



CYCLE RCT

Website: www.icucycle.com

February 2020

We would like to welcome our newly enrolling sites, Austin Health and Kingston General! Thank you to all of our sites for all of your continued contributions to CYCLE.

Screening and Enrollment (as of January 28, 2020)

Site	Screening	# Enrolled
St. Joseph's, Hamilton	✓	14
Juravinski, Hamilton	✓	14
Hamilton General, Hamilton	✓ (on hold)	5
St. Michael's, Toronto	✓	13
Duke, USA	✓	7
Ottawa Civic, Ottawa	✓	4
Ottawa General, Ottawa	✓	3
Sherbrooke, Quebec	✓	10
Niagara Health, St. Catharines	✓ (on hold)	10
London Victoria, London ON	✓	6
University of Maryland, USA	✓	9
Mount Sinai, Toronto	✓	-
Austin Health, Australia	✓	2
Brantford General, Brantford	✓	8
Sacre Coeur, Montreal	✓	6
Hotel Dieu, Levis	✓	18
Kingston General, Kingston	✓	2
Total	16 active	131
Total Enrolled from Vanguard	46	Total Left Before Interim Analysis
Total Enrolled from Vanguard and RCT	177	Total Left to Enroll
		183

Interim Analysis

We would like to remind sites that we will complete an interim analysis and have a data safety monitoring meeting when we enroll 180 patients.

We expect to reach 180 patients by the end of February 2020. We anticipate completion of the 90 day follow up assessment for the 180th patient in May 2020. The interim analysis is expected in September 2020.

In order to conduct the interim analysis, all data will need to be in the database and validated. Please prioritize data entry for all study patients at your site.

Figure 1. This graph depicts data entry and validation progress by site, as of Jan. 22, 2020. These data represent 129 pts. enrolled in CYCLE RCT. Of 90 pts. who have died or passed the 90 days post-randomization timepoint, 29 (32.2%) have validated data.

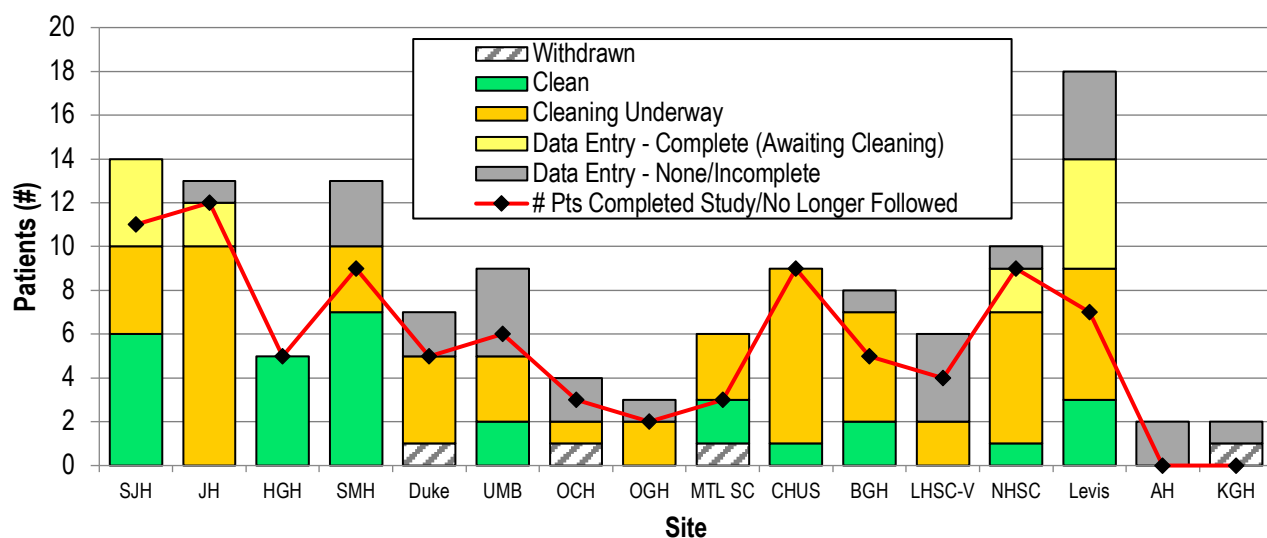
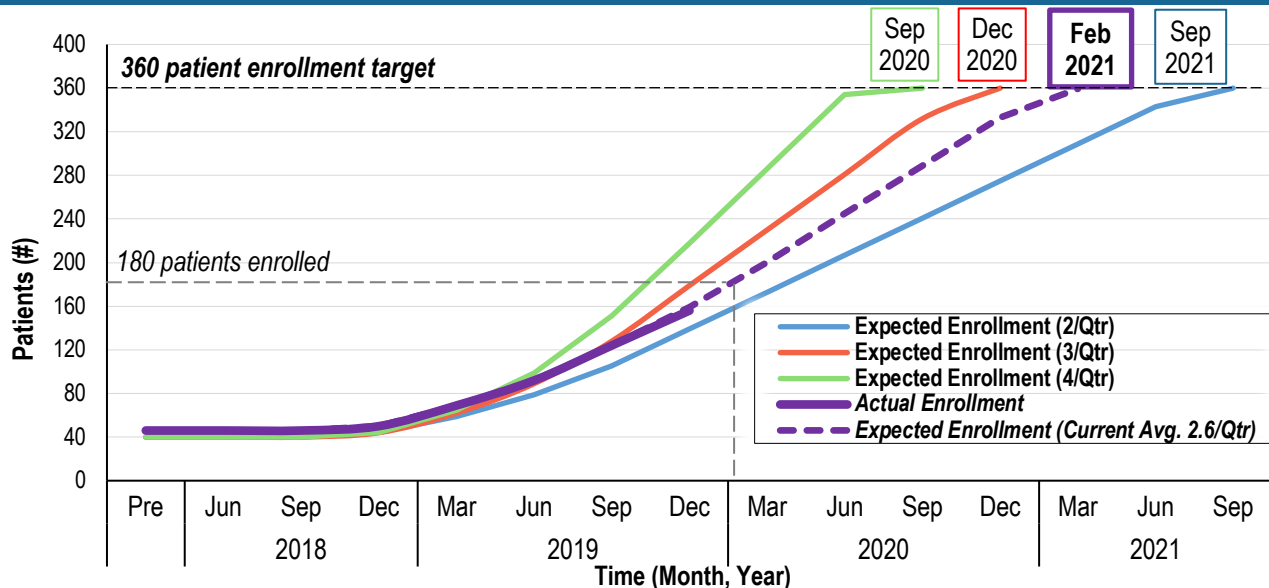


Figure 2. This figure depicts actual and expected enrollment for the CYCLE RCT as of Jan 1, 2020.

Months included in each quarter: Jan-Mar, Apr-Jun, Jul-Sept and Oct-Dec. The hashed enrollment projection is based on the current enrollment average of ~2.6 pts/site/quarter or 0.9 pts/site/month.

Projections are based on 17 sites enrolling at study end date.



Frequently Asked Questions

What forms should I prioritize when I am entering data into the database?

- Screening, randomization, daily data 4.1 on study day 1, final status, PT/RC Ax forms and intervention forms
- Daily data forms can be entered into the database last

What do I do if I find out a pt. is about to leave the hospital within the next hour and their hospital d/c Ax is not complete?

If possible, please collect the blinded Ax. If unable to find a blinded assessor, please try to collect the Ax unblinded.

Time-Saving Tips for Data Entry

- Daily data form 4.3 does not need to be completed on weekends or stat. holidays
- Please enter the total # of screening attempts for cyclers on all potential cycling days (Q.9 on form 4.3)
- If a patient did not complete 3 PT/rehab sessions on a given study day, please select "N/A" for session time and FiO2 boxes that do not apply (Form 4.3 and 5R)

Kudos!

Congratulations to Hotel Dieu for being our top enrolling site, enrolling 18 pts. since beginning enrollment in Sept!

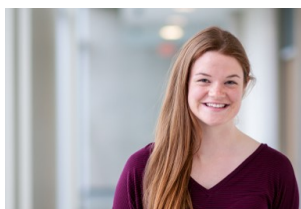
Congratulations to the CYCLE Team at Brantford General for their commitment to collecting all assessments!

New CYCLE Publications

Reid JC, McCaskell DS, Kho ME. Therapist perceptions of a rehabilitation research study in the intensive care unit: a trinational survey assessing barriers and facilitators to implementing the CYCLE pilot randomized clinical trial. Pilot and Feasibility Studies. 2019; 5: 131.

When Exercise Comes to the Hospital's Intensive Care Unit. Link: <https://undark.org/2020/01/22/exercise-hospital-icu/>

Staff Changes at the Methods Centre



We would like to thank Stacey Priest for all of her hard work and contributions to the CYCLE Methods Centre over the past year. We wish Stacey good luck as she moves on in her career.



We would like to welcome Chris Farley to the CYCLE Research Team! Chris is working on his MSc in Rehabilitation Science at McMaster University, under the supervision of Dr. Kho.

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