Information Letter & Consent Form for Medly-SOLAR Research Project

centre for digital therapeutics

Participant ID:

Date:

Study Title:	Adapting the Skills fOr Life Adjustment and Resilience (SOLAR) Program to Support the Mental Health of Patients and Caregivers Living with Heart Failure
Principal Investigator:	Soyun Oh Medly Team, Centre for Digital Therapeutics, Toronto General Hospital Research Institute, University Health Network Soyun.Oh@uhn.ca
Supervisor:	Dr. Quynh Pham, PhD Affiliate Scientist, KITE, UHN Scientific Director and Principal Investigator, Centre for Digital Therapeutics, Toronto General Hospital Research Institute, UHN Assistant Professor, IHPME, University of Toronto Scientist, Techna Institute, UHN Adjunct Professor, Telfer School of Management, University of Ottawa AMS Fellow in Compassion and Artificial Intelligence Q.Pham@uhn.ca

STUDY INFORMATION

Introduction:

You are being invited to participate in a research project conducted by the Medly team at the Centre of Digital Therapeutics of the University Health Network. Please take your time to read the following information carefully.

Study Purpose:

The purpose of this study is to design and evaluate a module aimed at addressing the mental health needs of heart failure (HF) patients and their caregivers. The study will involve multiple phases, including needs assessment, prototyping, and usability testing of the module.

Study Procedures:

If you agree to participate, you will be asked to take part in a 1 to 1.5-hour virtual interview to share any mental health challenges you may experience as a heart failure patient/caregiver and provide your feedback on the new mental health module.

Data Collection:

The study may involve the collection of personally identifiable information, including demographic data (e.g., sex and gender, age, English fluency, digital literacy, and socio-economic status) and data related to your mental health and well-being (e.g., degree of depressive and anxiety symptoms). This information will be collected through interviews and surveys/questionnaires.

Inclusion Criteria:

You are eligible to participate if you are:

- Currently enrolled in the Medly program as a patient,
- Previously enrolled in the Medly program, or
- A caregiver of a current or former Medly patient.

Exclusion Criteria:

You are not eligible to participate if you possess severe medical or psychiatric conditions (e.g., severe cognitive deficits) that could interfere with treatment or pose safety risks.

Risks and Benefits:

There are minimal risks associated with this study. Potential benefits include contributing to the development of a mental health module that may improve support for HF patients and caregivers.

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Confidentiality:

Your identity will be kept confidential according to all applicable laws. All data collected will be anonymized and securely stored. Only the research team will have access to the data.

Voluntary Participation:

Your participation in this study is voluntary. You may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. A reminder that participating in the session is completely voluntary and your decision will have no impact on your care or care for your partner.

Compensation:

You will receive an e-voucher of $50 per session of the study.

Contact Information:

Feel free to ask any questions you may have before deciding whether or not to participate. If you have any questions about the study, please contact Soyun at Soyun.Oh@uhn.ca

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PARTICIPANT CONSENT

By signing below, you indicate that you have read the above information, that you have had the opportunity to ask questions, and that you voluntarily agree to participate in this study.

Patient Name

Patient Signature

Date

RESEARCHER STATEMENT

I confirm that I have explained the nature and purpose of the study to the participant, that I have answered any questions raised, and that, to the best of my knowledge, the participant has understood the information provided.

Researcher Name

Researcher Signature

Date

*Please note: a copy of this consent form will be provided to you for your records.

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