Official Grant Title: Virtual Human Technology for Patients with Chronic Pain

Working Title: Virtual Human–Delivered Interviews for Patients with Chronic Pain: Feasibility, Acceptability, and a Pilot Randomized Trial of Standard Medical, Psychosocial, and Educational Interviews

NCT #: 04349033

Date: July 22, 2019

Study Protocol

Abstract

Chronic pain is accompanied by a host of emotional, behavioral, and cognitive psychosocial consequences. At the same time, psychosocial factors contribute to chronic pain, including fear of movement and catastrophizing, maladaptive emotional and cognitive processes, and adverse life experiences. Treatment guidelines stress the importance of psychosocial aspects in pain management. Unfortunately, both patients and medical providers find it difficult to discuss psychosocial problems. The goal of this project is to remedy this critical problem by developing and pilot testing novel therapeutic interviews delivered by next-generation Virtual Humans (VHs) to help patients engage in discussions about pain-related psychosocial factors. In this IRB application, we will develop VH-assisted therapeutic psychosocial interviews specifically for chronic pain. Three Virtual Human interview scripts will be developed: One that facilitates participant disclosure of psychological distress, coping, medication usage, and stressful live events; one that mirrors this condition but includes explanations of how the mind contributes to chronic pain, and a control condition that asks about participants' medical history, medications, and chronic pain background. Adult patients who experience chronic musculoskeletal pain, are fluent in English, have no visual and cognitive impairment that would interfere with participation, have an average pain score of 4 or higher during the past week on a 0 to 10-point scale, and are receiving treatment for their chronic pain will be recruited through flyers from the Keck Medical School and invited to participate in a session with a Virtual Human at USC's Institute for Creative Technologies (ICT). Each patient who agrees to participate will come to ICT and will be assigned to one of the three VH conditions. The session at ICT consists of written informed consent followed by online questionnaires (e.g., demographics, mental and physical health, stressful live events, pain medication usage, coping), followed by the VH session, followed by post-session online questionnaires (e.g., satisfaction with the VH session), and then a brief structured interview with a research assistant about patients' experience with the VH. Patients will also be invited to participate in a brief online survey one month after the session with the VH at ICT. Patients will be compensated $70 via Amazon gift card for the 1 1/2 to 2 hour session at ICT and an additional $10 via Amazon gift card, if they agree to complete the online survey about one month after the study visit at ICT. Based on participant feedback (qualitative and quantitative), the Virtual Human interviews will be refined as necessary to improve the sessions.

Describe the inclusion criteria for enrollment.

Adult patients who experience chronic musculoskeletal pain (e.g., pain in the neck, back, arms, and legs) will be recruited via flyers from the Keck Medical School (e.g., the Keck Pain Center). Patients are eligible to participate if they (1) are 21 years or older, (2) experience chronic musculoskeletal pain (i.e., pain for at least three months), (3) are fluent in English, (4) have no visual/cognitive impairment that would interfere with participation in the study, (5) receive treatment for their chronic pain, and (6) report an average pain severity during the past week of 4

or greater on a 0 to 10 point scale, and (7) are willing to participate in a 1 1/2 to 2 hour session at USC's Institute for Creative Technologies.

Describe the exclusion criteria for enrollment.

1) younger than 21 years, (2) no chronic musculoskeletal pain, (3) not fluent in English, (4) visual/cognitive impairment that would interfere with participation in the study, (5) not in treatment for chronic pain, and (6) average pain severity during the past week lower than 4 on a 0 to 10 point scale, (7) not willing to participate in a 1 1/2 to 2 hour session at USC's Institute for Creative Technologies.

If there are any age, ethnic, language, or gender-based exclusion criteria, please provide justification.

Patients must be fluent in English and adults as the Virtual Human interview scripts are developed in the English language and for adults.

Research Objectives and Background

Describe the specific objectives or aims of the study and hypotheses or research questions.

The goal of this project is to develop three Virtual Human (VH) interview conditions for patients who experience chronic pain. Two of these VH conditions will focus on participants' disclosure of negative mood, psychological distress, coping with chronic pain, stressful live experiences, pain medication usage, and personality characteristics. The third condition is a control condition that focuses on the medical aspects of patients' chronic pain experience including their pain medication usage. In order to develop the best possible VH interviews, stakeholder feedback by patients is critical. We will, therefore, pilot test the three VH interviews with patients who experience chronic pain to get their qualitative (e.g., structured interview) and quantitative feedback (e.g., questionnaires) about their experience and how the VH interviews could be improved. In order to examine the best features of a Virtual Human coach, we will compare Virtual Humans that deliver the session either with a computer-generated voice or a voice recorded by a real person. Half of the patients in each of the three conditions will hear the computer-generated Virtual Human voice and the other half will hear the voice recorded by a real person. Patient feedback will tell us whether patients might prefer one Virtual Human voice over the other.

Chronic pain is accompanied by a host of emotional, behavioral, and cognitive psychosocial consequences. At the same time, psychosocial factors contribute to chronic pain, including fear of movement and catastrophizing, maladaptive emotional and cognitive processes, and adverse life experiences. Treatment guidelines stress the importance of psychosocial aspects in pain management. Unfortunately, both patients and medical providers find it difficult to discuss psychosocial problems. The goal of this project is to remedy this critical problem by developing and pilot testing novel therapeutic interviews delivered by next-generation

Virtual Humans (VHs) to help patients engage in discussions about pain-related psychosocial factors.

Provide a summary of the background of the study and explain how this research will contribute to existing knowledge. Describe previous work that provides a basis to show that the proposed research can be carried out without undue risk to human subjects. Include relevant citations.

Our team at the University of Southern California's Institute for Creative Technologies consists of world leaders in the development of Virtual Human technology for health research. ICT has successfully developed Virtual Human prototypes and conducted many research studies at USC that relate to the proposed project with minimal risk to participants.

Methods and Procedures - Prospective Studies

Describe in detail the design and methodology of the study. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation and endpoint definition. If applicable, include information on stratification or randomization plans. Include the frequency and duration of each activity and the total length of subject participation.

If patients volunteer to participate in this study, they will schedule an individual 1.5 to 2-hour session at USC's ICT. At ICT, they will first read and sign a study consent form before entering the study. They will also get a copy of the consent form to keep. The research team will answer any questions they may have about the study before patients decide to participate. Once patients have agreed to participate and signed the consent form, they will be asked to complete four parts of this study. These are:

1) an online general health and well-being survey (approx. 15-20 minutes),

2) an interview with a Virtual Human about their life with chronic pain (approx. 45-60 minutes)

3) an online questionnaire after their Virtual Human interview (approx. 15 minutes), and

4) an interview with research staff about their experience with the Virtual Human (approx. 15 minutes).

Patients' overall time commitment for this study is expected to be between 1 and 2 hours and they will be compensated with $70 via Amazon gift card for their participation in this session at ICT.

Patients will also be invited to complete a brief (approx. 15 minutes) online questionnaire

(e.g., about their continued satisfaction with the Virtual Human session) about one month after the session at ICT that they can complete from their home computer. If patients agree to complete the survey, they will receive an additional $10 via Amazon gift card.

Gift cards will be emailed to patients about 4 weeks after their participation in the ICT session and the one-month post ICT session online survey.

During their visit at ICT:

1) We will ask patients to complete different questionnaires pertaining to their demographics and medical background, their emotions, chronic pain management and medication usage, and stressful events. These questionnaires will be completed in an online survey before and after the interview with a Virtual Human and in the brief online survey about a month after the visit at ICT for the study.

2) Patients will also be asked to interact with a Virtual Human interviewer. This study has three different types of interviews, and patients will be assigned to one of them. In the course of this interaction, they will be asked to answer personal questions, such as about their emotions, stressful life experiences, how they cope with chronic pain, and their medical treatment and pain medication usage for chronic pain. The Virtual Human interview will be audio-recorded for analysis purposes.

3) At the end of the ICT study visit, we will ask patients to tell us about their experiences with the Virtual Human in a structured interview with our research staff. The goal of this interview is to learn how they felt about their interaction with the Virtual Human and if we can improve the interviews. This interview with research staff will also be audio-recorded for analysis purposes.

If patients do not want to be audio-recorded, they cannot participate in this research study.

Describe the statistical considerations for the study, how the sample size was determined, and how the results will be analyzed, if applicable.

Pilot studies typically consist of relatively small sample sizes and our proposed study sample consists of 35 to 50 patients. Given that this study will iteratively refine the Virtual Human interview scripts depending upon participant feedback, we will recruit up to 50 participants, if the Virtual Human scripts more need refinement. Patient feedback will be in the form of qualitative (e.g., a brief structured interview with a research assistant at ICT) and quantitative (e.g., standard questionnaires) data. These data will inform us whether the Virtual Human interview scripts function as intended, need improvement, and whether participants enjoyed the interaction with the Virtual Human. The majority of patients will be assigned to the two psychosocial Virtual Human conditions and fewer to the control condition.

Deception

Describe why the research cannot be carried out without deception.

The goal of this research is to develop Virtual Human interview scripts for patients with chronic pain. Prior research has shown that patients are often reluctant to open up about psychosocial aspects (e.g., anxiety, depression, stressful live events, pain medication usage) with their healthcare providers or other people. We are developing these Virtual Human-assisted interviews to remedy this problem and give patients a space to talk about these issues. As part of the development process of the scripts and potential necessary refinement, the Virtual Human cannot be fully automated yet but requires a research assistant to deliver the Virtual Human lines in real-time. Telling patients before the Virtual Human study session that the Virtual Human is controlled a real person would be counterproductive to patients' feeling that they can talk openly with a computer-generated character. ICT has successfully conducted similar studies that involved participant interaction with a human-controlled Virtual Human. We will debrief participants after the structured interview with the research assistant and are attaching the debriefing statement.