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Level IV

CYCLE RCT: A Summer in Clinical Trials Management

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Introduction

This summer I had the opportunity to work under the supervision of Dr. Michelle Kho at St. Joseph's Healthcare Hamilton, Charlton Site. The work term was hosted by the McMaster School of Rehabilitation Sciences, as part of Dr. Kho's CYCLE research team. Working in the Department of Physiotherapy and as part of the Research Institute of St. Joseph's Healthcare, we are a team of researchers conducting clinical trials targeted at intensive care unit (ICU) rehabilitation.

Focusing on the ongoing critical condition of a patient, many fail to consider what happens to these individuals upon ICU discharge. Hundreds of patients enter the ICU every day in Canada, but without regular muscle activation, over half of these patients leave with severe leg weakness impairing their quality of life for up to 5 years after ICU discharge¹. Survivors of critical illness are thus left incredibly vulnerable to muscle weakness and disability. However, the innovative research of Dr. Kho's clinical research team has found a potential solution. In-bed cycling uses a specialized, easy-to-use bedside biking system that attaches to a patients' hospital bed, allowing them to gently exercise their legs in the ICU¹. The work of our CYCLE research team aims to minimize weakness, speed up recovery and improve the quality of life of ICU patients¹.

CYCLE is an acronym for Critical Care Cycling to Improve Lower Extremity Strength. It is a research program focused on improving patients' function after the ICU, funded by the Canadian Institutes of Health Research, Canada Research Chairs, Canada Foundation for Innovation, and Ontario Ministry of Economic Development, Job Creation and Trade. Having conducted several studies over the last few years such as TryCYCLE², CYCLE Pilot RCT, and CYCLE Vanguard, we have collected a foundation of knowledge on which to launch a full randomized controlled clinical trial known as CYCLE RCT. This year, with the help of 17 to 20 sites in Canada and across the globe, the goal of this study is to address the following research question:

“Among critically ill, mechanically ventilated adults, does early in-bed cycling and routine PT (physiotherapy) compared to routine PT alone improve the primary outcome of physical function at 3 days after ICU discharge and secondary outcomes of strength, physical function, frailty, psychological distress, quality of life, mortality and healthcare utilization?”

Responsibilities

As the CYCLE research team prepares for the well-anticipated upcoming CYCLE RCT, a main concern is clinical trial management. Often the key challenge is establishing a management system that is effective and responsive to both the trial and its members³. As a research assistant, my summer project primarily focused on creating a website for the clinical trial, found at icucycle.com. The hope is that this website will act as a central hub for research coordinators, research assistants and therapists

across all study sites. At any time during the trial, participating site staff will be able collect and download required documents, training videos, cycling materials and more. This website allows site staff to have immediate access to all resources and information, as well as high quality training to increase their comfort and troubleshooting materials to resolve unexpected issues quickly. With the demands on clinicians and research coordinators kept to a minimum, the efficiency and responsiveness of the website allows the CYCLE Methods Centre to actively manage and monitor every aspect of the study³.

The greatest challenge a trial manager is likely to face is maintaining a personal interface with a collaborative group of clinicians. However, a well maintained personal interface will often result in a more cohesive trial³. Using Wordpress, I successfully created both a public facing and privatized website. The public facing platform will offer interested individuals information on current and past studies, publications, media features and team information. Furthermore, with a personalized site login, CYCLE researchers will have full-access to additional resources catered to their position of either research coordinator or therapist and the materials needed at each stage of the trial for each role. In addition, the website features a “New Sites” page, assisting incoming sites in developing a better grasp of the various aspects of the study and how they may be able to get their own site started up.

In-bed cycling and rehabilitation research studies are both novel to the ICU environment. As the Methods Centre, we needed to develop resources to help participating ICUs conduct the trial as easily as possible in their institutions. With the help of another research assistant who created training videos, we were able to provide in-depth resources to address potential questions and concerns regarding biking and outcomes measure assessments. In addition to the website, I also updated documents and resources to match the new trial. Although many materials were already in place from previous studies, many had to be updated with changes to the study protocol, new logos, branding, outcomes measure information and training materials. Finally, the last month of my work term was dedicated to evaluating the website I had spent three months creating. Taking this as an opportunity to gain insight into the website’s real-life usability, I created a detailed survey asking sample research coordinators and therapists to explore the website, find specific documents and record their overall experience.

Learning Goals

Among the various key skills I developed throughout my summer work term, teamwork and applying constructive criticism were among the most notable. Although my past co-op experiences were also incredibly team focused, I have learned that the culture of teamwork varies greatly between different work environments. In my last co-op, I was working under 8 different individuals, each with their own tasks and projects where I was assigned a role. Once a project was completed, usually within a week, I would move on to the next. However, with CYCLE I found myself constantly driven and focused on a single project and overall objective. The team was no longer comprised of individuals

working towards different goals, but instead it was a collective team striving for the same goal, each contributing their own skills and expertise to a particular area. As each of the CYCLE members built off each other's work, each project became intertwined with another. I soon found myself consistently reaching out to each team member for their own insight and ideas.

It was invigorating being able to work in such a work culture where individuals were given independence and creative freedom while always being able to reach out for help as needed. As someone who was not familiar with the study, I was glad to have had two other students, experienced with the CYCLE research program, within arm's reach to help with my everyday questions and quickly bring myself up to speed. I was most surprised by the amount of creative freedom I was given with my project. I was able to put forth my own ideas while learning about a completely new field of graphic design. I developed self-driven learning strategies and most of all the ability to apply constructive criticism and feedback from my team. Fortunately, our team met on a bi-weekly basis to go over each of our projects. I was amazed at the amount of detail each meeting went into, sometimes even dedicating three hours for feedback on the website design.

Coming into this co-op term, I was looking forward to learning more about project management. I quickly learned that project management is not as easy as it may seem. There are several pieces necessary to launching a large phase III randomized controlled trial, one that takes not only months but even years to complete. Finishing the last year of my undergraduate degree, I am planning to apply to a Masters in Physiotherapy. However, my recent experience has unexpectedly increased my interest in pursuing clinical research. I learned about everything that goes into an ICU rehabilitation study from the ground up. I gained a vast amount of knowledge on case report forms, study protocol, research ethics board approval and the trials and tribulations of clinical trial management. Working on such a complex study, I was able to acquire several skills I am confident will prove invaluable in my future endeavors. Gaining valuable work experience targeting my learning goals, I developed key skills one can only truly gain from a hands-on experience.

References

1. Herridge MS, Tansey CM, Matte A, Tomlinson G, Diaz-Grandos N, Cooper A, et al. Functional disability 5 years after acute respiratory distress syndrome. *N Engl J Med*. 2011;364(14):1293–304.
2. Kho, M. E., Molloy, A. J., Clarke, F. J., Ajami, D., Mccaughan, M., Obrovac, K., . . . Cook, D. J. (2016). TryCYCLE: A Prospective Study of the Safety and Feasibility of Early In-Bed Cycling in Mechanically Ventilated Patients. *Plos One*,11(12). doi:10.1371/journal.pone.0167561
3. Farrell et al.: Managing clinical trials. *Trials* 2010 11:78.