USC Division of Occupational Science and Occupational Therapy
1540 Alcazar St., CHP-133, Los Angeles, CA 90089

STUDY TITLE: Evaluation of a Complex Intervention for Young Adults with Diabetes: The Resilient, Empowered, Active Living-Telehealth (REAL-T) Study

PRINCIPAL INVESTIGATOR: Elizabeth Pyatak, PhD, OTR/L

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs, or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

Date: _____ Time: _____

Signature: _____
(Research Participant)

INFORMED CONSENT

STUDY TITLE:	Evaluation of a Complex Intervention for Young Adults with Diabetes: The Resilient, Empowered, Active Living-Telehealth (REAL-T) Study
PRINCIPAL INVESTIGATOR:	Elizabeth Pyatak, PhD, OTR/L
DEPARTMENT:	Occupational Science and Occupational Therapy
TELEPHONE NUMBER:	323-442-2615

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your personal doctor. You may find some of the language difficult to understand. If so, please ask questions. If you decide to participate, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?

This study is about a lifestyle redesign program for young adults who have diabetes. We would like to find out if this program can help individuals aged 18-30 in managing their diabetes. You are invited as a possible participant because you are 18-30 years old, have type 1 diabetes, and have had difficulty controlling your diabetes. About 210 individuals will participate in this study.

WHAT IS INVOLVED IN THE STUDY?

If you are eligible for the study and you agree to take part, you will be randomly (like flipping a coin) assigned to one of two groups – the occupational therapy group or the control group. You have a 50% chance of being in the occupational therapy group, and a 50% chance of being in the control group.

Whether you are in the occupational therapy group or the control group:

You will participate in a testing session once every three months for a year, for a total of five sessions (at enrollment, 3 months, 6 months, 9 months, and 12 months). At these testing sessions, we will test your A1C (average blood sugar level). We will collect blood using a standard finger-prick procedure, similar to testing your blood sugar with a handheld meter. If we are unable to test your A1C in person, we will give you a mail-in kit where you will prick your finger, similar to testing your blood sugar, and mail the kit to a laboratory.

During testing sessions, you will also answer some questionnaires about your health, everyday activities, and how you feel about diabetes. These questionnaires should take about 1 hour to complete.

During the testing sessions at enrollment, 6 months, and 12 months, we will also use a continuous glucose monitor (CGM) to measure your blood glucose levels. The monitor will be placed by a trained member of the research team and worn on the back of your arm for two weeks. If we are unable to apply the CGM in-person, we will mail you the CGM application kit with instructions along with a prepaid postage box to be mailed back. The CGM is about the size of a quarter and does not interfere with any of your usual activities. At the end of two weeks, you will remove the CGM and mail it to the research team in an envelope we provide. The sensor will not tell you what your blood glucose levels are, or alert you to high or low blood glucose levels. You should continue your usual diabetes self-care regimen while wearing the sensor, including checking your blood glucose as prescribed by your healthcare provider.

If you wear a personal CGM and do not wear the study CGM, we may request a report from your personal CGM.

The information from your surveys, A1C tests, and CGM will be labeled with a code, instead of your name. Documents that have your name (consent form, recruitment questionnaire and therapist's notes) will be stored separately. Only the research team will have access to these.

In addition to the testing sessions, we will invite you to complete a survey once a month through a secure electronic system, asking about how many medical visits you have had within the past month. The survey should take less than 5 minutes to complete.

The study activities in either group will not replace your usual source of medical care for diabetes, nor any other medical services received. You will continue to access services from your usual doctor or other care provider. If you are having difficulty with your diabetes care, you should contact your regular doctor for assistance.

If you are in the occupational therapy group:

You will continue to see your regular health provider for your diabetes care. In addition, an occupational therapist will help you make lifestyle changes that may help you with your diabetes care. You will work with the occupational therapist to consider changes in your daily routine that can help you care for your diabetes. Examples of lifestyle change include changing your diet, taking medications or checking blood sugar more often, or talking with your family about diabetes. You will work with the occupational therapist for about 12 hours over the course of 6 months, on a schedule determined by you and your occupational therapist. The first session will be held at your home or at another place of your choice. Subsequent sessions will be held using videoconferencing, where you will connect with the occupational therapist using video and audio on a computer, tablet, or smartphone.

If you do not have a computer, we will loan you a laptop computer (if you are within driving distance from the study office) for the duration of the intervention period. If you have a

computer without a webcam, we will give you a webcam to facilitate videoconferencing. If you are loaned a laptop, you will not be responsible for the cost of any necessary repairs.

You may have one or more of your sessions observed and/or recorded to evaluate and improve the quality of the treatment being delivered, and for the education and training of members of the research team. Your face may be shown in these recordings. You can choose whether or not you agree to be observed and to have your sessions recorded. If you agree to be observed, one or more of your treatment sessions may be attended by a supervisor. Additionally, one or more of your sessions may be recorded and saved on a secure drive within the Chan Division of OS/OT. The information in the session will remain confidential. The recording will be deleted after it has been reviewed by the research team for training purposes. You will be asked at the end of the consent form to agree or not agree to have your session(s) observed or recorded.

An Instagram account will be made available to intervention participants for additional resources and support. Following this Instagram account is optional. If you choose to interact by following the Instagram account, understand that your identity or information may be disclosed to other participants and followers. We cannot guarantee the privacy and confidentiality of any information you choose to share on social media. You should never expect information you share on this Instagram account to remain private. Remember to regularly visit the site privacy policies and update your own privacy settings.

The total time anticipated for your participation is 18 hours. This includes 12 hours of occupational therapy sessions, 5 hours for testing sessions, and 1 hour to respond to brief electronic surveys.

If you are in the control group:

You will continue to see your regular health provider for your diabetes care. You will not receive any study-related occupational therapy. The total time anticipated for your participation is 6 hours. This includes 5 hours for testing sessions and 1 hour to respond to brief electronic surveys.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You might have some or all of the following discomforts or risks if you take part in this study:

- If you are in the occupational therapy group, a suggestion from the occupational therapist may not work out properly. If this happens, you might have difficulty with your diabetes care. Since the program is designed to help with your diabetes care, this is unlikely to occur.

- There is a small risk that people who are not connected with this study will learn your identity or your personal information.

- You may feel uneasy or embarrassed when talking about your lifestyle. You can skip or refuse to answer any questions that make you feel uncomfortable.

- The finger prick for the A1C may cause momentary pain, similar to what you experience when pricking your finger to test your blood sugar.

- There is a low risk for developing a local skin infection at the site of the CGM sensor needle placement. Itchiness, redness, bleeding, and bruising at the insertion site may occur as well as local tape allergies. We will conduct a follow-up call to assess for any skin reaction. If you have a known tape allergy, you will be provided a non-adhesive or hypoallergenic alternative.

- We will ask you about your mental well-being. If you tell us that you are thinking about suicide, we will stop your study participation, and help you access mental health care.

- During our home visits, you may experience some events unrelated to our study. We will carry a source of glucose in the event that you experience hypoglycemia. We will also carry a cell phone to contact emergency services if needed.

WILL YOUR INFORMATION BE KEPT PRIVATE?

Officials sent by the funding agency, the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health, may look at your research records and medical records. The University of Southern California's Institutional Review Board (IRB) may review your records. The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. Other people who provide medical care, or who handle billing and payment at USC, may review your research records and medical records if necessary to conduct the research. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

You may not receive any direct benefit from taking part in this study. However, it is also possible that you may feel good about helping to develop a program to help people live better with diabetes.

WHAT OTHER OPTIONS ARE THERE?

An alternative would be not to participate in the study and continue your regular care. This study will in no way interfere with your current diabetes care.

WHAT ARE THE COSTS?

The study will pay for all research tests and procedures. You and/or your health plan/insurance will not be billed for tests and procedures that are done in this research.

ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

You will receive a total of $250 for your study participation:

- $50 gift card (or electronic payment) upon completion of the initial assessment
- $50 gift card (or electronic payment) upon completion of the 3-month assessment
- $50 gift card (or electronic payment) upon completion of the 6-month assessment
- $50 gift card (or electronic payment) upon completion of the 9-month assessment
- $50 gift card (or electronic payment) upon completion of the 12-month assessment

If you receive more than $600 per year for taking part in one or more research studies, including this study, you may be required to pay taxes on that money. This does not include any payments you receive to pay you back for expenses such as parking fees. You may receive an Internal Revenue Service (IRS) Form 1099 if you receive more than $600 in one year for taking part in one or more research studies.

WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?

If you think you have been hurt by taking part in this study, tell the principal investigator, Elizabeth Pyatak, immediately. You can call her at 323-442-2615 or email her at beth.pyatak@usc.edu. If you require treatment because you were injured from participating in this study, treatment will be provided. You and/or your health plan/insurance will be billed for this treatment. The study sponsor will not pay for this treatment.

There are no plans to offer any type of payment for injury. However, by signing this form you have not given up any of your legal rights.

WILL YOU RECEIVE NEW INFORMATION ABOUT THIS STUDY?

During the study, we may learn new things about the risks or benefits of being in the study. If we do, we will share this information with you. You might change your mind about being in the study based on this information. If new information is provided to you, we will ask for your agreement to continue taking part in this study.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this study is voluntary. Your decision whether or not to take part will not affect your current or future care. You are not giving up any legal claims or rights. If you do decide to take part in this study, you are free to change your mind and stop being in the study without penalty at any time. If you choose to stop being in the study, please call the telephone number at the beginning of this form to inform the researchers that you no longer wish to participate.

CAN YOU BE REMOVED FROM THE STUDY?

You may be removed from this study without your consent if you do not follow the investigator's instructions, at the discretion of the investigator, if your disease gets worse, or the researcher closes the study. If this happens, the investigator will discuss other options with you.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

You may contact Elizabeth Pyatak, PhD, OTR/L at 323-442-2615 with any questions, concerns, or complaints about the research or your participation in this study. If you feel you have been hurt by taking part in this study, please contact Elizabeth Pyatak at 323-442-2615. If you have questions, concerns, or complaints about the research and are unable to contact the research team, you may contact the Institutional Review Board (IRB) Office at 323-442-0114 between the hours of 8:00 AM and 4:00 PM. (Email at irb@usc.edu).

If you have any questions about your rights as a research participant, or want to talk to someone independent of the research team, contact the Institutional Review Board Office at the numbers above.

You will get a copy of this consent form.

Please initial your choice below to agree or not agree to have your sessions observed. **You may continue to participate in the study regardless of whether you agree to your sessions being *observed*.**

_____ I agree to have my occupational therapy sessions observed.

_____ I do not agree to have my occupational therapy sessions observed.

Please initial your choice below to agree or not agree to have your sessions recorded. **You may continue to participate in the study regardless of whether you agree to your sessions being *recorded*.**

_____ I agree to have my occupational therapy sessions recorded.

_____ I do not agree to have my occupational therapy sessions recorded.

AGREEMENT:

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Name of Research Participant	Signature	Date Signed

I have personally explained the research to the research participant and answered all questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed

A witness is required when: (1) the participant cannot see, read, write, or physically sign the consent form, or (2) the Short Form method is used to obtain consent. In these situations, the witness must sign and date the consent form. If no witness is needed, leave this signature line blank.

Name of Witness	Signature	Date Signed