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)

Study ID: HS-18-00633 Valid From: 5/3/2022 To: 5/2/2023

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INFORMED CONSENT FOR RESEARCH

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

INTRODUCTION

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. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. A copy of the signed form will be provided to you for your records.

PURPOSE

The purpose of this study is to see if you are eligible to take part in additional research about a lifestyle redesign program for young adults (18-30 years old) who have type 1 diabetes. This study is the first phase of a two-part study. In this screening phase, we want to check your A1C level to see if you are eligible to take part in the second phase. You are invited as a possible participant because you have type 1 diabetes. About 210 participants will take part in the study. This research is being funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH).

PROCEDURES

If you decide to take part, this is what will happen:

1. We will test your A1C (blood sugar level) by collecting blood using a standard finger-prick procedure, similar to testing your blood sugar with a handheld meter.
2. The A1C analyzer will measure your A1C level. The entire process should take about 10 minutes. The data collector will let you know the results of the A1C test.
3. 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 you will mail the kit to the laboratory.

4. We will then determine if you are eligible for phase 2 of the study based on your A1C.

5. If you are eligible and decide to take part in phase 2 of the study, you will sign a separate consent form for that phase of the study. If you are not eligible, you will not be asked to participate in phase 2.

RISKS AND DISCOMFORTS

Possible risks and discomforts you could experience during this study include:

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

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

Unforeseen Risks: There may be other risks that are not known at this time.

BENEFITS

There are no direct benefits to you from taking part in this study.

PRIVACY/CONFIDENTIALITY

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who are required to review this information. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

The University of Southern California's Institutional Review Board (IRB) may review your records. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH) may also inspect and copy your information.

Your data or records will be retained for three years following the completion of the study. After that, the identifiers will be shredded and/or purged.

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

ALTERNATIVES

An alternative would be to not participate in this study.

PAYMENTS

You will not be compensated for your participation in this study.

COST

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.

VOLUNTARY PARTICIPATION

It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled. If withdrawal must be gradual for safety reasons, the study doctor will tell you.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can continue to collect data from your records. If you agree, this data will be handled the same as the research data. No new information or samples will be collected about you or from you by the study team without your permission.

The study site may still, after your withdrawal, need to report any safety event that you may have experienced due to your participation to all entities involved in the study. Your personal information, including any identifiable information, that has already been collected up to the time of your withdrawal will be kept and used to guarantee the integrity of the study, to determine the safety effects, and to satisfy any legal or regulatory requirements.

CONTACT INFORMATION

If you have questions, concerns, complaints, or think the research has hurt you, talk to the study investigator, Elizabeth Pyatak, PhD, OTR/L, at 323-442-2615

This research has been reviewed by the USC Institutional Review Board (IRB). The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. Contact the IRB if you have questions about your rights as a research participant or you have complaints about the research. You may contact the IRB at (323) 442-0114 or by email at irb@usc.edu.

STATEMENT OF CONSENT

Research Participant
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 and Time Signed

Person Obtaining Consent
I have personally explained the research to the participant and I have answered all the participant's questions. I believe that the participant understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date and Time Signed

Witness
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 and Time Signed

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