Spinal Cord Injury Program in Exercise

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03925077	RECRUITING	APRIL 23, 2019	FEBRUARY 17, 2021

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to examine two 8-week, remotely delivered exercise interventions: Movement-to-Music (M2M) and Standard Exercise Training (SET), with 327 adults with spinal cord injury. Enrolled participants will be randomized into one of three groups: a) M2M, b) SET, and c) attention control (AC).

Condition or Disease: Spinal Cord Injuries

Intervention/treatment: Other: Movement-to-Music
Other: Standard Exercise Training

Phase: N/A

DETAILED DESCRIPTION

The purpose of the Spinal Cord Injury Program in Exercise (SCIPE) study is to examine two 8-week, remotely delivered exercise interventions: Movement-to-Music (M2M) and Standard Exercise Training (SET), with 327 adults with SCI. The primary aim is to examine change in physical activity level after the 8-week M2M and SET interventions. We hypothesize that participants in M2M and SET will have significant increase in physical activity compared to an Attention Control (AC) group after the 8-week intervention. The secondary aim is to examine effects of the M2M and SET interventions on health and quality of life outcomes. We hypothesize that participants in M2M and SET will have significant increases in sleep quality and quality of life and decreases in pain and fatigue compared to AC after the 8-week intervention. Exercise enjoyment in M2M and SET participants will also be explored. The tertiary aim is to evaluate the demographic (age, race, sex), clinical (level of injury, type of injury), and psychosocial (social support, outcome expectations, self-efficacy, self-regulation) variables of two participant groups: 1) compliant participants who completed ≥ 50% of the intervention, and 2) noncompliant participants who completed post-testing but < 50% of the intervention or who did not complete post-testing.

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 327 participants

Intervention Model : Parallel Assignment

Masking: Single (Outcomes Assessor)

Primary Purpose: Other

Official Title: RERC on Technologies to Promote Exercise and Health Among People With Disabilities (A Scale Up Study Evaluating a Movement-to-Music Teleexercise Platform for Reaching a National Cohort of People With Spinal Cord Injury)

Actual Study Start Date: February 2021

Estimated Primary Completion Date: August 2022

Estimated Study Completion Date: September 2022

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Active Comparator: Movement to Music (M2M) All M2M sessions are delivered using videos uploaded to a secure study website (the SCIPE website). Participants in M2M will have access to the website and attend three 60-minute M2M sessions per week for a total of 8 weeks. Each session provides rhythmic-based exercises that are choreographed to music to target range of motion, muscular strength, cardiorespiratory fitness, and balance. In addition, participants in M2M will receive and read weekly educational articles on health and fitness through the SCIPE website.	Other: Movement-to-Music The M2M program has been developed for onsite instruction and will be repurposed into an eHealth version. The program is based on the positive effects of exercise and music on both physiological and psychosocial outcomes in people with disabilities. Investigators aim to advance our current M2M program by enabling more robust personalization features, allowing people with SCI to individualize their M2M program. Movement and tempo-based adaptations will also be available. A typical M2M session will consist of tailored movement routines starting with a warmup using range of motion exercises, followed by muscle strengthening, cardiorespiratory, and/or balance routines, and ending with a cool down emphasizing breathing and mindfulness.
Active Comparator: Standardised Exercise Training (SET) All M2M sessions are delivered using videos uploaded to the SCIPE website. Participants in SET will have access to the website and attend three 60-minute SET sessions per week for a total of 8 weeks. Each session provides traditional exercises that target range of motion, muscular strength, cardiorespiratory fitness, and balance. In addition, participants in M2M will receive and read weekly educational articles on health and fitness through the SCIPE website.	Other: Standard Exercise Training The SET program is based on the NCHPAD 14-Weeks to a Healthier You program launched in 2008. Exercise videos including range of motion, muscle strengthening, cardio and balance routines performed both seated and standing have been developed and will be restructured for use in this study. The SET program will be delivered through the same platform as M2M.

OUTCOME MEASURES

Primary Outcome Measures:	1. Changes from baseline physical activity level at week 8 [Time Frame: Baseline and post 8 week intervention] Physical activity is assessed using the Leisure Time Physical Activity Questionnaire for People with Spinal Cord Injury (LTPAQ-SCI). The LTPAQ-SCI is a 3-item, self-report questionnaire that measures the number of days and minutes people with SCI spend in mild, moderate, and heavy intensity leisure time physical activity in the last 7 days.
Secondary Outcome Measures:	1. Changes from baseline pain intensity week 8 [Time Frame: Baseline and post 8 week intervention] The intensity of pain is assessed using the NIH Patient-Reported Outcomes Measurement Information System (PROMIS®) Pain Intensity Adult Short Form 3a (v1.0). The instrument is a 3-item measure with the response scores ranging from 1 (Had no pain) to 5 (Very severe). Higher scores indicate higher pain intensity. The total raw score will be translated into a T-score for each participant for analysis. 2. Changes from baseline pain interference at week 8 [Time Frame: Baseline and post 8 week intervention] The influence of pain on performing daily activities is assessed with the NIH PROMIS Pain Interference Adult Short Form 8a (v1.0), which contains 8 items with 5 response options ranging from 1 (Not at all) to 5 (Very much). The form has raw scores range from 8 to 40, with higher scores indicating more pain interference. The total raw score will be translated into a T-score for each participant for analysis. 3. Changes from baseline sleep quality at week 8 [Time Frame: Baseline and post 8 week intervention] Sleep quality is assessed using the NIH PROMIS Sleep Disturbance Adult Short Form 8a, which contains 8 items on a 5-point Likert scale, ranging from 1 (Very much) to 5 (Not at all). The form has raw scores range from 8 to 40, with higher scores indicating worst sleep quality. The total raw score will be translated into a T-score for each participant for analysis. 4. Changes from baseline fatigue level at week 8 [Time Frame: Baseline and post 8 week intervention] Fatigue is measured using the NIH PROMIS Fatigue Adult Short Form. The instrument is a 8 items on a 5-point Likert scale, ranging from 1 (Not at all/Never) to 5 (Very much/Always). Higher scores indicate higher fatigue. The total raw score is translated into a T-score for each participant for analysis. 5. Changes from baseline health-related quality of life at week 8 [Time Frame: Baseline and post 8 week intervention] Health-related quality of life is assessed using the NIH PROMIS 10 Global Health Items. The Global-10 Health form is a 10-item measure with the response scores ranging from 1 (Poor/Not at all/Always/Very severe) to 5 (Excellent/Completely/Never/None). One question item, "how would you rate your pain on average?", is on a 11-point Likert scale that ranges from 0 (No pain) to 10 (Worst pain imaginable). Higher scores indicate better health-related quality of life. Two summary scores, a Global Physical Health score and a Global Mental Health score, can be derived from this instrument. 6. Changes from baseline ability to participate in social roles and activities at week 8 [Time Frame: Baseline and post 8 week intervention] Social participation is measured using the NIH PROMIS Ability to Participate in Social Roles and Activities Short Form 8a. The instrument is a 8-item measure with the response scores ranging from 1 (always) to 5 (never). The lowest possible total raw score is 8 and the highest possible score is 40. Higher scores indicate better ability to participate in social roles and activities. The total raw score is translated into a T-score for each participant for analysis. 7. Exercise enjoyment at week 8 [Time Frame: Post 8 week intervention] Exercise enjoyment is assessed using Physical Activity Enjoyment Scale. The Physical Activity Enjoyment Scale contains 8 items, with higher score indicates greater exercise enjoyment.
Other Outcome Measures:	1. Baseline self-efficacy [Time Frame: Baseline] Self-efficacy is measured using the Exercise Self-Efficacy Scale, which contains 8 items with response options of each item ranging from 0% (Not at all confident) to 100% (Highly confident). Higher scores indicate higher levels of exercise self-efficacy. 2. Baseline self-regulation [Time Frame: Baseline] Self-regulation is measured using the Exercise Goal-Setting Scale, which contains 10 items on a 5-point Likert scale that ranges from 1 (Does not describe) to 5 (Describes completely). A higher mean score indicate better goal-setting and self-monitoring for exercise. 3. Baseline social support [Time Frame: Baseline] Social support is measured using the Social Provisions Scale, which contains 24 items with response options ranging from 1 (Strongly disagree) to 4 (Strongly agree). A higher score indicates a greater degree of perceived support. 4. Baseline outcome expectations [Time Frame: Baseline] Outcome expectations is measured using the Multidimensional Outcome Expectations for Exercise Scale, which contains 15 items on a 5-point Likert scale, ranging from 1 (Strongly disagree) to 5 (Strongly agree). Three domains of outcome expectations, including the physical outcome expectations, the social outcome expectations, and the self-evaluative outcome expectations, will be derived from this scale. Each domain is scored individually and a higher score indicates higher level of outcome expectations for exercise. 5. Participant adherence throughout the 8-week intervention period [Time Frame: During the 8-week intervention] Participant dherence will be assessed using the percentage of the number of exercise session each participant attend over the 8-week intervention period.

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 to 65 Years (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
1. Diagnosed with a SCI resulting in incomplete or complete (C5 and below) paraplegia or tetraplegia;
2. Demonstrate readiness to physical activity by completing the Physical Activity Readiness Questionnaire for Everyone (PAR-Q+);
3. Obtain medical clearance if required by PAR-Q+;
4. Converse in and read English.

Exclusion Criteria:
1. No broadband internet access;
2. Significant visual impairment that prevents seeing a computer screen to follow a home exercise program;
3. Currently pregnant.

CONTACTS AND LOCATIONS

Contacts

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Locations

United States, Alabama	RecTech Center	Birmingham

Sponsors and Collaborators

University of Alabama at Birmingham

Investigator

MORE INFORMATION

Responsible Party :	University of Alabama at Birmingham
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Other Study ID Numbers :	IRB-300003133
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Last Update Posted :	February 17, 2021
Last Verified :	February 2021
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Additional relevant MeSH terms :	*Spinal Cord Injuries* *Wounds and Injuries*