

  
**CYCLE RCT**  
**Physical Outcome Assessor**  
**Refresher Meeting**

Wednesday, Jan 12, 2022 @ 12:00 -1:00 pm  
 Hosted by: Julie Reid, Geoff Strong & Alex Molloy






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### Agenda

Time	Activity
	<b>Pre-Meeting tasks:</b>
	- View website training videos
	- Complete outcome measures quiz
	- Review outcome measures competency checklist
	<b>Outcome Assessor Refresher Meeting</b>
60 mins	
5 mins	Welcome and introductions
5 mins	Quiz video questions
15 mins	Overview of CYCLE RCT physical outcome measures
	• Protocol, study schema, timepoints
	• Case report forms + lessons learned from interim analysis
10 mins	Scenarios
20 mins	Quiz review
5 mins	Questions + next steps

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**Quiz Video Questions**

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**Demographic Questions**

Y N Were you previously involved in the CYCLE research program (if yes, check all that apply)?

☐ Delivered cycling

☐ Collected physical outcome measures

☐ Conducted research coordinator assessments

☐ Other (specify):

Y N Did you review the website materials before this training session?

What is your role in CYCLE?

☐ PT

☐ PT Assistant

☐ Nurse

☐ Research Coordinator

☐ Other (specify):

**MMT**

	Pre	Post
8		
9		
10		
Score		

**30 Second STS**

	Pre	Post
11		
12a		
12b		
Score		

**2MWT**

	Pre	Post
13		
14		
15		
Score		

**CYCLE-Specific Processes**

	Pre	Post
16		
17		
18		
19		
20		
Score		

**Cycling**

	Pre	Post
1		
2		
3		
4		
5		
6		
7a		
7b		
8		
9		
Score		

**Research Coordinator**

	Pre
1	
2	
3	
4a	
4b	
5	
6	
7	

☐ Conduct the research coordinator hospital assessment

☐ Mark the hospital dis assessments as my

☐ Complete Final Study

☐ Complete the strong function hospital dis assessment

9

10

Score

Quiz sheet Q&A for:  
physical outcomes training

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**CYCLE RCT Study Materials**

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



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## CYCLE Study Materials

- Website – [www.icucycle.com](http://www.icucycle.com)
  - Training videos
  - Case report forms
  - Supplementary materials / 1-pagers
- Binders
  - Therapist (intervention and outcome measures)
  - Research Coordinator
  - Regulatory

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## Overview of CYCLE RCT

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### 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?



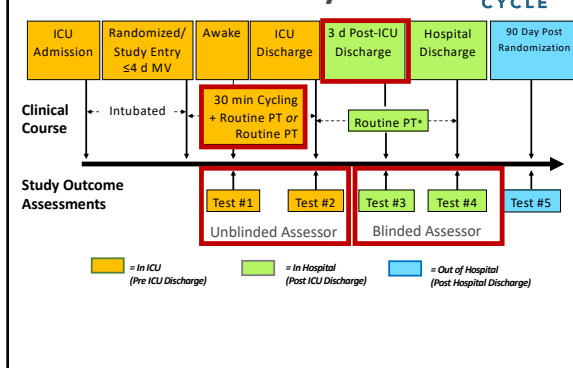
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## CYCLE

- **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

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## CYCLE RCT Study Schema



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## Key Responsibilities- ICU PT

- Assist RC when screening patients for study eligibility
- Screen patients for exemptions and deliver cycling and/or routine PT as appropriate
- **Determine patient eligibility and complete ICU awakening and discharge strength and function assessments as appropriate**
- Complete therapy session and assessment paperwork
- Maintain and clean equipment and report any issues to Research Coordinator
- Communicate with the Research Coordinator on:
  - **\*All safety events**
  - **\*Bike issues** (lasting > 5mins)
  - Delivery of intervention
  - **Assessment progress and completion**
  - **Patient status and location**
  - Deviations in protocol
  - **Staffing issues**

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## Physical Function Test for ICU “PFIT-s”



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### Sit to Stand Assistance

- Ideal positioning: Patient should have their arms crossed at the wrist and held against their chest.
- Patient can push off arms of chair if needed (you will indicate this on CRF) or use a gait aid
- Provide least amount of assistance required for patient to safely transfer to standing

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### Marching on the Spot

- Patient may use a gait aid if needed
- Provide standardized instructions and encouragement
- Each time a foot hits the floor this counts as one step
- Foot must completely clear the floor for a step to count towards patient's total. If patient's foot does not clear for 6 steps, test is over
- If patient stops marching for >2 seconds, test is over
- If patient has been marching continuously for 3 minutes, stop test. Patient will receive highest score

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### 30 Second Sit to Stand



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### 30 Second Sit to Stand

- Patient may use a gait aid if needed and as much assistance as needed to safely stand
- Same positioning as sit to stand if patient able. May push off arm rests if needed
- Must stand up and sit all the way back down for each repetition to count
- If more than halfway up at the end of 30 seconds count this as a full stand

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### Scoring considerations



- 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)

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- ## 2-Minute Walk Test
- 50-foot walking course (15.24m)
  - Provide standardized instructions and encouragement
  - Patient may use a gait aid, assistance from others, and/or supplemental O2 if needed
  - Count the number of laps completed and measure additional distance using trundle wheel

## Outcome Measures

# Case Report Forms

Patient ID	(1)	(patient #)	Coded Patient Initials	F	L	Therapist(s)	F	M	L	Text Date	2	0	(mm/yyyy)
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STRENGTH AND FUNCTION ASSESSMENT: 3 DAYS POST-ICU DISCHARGE (SFI)

Reason for admission:

1. Assessment (sx) merged with other or formi other timepoint (complete w/ TB) ☐
2. Patient did not pass cog. screen prior to ICU discharge (allw @ discharge) ☐
3. Patient died prior to reaching timepoint ☐
4. Goals or case changed to palliative ☐
5. Reason or Phony refusal ☐
6. Assessment missed ☐
7. Cognitive screen - patient too disoriented/delirious ☐

1A. Any part of assessment completed; any clinical data (Yes (go to TB) ☐ No (insert reason if not done, if "other," specify) → ☐ (specify).

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

ICU Anticipation <input type="checkbox"/>	ICU Discharge <input type="checkbox"/>	3 Post-ICU Discharge <input type="checkbox"/>	Hospital Discharge <input type="checkbox"/>
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2. **STRENGTH (MMT)** → Assessor blinded? ☐ Yes ☐ No

Reason if not done (specify) \_\_\_\_\_

RIGHT				LEFT				RIGHT				LEFT			
MUSCLE	SCORE	Reason if not done	SCORE	Reason if not done	MUSCLE	SCORE	Reason if not done	SCORE	Reason if not done	MUSCLE	SCORE	Reason if not done	SCORE	Reason if not done	
1. Shoulder Extension	/5	/5	/5	/5	5. Hip Flexion	/5	/5	/5	/5	6. Knee Extension	/5	/5	/5	/5	
2. Shoulder Abduction	/5	/5	/5	/5	7. Ankle Dorsiflexion	/5	/5	/5	/5						
3. Elbow Flexion	/5	/5	/5	/5											
4. Wrist Extension	/5	/5	/5	/5											

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

Reason if not done (specify) \_\_\_\_\_

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

2. Location ☐ Bed ☐ Chair → Assessor used? ☐ Yes ☐ No

3. **SIT TO STAND ASSISTANCE REQUIRED?** → Assessor blind? ☐ Yes ☐ No  
 Reason if 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 P** → Assessor blind? ☐ Yes ☐ No  
 Reason if not done (specify) \_\_\_\_\_

1. Steps \_\_\_\_\_ (ft) ☐ Attempted + usable (if checked, insert score = "0" in "steps")  
 2. Time \_\_\_\_\_ (min) \_\_\_\_\_ (sec) = \_\_\_\_\_ (seconds)

**Marching on the spot instructions**  
 "Once you are in the standing position, we will ask you to march on the spot. We would like to see you march on the spot for as long as you can. We are going to record how long you walk for and how many steps you do. The test is designed to record your maximum exercise ability, so it is very important that you march on the spot for as long as you possibly can."  
 Give standardized encouragement every 10 seconds: "Keep going for as long as you can," "You're doing very well," "Well done." (if applicable (in retest), then: "Last time you performed the best you marched for \_\_\_\_\_ and did \_\_\_\_\_ steps")

5. **30 SECOND SIT TO STAND** → Assessor blind? ☐ Yes ☐ No  
 Reason if not done (specify) \_\_\_\_\_

1. Sit to stand repetitions completed \_\_\_\_\_ (ft) ☐ Attempted + usable (if checked, insert score = "0" in "sit to stand repetitions completed")  
 2. Location ☐ 0 people ☐ 1 person ☐ 2 people (or more) ☐ Attempted + usable? ☐ Yes ☐ No  
 3. Location ☐ Bed ☐ Chair ☐ Armrest used? ☐ Yes ☐ No

6. **2 MINUTE WALK TEST** → Assessor blind? ☐ Yes ☐ No  
 Reason if not done (specify) \_\_\_\_\_

1. Distance \_\_\_\_\_ (meters) OR \_\_\_\_\_ (feet) ☐ Attempted + usable (if checked, insert score = "0" in "distance")  
 2. Level of assistance required ☐ 0 people ☐ 1 person ☐ 2 people (or more)  
 3. Gait aid used ☐ 1. 1 - None, 2 - Cane or crutches, 3 - Walker, 4 - Other (specify) (specify) \_\_\_\_\_

Comments \_\_\_\_\_

## Manual Muscle Testing

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### 1. Muscle Strength – Manual Muscle Testing

#### Medical Research Council Sum Score

##### • 6 muscle groups:

- Shoulder abduction
- Elbow flexion
- Wrist extension
- Hip flexion
- Knee extension
- Ankle dorsiflexion

- Scored 0 – 5 (higher scores, better strength)
- No plusses or minuses
- Tested in static position (not through range)
- Tested bilaterally = 6 muscle groups = max score 60
- ICU-acquired weakness: total score <48

MUSCLE &amp; NERVE 14:1103–1109 1991

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#### MRC scoring:

Scored 0 – 5 (higher scores, better strength)

**Table 2.** MRC-scale with full figures only. The patient is investigated in sitting posture and/or lying supine.

- 0 = No visible contraction
- 1 = Visible contraction without movement of the limb (not existent for hip flexion)
- 2 = Movement of the limb but not against gravity
- 3 = Movement against gravity over (almost) the full range
- 4 = Movement against gravity and resistance
- 5 = Normal

MUSCLE &amp; NERVE 14:1103–1109 1991

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### Supine MMT

- Recommend using ASIA muscle testing positions to test gravity-eliminated strength in lower extremities to reduce need to roll/reposition patient

#### Hip Flexion

##### Grade 2

**Patient Position:** Place the patient in the gravity eliminated position with the hip in external rotation and 45° of flexion. The knee is flexed at 90°.

**Examiner Position:** Support the leg.

**Instructions to Patient:** "Try to bring your knee out to the side," or "Try to flex your thigh toward the side of the body."

**Action:** The patient attempts to move through the full range of motion in hip flexion.



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#### Knee Extension

##### Grade 2

**Patient Position:** The hip is in external rotation and 45° of flexion. The knee is flexed at 90°.

**Examiner position:** Support the distal thigh and leg.

**Instructions to Patient:** "Straighten your knee."

**Action:** The patient attempts to move through the full range of motion.



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### Scoring

#### 2. STRENGTH (MMT) → Assessor blinded? ☐ Yes ☐ No

Reason # not done (Specify)

MUSCLE	RIGHT		LEFT		MUSCLE	RIGHT		LEFT	
	SCORE	Reason # not done	SCORE	Reason # not done		SCORE	Reason # not done	SCORE	Reason # not done
1. Shoulder Flexion <sup>a</sup>	<input type="checkbox"/> 5	<input type="checkbox"/>	<input type="checkbox"/> 5	<input type="checkbox"/>	5. Hip Flexion	<input type="checkbox"/> 5	<input type="checkbox"/>	<input type="checkbox"/> 5	<input type="checkbox"/>
2. Shoulder Abduction	<input type="checkbox"/> 5	<input type="checkbox"/>	<input type="checkbox"/> 5	<input type="checkbox"/>	6. Knee Extension <sup>a</sup>	<input type="checkbox"/> 5	<input type="checkbox"/>	<input type="checkbox"/> 5	<input type="checkbox"/>
3. Elbow Flexion	<input type="checkbox"/> 5	<input type="checkbox"/>	<input type="checkbox"/> 5	<input type="checkbox"/>	7. Ankle Dorsiflexion	<input type="checkbox"/> 5	<input type="checkbox"/>	<input type="checkbox"/> 5	<input type="checkbox"/>
4. Wrist Extension	<input type="checkbox"/> 5	<input type="checkbox"/>	<input type="checkbox"/> 5	<input type="checkbox"/>					

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## Physical Function Test for ICU "PFIT-s"



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## Physical Function Test for ICU (scored) "PFIT-s"

- 4 items:
  - Muscle strength
    - Shoulder flexion
    - Knee extension
  - Assistance from sitting to standing
  - Marching on the spot as long as possible
- Uses:
  - Exercise prescription
  - Prediction: Higher admission PFIT-s:
    - Discharge home
    - Reduced likelihood of discharge to inpatient rehab
    - Shorter hospital LOS

Skinner et al., Crit Care Resusc. 2009 Jun;11(2):110-5.  
Denehy et al., Phys Ther. 2013. 93(12):1-10.

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## Sit to Stand Assistance

- Ideal positioning: Patient should have their arms crossed at the wrist and held against their chest.
- Patient can push off arms of chair if needed (you will indicate this on CRF) or use a gait aid
- Provide least amount of assistance required for patient to safely transfer to standing

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## Scoring

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

**Note:** Only score as assist if hands-on support provided. If patient is able to stand with close supervision only, score as "0 people"

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## Marching on the Spot

- Patient may use a gait aid if needed
- Provide standardized instructions and encouragement
- Each time a foot hits the floor this counts as one step
- Foot must completely clear the floor for a step to count towards patient's total. If patient's foot does not clear for 6 steps, test is over
- If patient stops marching for >2 seconds, test is over
- If patient has been marching continuously for 3 minutes, stop test. Patient will receive highest score

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## Scoring

4. **MARCHING ON THE SPOT: CADENCE?** → Assessor blinded? ☐ Yes ☐ No  
☐ Reason # not done (specify) \_\_\_\_\_  
 1. Steps  (4) ☐ Attempted + unable (if checked, insert score = "0" in "steps")  
 2. Time  min  sec =  (seconds)  
 3. **Cadence?**  Steps (f)  (steps/min)  
 4. Cadence =  Time (seconds) × 60  
 5. 30 **SECOND SIT TO STAND** → Assessor blinded? ☐ Yes ☐ No

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## 30 Second Sit to Stand

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## 30 Second Sit to Stand

- # times sit to stand completed in 30s
- Patient may use a gait aid if needed and as much assistance as needed to safely stand
- Same positioning as sit to stand if patient able. May push off arm rests if needed
- Must stand up and sit all the way back down for each repetition to count
- If more than halfway up at the end of 30 seconds count this as a full stand

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## Scoring

5. 30 SECOND SIT TO STAND → Assessor blinded? ☐ Yes ☐ No  
☐ Reason if not done (specify) \_\_\_\_\_  
 1. Sit to stand repetitions completed ☐ (4) ☐ 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

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

score 30 second sit to stand = 1

\*Use level of assistance and data from sit to stand assessment

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## 2-Minute Walk Test

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## 2-Minute Walk Test

- 50-foot walking course (15.24m)
- Provide standardized instructions and encouragement
- Patient may use a gait aid, assistance from others, and/or supplemental O2 if needed
- Count the number of laps completed and measure additional distance using trundle wheel

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## Scoring

6. 2 MINUTE WALK TEST → Assessor blinded? ☐ Yes ☐ No  
☐ Reason if not done (specify) \_\_\_\_\_  
 1. Distance (1 meter = 3.28 feet) ☐ (meters) OR ☐ (feet) ☐ Attempted + unable (if checked, insert score = "0" in "distance")  
 2. Level of assistance required ☐ 0 people ☐ 1 person ☐ 2 people (or more)  
 3. Gait aid used ☐ #, 1 = None, 2 = Cane or crutches, 3 = Walker, 4 = Other (specify) (specify) \_\_\_\_\_

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## All Sites

- 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)

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## Reasons Not Done

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**REASON FOR NOT DOING ASSESSMENT - 3 UNLESS OTHERWISE SPECIFIED**

**Reason if not done**

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

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

☐ Yes (go to 18)

☐ No (insert reason if not done, if "other", specify) →

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

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

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## Scenarios

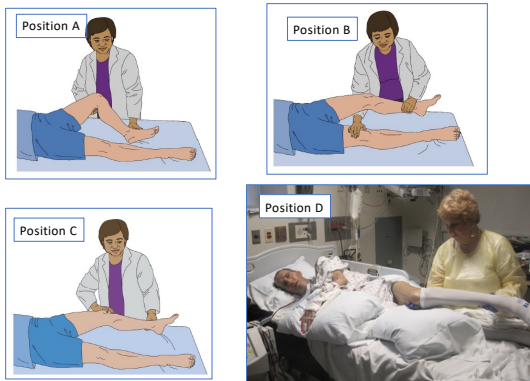
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### PFIT-S Scenario 1

- 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

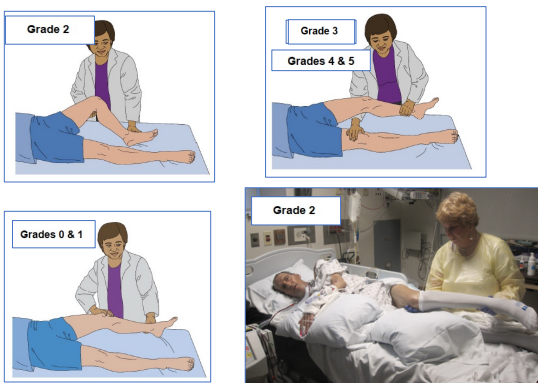
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### Scenario 1



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### Scenario 1



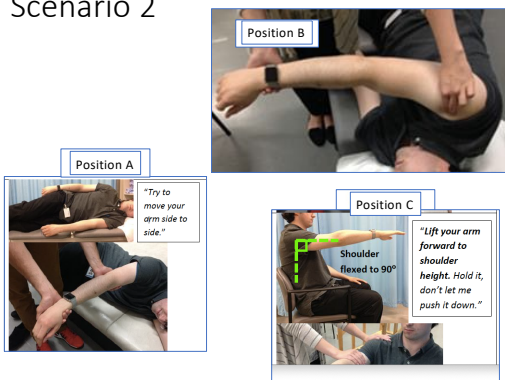
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### PFIT-S Scenario 2

- 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

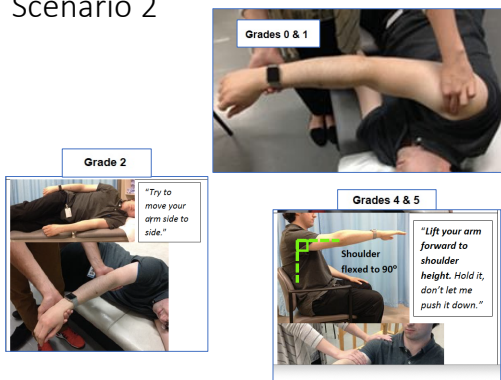
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### Scenario 2



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### Scenario 2



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### PFIT-S – Scenario 3

- For strength testing:  
Right shoulder flex: 5/5  
Left shoulder flex: 4/5  
Right knee ext: 5/5  
Left knee ext: 5/5
- For STS assist:  
You are closely guarding the patient but they are able to stand without any hands-on contact. They use the chair's arm rests to stand.
- For MOS:  
Patient is able to MOS for about a minute until they fatigue. They stop and rest for ~5 seconds and then proceed to resume stepping.

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### 30 Second Sit to Stand Scenario

You are performing the 30 second sit to stand test with your patient. They are rushing through the test and only standing up halfway with each repetition.

Answer the following true or false questions:

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## 2-Minute Walk Test Scenario

You are completing a 2-minute walk test with your patient. They have a history of COPD and poor exercise tolerance.

Answer the following questions:

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## Quiz Review

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**Demographic Questions**

Y N Were you previously involved in the CYCLE research program (if yes, check all that apply)?

☐ Delivered cycling  
☐ Collected physical outcome measures  
☐ Conducted research coordinator assessments  
☐ Other (specify):

Y N Did you review the website materials before this training session?

What is your role in CYCLE?

☐ PT  
☐ PTA Assistant  
☐ Nurse  
☐ Research Coordinator  
☐ Other (specify):

**PFIT-a**

	Pre	Post
1		
2		
3		
4		
5		
6		
7		

Score

**MMT**

	Pre	Post
8		
9		
10		
Score		

**30 Second STS**

	Pre	Post
11		
12a		
12b		
Score		

**2MMT**

	Pre	Post
13		
14		
15		
Score		

**Cycling**

	Pre	Post
1		
2		
3		
4		
5		
6		
7a		
7b		
8		
9		
Score		

**CYCLE-Specific Processes**

	Pre	Post
16		
17		
18		
19		
20		
Score		

**Research Coordinator**

	Pre
1	
2	
3	
4a	
4b	
5	
6	
7	
8	
9	
10	
Score	

**Quiz sheet Q&A for: physical outcomes training**

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## Questions?

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## Next Steps – Practice!

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## OM Competency Checklist

COMPETENCY	PROVIDED
Understands assessment time points and blinding status at each	
Understands how to assess eligibility for time points (e.g. walking assessment)	
Demonstrates ability to organize assessment and prioritize components appropriately	
<b>PFIT</b>	
Performs shoulder flexion strength testing	
Grades strength correctly	
Demonstrates understanding of testing position	
Tests muscle strength in a static position (not through range)	
Performs knee extension strength testing	
Grades strength correctly	
Demonstrates understanding of testing position	
Tests muscle strength in a static position (not through range)	
Assesses sit to stand assistance	
Uses patient for starting position	
Provides appropriate amount of assistance required	
Assesses step cadence (marching on the spot)	
Reads standardized instructions	
Demonstrates knowledge of when to stop test	
Counts patient's steps and keeps time	
Uses provided equation to calculate step cadence	
<b>Manual Muscle Testing</b>	
Completes components of PFIT in correct order	
Demonstrates understanding of grading system	
Demonstrates understanding of different testing positions for each limb/muscle/joint	
Tests muscle strength in a static position (not through range)	
<b>30 Second Sit to Stand</b>	
Uses patient for starting position	
Clearly explains to patient and demonstrates how to perform test	
Correctly scores number of stands while keeping time	
<b>2 Minute Walk Test</b>	
Demonstrates understanding of test contraindications, precautions, and criteria for stoppage	
Reads standardized instructions and encouragement	
Accurately measures total distance walked	
<b>6MWT</b>	
Properly completes strength and function assessment CRF	
Demonstrates understanding of how to apply "reason not done" codes appropriately	

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