Spinal Cord Injury Program in Exercise (SCIPE)

NCT03925077

Study Protocol

July 22nd, 2023

Participant ID: _____
Staff ID: _____

Checklist for SCIPE Participant Screening to Enrollment

Once a potential participant completes the SCIPE study *F01 Pre-screening Form* (*F01 Form*, *Application*) through the screening website, the pre-screening data will be automatically fetched to an inactive arm (Arm 2) of the study database (REDCap SCIPE) if the potential participant is eligible based on the **age** and **SCI diagnosis criteria**. If a potential participant made a wrong entry in the *F01 Form* and was rejected to be part of the study, See Appendix II.

Screening website - https://screen.scipe.org/#/apply
REDCap link- https://redcap.dom.uab.edu/index.php?action=myprojects

All data fetched to the Arm 2 will go through automatic duplicate checks to ensure that each individual has only one study ID. The duplicate check is performed based on the following rules: **Name** (first and last) and **Phone Number**. IDs that are identified as duplicates will remain in the Arm 2. Non-duplicate IDs and associated data will be transferred to active arm (Arm 1) in REDCap. All data moved to the Arm 1 will be automatically saved. This fetching, duplication check, and the saving process happen daily at a scheduled time (every 30 min) using a computer-generated script.

Once an ID with the fetched data is automatically saved under *F01 Form* in REDCap (status remains as incomplete, RED), it will trigger an automatic survey invitation and sent out *F02 Screening Interview Form* (*F02 Form*) to that individual. The *F02 Form* includes question items to obtain personal information, PAR-Q+, and secondary contact information. We can manually check whether or not the invitation was sent in two places (See Appendix III).

Recruitment Coordinator should check the study database daily to:

1) Ensure that data is fetched to REDCap (Step 1);
2) Monitor completion of the *F02 Form* (Step 2 – 6);
3) Identify individuals who need medical clearance, obtain one when necessary, and ensure individuals' mailing addresses (Step 7 – 11); and
4) Monitor completion of the consenting process (Step 12 – 17).

Please check each step below to complete the screening to enrollment process.
Please ensure all phone calls are documented using the *Call Log* in REDCap.

Step	√	Description
1		When a new user applies for the study, an email notification, *Application Received*, will be sent to the study email (scipe@uab.edu). Check the most recent email, *Application Received*, and ensure that the data is fetched to REDCap *F01 Pre-Screening* using the email address. This auto fetching/saving process happens daily, every 30 minutes (e.g., 10:00 am, 10:30 am, 11:00 am). If the auto fetching/saving process does not occur, inform **Data Team**. Note that the UAB server reboots and disables the auto-transcript every 2nd Wednesday of the month. Check all *F01 Pre-Screening* forms that contain the fetched data for any missingness. If not missing data identified, **Save and Exit Form** as **Complete**.

2		The auto invitation of the *F02 Form* is set to send up to 3 times, every 3 days: 1) The initial *F02 Form* is sent immediately after the *F01 Form* is automatically saved. No action is required. 2) When the ***initial*** *F02 Form* is not completed by the potential participant within 3 days (***3 days*** from the **initial** *F02 Form*), a ***second*** *F02 Form* will be sent automatically from REDCap. No action is required. 3) When the ***second*** *F02 Form* is not completed by the potential participant after 3 days (**6 *days*** from the **initial** *F02 Form*), a ***third*** *F02 Form* will be sent automatically from REDCap. If the potential participant completes the *F02 Form* before the third invitation, continue with **Step 7**. If the potential participant did not complete the *F02 Form* and the third invitation is sent, an email notification, *Incomplete Screening Form,* will be sent to the study email. Continue with **Step 3**.
3		Go to REDCap and call the potential participant using the phone number stored under the *F01 Form*. Contact him/her at preferred contact time. Record the phone call/attempt using the *Call Log* in REDCap. If the potential participant responds to the phone call, inform him/her that you sent the *F02 Form* again and ask to complete it within the next 3 days. If the potential participant does not respond to the phone call, leave a voice message and email to inform him/her that you sent the *F02 Form* again and ask to complete it within the next 3 days.
4		If the potential participant completes the *F02 Form* within 3 days, continue with **Step 7**.
5		If the potential participant did not complete the *F02 Form* within 3 days after the phone call (***9 days*** from the initial *F02 Form*), an email notification, *Incomplete Screening Form*, will be sent out to the study email. Continue with **Step 6**.
6		Under the *Lost to Contact/Withdrawn Form* in REDCap, mark the person as ***Unable to reach*** and indicate the **Date** and when the ***Unable to reach*** was determined during the study period (**Before screening**). No further action is required after the potential participant is marked as ***Unable to reach***.
7		Go to *Record Status Dashboard* on the left panel in REDCap and select the display option: *Medical Clearance Upload Needed* from the *Dashboard Displayed* dropdown list. This dashboard provides a list of potential participants who need medical clearance before enrolling in the SCIPE study. Continue with **Step 8**. An email notification will also be sent to the study email if the potential participant needs medical clearance, as identified in REDCap.
8		The Recruitment Coordinator should ensure that the potential participant met the **eligibility** prior to calling him/her for medical clearance. Indicating whether a potential participant is eligible or not is done by completing the 1st question under the *Medical Clearance Form* as below:

"Is the participant eligible for the study based on the screening?"

Under this question are self-reported age, presence of spinal cord injury, and current pregnancy from *F02 Form* completed by the potential participant. Eligibility is determined by three criteria: 1) between the ages of 18 to 65, 2) presence of spinal cord injury, and 3) not currently pregnant.

Go to REDCap and call the potential participant using the phone number stored under the *F01 Form*. Contact him/her at preferred contact time. Record the phone call/ attempt using the *Call Log* in REDCap.

Group 1: Ineligible, *Yes* for medical clearance

** A total of 3 call attempts should be made with each being at least 3 days apart if the potential participant cannot be reached.

** If the potential participant cannot be reached this time, please make sure to exit the *Medical Clearance Form* by clicking the **Cancel** button at the end of the form, which will ensure the form status remains as No Color (Incomplete or Red status indicates a person is ineligible).

(1) Eligibility

If the potential participant is outside of the age range, confirm the reported **Date of Birth** is accurate. If the **Date of Birth** is inaccurate, correct the information under *F02 Form.* Once the potential participant is determined as eligible, check **Yes** and obtain physician contact information.

If the potential participant does not respond 3 days after the 3rd call attempt, please assume the reported **Date of Birth** is accurate. Check **No** and **Save and Exit Form** as **Incomplete**. No further action is required at this point.

(2) Physical, mailing address

If the potential participant is determined as eligible, check and confirm the potential participant's mailing address for future equipment shipping. If change is needed, revise the address fields under the *F02 Form*.

Indicate whether or not the participant's mailing address has confirmed (yes/no). This question is located in the *F02 Form* as below:

"Participant's mailing address has been confirmed during the process of obtaining physician's contact information"

(3) Obtain physician contact Information (see Appendix I for script to obtain physician contact information)

Record the physician contact information under the *Medical Clearance Form* in REDCap.

Group 2: Eligible, *Yes* for medical clearance

** A total of 3 phone calls should be made with each being at least 3 days apart if the potential participant cannot be reached.

		** If the potential participant cannot be reached this time, please make sure to exit the *Medical Clearance Form* by clicking the **Cancel** button at the end of the form, which will ensure the form status remains as No Color (Incomplete or Red status indicates a person is ineligible). (1) Eligibility If the potential participant meets the three eligibility criteria, check **Yes** and continue with obtaining physician contact information. If the potential participant does not respond 3 days after the 3rd phone call, **Save and Exit Form** as **Incomplete**. Continue with **Step 15**. (2) Physical, mailing address Check and confirm the potential participant's mailing address for future equipment shipping. If change is needed, revise the address fields under the *F02 Form*. Indicate whether or not the participant's mailing address has confirmed (yes/no). This question is located in the *F02 Form* as below: *"Participant's mailing address has been confirmed during the process of obtaining physician's contact information"* (3) Obtain physician contact Information (See Appendix I for script to obtain physician contact information) Record the physician contact information under the *Medical Clearance Form* in REDCap.
9		Begin the physician clearance process. Fax the *Fax Cover Page and Statement of Medical Clearance for Exercise* to the potential participant's physician using the contact information obtained during **Step 8**.
		File the faxed documents in a secure cabinet until completed and signed *Statement of Medical Clearance for Exercise* arrives.
		Go to the *Medical Clearance Form* in REDCap. Enter the date when the first fax was sent, and change the form status to ***Unverified***. This marks the potential participants who are in the process of obtaining medical clearance as a yellow color.
10		After receiving the completed ***Statement of Medical Clearance for Exercise,*** **conceal all participant information** and scan the document. Upload the scanned form to REDCap to the "*Upload the signed medical clearance form*" section under the *Medical Clearance Form*. Shred the paper copy and mark the form status as **Complete** and save the record. This will trigger the auto invitation of the *e-Consent Form* (Initial). Continue with **Step 11**.
11		Upon completion of reaching out to potential participants who need medical clearance, change the display option of the *Record Status Dashboard* to the *Default Dashboard.*

Identify potential participants who do not need medical clearance (*F02 Form* has Complete status and is shown as **Green** & *Medical Clearance Form* is shown with No Color).

The Recruitment Coordinator should ensure the potential participant met the **eligibility** prior to a follow-up phone call. Go to the *Medical Clearance Form* and indicate whether the potential participant is eligible or not by completing the 1st question under the *Medical Clearance Form* as below:

> *"Is the participant eligible for the study based on the screening?"*

Under this question are self-reported age, presence of spinal cord injury, and current pregnancy from *F02 Form* completed by the potential participant. Eligibility is determined by three criteria: 1) between the ages of 18 to 65, 2) presence of spinal cord injury, and 3) not currently pregnant.

Go to REDCap and call the potential participant using the phone number stored under the *F01 Form*. Contact him/her at preferred contact time. Record the phone call/ attempt using the *Call Log* in REDCap.

Group 3: Ineligible, No medical clearance

**A total of 3 call attempts should be made with each being at least 3 days apart if the potential participant cannot be reached.

** If the potential participant cannot be reached this time, please make sure to exit the *Medical Clearance Form* by clicking the **Cancel** button at the end of the form, which will ensure the form status remains as No Color (Incomplete or Red status indicates a person is ineligible).

(1) Eligibility

If the potential participant is outside of the age range, confirm the reported **Date of Birth** is accurate. If the **Date of Birth** is inaccurate, correct the information under *F02 Form.* Once the potential participant is determined as eligible, check **Yes** and mark the status as Complete and save. This will immediately trigger *e-Consent Form* (initial) via REDCap. Continue with **Step 12**.

If the potential participant does not respond 3 days after the 3rd call attempt, please assume the reported **Date of Birth** is accurate. Check **No** and **Save and Exit Form** as **Incomplete**. No further action is required at this point.

(2) Physical, mailing address

If the potential participant is determined as eligible, check and confirm the potential participant's mailing address for future equipment shipping. If change is needed, revise the address fields under the *F02 Form*.

Indicate whether or not the participant's mailing address has confirmed (yes/no). This question is located in the *F02 Form* as below:

> *"Participant's mailing address has been confirmed during the process of obtaining physician's contact information"*

Group 4: Eligible, No medical clearance

		If the potential participant meets the three eligibility criteria, check **Yes** and mark the status as Complete and Save and Exit Form. This will immediately trigger *e-Consent Form* (initial) via REDCap. Continue with **Step 12**.
12	√	The auto invitation of the *e-Consent Form* is set to send up to 3 times with each being 3 days apart: 1) The ***initial*** *e-Consent Form* is sent after the *F02 Form* and *Medical clearance Form* are marked as Complete. No action is required. 2) When the ***initial*** *e-Consent Form* is not completed by the potential participant after 3 days (***3 days*** from the initial *e-Consent Form*), a ***second*** *e-Consent Form* will be sent automatically from REDCap. No action is required. 3) When the ***second*** *e-Consent Form* is not completed by the potential participant after 3 days (***6 days*** from the initial *e-Consent Form*), a ***third*** *e-Consent Form* will be sent automatically from REDCap. If the potential participant completes the *e-Consent Form* before the third invitation, continue with **Step 16**. If the potential participant did not complete the *e-Consent Form* and the third invitation is sent, an email notification, *Incomplete eConsent Form,* will be sent to the study email. Continue with **Step 13**.
13		Go to REDCap and call the potential participant using the phone number stored under the *F01 Form*. Contact him/her at preferred contact time. Record the phone call/attempt using the *Call Log* in REDCap. If the potential participant responds to the phone call, inform him/her that the *e-Consent Form* has been sent again and ask to complete it within the next 3 days. If the potential participant does not respond to the phone call, leave voice message and email to inform him/her that the *e-Consent Form* has been sent again and ask to complete it within the next 3 days.
14		If the potential participant completes the *e-Consent Form* within 3 days, continue with **Step 16**.
		If the potential participant did not complete the *e-Consent Form* within 3 days after the phone call (***9 days*** from the initial *e-Consent Form*), an email notification, *Incomplete e-Consent Form*, will be sent out to the study email. Continue with **Step 15**.
15		Under the *Lost to Contact/Withdrawn* Form in REDCap, mark the person as *Unable to reach* and indicate the **Date** and when the ***Unable to reach*** was determined during the study period (**Post screening**). No further action is required after the potential participant is marked as ***Unable to reach***.
16	√	The potential participant is officially enrolled in the study upon completion of the *e-Consent Form*. A baseline questionnaire packet will be automatically emailed to the participant via REDCap. No additional action is required.

Participant ID: _____
Staff ID: _____

Appendix I. Telephone Script for Obtaining Physician Clearance

Hi, my name is _____. I'm calling from the SCIPE Study at UAB. Thank you for answering our questions regarding your health. Based on the information you provided, you are eligible to participate in our study. In order for you to participate in the study, we will need to complete some additional paperwork. First, can I have your physician contact information? We will fax him/her to make sure that they feel this study is a good fit for you. Once we receive your medical clearance, we will contact you again and email you a consent form to complete the enrollment process.

Mailing address check.

Do you have any questions at this time?

We appreciate your time and interest in this study. We will be in touch as soon as we complete the medical clearance process.

Appendix II. When a potential participant made a wrong entry in the *F01 Form* and was rejected to be part of the study

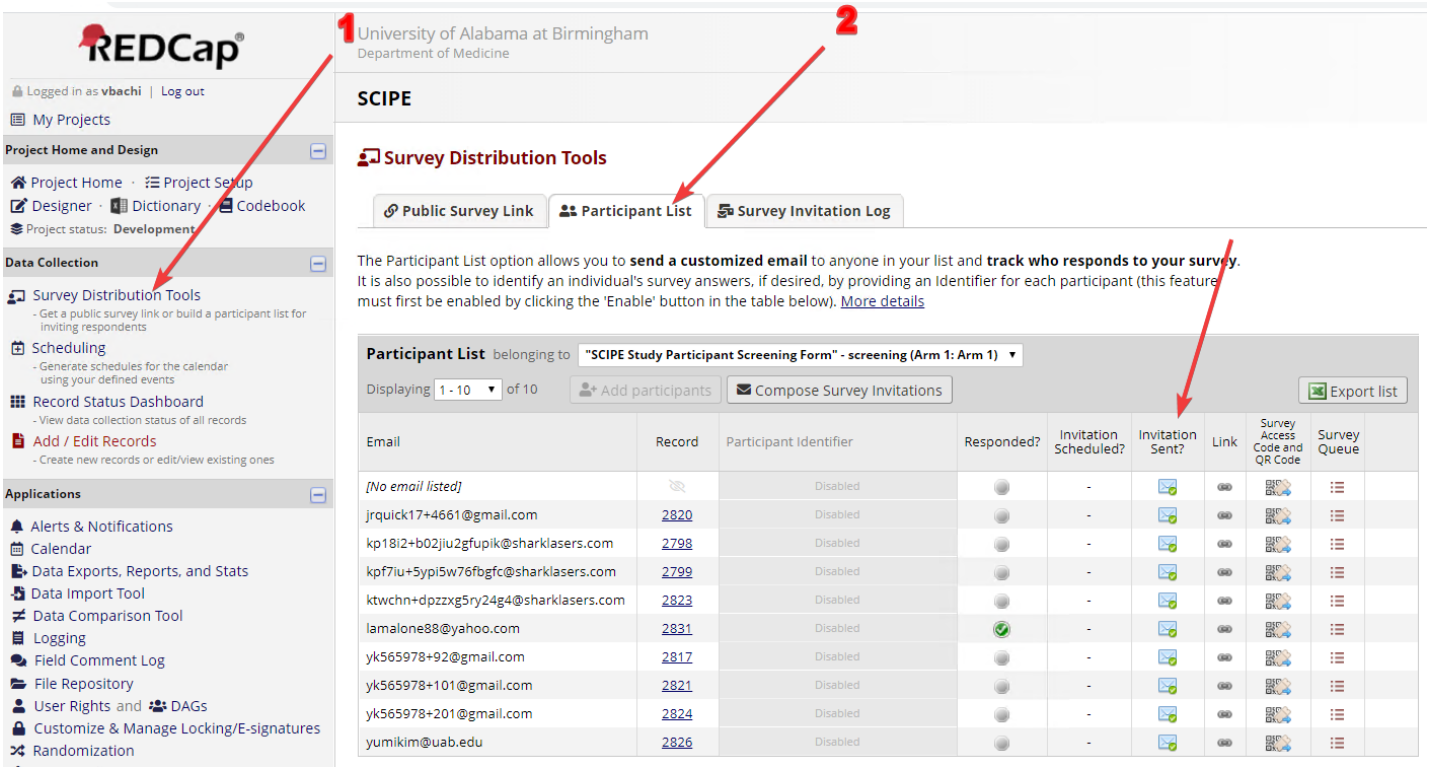
1. Login to the app.scipe.org as admin;
2. Go to the *User Management* option under *Content Management* section;
3. Find the rejected user using his/her email address;
4. Click the **edit icon** in the first column of the user to enter the record;
5. Under Status, change the user's status by typing ***application-pending*** (*No manual data correction)
6. Click **Edit** on the bottom of the page and finish the process
7. No further action is needed. The user's data will be fetched to Arm 2 in REDCap when the next run of fetching occurs.

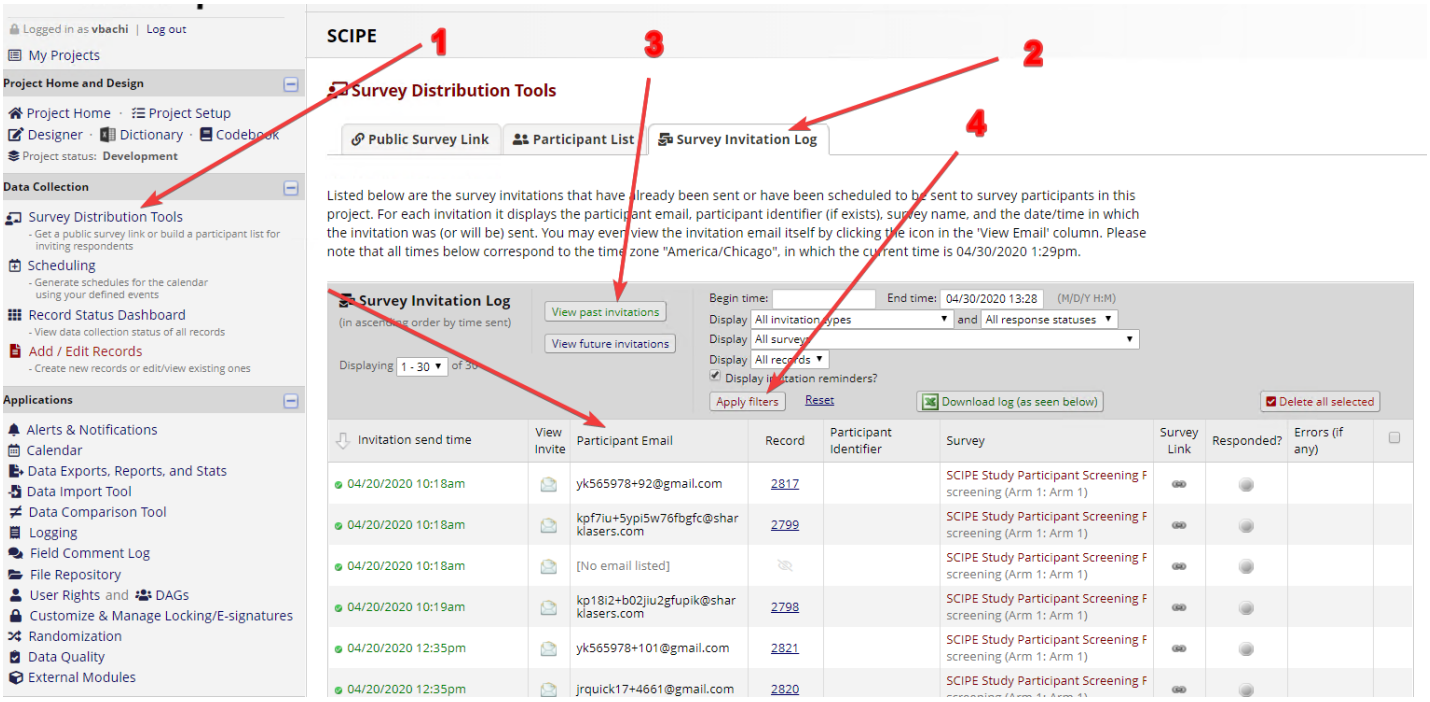
   Ensure to record communication in REDCap using the Other category of the Call Log. Under the Note section, please record the purpose of this call was for change of the user status due to (1) age range or (2) presence of SCI.

Participant ID: _____

Staff ID: _____

Appendix III. Manual check for auto survey invitation





Checklist for Overall management

Please check each step below for the overall management of the study.
Please ensure all phone calls are documented using the Call Log in REDCap.

Daily Action Items:

(1) Check completion status of baseline assessment (*Packet 1*). (Steps 1 – 4)
(2) Perform randomization. (Step 5)
(3) Confirm mailing address and equipment shipping (Steps 6 – 7)
(4) Provide access to the SCIPE website. (Step 8)
(5) Monitor user status flow on the SCIPE website (Step 9)
(6) Monitor notification emails through the study email. (Step 10)
   a. Bug Reports (Bug reported)
   b. Contact Staff (Contact staff initiated)
   c. Flagged and/or Blacklisted words contained post (A post has been reported)
   d. Flagged and/or Blacklisted words contained comment (A comment has been reported)
(7) Check completion status of post-intervention, 12-week, and 16-week assessments (*Packets 2 or 2-1, Packet 3, and Packet 4*) (Steps 12 – 15)

Weekly Action Items (Steps 11 and 16):

(8) Monitor adherence of participants (Step 11)
(9) Clean up the Applications page in the SCIPE website (admin) by declining ineligible participants' records. (Step 16)
(10) Contact *pre-application users.* (Step 17)

Post-Intervention Interview

(11) Scheduling and documenting post-intervention participant interview (Step 18)

Step	√	Description
Check Completion Status of Baseline Assessment		
1		The auto invitation of the *Packet 1* is set to send up to 3 times, every 7 days: 1) The initial *Packet 1* is sent immediately after a participant provided his/her informed consent. 2) When the ***initial*** *Packet 1* is not completed by the participant within 7 days (**7 *days*** from the **first** *Packet 1*), a ***second*** *Packet 1* will be sent automatically from REDCap. No action is required. 3) When the ***second*** *Packet 1* is not completed by the participant after 7 days (**14 *days*** from the **initial** *Packet 1*), a ***third*** *Packet 1* will be sent automatically from REDCap. If the participant completes *Packet 1* before the third invitation, continue with **Step 5**. An email notification, *Complete Baseline Event,* will be sent to the study email. If the participant did not complete *Packet 1* and the third invitation is sent, an email notification, *Incomplete Packet 1,* will be sent to the study email. Continue with **Step 2**. *If the participant has *Packet 1* partially completed (form status shown as Partial Survey Response, orange color), continue with the sub-section **(For Partially Completed Packet) of**

		Step 2.
2		Go to REDCap and call the participant using the phone number stored under *F02 Form*. If the participant responds to the phone call, inform him/her that you sent the *Packet 1* again and ask to complete it within the next 7 days. If the participant does not respond to the phone call, leave a voice message and email to inform him/her that you sent the *Packet 1* again and ask to complete it within the next 7 days. Record the call attempt using the call log in REDCap. **<u>For Partially Completed Packet (Follow up with 2 contact attempts)</u>** Go to REDCap and call the participant using the phone number stored under *F02 Form*. If the participant responds to the phone call, inform him/her that the questionnaire packet he/she completed has missing responses and ask if he/she is ok to provide you the responses over phone. If he/she agrees, open Packet 1 the participant partially completed in REDCap and click **Edit Response** on top of the packet. Go through the items with missing responses with the participants and enter responses obtained from the participants. **Save and Exit the Form** when finished. *In the case of a participant making the initial contact via email about not being able to re-open the packet again, please contact PI to obtain a direct link to the packet and send to the participant. Please consider this email contact as the 1st contact attempt. If the participant does not respond to the phone call, leave a voice message and email to inform him/her that you are contacting him/her about missing responses in the questionnaire packet and will call again within the next 7 days. Call again within the next 7 days to complete the 2nd contact attempt. Record the call attempt(s) using the call log in REDCap.
3		If the potential participant completes the *Packet 1* within 7 days, continue with **Step 5**
		If the potential participant did not complete the *Packet 1* within 7 days after the phone call (***22 days*** from the initial *Packet 1*), an email notification, *Incomplete Packet 1*, will be sent out to the study email. Continue with **Step 4**.
4		Under the *Lost to Contact/Withdrawn Form* in REDCap, mark the person as ***Lost to Contact*** and indicate the **date** when the lost to contact was determined during the study period (**Post screening & Before baseline**). No further action is required.
Perform Randomization		
5		Go to the *Randomization Form* of the *Record Status Dashboard* in REDCap. a. Press the ***Randomization*** button. After pressing the randomization button, a small pop-up window will appear for confirming this randomization process. Click **Randomize** in this pop-up window. b. The group assignment will automatically appear and recorded as **Arm 1**, **Arm 2**. c. Record the date when the randomization is performed using the **Randomization date**

		field. d. Change the form status as **Complete** and then click **Save and Exit Form**. Continue with **Step 6**. **If a participant is randomized into the intervention arms (SET), please follow **Step 6** to make sure mailing address is confirmed and ready to ship wrist weights.
Confirm mailing address and equipment shipping		
6		**<u>Confirm mailing address for participants randomized to SET:</u>** Participants who are randomized into the SET arm will be mailed a pair of wrist weights. The mailing address of some participants should be already confirmed during the medical clearance process. The confirmation is indicated in *F02 Screening Interview* form if the following item is checked **Yes**: *"Participant's mailing address has been confirmed (Yes/No)"* If mailing address is not confirmed yet, please call the participant using the phone number stored under *F02 Form* in REDCap **at preferred contact time** then confirm the reported **Address** is accurate. If the participant does not respond to the phone call, leave voice message and email to inform him/her that you would like to confirm address for mailing the wrist weights.
7		**<u>Tracking Equipment Shipping</u>** *Only when a participant is randomized to one of the intervention arms and his/her mailing address is confirm, his/her information would show up in the *Equipment Management* report for equipment shipping. Check the *Equipment Management* report and track equipment shipping using the *Equipment Shipping* form every other day. The Equipment Shipping form will show as: a. Yellow (Unverified) when the wrist weights have been ordered but not yet received by participant; b. Green (Complete) when the wrist weights have been received by participant. When shipping the wrist weights, the assigned team member will also include the following messages as a note to participant: "*Dear participant,* *You are receiving a pair of wrist weights as part of the SCIPE exercise program. Please begin using the wrist weights for the muscle strengthening exercises demonstrated in the videos. Thank you for participating in the SCIPE study and have a great day!* *The SCIPE study team*" For Control participants, please **Save and Exit** the *Equipment Shipping* form as **Complete** without entering any information to the form.
Provide participant access to SCIPE website		

8		a. Log in to the SCIPE intervention website (app.scipe.org) with admin ID and Password. b. Go to the *Application Management* page under To Do menu. c. Find the participant using the email address stored in *F02 Form*. d. Press *Activate* and select one of the *User Types* (Control and SET) under the drop-down list based on the randomization assignment of this participant. e. Once the information is submitted, the participant will receive an email notification that contains a link for him/her to access the website (Status: *Application approved*). *The start date/time of the intervention will be automatically recorded when the participant completes pre-surveys (profile, pain/function, workout preference) on the SCIPE website.
Monitor user status flow in SCIPE website		
9		Monitor the user flow on the *User Status Management* page on the SCIPE website. When clicking page display button at the top-right corner, 7 user status are shown. The descriptions of each user status are as below. **User status – Description – Content of the reminder email** • Awaiting Email Confirmation -- User has accepted the terms and conditions – *Email Confirmation* • Email Confirmed -- User has confirmed email but not finished the application – *Application form* • Browser Confirmed – User has submitted application and browser check was performed, but not necessarily valid. • Speed Confirmed – User has submitted application and speed check was performed, but not necessarily valid. • ~~Application Denied~~ -- User denied after submitting application • ~~Application Pending~~ -- User has submitted application successfully. • Application Approved -- User approved for study, needs to set password – *Invitation to the SCIPE website* • Need Profile Complete -- User has set password, but has not finished the complete profile surveys – *Completion of the pre-surveys* • ~~Profile Complete~~ -- User has completed their profile and able to access the app **Display Awaitng Email Confirmation and Email Confirmed status.** ***1.*** Identify users who remains in the **Awaitng Email Confirmation or Email Confirmed** status under the *To Do* tab and *User Status Management* menu for **6 days** using *Days in Status.* a. Send the 1st follow-up email using the **Email** button and record the date of this email attempt under the **1st Email Sent Date** column in the *SCIPE Pre-application Users Contact* excel sheet. b. Select your name under the dropdown list under **Contact By?** ***2.*** Identify users who remains in the **Awaitng Email Confirmation or Email Confirmed** status under the *To Do* tab and *User Status Management* menu for **12 days** using *Days in Status.* *a.* Send the 2nd follow-up email using the **Email** button and record the date of this

email attempt under the **2nd Email Sent Date** column in the *SCIPE Pre-application Users Contact* excel sheet.

b. Select your name under the dropdown list under **Contact By?**

c. **Check (√)** to confirm no more contact under the **No More Contact Confirmation** column.

Subject: REMINDER: Complete the Pre-Screening Process for SCIPE Study

Hi,
Thanks for visiting the SCIPE website! We would love to have you enroll in this 8-week home-based exercise program offered by the University of Alabama at Birmingham! Enrollment in this program provides an opportunity for you to participate in regular physical activity, and your valuable feedback could help us to deliver an effective exercise program for people at home. If you are still interested in the SCIPE study, please click here to continue with the enrollment process. Please reach out to XXXX, Research Assistant, at ###-###-#### or reply with any further questions you may have!

Best,
SCIPE Study Team

Display Browser Confirmed and Speed Confirmed status.

1. Identify users who remains in the **Browser Confirmed or Speed Confirmed** status under the *Content Management* tab and *User Management* menu for **6 days** using *Days in Status.*

a. Make 1st phone call using the phone number submitted by the user during the application process, which is stored in the *User Management* page under the *Content Management* tab and record the date of this call attempt under the **1st Phone Call Date** column in the *SCIPE Pre-application Users Contact* excel sheet.

b. If no response from the 1st call attempt, make 2nd phone call and record the date of this call attempt under the **2nd Phone Call Date** column in the *SCIPE Pre-application Users Contact* excel sheet.

c. If no response from the 2nd call attempt, **check (√)** to confirm no more contact under the **No More Contact Confirmation** column.

Display Application Approved status. A total of 3 invitation emails are set to be sent automatically (1 initial at day 1 and 2 auto invitations for day 2 and 3).

a. Under the *To Do* tab and *User Status Management* menu, identify users who remains in the same status for **6 days** using *Days in Status.*
b. Go to REDCap and identify record ID using email address.
c. Call participant using the phone number stored under *F02 Form*.
- If the **participant** responds to the phone call, inform him/her that you sent the *user invitation* email, titled 'Congratulations! We would like to welcome you as a new SCIPE user,' and ask to complete the steps within the **next 6 days**.
- If the **participant** does not respond to the phone call, leave voice message and email to inform him/her that you sent the *user invitation* email and ask to complete the steps within the **next 6 days**.

d. Record on the Call Log that the final follow-up phone call has been made to follow up on the *Application Approved* status.

e. Identify users who remains in the same status for **12 days** using *Days in Status.*

f. Go to REDCap and identify record ID using email address.

g. Under the *Lost to Contact/Withdrawn Form* in REDCap, mark the person as ***Lost to Contact*** and indicate the **date** when the lost to contact was determined during the study period (**Between baseline and start of intervention**). No further action is required.

Display Need Profile Complete status.
Repeat the processes for the *Need Profile Complete* status.

Monitor notification emails through the study email

10

a. Bug Reports (Bug reported)
b. Contact Staff (Contact staff initiated)
- Please respond to participants via the study email account (scipe@uab.edu) by forwarding the original Contact Staff email notification from the website.
c. General FAQs through scipe@uab.edu.
d. Red-flagged Post (A post has been reported)
- Open the SCIPE website (admin page) in a window tab.
1. Open another tab and copy/paste the post URL from the email notification.
2. Check the post.
3. If inappropriate, **Delete**.

Monitor adherence of participants

11

Participant's adherence will be monitored using the adherence report uploaded to the *SCIPE Adherence Report* in Box by **Vinoth**. Only participants who are inactive (not accessing the website) or are below the weekly video watch minute cut-point for **two** consecutive weeks will show in the report. The table below shows the cut point for each week:

Week	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Video Watch Minute Cut-Point	9	13.5	22.5	27	31.5	36	40.5	40.5

For participants who are in the adherence report (2 weeks of inactivity or low activity):

1. **First Call:** Go to REDCap and call the participant using the phone number stored under *F02 Form*. If the participant responds to the phone call, inform him/her that you are just checking in to make sure everything is ok since he/she hasn't been on the website for past 2 weeks. Encourage him/her to watch and exercise three times per week;
2. If the participant does not respond to the phone call, leave a voice message and inform him/her that you are just checking to make sure everything is ok since he/she hasn't been on the website for 2 weeks. Encourage him/her to watch and exercise three times per week.
3. Record this 1st call attempt using the *Adherence Call* section under the *Call Log* in REDCap.
4. **Second Call:** The same participant will show up in the report again if he/she did not access the website or was below the weekly video watch minute cut-point for the past week (3rd week). Go to REDCap and call the participant using the phone number stored under *F02 Form*. If the participant responds to the phone call, inform him/her that you

		are just checking to make sure everything is ok since he/she hasn't been on the website for past 3 weeks. Encourage him/her to watch and exercise three times per week; a. If the participant does not respond to the phone call, leave a voice message and inform him/her that you are just checking to make sure everything is ok since he/she hasn't been on the website for 3 weeks. Encourage him/her to watch and exercise three times per week. b. If the same participant shows up in the report again the week after (4th) week, please go to *Packet 2* (if SET) or *Packet 2-1* (if Control) of that participant and check the the date when the survey will be sent via the *Invitation Status* icon. **Put the date on your calendar as a reminder for the 3rd Call.** c. Under the *Lost to Contact/Withdrawn Form* in REDCap, mark the person as ***Lost to Contact*** and indicate the **date** when the lost to contact was determined during the study period (**During intervention**). This will remove the participant from the *Adherence Report*. 5. Record this 2nd call attempt using the Adherence Call section under the Call Log in REDCap. 6. **Third Call**: Call the participant on the date when the *Packet 2 or Packet 2-1* is scheduled to send. If the participant responds to the phone call, inform him/her that the post-intervention questionnaire packet has been sent and ask him/her to complete in order to receive the gift card. a. If the participant does not respond to the phone call, leave a voice message and inform him/her that the post-intervention questionnaire packet (*Packet 2 or 2-1*) has been sent and ask him/her to complete in order to receive the gift card. d. If the participant completes *Packet 2 or 2-1*, remove him/her from the **Lost to Contact** status under the *Lost to Contact/Withdrawn Form* in REDCap b. If the participant does not respond to the phone call and does not complete Packet 2 or 2-1, his/her **Lost to Contact** status remains. 7. Record this 3rd call attempt using the Adherence Call section under the Call Log in REDCap.
Check Completion Status of Post-Intervention, 12-Week, and 16-Week Assessments:		
12		The auto invitation of the *Packet 2 or 2-1 (post-intervention), Packet 3 (12-week), and Packet 4 (16-week)* are set to send up to 3 times, every 3 days: 1) The initial *Packet 2 or 2-1* is sent 58 days after participant completed randomization. 2) When the ***initial*** *Packet 1* is not completed by the participant within 3 days (**3 *days*** from the **first** *Packet 1*), a ***second*** *Packet 2 or 2-1* will be sent automatically from REDCap. No action is required. 3) When the ***second*** *Packet 2 or 201* is not completed by the participant after 3 days (6 ***days*** from the **initial** *Packet 1*), a ***third*** *Packet 2 or 2-1* will be sent automatically from REDCap. If the participant completes *Packet 2 or 2-1* before the third invitation, an email notification, *Complete Post-Intervention Event,* will be sent to the study email. If the participant did not complete *Packet 2 or 2-1* and the third invitation is sent, an email notification, *Incomplete Packet 2 or 2-1,* will be sent to the study email. Continue with **Step 13**. *If the participant has *Packet 2 or 2-1* partially completed (form status shown as Partial Survey Response, orange color), continue with the sub-section (For Partially Completed Packet) of **Step 13**.

13		Go to REDCap and call the participant using the phone number stored under *F02 Form*. If the participant responds to the phone call, inform him/her that you sent the *Packet 2 or 2-1* again and ask to complete it within the next 3 days. **Continue with Step 15**. If the participant does not respond to the phone call, leave a voice message and email to inform him/her that you sent the *Packet 2 or 2-1* again and ask to complete it within the next 3 days. **Continue with Step 14.** Record the call attempt using the call log in REDCap. **<u>For Partially Completed Packet (Follow up with 2 contact attempts)</u>** Go to REDCap and call the participant using the phone number stored under *F02 Form*. If the participant responds to the phone call, inform him/her that the questionnaire packet he/she completed has missing responses and ask if he/she is ok to provide you the responses over phone. If he/she agrees, open Packet 2 or 2-1 the participant partially completed in REDCap and click **Edit Response** on top of the packet. Go through the items with missing responses with the participants and enter responses obtained from the participants. **Save and Exit the Form** when finished. *In the case of a participant making the initial contact via email about not being able to re-open the packet again, please contact PI to obtain a direct link to the packet and send to the participant. Please consider this email contact as the 1st contact attempt. If the participant does not respond to the phone call, leave a voice message and email to inform him/her that you are contacting him/her about missing responses in the questionnaire packet and will call again within the next 3 days. Call again within the next 3 days to complete the 2nd contact attempt. Record the call attempt(s) using the call log in REDCap.
14		If the potential participant did not complete the *Packet 2 or 2-1* within 3 days after the phone call (***10 days*** from the initial *Packet 2 or 2-1*), an email notification, *Incomplete Packet 2 or 2-1*, will be sent out to the study email. Under the *Lost to Contact/Withdrawn Form* in REDCap, mark the person as ***Lost to Contact*** and indicate the **date** when the lost to contact was determined during the study period (**Post 8-week intervention**). **Continue with Step 15**.
15		Follow Steps 13 -15 for Packet 3 and 4. If the potential participant did not complete the *Packet 3 or 4* after ***10 days*** from the initial *Packet 3 or 4*), an email notification, *Incomplete Packet 3 or Incomplete Packet 4*, will be sent out to the study email. Under the *Lost to Contact/Withdrawn Form* in REDCap, mark the person as ***Lost to Contact*** and indicate the **date** when the lost to contact was determined during the study period (**Post 8-week [for Packet 3] or post 16-week [for Packet 4])**. No further action required.
Clean up application records		

16		**Decline** participant record who were identified as inxle.
Contact pre-application users		
17		**Status of pre-application users – Description** • Awaiting Email Confirmation -- User has accepted the terms and conditions by submitting email address. • Email Confirmed -- User has confirmed email but not finished the application. • Browser Confirmed – User has submitted application and browser check was performed, but not necessarily valid. • Speed Confirmed – User has submitted application and speed check was performed, but not necessarily valid. **Update pre-application users list** Retrieve status report of ALL users through ICT team (*Name of responsible personnel here*). The interested variables are (1) Record ID, (2) Email, (3) Start time, (4) Status, and (5) Days in Status. When request, provide the following codes: SE**LECT u.id, u.email, u.status, u.start_time** FROM users; Organize the report based on *Status* and identify users in 'Awaiting Email Confirmation,' 'Email Confirmed,' 'Browser Confirmed,' and 'Speed Confirmed' status. Update *Pre-Application Users* list (https://uab.app.box.com/file/830471361190). **Contact potential participants in pre-application users in *Awaiting Email Confirmation* and *Email Confirmed* status** Send reminder email via scipe@uab.edu using the language below. Subject: REMINDER: Complete the Pre-Screening Process for SCIPE Study Hi, Thanks for visiting the SCIPE website! We would love to have you enroll in this 8-week home-based exercise program offered by the University of Alabama at Birmingham! Enrollment in this program provides an opportunity for you to participate in regular physical activity, and your valuable feedback could help us to deliver an effective exercise program for people at home. If you are still interested in the SCIPE study, please click here to continue with the enrollment process. Please reach out to XXX, Research Assistant, at ###-###-#### or reply with any further questions you may have! Best, SCIPE Study Team **Contact potential participants in pre-application users in *Browser-Confirmed* status** 1. Through ICT team (*Name of responsible personnel here*), identify (1) type and (2) version of the browser that were used when submitting application. If the potential participant used **unsupported browsers** for the SCIPE website (Internet Explorer, Microsoft Edge, and Samsung Internet), call and provide further technical support.

If the potential participants used **supported browsers** (Chrome, Firefox, and Sarari) **but outdated version**, call and provide further technical support.

If the potential participants used **supported and up-to-date version of browser**, override the browser confirm process: (1) Go to https://screen.scipe.org/#/apply and (2) submit the same email address of user that were previously submitted and failed for the browser check. Call and inform the user to complete *F02 Form* that are delivered to their email.

Platform	**Chrome**	**Firefox**	**Safari**
Windows	92.0.4515.159	91.0.1	-
MacOS	92.0.4515.159	91.0.1	14.1
Linux	92.0.4515.159	91.0.1	-
Android	92.0.4515.159	91.0	-
iOS	92.0.4515.90	36.0	-
	Release Date: 8.17.2021	Release Date: 8.11 & 17.2021	Release Date: 4.26.2021

Scheduling and Documenting Post-Intervention Participant Interview

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Participants who are in the **SET** arm will be invited to participate in a post-intervention interview after they completed the 8-week intervention. For a list of participants who need to be contacted and scheduled for an interview, please refer to the report *Participants to be Invited for Interview* in REDCap. Please call the participant using the phone number stored under the report. If the participant responds to the phone call, ask whether him/her is interested in being interviewed about his/her experience with the SCIPE program with a study investigator and complete the following actions:

1) Go to the *Post-Intervention Participant Interview* form in REDCap and enter the **date** when this phone call is made. If participant is not interested in the interview, check **No** to the first question "*Is this participant interested in completing the post-intervention interview?"*. **Save and Exit** the form as **Incomplete**. This action will remove the participant from the *Participants to be Invited for Interview* report.

   If participant is interested in the interview, check **Yes** to the first question and continue with **Action #2**.

2) Schedule the interview based on the participant's and the ICT team's availability and mark the scheduled interview date and time in the *Post-Intervention Participant Interview* form. **Save and Exit** the form as **Unverified**.
3) When the interview is completed, please enter the actual interview date and time in the *Post-Intervention Participant Interview* form. **Save and Exit** the form as **Complete**. This action will remove the participant from the *Participants to be Invited for Interview* report.

If the participant did not respond to the phone call, please make 2 additional call attempts, with each 3 days apart. Enter the **date** when the 2nd or 3rd call attempt is made under the *Post-Intervention Participant Interview* form in REDCap.

		If participant answers the call, follow **Action #1-3** to complete the interview process. If participant still did not respond to the 3rd call attempt, please **Save and Exit** the form as **Incomplete**. This action will remove the participant from the *Participants to be Invited for Interview* report.

Statistical Analysis for Pilot Usability Phase

Descriptive statistics for participant demographics, feasibility, usability, acceptability metrics, and preliminary study outcomes were computed as mean ± SD or median (minimum, maximum) for continuous variables and percentage (*n*) for categorical variables. A sample size of 36 was determined based on recommendations for feasibility studies assessing feasibility, usability, and acceptability[38].

Preliminary data (LTPAQ-SCI and PROMIS) collected at baseline and Week 8 were analyzed, with Week 8 as the primary endpoint. Prior to analyses, data were examined for errors, missingness, and normality. Three participants (*n*=1 in SET, *n*=2 in AC) were identified as outliers for all LTPAQ-SCI categories (Studentized residual > 3.0 and high leverage on predictors of interest). These data were presumed to result from measurement errors and were excluded from all LTPAQ-SCI analyses.

Given the exploratory nature of this interim analysis and the small sample size, we focused on effect sizes for the preliminary study outcomes. Linear mixed models were used to assess within- and between-group effects using an intent-to-treat approach and included fixed effects for Time (Week 8 vs baseline) and Intervention Arm, a random effect for participant, and a Time x Intervention Arm interaction. Estimates were derived from least-square mean differences, with bootstrap confidence intervals (CIs) calculated at the 95%, 85%, and 75%. All LTPAQ-SCI measures were square-root transformed for analysis to meet normality assumption.

Effect sizes were calculated using Hedge's *g*, which is based on the pooled SD and corrected for small samples. Interpretations of g were: g <0.2=very small; 0.2≤ g <0.5=small; 0.5≤ g <0.8=medium; g ≥0.8=large[39]. Rank-biserial correlation index (r_{rb}) were also used with the following interpretations: 0.05≤ r_{rb} <0.1=very small; 0.1≤ r_{rb} <0.2=small; 0.2≤ r_{rb} <0.3=medium; 0.3≤ r_{rb} <0.4=large; r_{rb} ≥0.4=very large[40].

Analyses were performed using R version 4.3.3 (R Core Team, 2024)[41] and the following packages: tidyverse v2.0.0[42], DescTools v0.99.54[43], gtsummary v1.72[44], lme4 v1.1-35.3[45], lmerTest v3.1-3[46], emmeans v1.11.0[47], effectsize v0.8.7[48], broom.mixed v0.2.9.6[49], ggplot2 v3.5.2[50], and ggpubr v0.6.0[51].

Statistical Analysis for Feasibility Phase

Data collected at baseline and Week 8 were included in the current analyses, with Week 8 evaluated as the primary endpoint. The primary outcome for this study was change in physical activity (LTPAQ-SCI), whereas changes in physical, mental and social health (NIH PROMIS) were evaluated as secondary outcomes. All data were examined prior to analysis for errors, missingness, and normality. For LTPAQ-SCI measures, five participants (n=3 in Arm 1 and n=2 in Arm 2) had unusually high scores for mild, moderate, and total LTPA, and were identified as model outliers for these outcomes (Studentized residual > 3.0 and high leverage). Ultimately, these participants were excluded from analyses of the primary outcome due to the high likelihood of data entry errors during data collection.

Descriptive statistics were computed as mean (SD) and median (min, max) for continuous variables, and n (%) for categorical variables. Characteristics for the overall sample and by intervention arm were reported for 1) demographics, spinal cord injury, health, and lifestyle at baseline; and 2) primary and secondary outcomes at baseline and Week 8. Additionally, results for exercise enjoyment (PACES) were reported for Arm 2 participants at Week 8. Group differences in descriptive characteristics were assessed with the Wilcoxon rank-sum test (non-parametric two-sample t-test), Pearson's Chi-squared test, or Fisher's exact test as appropriate. Mixed models were used to evaluate within- and between-group effects on the primary and secondary outcomes, with analyses conducted using an intent-to-treat approach. Models included time (baseline vs Week 8) and intervention (Arm 1 vs Arm 2) as fixed effects, participant as a random effect, and an interaction term for time x intervention arm. Within- and between-group estimates were derived from the interaction term and are reported as the difference in least-square means (95% CI). For these analyses, all LTPAQ-SCI measures were square-root transformed to ensure that the normality assumption was met, and confidence intervals were estimated via bootstrap methods. All analyses were performed using R version 4.5.0 (R Development Core Team, 2025) (3) and the following packages: tidyverse (4), doBy (5), broom.mixed (6), DescTools (7), gtsummary (8), lme4 (9), lmerTest (10), emmeans (11), effectsize (12), psych (13), and ggplot2 (14). Significance was set at α=0.05 for all analyses.

CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research:	**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)
UAB IRB Protocol #:	IRB-300003133
Principal Investigator:	James Rimmer, Ph.D.
Sponsor:	National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)

Concise Summary for Intervention Study

General Information	You are being asked to take part in a research study. This study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to test the effects of an online standard exercise training (SET) program on health and quality of life outcomes in people with spinal cord injury.
Duration & Visits	You will be in the study approximately 18 weeks, which involves the screening and enrollment process, 8-week exercise program, and 4 testing sessions (baseline, post-intervention, 12-week follow up, and 16-week follow up). There is no in-person visit. You will complete the exercise program and testing sessions online at your convenience.
Overview of Procedures	If you decide to take part in this study, you will be asked to complete a series of questionnaires that assess your baseline health status, perceptions to exercise, and quality of life outcomes. Upon completion of the baseline questionnaire, a computer will then assign you to one of the study groups by chance: SET or a Control group. If you are in the SET group, you will receive a weekly exercise program for the next 8 weeks via a secured website. The exercise programs include range of motion, muscle strengthening, cardiovascular fitness, and balance exercises. If you are in the Control group, you will be asked to maintain your usual activities for the next 8 weeks. At the end of 8th week, 12th week, and 16th week (optional), you will be asked to complete the same questionnaires from the baseline session.
Risks	The potential risks for participating in an exercise program include shortness of breath, falls, chest pain, heart attack, and the remote risk of sudden death. You will be assigned to a group by chance, which may prove to have more or less benefits than the other study group.
Benefits	There is evidence that exercise training can improve health and functional outcomes. This study may also help us better understand how to deliver exercise programs via a telehealth platform to people with spinal cord injury.
Alternatives	The alternative is to not participate in this study.

Purpose of the Research Study

We are asking you to participate in a research study. The purpose of this research is to test the effects of an 8-week standard exercise training program (SET) on health and quality of life outcomes in people with spinal cord injury. People who enter the study will be asked to participate in the 8-week SET program or a control group. In addition, they will be asked to complete assessments that will take place before beginning the program (baseline), at week 8 (post-intervention), at week 12 (follow-up), and at week 16 (optional follow-up). The study will enroll a total of 96 participants.

Study Participation & Procedures

By enrolling in this study, you are consenting to be randomly assigned to one of two groups: 1) SET, or 2) a control group. Randomization is like flipping a coin to determine your group assignment. Therefore, you will be assigned to a group by chance, which will occur through a computer-generated code. If you are in the SET group, you will be asked to participate in 3 exercise classes per week for 8 weeks, with each class ranges from approximately 10 to 60 minutes long. The classes will take place via exercise videos through a secure study website. You can access exercise videos at your convenience. If you are in the control group, you will be asked to maintain your usual activities for the next 8 weeks.

Prior to randomization, you will be asked to complete a **Baseline Assessment Session** that includes a series of questionnaires related to your demographics, health, functional status, fitness, and quality of life. It will take approximately about 45 minutes to complete. The questionnaires are listed below,

Questionnaires – you will complete a series of questionnaires that ask you about your demographics, health, physical activity, dietary patterns, and quality of life. We will also ask questions about barriers you may experience in participating in physical activity, exercise self-efficacy, exercise goal-setting, outcome expectations for exercise, and social support. The questionnaires include:

- Demographics and Health History Questionnaire
- Leisure Time Physical Activity Questionnaire for People with Spinal Cord Injury
- Godin Leisure-Time Exercise Questionnaire
- NIH PROMIS 10 Global Health Items
- NIH PROMIS Ability to Participate in Social Roles and Activities
- NIH PROMIS Pain Interference Short Form
- NIH PROMIS Pain Intensity Short Form
- NIH PROMIS Sleep Quality Short Form
- NIH PROMIS Fatigue Short Form
- Physical Activity Enjoyment Scale
- Social Provisions Scale
- Multidimensional Outcome Expectations for Exercise Scale
- Exercise Self-Efficacy Scale
- Exercise Goal-Setting Scale

Once you complete the **Baseline Assessment Session**, you will be informed about your randomization group assignment: **SET** or **Control** and will be directed to a secure study website. You will have access to new weekly articles on physical activity and health through the study website. If you are in the SET group, you will have access to exercise videos via the study website and will receive exercise equipment (a pair of wrist weights) in the mail at the address you provide us. Details of each group are described below.

Standard Exercise Training (SET). The **SET** program involves typical exercises performed to improve range of motion, muscular strength, cardiorespiratory fitness, and balance. Every class will begin with exercises that target range of motion, followed by muscle strengthening, cardio, and balance exercises performed either seated or standing with or without support of a chair. The class will end with a cool-down routine.

Control Group. If you are in the control group, you will be instructed to maintain your usual activities for the next 8 weeks.

8 Week Post-Intervention Assessment Session. You will be asked to complete the same set of questionnaires described above for the baseline assessment session and at the end of the 8-week period, regardless of your group assignment. You will also be asked to complete 3 additional questionnaires, regarding the usability of the website and technology. It will take approximately 60 minutes to complete. In addition, up to 50 participants will be randomly selected and will be asked to participate in a semi-structured one-on-one interview via phone call to provide feedback regarding the exercise programs. The interview will be scheduled at your convenience and will take approximately 45 minutes to complete.

12 Week Follow-Up Assessment Session. You will be asked to complete the same set of questionnaires again at week 12 regardless of your group assignment. It will take approximately 45 minutes to complete.

16 Week Follow-Up Assessment Session (optional). The same set of questionnaires will be sent to you if you are interested in completing them again at week 16. It will take approximately 45 minutes to complete.

Risks and Discomforts

The risk of participating in an exercise program is similar to the risk of engaging in all moderate exercise and may possibly result in muscular fatigue and soreness, dizziness, and fainting. Soreness and fatigue from the SET classes will vary based on your fitness level but you should be fully recovered in 1-3 days. There is a chance for falls during the exercise classes as any movement-based program presents a risk of falls; however, the classes will be personalized toward your physical ability to minimize your chance of falling. You may have shortness of breath, chest pain, heart attack and the remote risk of sudden death.

Benefits

There could potentially be no direct benefit from participating in this study. However, your participation may provide valuable information to the medical and research communities about delivering exercise programs via a telehealth platform to people at home. Additional benefits to participation include analyses of health status and potential health and fitness improvements from participating in physical activity regularly.

Alternatives

Your alternative is to not participate in this study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study staff must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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 website at any time.

Who may use and give out information about you?
Information about your health may be used and given to others by study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and other staff performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization),
Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the University of Alabama at Birmingham (UAB) – staff working on the research study; the UAB Institutional Review Board (IRB) and its staff
- National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR). NIDILRR is the sponsor of this study.

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with Lakeshore Foundation or UAB. You will be requested for a brief interview concerning study withdrawal.

You may be removed from the study without your consent if the sponsor ends the study, or if the study staff decides it is not in the best interest of your health.

Cost of Participation
There will be no cost to you for taking part in this study. All testing assessments and exercise classes for this study will be given to you at no cost. If you are randomized into the SET group, you will also receive a pair of wrist weights from the study at no cost.

Payment for Participation
You will be paid for the completion of each assessment session If you complete all 4 assessment sessions, the total payment you may receive is up to $160.

- $40 for completing the baseline assessment session
- $40 for completing the 8 week post-intervention assessment session
- $40 for completing the 12-week follow-up assessment session
- $40 for completing the 16-week follow-up assessment session

If you are invited and participated in the interview, the total payment you may receive is up to $175.

- $15 for an 8-week phone interview

Payments will be made upon completion of each assessment session. Payment will be made using a pre-paid debit card (ClinCard Prepaid MasterCard®). We will give you a ClinCard upon participation in this study and the money will be added to the card after each completed visit.

You may use your ClinCard at any store that accepts credit cards or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals and inactivity. You will receive letters with additional information on how you can use this card and who to call if you have any questions.

The ClinCard system is administered by an outside company. The company, Greenphire, will be given your name and social security number. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Due to federal tax law, you are required to provide us your social security number in order to process your payments. If you receive over $600 from University of Alabama at Birmingham in a single calendar year (either in a single study or multiple studies), you will be issued an IRS 1099 form. This may affect your taxes. You will be asked to provide your social security number at the end of this form.

Payment for Research-Related Injuries

UAB, NIDILRR, and Lakeshore Foundation have not provided any payment to cover if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

New Findings

You will be told by the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury, including available treatments, you may contact Dr. James Rimmer at (205) 975-9010.

If you have any questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Storage of Information for Recruitment Database

With your permission, the research team will store your demographics and contact information in a recruitment database where we can contact you regarding future research opportunities that you might be interested in. The information will include your name, phone number, mailing address, email address, date of birth, gender, race/ethnicity, and primary/secondary diagnosis. You do not have to agree to allow your information to be stored in our recruitment database in order to be part of this study.

Please initial your choice below:

_____I agree to have my information to be stored in the recruitment database and be contacted for future research opportunities.

_____I do not agree to have my information to be stored in the recruitment database and do not want to be contacted for future research opportunities.

Storage of Data for Future Use

As part of this study, we would like to store the data collected from you for future research on disability. The future research may be conducted by Dr. James Rimmer or by other researchers that obtain IRB approval for their research. The data will be labeled with a code that only the staff of this study can link back to you. Results of any future research will not be given to you or your doctor. The data obtained from you in this research may help in development of future programs in the community. There are no plans to provide financial compensation to you should this occur.

You do not have to agree to allow your data to be stored in order to be part of this study.
You may request at any time that your data be removed from storage and not be used for future research. If you decide that you want your data removed, you may contact Dr. James Rimmer at the University of Alabama at Birmingham at 205-975-9010. If you do not make such a request, your data will be stored indefinitely.

Please initial your choice below:

____ I agree to allow my data to be stored and used for future research.

____ I do not agree to allow my data to be stored and used for future research.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

_____

Social Security Number of Participant

O I decline to provide my social security number and would like to talk to the SCIPE team about an alternative option.

_____

Signature of Person Obtaining Consent Date