

  
**CYCLE RCT**  
**Physical Outcome Assessor**  
**Startup + Refresher Meetings**  
**Levis + SMH**  
 Wednesday, June 9 @ 11:45-12:45 (Startup)  
 Wednesday, June 16 @ 11:45-12:45 (Startup + Refresher)  
 Hosted by: Michelle Kho, Laurel Kelly, Geoff Strong  





1





Agenda	
<b>Pre-Meeting tasks:</b>	
<ul style="list-style-type: none"> <li>- Complete Outcome Measure competency checklist</li> <li>- Complete outcome measures quiz</li> </ul>	
<b>60 mins</b>	<b>Outcome Assessor – Startup + Refresher Meeting Wednesday, June 16 @ 11:45-12:45</b>
5 mins	<b>Welcome and introductions</b>
5 mins	<b>Quiz video questions</b>
5 mins	<b>Review CYCLE protocol</b>
10 mins	<b>CYCLE RCT Progress</b> <ul style="list-style-type: none"> <li>• Enrollment update</li> <li>• Outcome Measure Ascertainment</li> <li>• Lessons learned (post-interim analysis)</li> </ul>
20 mins	<b>Scenarios + Discussion (site processes and internal communication plans)</b>
10 mins	<b>Quiz review</b>
5 mins	<b>Questions, next steps, feedback</b>

2

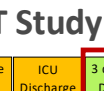
  
**CYCLE: Critical Care Cycling to Improve Lower Extremity Strength**  
**Research Question:**  
 In medical-surgical ICU patients, does 30 minutes of in-bed cycling and routine PT started within the first 4 days of mechanical ventilation, compared to routine PT improve patient function at 3 days post-ICU?  




3

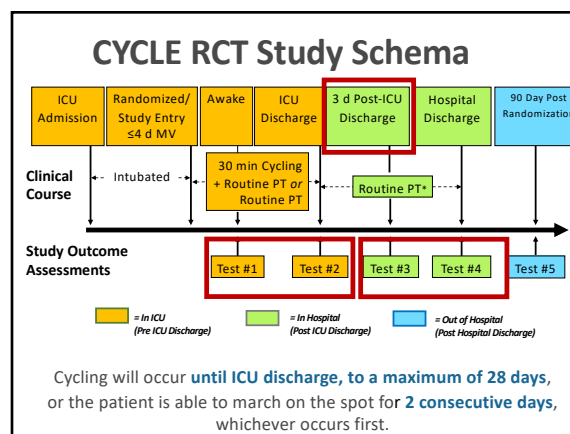
  
**CYCLE: Critical Care Cycling to Improve Lower Extremity Strength**  
**Research Question:**  
 In medical-surgical ICU patients, does 30 minutes of in-bed cycling and routine PT started within the first 4 days of mechanical ventilation, compared to routine PT improve patient function at 3 days post-ICU?  




4

  
**CYCLE**

- **Design:** 360 patient, multicenter, international open-label randomized trial
- **Population:** Medical-surgical adults within the first 4 days of mechanical ventilation
- **Intervention:** 30 minutes/ day of in-bed cycling + routine physiotherapy
  - Until ICU discharge, 28 days, or able to march on the spot for 2 consecutive days, whichever comes first
- **Comparison:** Routine physiotherapy
- **Primary Outcome:** Physical Function ICU Test @ 3 days post-ICU discharge by blinded outcomes assessors

5



6

## CYCLE RCT Physical Outcome Measures

### By PTs:

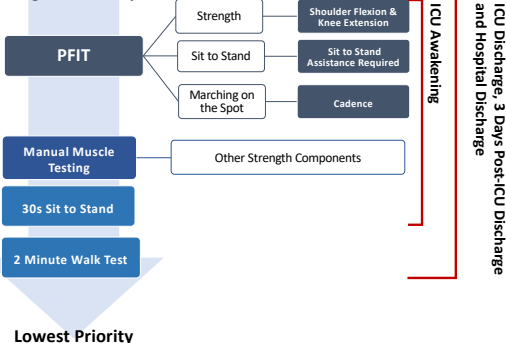
- **Physical Function Test for ICU\*** (PFIT-s)
  - blinded @ 3 days post-ICU discharge
- Muscle strength
- 2-minute walk test
- 30s sit to stand

\*= Primary outcome for full RCT

7

## Strength and Function Assessment Prioritization

### Highest Priority



As of Aug 08, 2018

8

## Key Responsibilities- Blinded Outcomes PT

- Liaise with Research Team on patient status to plan for blinded outcomes assessments
- Complete strength and function outcome measurements at 3 days post ICU discharge and hospital discharge
- Complete assessment paperwork
- Maintain and clean equipment and report any issues to Research Coordinator
- Communicate with the Research Coordinator on:
  - Assessment progress and completion
  - Deviations in protocol
  - Staffing issues

9

## ENROLLMENT UPDATES

10

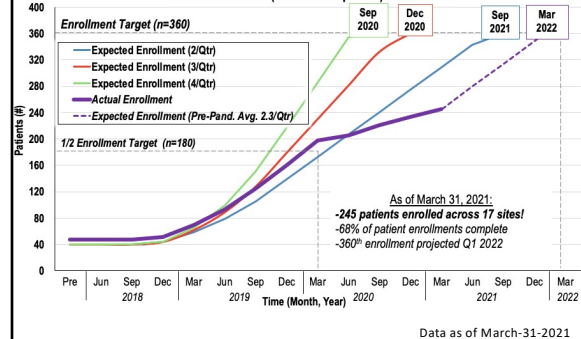
### Enrollment Progress by Site – CYCLE RCT

Site	Vanguard	RCT	# Enrolled	Screening status
St. Joseph's, Hamilton	11	19	30	Resumed June 15/20
Juravinski, Hamilton	9	20	29	Resumed June 22/20
Hamilton General	3	5	8	On Hold
St. Michael's, Toronto	-	14	14	1 <sup>st</sup> Pause (COVID)
Mount Sinai, Toronto	-	0	0	On Hold
Ottawa Civic	1	11	12	2 <sup>nd</sup> pause (COVID)
Ottawa General	8	4	12	Resumed Sep 8/20
Austin Health, Australia	9	5	14	Resumed Nov 9/20
Duke, USA	6	9	15	Resumed Oct 19/20
University of Maryland, USA	-	10	10	1 <sup>st</sup> Pause (COVID)
Montreal Sacre Coeur, Quebec	-	8	8	Resumed May 10/21
Sherbrooke, Quebec	-	25	25	Resumed June 22/20
Hotel Dieu de Levis, Quebec	-	34	34	2 <sup>nd</sup> pause (COVID)
Brantford General	-	16	16	Resumed May 20/20
Niagara Health, St. Catharines	-	11	11	Resumed Nov 23/20
London Victoria	-	14	14	2 <sup>nd</sup> pause (COVID)
Kingston General	-	2	2	2 <sup>nd</sup> pause (COVID)
<b>OVERALL</b>	<b>47</b>	<b>207</b>	<b>254</b>	<b>71% total</b>

As of June-15-2021

11

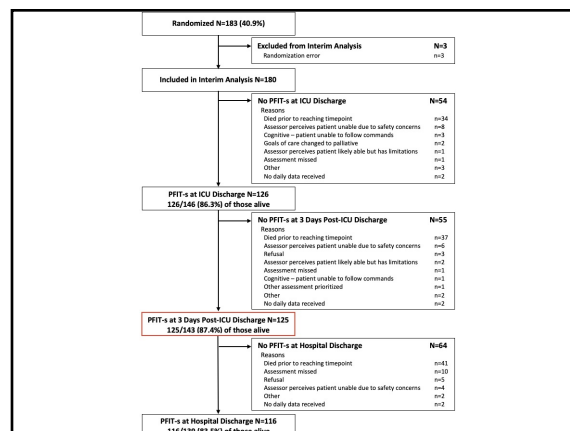
### Patient Enrollment (Actual vs Expected) - CYCLE RCT



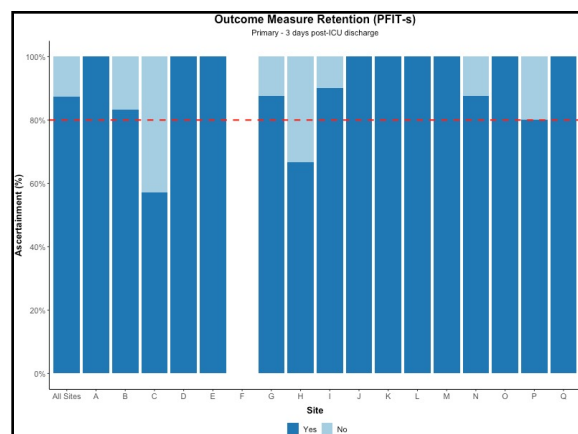
12

## Outcome Measure Ascertainment

13



14



15

## Lessons Learned From Interim Analysis

16

## All Sites

- If patient **performs sit to stand assistance** but is **unable to perform 30 second sit to stand**,

- score 30 second sit to stand = 1

- Levels of assistance:

- Supervision (without physical contact) should not** be considered as assistance.
- However, if physical assistance is provided, please grade as assistance (ex. contact guard with sit to stand)

17

3. **SIT TO STAND: ASSISTANCE REQUIRED** → Assessor blinded? ☐ Yes ☐ No

Reason # not done (specify): \_\_\_\_\_

1. Level of assistance required: ☐ 0 people ☐ 1 person ☐ 2 people (or more) ☐ Attempted + unable

2. Location: ☐ Bed ☐ Chair → Armrest used? ☐ Yes ☐ No

4. **MARCHING ON THE SPOT: CADENCE** → Assessor blinded? ☐ Yes ☐ No

Reason # not done (specify): \_\_\_\_\_

1. Steps: ☐ (#) ☐ Attempted + unable (if checked, insert score = "0" in "steps")

2. Time: ☐ (mm:sec) = ☐ (seconds)

3. Cadence: ☐ (steps/min)

1. Cadence =  $\frac{\text{Steps (steps/min)}}{\text{Time (seconds)}} \times 60$

2. "You're doing very well, 'Well done' if applicable (ie. retest), then 'Last time you performed the best you marched for - and did steps'"

5. **30 SECOND SIT TO STAND** → Assessor blinded? ☐ Yes ☐ No

Reason # not done (specify): \_\_\_\_\_

1. Sit to stand repetitions completed: ☐ (#) ☐ Attempted + unable (if checked, insert score = "0" in "sit to stand repetitions completed")

2. Level of assistance required: ☐ 0 people ☐ 1 person ☐ 2 people (or more)

3. Location: ☐ Bed ☐ Chair → Armrest used? ☐ Yes ☐ No

18

## Discussion

19

## Discussion

- Pre-meeting tasks:
  - Competency checklist
  - Reviewing OMs
  - How was practicing OMs with patients?
- Past experiences with OM
  - Questions and clarifications
- Are there any tips that you have learned during CYCLE that you would pass on to new team members or CYCLE Methods Centre?
- State of equipment
  - Any missing or damaged items that need to be replaced?

20

## OM C

COMPETENCY
Protocol
<ul style="list-style-type: none"> <li>• Understands assessment time points and blinding status at each</li> <li>• Understands how to assess eligibility for time points (e.g. awakening assessment)</li> <li>• Demonstrates ability to organize assessment and prioritize components appropriately</li> </ul>
PFIT
<ul style="list-style-type: none"> <li>• Performs shoulder flexion strength testing               <ul style="list-style-type: none"> <li>- Grades strength correctly</li> <li>- Demonstrates understanding of testing position</li> <li>- Tests muscle strength in a static position (not through range)</li> </ul> </li> <li>• Performs knee extension strength testing               <ul style="list-style-type: none"> <li>- Grades strength correctly</li> <li>- Demonstrates understanding of testing position</li> <li>- Tests muscle strength in a static position (not through range)</li> </ul> </li> <li>• Assesses sit to stand assistance               <ul style="list-style-type: none"> <li>- Cues patient for starting position</li> <li>- Records appropriate amount of assistance required</li> </ul> </li> <li>• Assesses step cadence (marching on the spot)               <ul style="list-style-type: none"> <li>- Reads standardized instructions</li> <li>- Demonstrates knowledge of when to stop test</li> <li>- Provides patient's time and leave time</li> </ul> </li> </ul>
Manual Muscle Testing
<ul style="list-style-type: none"> <li>• Demonstrates understanding of grading system</li> <li>• Demonstrates understanding of different testing positions for each limb/muscle/grade</li> <li>• Tests muscle strength in a static position (not through range)</li> </ul>
30 Second Sit to Stand
<ul style="list-style-type: none"> <li>• Cues patient for starting position</li> <li>• Clearly explains to patient and demonstrates how to perform test</li> <li>• Correctly scores number of stands while keeping time</li> </ul>
2 Minute Walk Test
<ul style="list-style-type: none"> <li>• Demonstrates understanding of test contraindications, precautions, and criteria for stoppage</li> <li>• Reads standardized instructions and encouragement</li> </ul>

21

## Practice

22

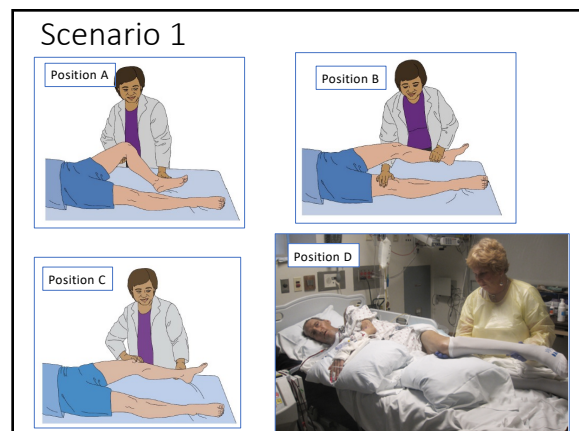
## Scenarios

23

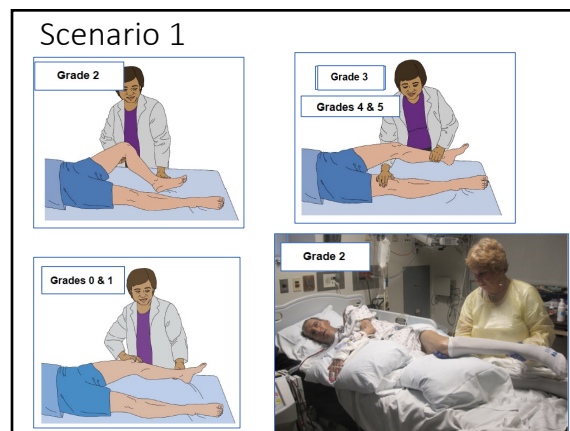
## PFIT-S Scenario 1

- You are preparing to conduct the ICU awakening assessment with an ICU patient who has woken up after a month in bed.
- Patient is very deconditioned (mechanical lift to transfer; assist x2 to roll)
- They are unable to extend knee against gravity

24



25

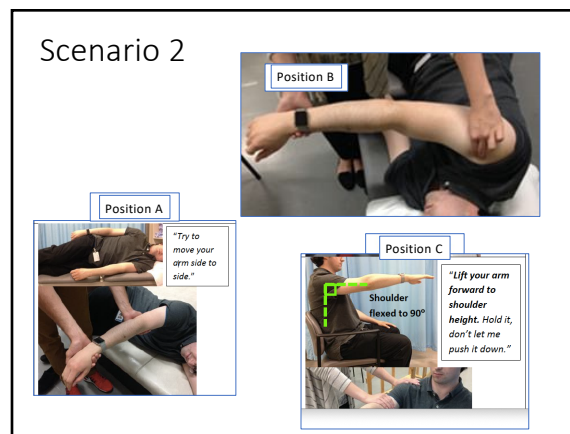


26

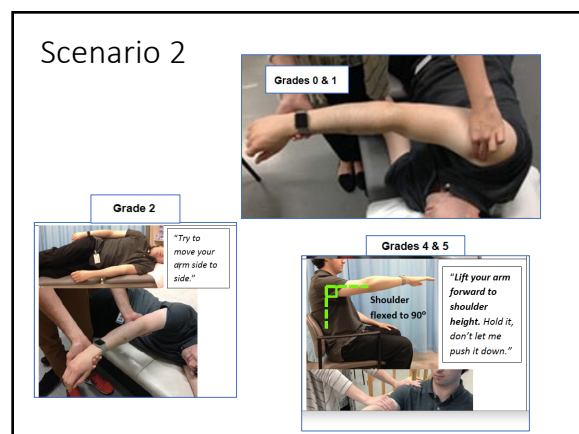
### PFIT-S Scenario 2

- You are preparing to conduct the ICU awakening assessment with an ICU patient who has woken up after a month in bed.
- Patient is very deconditioned (mechanical lift to transfer; assist x2 to roll)
- They are unable to complete shoulder flexion against gravity

27



28



29

### Reasons Not Done

Reason # if not done:

- Assessment (ax) merged with other ax form/ other timepoint (complete of 18)
- Patient did not pass cog. screen, prior to ICU discharge (alive or discharge)
- Patient died prior to reaching timepoint
- Goals of care changed to palliative
- Patient or Proxy refusal
- Assessment missed
- Cognitive issue - patient too sedated/delirious
- Assessor perceives patient unable to follow commands
- Assessor perceives patient unable to perform due to safety concerns (i.e. physiological or physical)
- Assessor perceives that patient is likely able to but has a limitation such as pain, lines, amputation, fatigue, etc.
- Other assessment prioritized
- Other (specify)

1A. Any part of assessment completed/ any clinical data

Yes (go to 18) ☐ No (insert reason # not done, if "other", specify) → ☐

1B. Clinical data should apply to the following timepoints (check all)

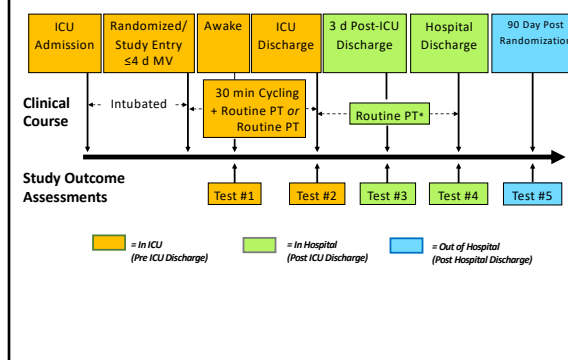
ICU	ICU	3 D Post-ICU	Hospital
Awakening	Discharge	Discharge	Discharge
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

30

## Site Processes + Communication Plans

31

## CYCLE RCT Study Schema



32

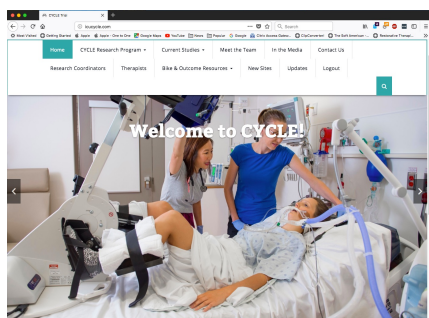
## Quiz Review

33

## CYCLE RCT Study Materials

34

[www.icucycle.com](http://www.icucycle.com)



35

## Questions, next steps, feedback

36