

CYCLE RCT #142 **Plate #016**

Study Day

Patient ID (site #) (patient #) Coded Patient Initials F L

Date (dd/mm/yyyy)

5. Nutrition

DAILY DATA (Form 4.2 of 4)

1. Enteral nutrition (EN) received today (check ONE type below; if >1 type received, select type providing the highest volume received)

☐ No ☐ Yes → 24 hour total EN volume delivered (ml)

- | | | | |
|---|--|---|--|
| <input type="checkbox"/> Ensure High Protein (1.0 kcal/mL) | <input type="checkbox"/> IsoSOURCE VHN/Fiber (1.0 kcal/mL + fibre) | <input type="checkbox"/> Nutrison Protein Plus w/ Multifibre | <input type="checkbox"/> Peptamen Intense |
| <input type="checkbox"/> Ensure Plus Calories (1.5 kcal/mL) | <input type="checkbox"/> IsoSOURCE VHP/1.0 HP (1.0 kcal/mL) | <input type="checkbox"/> Nutrison Concentrated | <input type="checkbox"/> Promote (1.0 kcal/mL) |
| <input type="checkbox"/> Fibersource HN | <input type="checkbox"/> Jevity 1.0 Cal (+ fibre) | <input type="checkbox"/> Novosource GI Forte | <input type="checkbox"/> Resource 2.0 |
| <input type="checkbox"/> Glucerna 1.0 kcal/mL + fibre | <input type="checkbox"/> Jevity 1.2 Cal (+ fibre) | <input type="checkbox"/> Novosource Renal 2.0 | <input type="checkbox"/> Resource Diabetic |
| <input type="checkbox"/> Impact Adv. Rec. | <input type="checkbox"/> Jevity 1.5 Cal (+ fibre) | <input type="checkbox"/> Optimental 1.0 kcal/mL | <input type="checkbox"/> TwoCal HN 2.0 (+ fibre) |
| <input type="checkbox"/> IsoSOURCE | <input type="checkbox"/> Nepro Carb Steady (1.8 kcal/mL + fibre) | <input type="checkbox"/> Osmolite | <input type="checkbox"/> Vital 1.0 |
| <input type="checkbox"/> IsoSOURCE HN 1.2 | <input type="checkbox"/> Novosource Renal 2.0 | <input type="checkbox"/> OXEPA (1.5 kcal/mL) | <input type="checkbox"/> Vital 1.5 |
| <input type="checkbox"/> IsoSOURCE HN/Fiber 1.2 (+ fibre) | <input type="checkbox"/> Nutren 1.5 | <input type="checkbox"/> Peptamen 1.0 | <input type="checkbox"/> Vital Peptide 1.5 |
| <input type="checkbox"/> IsoSOURCE 1.5 | <input type="checkbox"/> NutriHep (1.5 kcal/mL) | <input type="checkbox"/> Peptamen 1.5 | <input type="checkbox"/> Vivonex Plus |
| <input type="checkbox"/> IsoSOURCE 1.5/Fiber (+ fibre) | <input type="checkbox"/> Nutrison 8000 | <input type="checkbox"/> Peptamen AF 1.2 Cal (fish-oils and prebiotics) | <input type="checkbox"/> Vivonex T.E.N. |

☐ Other (specify) _____

2. Modular products received today? (check type(s), and record # packages received)

☐ No ☐ Yes →

Beneprotein <input type="checkbox"/> Yes → <input type="text"/> <input type="text"/> # pkgs	Prosource <input type="checkbox"/> Yes → <input type="text"/> <input type="text"/> # pkgs
Bramino <input type="checkbox"/> Yes → <input type="text"/> <input type="text"/> # pkgs	Other (specify) <input type="checkbox"/> Yes → <input type="text"/> <input type="text"/> # pkgs
EAS L-Glutamine <input type="checkbox"/> Yes → <input type="text"/> <input type="text"/> # pkgs	

3. Parenteral nutrition (PN) received today (record total PN volume received and macronutrients (specify units) received during 24 hour period)

☐ No ☐ Yes →

Volume	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (ml)
Dextrose	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (grams)
Amino Acid	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (grams)
Lipid	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (grams)

4. Oral intake received today?

☐ No ☐ Yes →

<input type="checkbox"/> Oral (food) intake	volume not required
<input type="checkbox"/> Oral (fluid) intake	

5. Patient highest level of activity TODAY (including therapy sessions) [see Form 5, 5R, 5C; patient's chart (e.g. OT/PT/nursing notes)]

SCORE
 (0-11)

- | | |
|---|---|
| 0 - Passively moved by staff (includes passive cycling only) | 6 - Marching on the spot (at bedside; ≥ 2steps/foot) |
| 1 - Any activity in bed, but not moving out of or over edge of bed (includes cycling) | 7 - Walking with assistance of 2 or more people (≥5m) |
| 2 - Passively moved to chair (no standing or sitting at edge of bed) | 8 - Walking with assistance of 1 person (≥5m) |
| 3 - Actively sitting over side of bed with some trunk control (may be assisted) | 9 - Walking independently with gait aid (≥5m) |
| 4 - Standing | 10 - Walking independently without gait aid (≥5m) |
| 5 - Transferring from bed to chair | 11 - Walking up and down stairs |

6. Is today a stat. holiday or weekend (i.e. ineligible day to offer and complete CYCLE trial intervention(s))

☐ No ☐ Yes (no CYCLE Trial intervention today)

→ Did the patient receive any rehab therapy today from PT or OT? (check one; go to q 13)

☐ No ☐ Yes



CYCLE RCT #142

Plate #017

Study
DayPatient ID 1
(site #) (patient #)Coded Patient Initials
F LTherapist(s) Initials
F M L F M LDate 2 0
(dd/mm/yyyy)

DAILY DATA (Form 4.3 of 4)

Day of week
M Tu W Th F Sa Su

7. Was routine PT/ rehab done today?

☐ Yes (submit Form 5R)☐ No (check one of a, b, c, or d and specify where necessary)a) ☐ Patient discharged from ICU before 1200pmb) ☐ Temporary exemption criteria met (check ALL; if #10 specify)

- ☐ 1. Increase in inotropes/vasopressors (2h)
- ☐ 2. Active MI, or unstable/uncontrolled arrhythmia per ICU team
- ☐ 3. MAP <60 or >110 (2h) or out of range for this patient per ICU team
- ☐ 4. HR <40 or >140 (2h)
- ☐ 5. SpO₂ <88% (2h) or out of range for this patient per ICU team
- ☐ 6. Neuromuscular blocker (4h)
- ☐ 7. Severe agitation RASS >2 or SAS >6 or equivalent (2h)
- ☐ 8. Uncontrolled pain
- ☐ 9. Changes in goals to palliative care
- ☐ 10. Other concern [e.g., active haemorrhage, acute peritonitis, new pelvic, groin, or extremity wound precluding routine PT/ rehab, new known or suspected muscle inflammation (specify below)]

c) ☐ Other reasons routine PT/rehab not received (check all that apply)

Refusals

- ☐ Tired ☐ Non-verbal behaviours indicating disinterest
- ☐ Having a bad day ☐ Other reason patient declined (specify)
- ☐ Family declined

Other activity prioritized by therapist

- ☐ Cycling ☐ Other (specify) _____
- ☐ Patient not scheduled for therapy

Therapist not available

- ☐ Workload ☐ Other (specify) _____

Patient not available

- ☐ Out of ICU ☐ While in ICU (procedure, test, etc.)
- ☐ Other (specify) _____

d) ☐ Other reason (specify) _____

8. Was cycling done today?

☐ N/A, patient not randomized to cycling☐ Yes (submit Form 5C)☐ No (check one of a, b, c, d, or e and specify where necessary)a) ☐ Patient discharged from ICU before 1200pmb) ☐ Patient marched on the spot for 2 consecutive daysc) ☐ Temporary exemption criteria met (check ALL; if #10 specify)

- ☐ 1. Increase in inotropes/vasopressors (2h)
- ☐ 2. Active MI, or unstable/uncontrolled arrhythmia per ICU team
- ☐ 3. MAP <60 or >110 (2h) or out of range for this patient per ICU team
- ☐ 4. HR <40 or >140 (2h)
- ☐ 5. SpO₂ <88% (2h) or out of range for this patient per ICU team
- ☐ 6. Neuromuscular blocker (4h)
- ☐ 7. Severe agitation RASS >2 or SAS >6 or equivalent (2h)
- ☐ 8. Uncontrolled pain
- ☐ 9. Changes in goals to palliative care
- ☐ 10. Other concern [e.g., active haemorrhage, acute peritonitis, new pelvic, groin, or extremity wound precluding cycling, new known or suspected muscle inflammation (specify below)]

d) ☐ Other reasons cycling not received (check all that apply)

Refusals

- ☐ Tired ☐ Non-verbal behaviours indicating disinterest
- ☐ Having a bad day ☐ Other reason patient declined (specify)
- ☐ Family declined

Other activity prioritized by therapist

- ☐ Other (specify) _____

Therapist not available

- ☐ Workload ☐ Other (specify) _____
- ☐ No CYCLE-trained therapist available

Patient not available

- ☐ Out of ICU ☐ While in ICU (procedure, test, etc.)
- ☐ Other (specify) _____

e) ☐ Other reason (specify) _____

9. Total # of screening attempts for cycling today?

☐ N/A ☐ (#)

10A. Therapy session duration (min)

- ☐ No PT/ rehab Session 1 (min)
- ☐ N/A Session 2 (min)
- ☐ N/A Session 3 (min)

10B. Therapy type(s) received

- ☐ Routine PT/ rehab ☐ Cycling
- ☐ Routine PT/ rehab ☐ Cycling
- ☐ Routine PT/ rehab ☐ Cycling

10C. Safety Events reported

- ☐ No ☐ Yes (complete Form 5S)
- ☐ No ☐ Yes (complete Form 5S)
- ☐ No ☐ Yes (complete Form 5S)

11. Patient highest level of activity from ALL rehabilitation/therapy sessions (includes Forms 5R, 5C, applicable S&F ax's)

☐ No PT/ rehab

SCORE

 (0-11)

- 0 - Passively moved by staff (includes passive cycling only)
- 1 - Any activity in bed, but not moving out of or over edge of bed (includes cycling)
- 2 - Passively moved to chair (no standing or sitting at edge of bed)
- 3 - Actively sitting over side of bed with some trunk control (may be assisted)
- 4 - Standing
- 5 - Transferring from bed to chair
- 6 - Marching on the spot (at bedside; ≥ 2 steps/foot)
- 7 - Walking with assistance of 2 or more people (≥ 5m)
- 8 - Walking with assistance of 1 person (≥ 5m)
- 9 - Walking independently with gait aid (≥ 5m)
- 10 - Walking independently without gait aid (≥ 5m)
- 11 - Walking up and down stairs

12. Cognitive screening for ICU Awakening Ax: Strength and Function (Ask the patient to perform all 5 commands; check ALL successful commands)

☐ No PT/ rehab

Successful Commands	
SCORE	<input type="checkbox"/> Open your eyes
<input type="text"/> /5	<input type="checkbox"/> Look at me
	<input type="checkbox"/> Open your mouth and stick out your tongue
	<input type="checkbox"/> Nod your head
	<input type="checkbox"/> Raise your eyebrows when I count to 5

- ☐ Not done, patient unable to follow commands
- ☐ No, score ≤ 2/5 (continue screening)
- ☐ Yes, score ≥ 3/5 + not appropriate for PT ICU Awakening Ax (continue screening)
- ☐ Yes, score ≥ 3/5 + appropriate for PT ICU Awakening Ax (initiate assessment)
- ☐ Not done, PT ICU awakening Ax in progress/ complete



CYCLE RCT #142

Plate #018

Study
Day

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Patient ID

		1		
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(site #) (patient #)

Coded Patient Initials

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F L

Date

				2	0		
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(dd/mm/yyyy)

DAILY DATA (Form 4.4 of 4)

13. Was the ICU Awakening: Strength and Function Form initiated today?

- ☐ No
☐ Yes (*submit Form SF1*)

14. Was the IPAT Form initiated today?

- ☐ No
☐ Yes (*submit Form RC1*)

15. Last day of study today?

- ☐ No, patient still within study day 28 protocol
☐ No, returned to ICU within 72 hours of ICU discharge
☐ Yes, patient discharged from the ICU >72 hours, died, or CYCLE RCT protocol stopped at 28 days (submit Forms: SF1-SF4, RC1-RC4, 6 and 7)
☐ Yes, consent withdrawn for further data collection (submit Form 7)

→ Who withdrew consent? (specify)

☐ Patient ☐ Legal SDM/ LAR ☐ Other family member ☐ Physician ☐ Other (specify) _____

→ Reason for Withdrawal? (specify) _____