbit for at least 10 hours per day for 6 of 7 days that week, and
- answered the weekly survey from that week

You may be selected and win up to 10 times ($1,500 total) during the 10 weeks, though this is unlikely.

If the total payment you receive from Northwell Health during one calendar year is equal to $600 or more, the payment is required to be reported to the IRS. It is possible your study payment could end up totaling $600. If this occurs, the payment you receive on this study will be reported to the IRS. In this case, you will be issued a 1099 form. You will be required to provide your social security number at that time for reporting purposes. You will also be responsible for reporting this income while filing your tax return.

What are your rights as a research participant?
Your participation in this research project is voluntary. If you join the study, you may withdraw at any time without prejudice (negative impact) to your future care at Northwell Health. Whether you join, refuse to join, or decide to leave the study:

- the quality of your medical care at Northwell Health will be the same.
- the quality of medical care of those you provide care to if they are a Northwell patient will be the same.
- your employment status if you are a Northwell employee will be the same
- you will not be penalized or lose benefits you are entitled to.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to follow study procedures,
- it is not in your best interest to continue this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data already collected will continue to be used. You will be given the option to "partially withdraw" by continuing to share your Fitbit data for the rest of the 12-week trial. You will be given the option

to complete an end of study survey. However, no new data will be collected if you decide not to continue sharing your Fitbit data or answer the end of study survey.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect protected information such as your demographics, phone number, and address. We will collect protected health information directly from your Fitbit such as your step count and heart rate. The study team will stop collecting data from your Fitbit when your participation ends. This information could identify you. We will also collect answers to surveys about caregiving, your satisfaction, mood, stress, health and activity. We will only collect information needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your protected information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

This study uses a commercially available activity tracker produced by Fitbit, which is owned by Google. Google and Fitbit's Terms of Service and Privacy Policy are separate from this research consent form. Using the Fitbit™ activity tracker and app requires that you agree to the following:

Policy	Information in Policy	Website
Google's Terms of Service	Your legal rights when using Fitbit's products. These may differ from your rights as a participant in this study	https://policies.google.com/terms
Fitbit's Additional Terms of Service		https://support.google.com/product-documentation/answer/13511576
Google's Privacy Policy	Describe how Fitbit collects, uses, shares, and protects your data	https://policies.google.com/privacy
Fitbit's FAQs on Privacy		https://support.google.com/product-documentation/answer/13532616

We do not control these terms and policies. They can change at any time. You should read the terms and the policies before using the Fitbit activity tracker and app. You may want to check for any updates to Google and Fitbit policies. You should also review your privacy settings often. You can exercise your right to access your personal information by logging into your account and using your account settings. We do not have control over how Google/Fitbit will protect your data and privacy. For more information about the information that Fitbit may have access to, refer to Google's Privacy Policy and/or Fitbit's FAQs on Privacy.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

Investigators will share information collected from this research study with:

- The National Institutes of Health (NIH) and its authorized representatives

- study sponsor (National Institute on Aging) and/or its agents,
- other researchers,
- accrediting agencies,
- study Safety Officer,
- study collaborators at Columbia University,
- The Quantitative Intelligence team at Northwell's Feinstein Institutes for Medical Research, a group of data management professionals who support research studies in collecting and analyzing research data.

The following reviewers may access, inspect, and copy your study records:

- Representatives from Federal and state government oversight agencies, such as the Department of Health and Human Services
- Representatives from Northwell Health's Human Research Protection Program (a group of people that oversee research at this institution)
- Representatives from the National Institutes of Health, including the National Institute on Aging (the study sponsor)

We will do our best to protect the privacy of your study records. It is possible that once information is shared with people listed on this form it may be released to others. If this happens, your information may no longer be protected by federal law.

In the future, we may publish results of this study in scientific journals. We may present it at scientific meetings. If we do, we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research. It may be analyzed for many years. We will keep it as long as it is useful. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your information, you need to send a letter via email to the researcher at the following email address: RoybalTrials@northwell.edu

Your email needs to say that you have changed your mind and do not want the researcher to collect and share your information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?
De-identified (i.e. coded) data may be used for future research studies or shared with internal or external collaborators. Your data may be retained indefinitely in government-supported or

private databases developed to make data available to researchers [and/or a central storage facility for data called a repository]. Research results and data may be submitted to and shared via these entities.

A description of this clinical trial will be available on http://www.Clinical Trials.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 website at any time.

Certificate of Confidentiality
To help us protect your privacy, this research is covered by a Certificate of Confidentiality from the US Department of Health and Human Services (DHHS). The Certificate of Confidentiality means that researchers cannot be forced to identify you, even under a court subpoena. The Certificate does not mean the Secretary of DHHS approves or disapproves of the project. It adds special protection for the research information about you. You should know, however, that researchers may provide information to appropriate individuals or agencies if harm to you, harm to others or child abuse becomes a concern. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. However, if an insurer, employer or other person learns about your participation and gets your consent to receive research information, then the researchers will have to provide your information.

Will my information be used for research in the future?

Information collected from you for this research will be kept in an internal data registry and may be used for future research studies or shared with internal or external collaborators. Information like your name or other direct identifiers will be accessible by members of the study team, but all identifying information will be removed before any information is shared with researchers who are not part of the study team. By consenting to participate in this study you are agreeing to allow your data to be used by future researchers without additional consent.

Information collected during this study that can identify you will be kept to contact you, like for future participation in research studies. This information will be stored on a secure database. It will only be accessible by trained members of the study team. If you change your mind about being contacted in the future, you can notify the researcher.

Does the investigator of this study receive money if you take part?
The investigators on this study receive money to conduct the study. They do not financially benefit from your participation. The money they receive is to pay them back for the costs of conducting the research study. This research study is funded by the National Institutes of Health.

Who can answer your questions about this study?
If you have any questions about the study, you may call Dr. Ashley Goodwin at 646-995-8958. If you have questions about side effects or injury caused by research you should call Dr. Goodwin at 646-995-8958. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study,

or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910.

A signed copy of this consent form will be made available to you.

[Signature Page Follows]

Please respond to the following questions to demonstrate your understanding of study procedures and your rights as a research participant.

1. As a participant, I will be asked to wear my Fitbit at least 10 hours each day and answer weekly surveys.
    - ☐ True
    - ☐ False
2. As a participant, I will receive 7 daily BCTs (behavior change techniques) delivered by text message if I continue to the intervention period.
    - ☐ True
    - ☐ False
3. As a participant, I can remove myself from the study at any time by contacting the researcher.
    - ☐ True
    - ☐ False

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____ _____

Signature of **Legal** Name of Participant Date