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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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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: *HRPO approval received (Project 1)*
 - *Target completion date: months 10-13*
 - *Actual completion date: ----*
 - *Percent completed/Status: 0% - HRPO submission is pending IRB approval*
- 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 *HRPO approval received (Project 2)*
 - *Target completion date: months 7-9*
 - *Actual completion date: ----*
 - *Percent completed/Status: 0% - HRPO submission is pending IRB approval*
- 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 *HRPO 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: *HRPO approval received (Project 4)*
 - *Target completion date: months 3-6*
 - *Actual completion date: ----*
 - *Percent completed/Status: 0% - HRPO submission is pending IRB approval*
- 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?

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.

Y1 (months 1-12, September 29 2021 - September 28, 2022)					
Subtask or Milestones from SOW	Was activity planned Year 1?	Did activity occur Year 1?	Planned completion Quarter	Actual Completion Quarter	Status
Subtask 1: Develop initial interview script	Yes	Yes	Y1Q2	TBD	See 1
Subtask 2: Submit documents for local IRB review	Yes	No	Y1Q3	TBD	See 2
Subtask 3: Submit IRB approval and documents for HRPO review.	Yes	No	Y1Q4	TBD	See 3
<i>Milestone #1: HRPO approval received (Project 1)</i>	Yes	No	Y2Q1	NA	NA
Subtask 4: Complete Interviews on N=32 individuals with SCI	No	No	Y3Q1	NA	NA
Subtask 5: Code transcripts, consult critical friends, identify themes, generate report	No	No	Y3Q1	NA	NA
<i>Milestone #2: Co-author manuscript on “Meaningful Change” based on Project 1</i>	No	No	Y3Q3	NA	NA
<i>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</i>	No	No	Y3Q4	NA	NA

Status 1: At the end of Y1Q4, the interview script was 90% complete. Multiple problems identified in section 4 “Changes/Problems” delayed the completion of the interview script.

Status 2: IRB forms were 90% completed. IRB submission is planned for the first month of Y2Q1. Multiple problems identified in section 4 “Changes/Problems” delayed the submission of the IRB.

Status 3: OHARO submission is delayed due to delayed IRB submission.

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.

Y1 (months 1-12, September 29 2021 - September 28, 2022)					
Subtask or Milestones from SOW	Was activity planned Year 1?	Did activity occur Year 1?	Planned completion Quarter	Actual Completion Quarter	Status
Subtask 1: Develop Vignettes	Yes	Yes	Y1Q2	Y1Q4	Completed
Subtask 2: Submit documents for local IRB review	Yes	No	Y1Q3	TBD	See 1
Subtask 3: Submit IRB approval and documents for HRPO review.	Yes	No	Y1Q3	TBD	See 2
Subtask 4: Develop RedCap database	Yes	No	Y1Q3	TBD	See 3
<i>Milestone #4: HRPO approval received (Project 2)</i>	Yes	No	Y1Q3	TBD	See 4
Subtask 5: Complete pilot studies for Survey 1 and 2, determine sample size, revise vignettes if need	Yes	No	Y2Q3	NA	NA
Subtask 6: Complete Survey 1 on N=300	No	No	Y2Q2	NA	NA
Subtask 7: Integrate results of Survey 1 with initial award data to identify fitness levels and differences associated with meaningful change	No	No	Y2Q4	NA	NA
<i>Milestone #5: Co-author manuscript on “Meaningful Change” based on Survey 1</i>	No	No	Y2Q4	NA	NA
Subtask 8: Complete Survey 2 on N=300	No	No	Y3Q1	NA	NA
Subtask 9: Integrate results of Survey 2 with initial award data to identify fitness levels and differences associated with meaningful change	No	No	Y3Q2	NA	NA
<i>Milestone #6: Co-author manuscript on “Meaningful Change” based on Survey 2</i>	no	No	Y3Q2	NA	NA

Status 1: IRB forms were 90% completed. IRB submission is planned for the first month of Y2Q1. Multiple problems identified in section 4 “Changes/Problems” delayed the submission of the IRB.

Status 2: OHARO submission is delayed due to delayed IRB submission.

Status 3: Drafting of RedCap database delayed due to multiple problems identified in section 4 “Changes/Problems” delayed the submission of the IRB. PI is considering using Qualtrics instead of RedCap because Qualtrics is more visually appealing to participants.

Status 4: OHARO approval delayed due to delayed OHARO submission.

Goal 3: Complete Sub-Award Study (Project 4*-Longitudinal): Project 4 involves assessing the fitness and function of up to N=60 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.

Y1 (months 1-12, September 29 2021 - September 28, 2022)					
Subtask or Milestones from SOW	Was activity planned Year 1?	Did activity occur Year 1?	Planned completion Quarter	Actual Completion Quarter	Status
Subtask 1: Translate SCIM-III self-report & Fall Concern Scale	Yes	Yes	Y1Q1	Y1Q2	completed
Subtask 2: Submit documents for local IRB review	Yes	Yes	Y1Q1	Y1Q2	completed
Subtask 3: Submit IRB approval and documents for HRPO review.	Yes	Yes	Y1Q2	Y1Q4	completed
Subtask 4: Develop RedCap database	Yes	Yes	Y1Q2	Y1Q4	completed
<i>Milestone #7: HRPO approval received (Project 3)</i>	Yes	Yes	Y1Q2	Y1Q4	completed
Subtask 5: Enroll and test N=27 (minimum)	Yes	No	Y3Q2	NA	See 1
Subtask 6: Characterize the training program used to increase fitness	Yes	No	Y3Q2	NA	See 2
<i>Milestone #8: Co-author manuscript on "Meaningful Change" based on Project 3</i>	No	No	Y3Q4	NA	NA

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.

Status 1: Enrollment will begin in Y2Q1.

Status 2: Once enrollment begins, data collection to characterize the training program used to increase fitness can begin. This data collection is a 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.

Y1 (months 1-12, September 29 2021 - September 28, 2022)					
Subtask or Milestones from SOW	Was activity planned Year 1?	Did activity occur Year 1?	Planned completion Quarter	Actual Completion Quarter	Status
Subtask 1: Submit documents for local IRB review	No	No	Y1Q1	TBD	See 1
Subtask 2: Submit IRB approval and documents for HRPO review.	No	No	Y1Q2	TBD	See 2
Subtask 3: Develop RedCap database	No	No	Y1Q2	TBD	See 3
<i>Milestone #9: HRPO approval received (Project 4)</i>	No	No	Y1Q2	TBD	See 4
Subtask 4: Enroll and test N=60	Yes	No	Y3Q2	NA	NA
<i>Milestone #10: Co-author manuscript on External Validity and Clinical Utility of the model based on Project 4 results.</i>	No	No	Y3Q4	NA	NA

Status 1: IRB forms were 90% completed. IRB submission is planned for the first month of Y2Q1. Multiple problems identified in section 4 “Changes/Problems” delayed the submission of the IRB.

Status 2: OHARO submission was delayed due to delay in IRB submission.

Status 3: Drafting of RedCap database delayed due to multiple problems identified in section 4 “Changes/Problems” delayed completion of the database.

Status 4: OHARO approval delayed due to delayed OHARO submission.

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.

Y1 (months 1-12, September 29 2021 - September 28, 2022)					
Subtask or Milestones from SOW	Was activity planned Year 1?	Did activity occur Year 1?	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.	No	No	Y3Q2	NA	NA
Subtask 2: Assemble descriptions of published exercise interventions (and Project 3). Contact study authors if needed to gather greater detail	No	No	Y3Q3	NA	NA
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
<i>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.</i>	Yes	No	Y3Q4	NA	NA

Per the SOW, no activities are planned until grant year 3 (Oct 2023 – Sept 2024)

What opportunities for training and professional development has the project provided?

Nothing to Report

How were the results disseminated to communities of interest?

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

During year 2 to achieve the stated goals, the following will occur

- Staff will be hired
- 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 Projects 1, 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.
- WHO contract will be completed in Q2, returning workloads to normal 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:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

No changes in approach occurred during year 1.

Actual or anticipated problems or delays and actions or plans to resolve them

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

Problem: Publication of the SCIM-IV, a new version of a critically important outcome measure/assessment tool used in the original award and in this expansion award:

Impact: The impacts of this problem are both positive and negative. The negative impact was a initial delay in the IRB submissions of Projects 1, 2, and 3 as the team determined how to best implement both the old and new version in all Projects without dramatically impacting participant and investigator burden. The positive impact is that we can ensure that the differences between the old and new version of this Key Outcome are appropriately implemented in each of the four Projects, thereby maintaining a strong link to the prior award efforts, while also ensuring relevance to implementation of the new version in future worldwide research studies.

Corrective Action: The PI spent a substantial portion of her effort in Y1Q1 to defining the differences between the old and new versions; in determining how to best implement the old and new version in all Projects without excessively increasing participant burden and while maintaining fidelity to the award objective; and to maintaining scientific rigor. Implementation decisions will be reported in the Year 2 report.

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 UAB-Lakeshore Research Collaborative. 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. Discussions are underway with the Research Collaborative Director, James Rimmer, PhD, as to if the fee per test

model (proposed approach) or if % personnel effort will be used to fund fitness testing. At this time either approach is expected to work within the approved funding amount. 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.

As of the end of Y1Q4, the re-budget request was still under review.

Problem: Significant health problems experienced by Dr. Cowan (PI): Dr. Cowan began experiencing the effects of a significant, unexpected health problem during Y1Q2 (~ month 5). The health problem was not diagnosed until late Y1Q3 (month 9). Treatment began less than a week after diagnosis. Full recovery (i.e. return to 100% capacity) is expected to take up to 6 months (Y2Q1, month 15)

Impact: The immediate impact of the health problem was a large reduction in Dr. Cowan's work capacity and performance during Y1Q1, Y1Q2, and Y1Q3. This affected all of her responsibilities, not just this grant. The long term impact is anticipated to be delays in completing project 1, 2, and 3 activities originally planned for Y1Q2, Y1Q3, Y1Q4, and Y2Q1 (months 3-15). Dr. Cowan estimates an approximate 6 month delay in completion of projects 1, 2, and 3 tasks and milestones originally slated for months 3-15. The 6 month delay roughly corresponds to 3 months of the health problem prior to treatment and the first 3 months of treatment. It is not yet clear if these delays will meaningfully impact the planned completion dates of the planned studies, as each one has over a year of accrual planned. It is still possible that projects 1, 2, and 3 can be completed by the end of the award period.

Corrective Action: Upon realizing that a health problem was the likely source of her reduced work capacity, Dr. Cowan scheduled a Dr. appointment and met with her Executive Administrator to develop a corrective plan. During Y1Q2 and Y1Q3, Dr. Cowan was scheduled to complete prior obligations on several other projects, thereby allowing her to fully ramp up effort on this grant. The need to complete these prior obligations is reflected in the approved SOW, specifically by the slow and staggard ramp up of projects 1, 2, & 3. Dr. Cowan's health problems also affected her ability to complete these obligations as planned. Therefore, the corrective plan needed to accommodate completion of these prior obligations in order to allow Dr. Cowan to focus as intended on execution of this project.

Dr. Cowan and her Executive Administrator (EA) agreed that Dr. Cowan would use the final two Quarters of year 1 (months 7-12) to complete the majority (~90%) of her prior obligations and get projects 1, 2, 3 of this award submitted for local IRB review. In parallel Dr. Cowan and her EA would meet approximately biweekly to review her progress. To better enable her to complete her prior obligations and thus shift focus and effort on this award, some of Dr. Cowan's colleagues and trainees have agreed to assist Dr. Cowan with completion of her prior obligations.

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 1 report), it is not clear if this period of increased workload will delay completion of study accrual in the local projects. The period of increased workload coincides with the local IRB and OHARO reviews and should conclude by the time OHARO approval is secured.

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

Impact: Delays in staff hiring have contributed to delays in IRB submission and database development.

Corrective action: Prioritize hiring in Y2 and determine if some of the funds allocated to personnel are better deployed on contract services to complete database development or assist with study execution. A re-budget request will be submitted if warranted.

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 have contributed to the delay in securing IRB/OHARO approval for Projects 1, 2, and 3 and completion of the underlying study databases.

Impact: These delays have delayed initiation of accrual for these projects. It is not clear if completion of accrual will require a no cost extension. All three projects had a buffer built in as regards completion of accrual. This may be sufficient.

Corrective Action: Once all three Projects have OHARO approval and staff are hired, we will be able to develop new plans to achieve the targeted accruals. Accrual for all three projects will begin in Year 2.

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

Anticipated Problem: Unanticipated increase in Dr. Cowan’s (PI) workload: As described in the Actual problems section, Dr. Cowan had an unexpected increase in workload due to assuming the PI role of UAB’s newly funded SCI model system.

Impact: The year 2 negative impact is expected to be minimal as Dr. Cowan will complete contractual obligations to WHO in Y2Q2, which is approximately when OHARO approval will be secured. I. The longer term impact will be positive as the leadership position 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. At this time (Year 1 report), it is not clear if this period of increased workload will delay completion of study accrual in the local projects.

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.

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: Once all three Projects have OHARO approval and staff are hired, we will be able to develop new plans to achieve the targeted accruals. It is highly likely that Project 1 and 2 accruals can be completed & manuscripts submitted by the end of Y3Q4, as the proposed completion for both was Y3Q1 and the recruitment area is nationwide. Project 3 will be more challenging to complete by the end of Y3Q4 as the subject burden is higher, inclusion criteria more restrictive, and participants must come to the laboratory for testing.

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

Actual problems reported in the previous section resulted in a significant reduction in spending from the projected/budgeted spending. Year 1 projected spending was (total costs) Actual spending was (total costs) (27% of projected). The primary culprit was Dr. Cowan's health problems, which resulted reduction of Dr. Cowan's effort in Q3 & Q4 (5% of direct costs) in delays in hiring (23% of year 1 direct costs), delays in utilizing domestic sub-awards and consultants (10% of year 1 direct costs), delays in use of funding in non-personnel areas to support execution of Projects 1, 2, 3 (3.5% of year 1 direct costs), and a one quarter delay in establishing the international sub-award (9% of year 1 direct costs) among other things. Year 2 spending will be closer to projected and Year 3 may exceed projected (but cumulative grant expenditures will not exceed the awarded amount). A re-budget may be requested to shift funds from staff to university services or external contracts if it is determined that those approaches will better facilitate timely achievement of study accrual.

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

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:

- **Publications, conference papers, and presentations**

Journal publications.

Nothing to Report

Books or other non-periodical, one-time publications.

Nothing to Report

Other publications, conference papers and presentations.

Nothing to Report

- **Website(s) or other Internet site(s)**

Nothing to Report

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Rachel Cowan, PhD
Project Role:	Principle Investigator
Research Identifier:	0000-0002-3320-0653
Nearest person month worked*:	1 (4)
Contribution to Project:	Dr. Cowan worked on all four Projects
Name:	Kim Anderson, PhD
Project Role:	Consultant
Research Identifier:	0000-0001-9252-161X
Nearest person month worked*:	0 (<1)
Contribution to Project:	Dr. Anderson assisted with development of the Vignettes (Project 2) and with how to accommodate the differences between the SCIM III and SCIM IV.
Name:	Sonja de Groot, PhD
Project Role:	Co-Investigator
Research Identifier:	0000-0001-8463-2563
Nearest person month worked*:	<1 (<1)
Contribution to Project:	Dr. de Groot assisted with all efforts related to Project 4
Name:	Ingrid Kouwijzer, PhD
Project Role:	Co-Investigator / Post-Doc
Research Identifier:	0000-0003-1012-3509
Nearest person month worked*:	3 (9)
Contribution to Project:	Dr. Kouwijzer led all efforts related to Project 4
Name:	Jereme Wilroy, PhD
Project Role:	Co-Investigator
Research Identifier:	0000-0002-3496-7389
Nearest person month worked*:	0 (<1)
Contribution to Project:	Dr. Wilroy assisted with development of the interview script (Project 1)
*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?

Senior/Key Personnel

- Rachel Cowan, PhD:
 - Funded effort as the PI of the UAB SCI model systems began September 1, 2022 (90SIMS0020, NIDILRR). Funded effort is 30% of FTE (3.6 months)

- Yuying Chen, MD, PhD
 - Funded effort as the Co-I of the UAB SCI model systems began September 1, 2022 (90SIMS0020, NIDILRR). Funded effort is 15% of FTE (1.8 months)

- Jerome Wilroy, PhD
 - Funded effort as the Co-Director of the UAB SCI model systems began September 1, 2022 (90SIMS0020, NIDILRR). Funded effort is 10% of FTE. (1.2 months)

 - Funded effort as on RERC On Exercise And Recreational Technologies For People With Disabilities (RECTECH IV) began September 1, 2022 (90REGE0002, NIDILRR). Funded effort is 2% of FTE (0.24 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?

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

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES:

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)

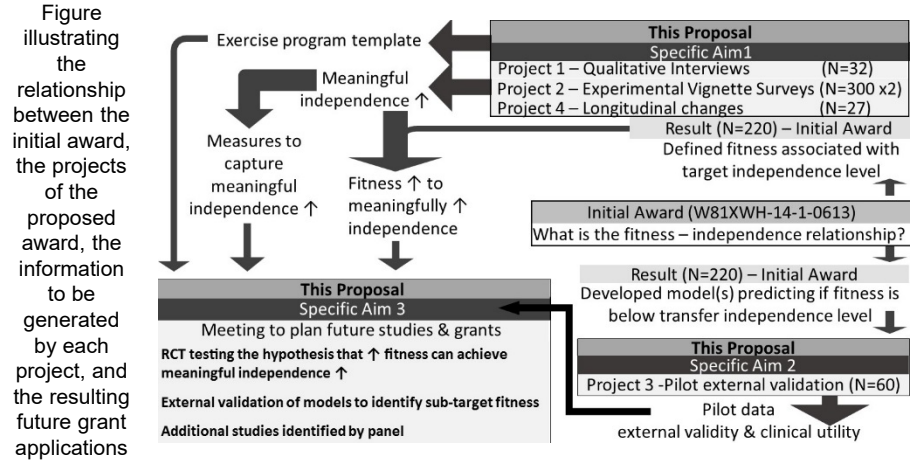
Aim 1: Identify 'meaningful changes' in self-care, mobility, and transfer independence that can be measured with existing measurement tools and are associated with fitness level or changes. (Projects 1, 2, 4)

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



No scientific accomplishments during Year 1 (September 29, 2021 – September 28 2022)

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 30, 2022

Reporting Period: Year 1

Goals/Milestones as defined in the SOW

GY 1 Goal – Launch all Projects

- 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 (4 planned)
- Plan future studies during planning meeting

Comments/Challenges/Issues/Concerns

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

Budget Expenditure to Date

Projected Total Cost Expenditure: \$549,187

Actual Total Cost Expenditure: \$151,972