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TITLE: Meaningful Changes in Fitness, Functional Independence, and Transfer Independence as Defined by Individuals Living with Spinal Cord Injury

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CONTRACTING ORGANIZATION: University of Alabama at Birmingham

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Meaningful Changes in Fitness, Functional Independence, and Transfer Independence as Defined by Individuals Living with Spinal Cord Injury

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None

14. ABSTRACT

Purpose: Fitness is a major independence/functional status determinant in individuals with spinal cord injury (iSCI). Fitness thus impacts quality of life (QOL), as QOL after spinal cord injury is more dependent on participation, mobility, and personal care independence than impairment/injury level. What remains unknown are the fitness levels that confer desired levels of self-care, mobility, and transfer independence and what fitness gains might confer a *meaningful* gain in these domains. Parallel to this, clinicians (and consumers) lack an easy to use method to determine if an iSCI's fitness level is suboptimal and few interventions have been evaluated for their effectiveness at improving self-care, mobility, and transfer independence. Our long term objective is to fill these gaps.

Specific Aims: Specific Aim 1 (SA1): Identify 'meaningful changes' in self-care, mobility, and transfer independence that can be measured with existing measurement tools and are associated with fitness level or changes. **Specific Aim 2 (SA2):** Assess the external validity and clinical utility of the model predicting if fitness is below the amount required to independently complete bed transfers. **Specific Aim 3 (SA3):** Plan an exercise intervention clinical trial to test if improved fitness can achieve meaningful self-care, mobility, and/or transfer independence gains.

Study Design/Scope: We will complete four projects and one meeting. Projects 1-3 will address SA1. Project 1 will use qualitative interviews coupled with a thematic analysis to identify self-care, mobility, and transfer independence changes that are meaningful to iSCI (N=32). This allows identification of meaningful change without regard to the measurement tools used by researchers. Project 2 will use Experimental Vignettes administered via two online surveys to determine what 'meaningful change' looks like for transfers included in the SCIM-III (Survey 1) and SCI-FI (Survey 2) (N=300 each survey). Project 3 will be a longitudinal observational study collecting data before and after iSCI participate in a community based exercise program (N=27). Meaningful change will be computed using distribution and anchor based methods. Results of Projects 1-3 will be evaluated for congruence, overlap with measurement tools, and association with fitness. Project 4 will address SA2. Project 4 is a cross-sectional study replicating the methods of the original award (N=60). The data collected will be used to assess the external validity and clinical utility of a 'clinic friendly' approach to predict if fitness is below the amount needed for independent bed transfers. A year 3 meeting will address SA 3. We will review Projects 1-4 outcomes and plan an exercise trial to determine if improving fitness can achieve meaningful independence gains and plan a study to fully externally validate all models developed in the initial award.

Results and Significance: No results to report for Year 1

15. SUBJECT TERMS

spinal cord injury, exercise, fitness, rehabilitation, function, activities of daily living, transfer

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1. INTRODUCTION:

The overall objectives of the CDMRP funded grant are to 1) identify meaningful changes in self-care, mobility, and/or transfer independence as defined by individuals with SCI (iSCI) that can be measured with existing tools and are likely to respond to changes in fitness, 2) preliminary assess if the model developed in the initial award to predict if fitness is below the amount required to complete independent bed transfers demonstrates adequate external validity and clinical utility, and 3) Plan a clinical trial to test if improved fitness can achieve meaningful changes in self-care, mobility, and transfer independence.

To achieve objectives 1 and 2, four independent research studies/projects will be conducted. Objective 3 will be achieved by way of an end of award meeting.

2. KEYWORDS:

spinal cord injury, exercise, fitness, rehabilitation, function, activities of daily living, transfer

3. ACCOMPLISHMENTS:

What were the major goals of the project?

What follows are the 'Major Tasks' and associated milestones in the approved SOW. Major tasks are reported as goal.

Goal 1: Complete qualitative interview study (Project 1)

- Milestone #1: *OHARO approval received (Project 1)*
  - *Target completion date: months 10-13*
  - *Actual completion date: month 19, 4/10/2023*
  - *Percent completed/Status: 100%*
- Milestone #2 *Co-author manuscript on "Meaningful Change" based on Project 1*
  - *Target completion date: months 25-32*
  - *Actual completion date: ----*
  - *Percent completed/Status: 0%*
- Milestone #3: *Develop list of measurement tools that may capture 'meaningful changes' as described by Project 1 participants & assess for potential to respond to changes in fitness*
  - *Target completion date: months 13-34*
  - *Actual completion date: ----*
  - *Percent completed/Status: 0%*

Goal 2: Complete Experimental Vignette Study (Project 3)

- Milestone #4 *OHARO approval received (Project 2)*
    - *Target completion date: months 7-9*
    - *Actual completion date: month 20, 5/1/2023*
    - *Percent completed/Status: 100%*
- Milestone #5 *Co-author manuscript on "Meaningful Change" based on Survey 1*
    - *Target completion date: months 15-23*
    - *Actual completion date: ----*
    - *Percent completed/Status: 0%*
- Milestone #6 *Co-author manuscript on "Meaningful Change" based on Survey 2*
    - *Target completion date: months 23-30*
    - *Actual completion date: ----*
    - *Percent completed/Status: 0%*

Goal 3: Complete Sub-Award Study (Project 4*-Longitudinal)

- Milestone #7 *OHARO approval received (Project 3)*
    - *Target completion date: months 2-5*
    - *Actual completion date:*
        - *Month 12, September 27, 2022 (main study)*
        - *Month 12, September 29, 2022 (sub-study)*
    - *Percent completed/Status: 100%*
- Milestone #8*: Co-author manuscript on "Meaningful Change" based on Project 3*
    - *Target completion date: months 26-34*
    - *Actual completion date: ----*
    - *Percent completed/Status: 0%*

Goal 4: Complete External Validation Study (Project 3*)

- Milestone #9: *9: OHARO approval received (Project 4)*
    - *Target completion date: months 3-6*
    - *Actual completion date: month 22, 7/24/2023*
    - *Percent completed/Status: 100%*
- Milestone # 10: *Co-author manuscript on External Validity and Clinical Utility of the model based on Project 4 results.*
    - *Target completion date: months 24-35*
    - *Actual completion date: ----*
    - *Percent completed/Status: 0%*

Goal 5: Strategic planning session to create roadmap to move outcomes toward clinical utility

- Milestone #11: *Roadmap of future studies including Exercise Clinical Trial, full external validation of models to predict fitness, and other studies as determined to be needed.*
    - *Target completion date: months 33-36*
    - *Actual completion date: ----*
    - *Percent completed/Status: 0%, Planning not yet initiated*

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Goals that involve a human subjects research study include a brief description of the study.

Goal 1: Complete qualitative interview study (Project 1): Project 1 involves interviewing N=32 iSCI to determine in their own words what changes in transfer independence, mobility, and self-care are meaningful and then determining if these changes are adequately captured by existing assessments.

Y2 (months 13-24, September 29 2022 - September 28, 2023)					
Subtask or Milestones from SOW	**Was activity planned Y2?**	**Did activity occur Y2**	**Planned completion Quarter**	**Actual Completion Quarter**	**Status**
Subtask 1: Develop initial interview script	No	YES	Y1Q2	Y2Q1	completed
Subtask 2: Submit documents for local IRB review	No	YES	Y1Q3	Y2Q1	completed
Subtask 3: Submit IRB approval and documents for OHARO review.	No	YES	Y1Q4	Y2Q3	completed
Milestone #1: OHARO approval received (Project 1)	YES	YES	Y2Q1	Y2Q3	completed
Subtask 4: Complete Interviews on N=32 individuals with SCI	YES	No	Y3Q1	TBD	See 1
Subtask 5: Code transcripts, consult critical friends, identify themes, generate report	YES	No	Y3Q1	TBD	See 2
Milestone #2: Co-author manuscript on "Meaningful Change" based on Project 1	No	No	Y3Q3	NA	NA
Milestone #3: Develop list of measurement tools that may capture 'meaningful changes' as described by Project 1 participants & assess for potential to respond to changes in fitness	YES	No	Y3Q4	TBD	See 3

The project was submitted to and approved by OHARO this year.

Status 1: Accrual for Project 1 was projected to begin Y2Q1. Accrual is anticipated to begin in Y3Q2.

Status 2: subtask 5 activities will begin once accrual begins

Status 3: Milestone # activities will begin after accrual begins

Goal 2: Complete Experimental Vignette Study (Project 2): Project 2 involves administering a series of surveys to iSCI to determine what changes in the transfers addressed in key outcome measures are meaningful. A minimum of two surveys will be developed and administered, with a minimum of N=300 iSCI completing each 'main' survey. Each 'main' survey will be preceded by a smaller pilot survey.

Y2 (months 13-24, September 29 2022 - September 28, 2023)					
Subtask or Milestones from SOW	**Was activity planned Y2?**	**Did activity occur Y2**	**Planned completion Quarter**	**Actual Completion Quarter**	**Status**
Subtask 1: Develop Vignettes	No	No	Y1Q2	Y1Q4	completed
Subtask 2: Submit documents for local IRB review	No	YES	Y1Q3	Y2Q1	completed
Subtask 3: Submit IRB approval and documents for OHARO review.	No	YES	Y1Q3	Y2Q3	completed
Subtask 4: Develop RedCap database	No	No	Y1Q3	TBD	See 1
Milestone #4: OHARO approval received (Project 2)	No	YES	Y1Q3	Y2Q3	completed
Subtask 5: Complete pilot studies for Survey 1 and 2, determine sample size, revise vignettes if need	YES	No	Y2Q3	TBD	See 2
Subtask 6: Complete Survey 1 on N=300	YES	No	Y2Q2	TBD	See 3
Subtask 7: Integrate results of Survey 1 with initial award data to identify fitness levels and differences associated with meaningful change	YES	No	Y2Q4	TBD	See 4
Milestone #5: Co-author manuscript on "Meaningful Change" based on Survey 1	YES	No	Y2Q4	TBD	See 5
Subtask 8: Complete Survey 2 on N=300	YES	No	Y3Q1	NA	See 6
Subtask 9: Integrate results of Survey 2 with initial award data to identify fitness levels and differences associated with meaningful change	YES	No	Y3Q2	NA	See 7
Milestone #6: Co-author manuscript on "Meaningful Change" based on Survey 2	YES	No	Y3Q2	NA	See 8

The project was submitted to and approved by OHARO this year.

Status 1: RedCap development is paused until revision of the Vignettes, process, and response options is completed

Status 2: Accrual for the pilot studies is delayed due to the delay in OHARO approval.

Status 3: Completion of Survey 1 is delayed due to the delay in the start of accrual

Status 4: Integration of Survey 1 results with prior award results is delayed due to the delay in Survey 1

Status 5: Development of the first manuscript is delayed until accrual begins. Once accrual begins, methods will have finalized & can be drafted for the manuscript

Status 6: Accrual for Survey 2 is delayed due to the delay in Survey 1

Status 7: Integration of Survey 2 results with prior award results is delayed due to the delay in Survey 2

Status 8: Development of the second manuscript is delayed until accrual begins. Once accrual begins, methods will have finalized & can be drafted for the manuscript

Goal 3: Complete Sub-Award Study (Project 4*-Longitudinal): Project 4 involves assessing the fitness and function of up to N=180 iSCI before and after participation in an exercise training program in order to capture longitudinal changes in fitness and function. These measured changes will be used to generate estimates of meaningful change using techniques that require longitudinal data. In addition, the training program used to achieve the measured changes will be characterized. The training program is an ongoing community based program that occurs independent of the CDMRP award.

Y2 (months 13-24, September 29 2022 - September 28, 2023)					
Subtask or Milestones from SOW	**Was activity planned Y2?**	**Did activity occur Y2**	**Planned completion Quarter**	**Actual Completion Quarter**	**Status**
Subtask 1: Translate SCIM-III self-report & Fall Concern Scale	No	No	Y1Q1	Y1Q2	completed
Subtask 2: Submit documents for local IRB review	No	No	Y1Q1	Y1Q2	completed
Subtask 3: Submit IRB approval and documents for OHARO review.	No	No	Y1Q2	Y1Q4	completed
Subtask 4: Develop RedCap database	No	No	Y1Q2	Y1Q4	completed
Milestone #7: OHARO approval received (Project 3)	No	No	Y1Q2	Y1Q4	completed
Subtask 5: Enroll and test N=27 (minimum)	Yes	Yes	Y3Q2	NA	See 1
Subtask 6: Characterize the training program used to increase fitness	Yes	Yes	Y3Q2	NA	See 2

Milestone #8: Co-author manuscript on "Meaningful Change" based on Project 3	YES	No	Y3Q4	NA	NA

As indicated in the Y1Q1 report, all activities for Goal 3 have been delayed by a quarter due to the delay in execution of the subaward. Other than the delay in the start of Goal 3 activities, this project is progressing according to the proposed timeline.

During Y2, Dr. Cowan, Dr. de Groot and post-doc Dr. Kouwijzer met monthly as needed.

Status 1: The study activities of the first cohort (2023) have finished. Participants performed exercise tests before and after training. They filled out questionnaires before, during, and after the training period.

Status 2: Participants used a training app to monitor their training sessions. These training data will be used to complete subtask 6. This data collection is part of the IRB and OHARO approved protocols.

Goal 4: Complete External Validation Study (Project 3):** Project 3 involves assessing the fitness and function of N=60 iSCI in order to preliminarily assess the validity and clinical utility of an algorithm predicting if fitness is below the amount required to complete independent bed transfers.

**In the SOW, this project is referred to as Project 4.

Y2 (months 13-24, September 29 2022 - September 28, 2023)					
Subtask or Milestones from SOW	**Was activity planned Y2?**	**Did activity occur Y2**	**Planned completion Quarter**	**Actual Completion Quarter**	**Status**
Subtask 1: Submit documents for local IRB review	No	No	Y1Q1	Y1Q4	completed
Subtask 2: Submit IRB approval and documents for OHARO review.	No	YES	Y1Q2	Y2Q3	completed
Subtask 3: Develop RedCap database	No	YES	Y1Q2	TBD	See 1
Milestone #9: OHARO approval received (Project 4)	No	YES	Y1Q2	Y2Q4	completed
Subtask 4: Enroll and test N=60	YES	No	Y3Q2	TBD	See 2
Milestone #10: Co-author manuscript on External Validity and Clinical Utility of the model based on Project 4 results.	YES	No	Y3Q4	NA	NA

This project was approved OHARO this year.

Status 1: RedCap development is delayed due to multiple problems identified during Y1 and Y2 in section 4 "Changes/Problems."

Status 2: Initiation of Accrual is delayed due to to multiple problems identified during Y1 and Y2 in section 4 "Changes/Problems."

Goal 5: Strategic planning session to create roadmap to move outcomes toward clinical utility: Goal 5 is a meeting at the end of the award period attended by all key personnel. During this meeting a) outcomes of all projects 1-4 will be reviewed, b) an exercise trial will be planned to test the hypothesis that improving fitness will achieve meaningful independence gains and c) if warranted, a trial will be planned to fully externally validate all models of the 'clinic friendly' tool.

Y2 (months 13-24, September 29 2022 - September 28, 2023)					
Subtask or Milestones from SOW	**Was activity planned Y2?**	**Did activity occur Y2**	**Planned completion Quarter**	**Actual Completion Quarter**	**Status**
Subtask 1: Assemble results from Projects 1, 2, 3 & identify areas of convergence as regards meaningful change, measurement tools, and potential to respond to exercise interventions.	YES	No	Y3Q2	NA	See 1
Subtask 2: Assemble descriptions of published exercise interventions (and Project 3). Contact study authors if needed to gather greater detail	YES	No	Y3Q3	NA	See 2
Subtask 3: Assemble result from project 4 (external validation)	No	No	Y3Q3	NA	NA
Subtask 4: Hold strategic planning meeting	No	No	Y3Q4	NA	NA
Milestone #11: Roadmap of future studies including Exercise Clinical Trial, full external validation of models to predict fitness, and other studies as determined to be needed.	No	No	Y3Q4	NA	NA

No activities during Y2

Status 1: Delayed due to the delay in starting accrual in all projects.

Status 2: Delayed due to delay in hiring study personnel.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor.

"Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

During year 3 to achieve the stated goals, the following will occur

- Accrual for Projects 1, 2, and 3 will begin
- Study databases for Projects 1, 2, and 3 will be completed
- New plans for completing accrual for Projects1, 2, and 3 will be developed. This will include leveraging the PI's new position of SCI model system to facilitate targeted recruitment.
- PI will return to full funded effort levels.
- A re-budget may be requested to move money from personnel (non-key) to other expenses to outsource development of databases and get assistance with study execution if that would produce a more timely achievement of study goals.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

No changes in approach occurred during year 2.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

ACTUAL problems or delays and actions or plans to resolve them:

Problem: Change in institution for Robert Motl, PhD (Key Personnel): Dr. Motl accepted a new position at the University of Illinois Chicago during Y1Q1. Dr. Motl's roles include providing guidance on the thematic analysis process for Project 1 (Interviews); overseeing the fitness tests in Project 3 (Model Validation); participating in the end of award meeting (Specific Aim 3); and providing general mentorship and guidance to Dr. Cowan.

Impact: The main impact is a delay in beginning enrollment for Project 3 (model validation). This delay will occur in part because Dr. Cowan shifted effort from submission of the Project 3 IRB during Y1Q1 to identifying and implementing solutions for Dr. Motl's shift.

Corrective Action: Except for oversight of the Project 3 fitness testing, all of Dr. Motl's responsibilities can be conducted remotely from his new institution. Therefore, we requested a budget modification in Y1Q2 to shift Dr. Motl from Key Personnel at UAB to a subaward and will subsequently execute the subaward. Fitness testing will shift from the UAB Center of Exercise Medicine to the Lakeshore Foundation. Staff there have extensive experience administering the required fitness tests to individuals with SCI. Dr. Cowan will work closely with the staff to ensure fidelity to the testing Protocol and will include discussion of the testing and outcomes with Dr. Motl. Dr. Cowan oversaw over 150 fitness tests as a part of the previous award and is thus well positioned to take on a more active role than previously planned. A contract between UAB and Lakeshore Foundation to support their efforts was implemented in Year 2. Additional re-budgeting requests are not anticipated at this time as any re-allocation of funds would likely occur within the existing budget categories. Additional funding will not be needed.

The re-budget request was approved in Y2Q2.

Problem: Unanticipated increase in Dr. Cowan's (PI) workload: In July-August 2022 (Y1Q4, month 1), Dr. Cowan took over as PI of UAB's newly awarded SCI Model System (NIDILRR funded). The original PI took a new position at a different institution and Dr. Cowan stepped forward to take over the PI position.

Impact: The immediate impact was a significant increase in workload just as Dr. Cowan was completing other major obligations to a WHO funded contract and was ramping up effort on this award. This increase in workload, coupled with a high degree of Y1Q4 effort on securing rapid OHARO approval for the sub-award project (due to its time sensitive nature), decreased the amount of effort that could be put towards submission of Project 1 (interviews), 2 (survey), and 3 (model validation) IRBs. The result is a delay in submission of these protocols to the local IRB by ~1 month (Y2Q1). The excessive workload is expected to last through Y2Q2, when Dr. Cowan's WHO funded contract will be completed and workloads will return to normal levels.

There are also beneficial impacts to Dr. Cowan's new leadership position. Most importantly, it provides intimate access to the study staff who interact with SCI model systems participants on a daily basis and the underlying database of over 2000 individuals with SCI (most who live in Alabama). Dr. Cowan intends to leverage this access in Y2 and Y3 to support targeted recruitment of individuals for participation in the local studies. The period of excessive workload will be completed in Y2Q2 as the WHO contract is completed.

Corrective action: To manage the excessive limited term increase in workload, obligations to each award (WHO, SCI model systems, the award) will be prioritized based on their impact and urgency. This means that obligations with low impact if delayed will be delayed and obligations with high impact if delayed will be delayed and completed according to their urgency/impact. This approach is in part why this report is so delayed. To balance reporting delays, Dr. Cowan has been in communication with her Science Officer to keep him up to date. In addition, all obligations that can be delegated to others will be delegated and assistance from staff sought as fits their capabilities and availability.

At this time (Year 2 report), this period of increased workload has partly delayed the start of accrual of the local projects. The period of excessive workload has generally concluded at the time of this report.

Problem: Delays in Hiring Staff: Due to Dr. Cowan's health problems and the unexpected increase in workload in Y2, staff hiring has been delayed.

Impact: Delays in staff hiring have contributed to delays in IRB submission, database development, and start/completion of study accrual.

Corrective action: Staff were hired and started at the end of Y2Q3, but only 50%FTE was dedicated to this award due to widespread staffing shortages on multiple grants in the Department. Accrual on all projects will begin in Y3.

Problem: Delay in execution of International subaward contract – Project 4 (Longitudinal): The international sub-award was fully executed at the beginning of Y1Q2, instead of the scheduled Y1Q1.

Impact: Delay in the start and completion of Project 4 accrual.

Corrective Action: A 1 year no cost extension will likely be required in order to complete Project 4 target accrual. Rationale for the likely no cost extension is addressed in the next section (Anticipated Problems) under "Delay in the start and completion of Project 4 enrollment."

Problem: Delays in initiating and completing accrual for Projects 1, 2, and 3: Many of the problems described in the Actual delays section in this report (Y2) and the prior report (Y1) have contributed to the delay in securing IRB/OHARO approval for Projects 1, 2, and 3, completion of the underlying study databases, and accrual start/completion.

Impact: These delays have delayed initiation of accrual for these projects. Projects 1 and 2 may still be completed in the final year. Project 3 will likely require a no-cost extension to complete. All three projects had a buffer built in as regards completion of accrual

Corrective Action: Accrual for all three projects will begin in Year 3.

Problem: Dr. Cowan's Family Health Problems: One of Dr. Cowan's immediate family members began experiencing a serious health problem in Y2Q4. Dr. Cowan has been heavily involved in managing the problem and took substantial accrued vacation time during Y2Q4.

Impact: The long term impact is a delay in completing Projects 1, 2, and 3.

Corrective Action: Extension of the award period will likely be needed

ANTICIPATED problems or delays and actions or plans to resolve them:

Anticipated Problem: Delays in completing accrual for Projects 1, 2, and 3: They delay in initiation of accrual will delay accrual completion.

Impact:. It is not clear if completion of accrual will require a no cost extension. All three projects had a buffer (3-12 months) built in as regards completion of accrual. This may be sufficient.

Corrective Action: It is probable that Project 1 and 2 accruals can be completed & manuscripts submitted by the end of Y3. Project 3 will likely require a non-cost extension to complete.

Problem: Dr. Cowan's Family Health Problems: One of Dr. Cowan's immediate family members began experiencing a serious health problem in Y2Q4. Dr. Cowan has been heavily involved in managing the problem and took substantial accrued vacation time during Y2Q4. This health problem may take 8-10 months to resolve

Impact: The long term impact is a delay in completing Projects 1, 2, and 3.

Corrective Action: Extension of the award period will likely be needed

Anticipated Problem: Delay in start and completion of Project 4 (International Longitudinal) enrollment: The international sub-award was fully executed at the beginning of Y1Q2, instead of the scheduled Y1Q1. This resulted in a 1 year delay in beginning study accrual.

Impact: The delay in execution of the international sub-award resulted in a 1 year delay in the start of Project 4 accrual (Y1Q2 to Y2Q2). This extended delay is due to the unique nature of Project 4. Project 4 is an observational study that measures the impact of a community based physical activity program that operates independently of the award. This physical activity program is annual program that has a defined start and end each calendar year (Jan-Dec). Participants in the program generally complete their pre-exercise/training program assessments in January and their post-training assessments in May. The delay in execution of the international subaward made it impossible to secure IRB and HRPO approval in time to enroll participants in January 2022 (Y1Q2) as specified in the SOW. And because the program operates independently of this award, it is not possible to begin the program immediately after HRPO approval is secured.

Corrective Action: Achieving our target accrual for Project 4 and completion of all deliverables will likely require a 1 year no cost extension. Because Project 4 is dependent on the community based program and the program runs once a year, there is no way that we can increase annual accrual numbers. OHARO approval was secured and the study database completed in Y1Q4, which will allow Project 4 to generally adhere to the projected timeline after adjustment for this initial delay. OHARO approval in record time (~6 weeks) was due to the extreme support of OHARO staff from the top down. Our sincerest gratitude and appreciation for the efforts and guidance of

Anticipated problem: Possible disruption of participant inclusion in Project 4 (International Longitudinal): If the community based activity program related to the community based physical activity program cannot proceed due to Covid-19 or another unanticipated problem, this might lead to a lower inclusion of participants or a disruption of their longitudinal follow-up. This potential problem was identified in the grant application.

Corrective Action: although something like a pandemic is beyond our control, we have included a local handcycle training program in De Hoogstraat Rehabilitation Center in Utrecht, the Netherlands, to the study protocol. As such, similar information can be generated. A sub-study has been included for this purpose and will enroll participants in parallel to the main study.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Actual problems reported in the previous section resulted in a significant reduction in spending from the projected/budgeted spending. Year 1 and 2 projected cumulative spending was $1,054,000 (total costs) Actual spending was $350,268 (total costs) (33% of projected). The primary culprit was Dr. Cowan's health problems (Y1) and family health problems (Y2) which reduced her effort, delays in hiring and delays in starting Projects 1-3. Year 3 spending should be closer to projected and a no-cost extension will likely be needed to complete all projects, but cumulative grant expenditures will not exceed the awarded amount.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. **PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  Nothing to Report

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  Nothing to Report

  Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

  Nothing to Report

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

  Nothing to Report

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

  Nothing to Report

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

  Nothing to Report

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

  Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Name:	Rachel Cowan, PhD
Project Role:	Principle Investigator
Research Identifier:	0000-0002-3320-0653
Nearest person month worked*:	7
Contribution to Project:	Dr. Cowan began training the new hire and met and/or corresponded with co-investigators as needed
Name:	Kim Anderson, PhD
Project Role:	Consultant
Research Identifier:	0000-0001-9252-161X
Nearest person month worked*:	<1
Contribution to Project:	Dr. Anderson corresponded with Dr. Cowan as needed during this period to provide feedback on Project 2.
Name:	Sonja de Groot, PhD
Project Role:	Co-Investigator
Research Identifier:	0000-0001-8463-2563
Nearest person month worked*:	<1
Contribution to Project:	Dr. de Groot participated in meetings on Project 4 and provided guidance and oversight to Dr. Kouwijzer
Name:	Ingrid Kouwijzer, PhD
Project Role:	Co-Investigator / Post-Doc
Research Identifier:	0000-0003-1012-3509
Nearest person month worked*:	21
Contribution to Project:	Dr. Kouwijzer was responsible for all recruitment and assessments for Project 4.
Name:	Jereme Wilroy, PhD
Project Role:	Co-Investigator
Research Identifier:	0000-0002-3496-7389
Nearest person month worked*:	<1
Contribution to Project:	Dr. Wilroy was consulted as needed for Project 1
Name:	Yu-Ying Chen, PhD
Project Role:	Co-Investigator
Research Identifier:	0000-0003-3512-5316
Nearest person month worked*:	<1
Contribution to Project:	Dr. Chen was consulted as needed for project 2
Name:	Allen Heinemann, PhD
Project Role:	Co-Investigator
Research Identifier:	0000-0003-2782-7326
Nearest person month worked*:	<1
Contribution to Project:	Dr. Heinemann was consulted as needed for project 2.
Name:	Robert Motl, PhD

Project Role:	Co-Investigator
Research Identifier:	Not available
Nearest person month worked*:	<1
Contribution to Project:	Dr. Motl was consulted as needed for all projects.
Name:	Chloe Sapalaran
Project Role:	Clinical Research Coordinator
Research Identifier:	NA
Nearest person month worked*:	1
Contribution to Project:	Ms. Sapalarn began training in Q4 and began working on the study database for project 4.
*Nearest person month worked reported as "months worked this quarter (cumulative months worked)	

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Senior/Key Personnel

- Rachel Cowan, PhD:
    - Funded effort as Co-Investigatior on an award titled Examining the effects of live telehealth exercise training on cardiometabolic outcomes in wheelchair users began on February 1, 203 (R01HD111059, NIH). Funded effort is 5% (0.60 months)

- Yuying Chen, MD, PhD
    - Funded effort as Co-Investigator on a subaward as a part of the award titled The Context of Living with Spinal Cord Injury: A Collaborative Program of Research to Advance the Science of Environmental Factors and Disability began September 1, 2022 (90SIMS0021, NIDILRR). Funded effort is 4% FTE (0.48 months)

- Jereme Wilroy, PhD

    - Funded effort as PI on an award titled Examining the effects of live telehealth exercise training on cardiometabolic outcomes in wheelchair users began on February 1, 203 (R01HD111059, NIH). Funded effort is 37.5% (4.50 months)

    - Funded effort as Co-Investigator on a subaward as a part of the award titled The Context of Living with Spinal Cord Injury: A Collaborative Program of Research to Advance the Science

of Environmental Factors and Disability began September 1, 2022 (90SIMS0021, NIDILRR). Funded effort is 15% FTE (1.80 months)

- Funded effort as Co-Investigator on award titled Acceptance and Commitment Therapy Accompanied by Psychoeducation for Mental Health of Depressed Individuals Living with Spinal Cord Injury within Five Years: A Pilot Randomized Controlled Trial began on 3/1/23. (Paralyzed Veterans of America). Funded at 0.60 calendar months.

- Effort completed on Feasibility of the First Known Adaptive Intervention Delivering Innovative Exercise Program Optimized for People with SCI completed on 4/29/23. (645335, Craig Neilsen Foundation). Funded at 1.20 calendar months.

- Effort completed on Scale-Up of an Innovative, Evidence-Based Movement 2-Music (M2M) Intervention for Adults with Physical/Mobility Disability on 9/29/23. (90DPGE0005, NIDILRR). Funded at 1.80 calendar months.

All of the above named personnel are still able to meet their obligations (i.e. funded effort) to the current award.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Organization Name: Vrije University
Location of Organization: (if foreign location list country) Amsterdam, Netherlands
Partner's contribution to the project (identify one or more): Sub-Award contract for Project 4 (Longitudinal). Responsible for all aspects of execution for Project 4

Organization Name: Kim Anderson, PhD (Consultant)
Location of Organization: (if foreign location list country): Cleveland, OH
Partner's contribution to the project (identify one or more): Consultation on Project 2 (Surveys) and how to adapt all projects to include the SCIM-IV

Organization Name: Shirley Ryan Ability Lab
Location of Organization: (if foreign location list country): Chicago, IL
Partner's contribution to the project (identify one or more): Providing Intellectual support for all four projects; providing guidance/recommendations as regards best practice for the questionnaires used in all projects, developing impressions of change questions and scoring; and on general study design and project execution for all Projects; providing information to UAB as needed/requested for Sponsor reports; participating/leading (as appropriate) analysis, interpretation, and dissemination activities (e.g. conferences and manuscripts); and attending and participating in the end of award meeting.

Organization Name: University of Illinois Chicago
Location of Organization: (if foreign location list country): Chicago Illinois
Partner's contribution to the project (identify one or more): Providing intellectual support for the execution of Projects 1, 2, and 3 as needed/requested; participating in mentoring sessions, training sessions, and meetings as needed/requested to support Projects 1, 2, 3; providing guidance on thematic analysis and interpretation for project 1; providing information to UAB as needed/requested for Sponsor reports; participating/leading (as appropriate) analysis, interpretation, and dissemination activities (e.g. conferences and manuscripts); and attending and participating in the end of award meeting.

Organization Name: Lakeshore Foundation
Location of Organization: (if foreign location list country): Homewood, AL
Partner's contribution to the project (identify one or more): Perform fitness and anthropometric assessments for Project 3

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *N/A*

QUAD CHARTS: *N/A*

9. APPENDICES: *N/A*

Meaningful changes in fitness, functional independence, and transfer independence as defined by individuals living with spinal cord injury

Log # SC200263

Award # W81XWH2110813

PI: Rachel Cowan, PhD **Org:** University of Alabama at Birmingham **Award Amount: $1,652,053**

Study Aim(s)

Aim 1: Identify 'meaningful changes' in self-care, mobility, and transfer independence that can be measured with existing measurement tools and are associated with fitness level or changes. (Projects 1, 2, 4)

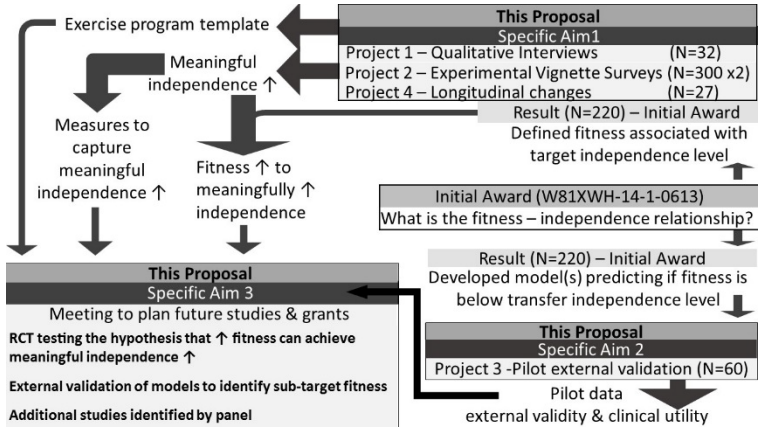
Aim 2: Assess the external validity and clinical utility of the model predicting if fitness is below the amount required to independently complete bed transfers. (Project 3)

Aim 3: Plan an exercise intervention clinical trial to test if improved fitness can achieve meaningful changes in self-care, mobility, and/or transfer independence (Meeting year 3)

Approach

We will complete FOUR projects and a meeting. Project 1 will be interviews of N=32 iSCI. Project 2 will be two surveys, each administered to N=300 iSCI. Project 3 will be an observational study measuring fitness and function before and after a community based training program (N=27). Project 4 will replicate the methods of the original award on N=60 iSCI to externally validate one model from the original award. A meeting in year 3 will be used to evaluate the results of all projects and plan future studies

Figure illustrating the relationship between the initial award, the projects of the proposed award, the information to be generated by each project, and the resulting future grant applications



No scientific accomplishments during Y2Q2
(July 1, 2023 – September 30, 2023)

Timeline and Cost

Activities	Grant Year (GY)		
	1	2	3
Project 1 – Interviews			
Project 2 – Surveys			
Project 3 – Validation			
Project 4 – Longitudinal			
Requested Total Budget ($K)	$529	$525	$523

Updated: December 22, 2023
Reporting Period: Y2Q4

Goals/Milestones as defined in the SOW

GY 1 Goal – Launch all Projects

X HRPO approval for all projects (1, 2, 3, 4)

☐ Begin enrollment for Project 1, Project 3, & Project 4

GY 2 Goals – Maintain target accrual rates on all projects

☐ Begin enrollment for Project 2

☐ Maintain target accrual for Projects 1, 3, & 4

GY 3 Goal – Production readiness

☐ Complete enrollment for all Projects

☐ Complete submission of all manuscripts

☐ Plan future studies during planning meeting

Comments/Challenges/Issues/Concerns

- Projects 1, 2, 3 delayed due to PI health issues & new workload.
- Spending is behind, re delay hiring staff & subaward execution.

Budget Expenditure to Date

Projected Total Cost Expenditure: $1,054,000

Actual Total Cost Expenditure: $350,268