COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
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YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL: SMILOW CANCER CENTER
Study Title: Assessing the feasibility of a patient-centered activity regimen in patients with lung cancer.

Principal Investigator: Brett Bade, MD. Yale University School of Medicine. Department of Internal Medicine. Section of Pulmonary and Critical Care. PO Box 208057. 300 Cedar Street. TAC -441 South. New Haven, CT 06520.

Funding Source: NIH

Invitation to Participate and Description of Project

You are invited to participate in a research study designed to look at the ability of a low-impact, individualized walking regimen to increase your physical activity. You have been asked to participate because you have lung cancer and a low physical activity level. This study is being performed at Yale University and the Medical University of South Carolina (MUSC; in Charleston, South Carolina).

Inactivity is associated with worse outcomes in patients with cancer and many other chronic diseases. Though activity appears to help patients with lung cancer, the "best" way to increase a patient's activity is not clear. The goal of this study is to evaluate if a new physical activity regimen that focuses on daily walking and motivational text messages can increase your activity level.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to participate in this study and meet inclusion criteria, several things will happen today:

1. We will ask you to complete 4 questionnaires today that evaluate your quality of life, shortness of breath, activity level, and symptoms of depression. Example questions are:
    a. "On a scale of 1-4, do you have any trouble taking long walks?"
    b. "How short of breath do you get when you exercise?"

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c. "In the last 2 weeks, how often have you felt tired or had little energy?"

2. We will obtain a blood sample (5 tubes; total of 39 mL of blood) to analyze levels of inflammation, metabolism and cancer markers.
3. We will have a short discussion about the potential benefits of physical activity in lung cancer.
4. We will discuss the design of this study, specifically that patients may be assigned to 1 of 2 groups. One of the groups will be asked to increase their activity; the other group will be asked to continue their current patterns. Both groups will receive FitBit® devices (i.e., accelerometers) by the end of the study.
5. If in the intervention group, we will provide you a FitBit Flex® at enrollment, ask you to wear it every day for 12 weeks, and request that you charge it every 3-4 days (or when the battery is low).
    a. We will download the FitBit® application to your smartphone.
    b. We will set up a generic Yale e-mail address and sign-in to the FitBit® application using that account.
    c. We will show you how to use the FitBit® and how to use the phone application.
6. If in the control group, we will provide you a FitBit® at the end of the study period. If desired, we can help you connect the device to your phone.
7. We will give you contact information for study personnel in case you have any questions or problems.

After you leave your visit, we will collect information about you from the medical record including your age, type of cancer, type of treatment, other medications you take, etc. This information will be used to determine if certain patients benefit more (or less) from physical activity. Patients will be enrolled at Yale and MUSC. The data that we will collect will be kept in a de-identified REDCap databases managed by Yale and MUSC. At the end of the study, the de-identified databases will be combined for review.

If enrolled the intervention group, starting the day after your enrollment, we will begin sending you text messages twice/day. These text messages will include your name, "gain-framed" messages (that focus on the benefits of walking), motivational statements, and summaries of how much you've walked. We will keep track of your step counts daily and record them. After one week, we will calculate an average of how far you've walked. After that, we will recommend that you walk a little farther than you walked the week before. Each week, we will calculate how far you walked and recommend that you walk a little farther than the week before. This process will continue for 3 months.

If your walking distance decreases, we will send you a text message reminder to wear the FitBit. If we don't see any information after 2 days, we will call you to ensure there is no problem with the device.

After 12 weeks, we will meet you at your next clinic appointment. At that time, we will ask you how the study went and if you had any problems during the study. We will ask you to complete 5 surveys evaluating your quality of life, shortness of breath, activity level, depression symptoms, feedback about the study, and draw another blood sample (5 tubes; total 39 mL of blood). If in the usual care group, we will provide a FitBit device. In either group, we will offer to help you add or remove the application from your phone (if you wish). If our study staff cannot meet you

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at a clinic visit within 4 weeks of completing the study, the final surveys will be mailed to you with a self-addressed envelope. As a last resort, surveys may be completed over the phone, and the FitBit device will be provided at an upcoming clinic visit or another meeting place agreed upon by you and the study staff.

Involvement in this study will not influence your cancer treatment. We have discussed your participation with your Oncologist to ensure that he or she agrees with your involvement. If you decide that you don't want to participate (at any time) please contact us, and we will stop monitoring your activity and sending you messages. If you choose not to participate in the study, it is reasonable to ask your physician for recommendations about low impact exercise. In addition, if you decide (at any time) that you no longer want to participate in the study, once we are notified the text messages and data collection will stop. Your medical card will not be affected in any way by choosing to stop participating in the study.

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.

Risks and Inconveniences

There is minimal risk to participation in this study. For the study, you will complete the surveys mentioned above, receive twice daily text messages for 3 months, and wear a physical activity monitor. Risks include:

- inconvenience or psychological discomfort from taking the surveys,
- annoyance from the text messages or wearing the activity monitor, or
- injury while increasing your daily walking distance.
- Blood draw- There is a small risk of bleeding, bruising, infection, inflammation, phlebitis, blood clot or discomfort at the site of the blood collection. You may feel dizzy, so we will ask you to lie down for a few minutes until any dizziness passes.

Your cell phone number may be made public through some oversight or data breach. The study team will make all necessary steps to protect you cell phone number and your identity during this study. The text message application is secure, password-protected, and HIPAA-compliant. Only you and members of the study team will have access to the website containing the data.

Participation in this study may involve risks that are currently not known.

Benefits

The overall goal of this research topic is to evaluate if low-impact physical activity improves quality of life, physical symptoms, and depression symptoms in patients with advanced lung cancer. Participation in this study may increase your physical activity level and may improve your quality of life.

We hope that this study will help us better understand if physical activity levels can be increased via a text message-based approach.

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Economic Considerations

There is no monetary compensation for participation in this study, though intervention group subjects will keep their FitBit® at the end of the study, and usual care group subjects will be provided the FitBit® at study completion. You will be responsible for your cell phone charges (including any charges resulting from the text messages). Though we will meet you at your standard of care clinic visits, the study will not pay for any part of these visits. You and/or your health plan/insurance will need to pay for your clinic visits.

Treatment Alternatives

You may choose not to participate in this study. If you are interested in safely increasing your physical activity but not participating in this study, you may ask your Oncologist for activity recommendations.

Optional Specimens for Future Storage

You are invited to allow some of your samples (called specimens) and related information to be stored (banked) for future research to investigate blood biomarkers associated with lung cancer. This may help researchers in the future learn more about how to prevent, find and treat lung cancer. Your specimens will be stored for an unlimited time. When your specimens and information are stored, we are careful to try to protect your identity from discovery by others. Your samples and information will receive a unique code. Other researchers, who may be located at other institutions, will only receive coded samples and information, and will not be able to link the code to you. Strict security safeguards are in place to reduce the chance of misuse or unplanned release of information. Using your specimens for research will probably not help you. We do hope the research results will help people in the future.

There is a risk that your information could be misused, such as loss of confidentiality. The chance of this happening is very small. We have protections in place to lower this risk such as only using ID number and date of collection on the samples. Your specimens and information will only be used for research and will not be sold. There is a possibility that this research may lead to development of products that will be commercialized. If this happens, there is no plan to share any financial gain with you.

Research results will not be returned to you or your doctor. If research results are published, your name and other personal information will not be given.

The choice to take part is up to you. You may choose not to let us store and use your samples, and your care will not be affected by this decision. If you change your mind, your samples will not be destroyed but the code connecting your identifiers to the samples will be deleted so your samples will then be anonymous. You can contact the study staff by phone or mail Dr. Brett Bade, Section of Pulmonary and Critical Care, 300 Cedar Street, TAC -441 South, New Haven, CT 06520-8057 to let them know that you have changed your mind about storing your identified samples and request your samples be made anonymous.

I give my permission for my blood sample to be stored and used for other studies related to lung disease after the end of the current study

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YES [ ] NO [ ]

I give my permission to be contacted following the end of this study regarding futurestudies.
YES [ ] NO [ ]

Confidentiality

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases.

All paper forms that you complete will be stored in a locked office in the Anlyan Building. Other than your signed consent form, paper forms will identify you by a patient ID number (rather than your name or medical record number). When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

Representatives from the Yale Human Research Protection Program, the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and/or date of birth. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator (PI) will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. The research team will only give this coded information to others to carry out this research study. The data will be kept in an anonymous form indefinitely. The information about your health that will be collected in this study includes:

- Medical and laboratory records of only those services provided in connection with this study.
  - Records about your Oncology visits
    Physical exams
    Laboratory, x-ray, and other test results may be reviewed
    Questionnaires
  - Records about any lung cancer treatment you received

Information about you and your health which might identify you may be used by or given to:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University and the Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all

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information confidential.

- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator: Brett Bade,MD
- Co-Investigators and other investigators
- Members of the research team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

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 biospecimens 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 biospecimens 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 Cancer Institute 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.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document including to investigators at Yale; the U.S. Department of Health and Human Services (DHHS) agencies; laboratories and other individuals and organizations that analyze your health information in connection with this study,

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according to the study plan; representatives from Yale University, the Human Investigation Committee, and the Yale Cancer Center Office of Protocol Review and Monitoring (OPRM), who are responsible for ensuring research compliance; the Principal Investigator (Brett Bade, M.D.), Co-Investigators and other investigators; Study Coordinator and Members of theResearch Team.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale New Haven Hospital is required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information; agreements are in place with these individuals and/or companies that require that they keep your information confidential.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

In Case of Injury

Low impact physical activity (e.g., walking) is considered safe for most patients with lung cancer. Though walking should not place you at higher risk, the study is monitoring for any muscle injuries, falls, hospitalizations, or ER visits that occur during the study period. Though likely not due to walking, if any of these events occur please contact the study team. If you are injured while on study, seek treatment and contact the study doctor as soon as you are able. You do not give up any of your legal rights by signing this form.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

Withdrawing from the Study

If you do become a subject, you are free to stop and withdraw from this study at anytime during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future data collection or text messages. Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors, with Smilow Cancer Center, or with Yale New Haven Hospital.

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When you withdraw from the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

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Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name of Subject:_____

Signature:_____

Relationship:_____

Date:_____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator:

Brett Bade, MD
Pulmonary and Critical Care Section
Department of Internal Medicine
Yale University School of Medicine
P.O. Box 208057
300 Cedar Street TAC - 441 South
New Haven, CT 06520-8057
Office: (203) 785-6670

If, after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

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