

## UTOPIAN Primary Care Trials Group – Session 3

Wednesday, March 25, 2020 from 4:00 p.m. to 5:00 p.m., Zoom teleconference

<b>Attendance:</b>	Andrew Pinto (AP) – Chair Aashka Bhatt (AB) Noah Crampton (NC) Olga Klenova (OK) Marjan Moeinedin (MM) Rahim Moineddin (RM) Braden Gregory O'Neill (BGO) Ann Burchell (AB)	Carolyn Steele Gray (CSG) Sumeet Kalia (SK) Christopher Meaney (CM)
<b>Regrets:</b>	Payal Agarwal (PA) Noah Ivers (NI) Sheila Dunn (SD) Michelle Greiver (MG) Aisha Lofters (AL) Donatus Mutasingwa (DM) Jennifer Rayner (JR) Peter Selby (PS)	Abhimanyu Sud (AS) Ross Upshur (RU) Joanna King (JK)

Item	Topic	Minutes	Action	Responsible
1	Introductions (Andrew Pinto)	<p>Andrew Pinto introduced those present on the phone. This is a group of people interested in clinical research through our research network and particularly interested in clinical trials and growing our skills, proposing trials. We will turn to Chris to talk about pragmatic trials. We will then open the floor to the team to discuss ideas relevant to this group. Ann had sent an email with ideas relevant to this group. Andrew has a project related to COVID that has come about from St. Michale's Hospital FHT to discuss with the team and would like group feedback.</p> <p>If we have time, we can get an update from Braden on BedMed project and Caroline can update on projects as well.</p> <p>Andrew – much of our research has stopped and we are focusing a lot of our energy on dealing with COVID. Consequently, many projects' progress has been halted.</p>		

2	Review and approval of January 29, 2020 draft meeting minutes (All)	Minutes of the previous meeting were approved by those present.		
3	Group member needs (All)	<p>Group members agreed that the format of the Primary Care Trials meetings is useful.</p> <p>Marjan Moeinedin proposed that a database that lists research studies and key information pertaining to those studies would also be useful. Key information would include the Principal Investigator, sites from which subjects are being recruited, etc.</p> <p>Dropbox is for internal resources.</p> <p>Members added that templates for grant applications, study protocols, REB submissions, based on intervention type would be very helpful.</p> <p>Important information which the group members wish to know about individual sites are as follows:</p> <ul style="list-style-type: none"> <li>• Individual faculty interests</li> <li>• REB process: forms, contact, staff at REB who can support researchers with issues</li> <li>• Timelines of full versus delegated review</li> <li>• Finances</li> <li>• Communications</li> <li>• Contracts (ex. DSAs)</li> <li>• Types of patients</li> <li>• Recruitment infrastructure</li> <li>• "Research allies"</li> </ul> <p>A process map for each site would be a useful tool to integrate this information.</p> <p>If researchers would like to know sites have which kinds of patients, they should be able to make a request for data from the Data Safe Haven (Sumeet Kalia could facilitate this type of request).</p> <p>Andrew Pinto contributed that UTOPIAN should aim to visit sites once per year, providing an opportunity to thank the site for its contribution, gather its ideas and provide an update on UTOPIAN. He hopes that Community Health Centres and large family health teams will become involved with UTOPIAN in the future.</p>		
4	Learning topic: Pragmatic trials (Chris Meaney)	I am going to give an introduction about trials pulled right from Wikipedia, will then talk about internal validity because trials afford the opportunity for strong control internal validity, then I will give the definition of pragmatic trials (Schwartz and Lellouch, 1967), then I will discuss the big bullet points from the consort paper and the prescis 2 papers, then I will talk about my involvement in pragmatic trails at UTOPIAN-DFCM with Dr. Eva Grunfeld on Better 1 and Better 2. Very interested to hear from the group about		

		<p>their experiences with pragmatic trials and how they feel it is similar or different from regular trials.</p> <p>How RCT's fit into this landscape - "RCTs are considered to be the most reliable form of scientific evidence in the hierarchy of evidence that influences healthcare policy and practice because RCTs reduce spurious causality and bias. Results of RCTs may be combined in systematic reviews which are increasingly being used in the conduct of evidence-based practice" (Wikipedia)</p> <p>What is Internal Validity? "Internal validity is the extent to which a piece of evidence supports a claim about cause and effect, within the context of a particular study. It is one of the most important properties of scientific studies, and is an important concept in reasoning about evidence more generally. Internal validity is determined by how well a study can rule out alternative explanations for its findings (usually, sources of systematic error or 'bias'). It contrasts with external validity, the extent to which results can justify conclusions about other contexts (that is, the extent to which results can be generalized)." (Wikipedia)</p> <p>Trials because of randomization</p> <p>RCTs were first suggested by Shwartz and Lellouch (seminal article from 1967)</p> <p>Current examples of cluster RCTs are the <a href="#">BETTER Health: Durham</a>, <a href="#">SPARK</a>, and <a href="#">SPIDER</a> studies.</p> <p>Noah Ivers mentioned that there are pros and cons to this approach and that it is useful when researchers are concerned with contamination in clinics. Groups are randomized; the cluster is the doctor and the patient is the unit of analysis.</p>		
5	Discussion of trial proposals and ongoing work (All)	<p>Braden O'Neill updated the group that the BedMed study (individual RCT) has been submitted to REB at U of T for full review.</p> <p>Andrew Pinto added that the SEISMIC study is hosting a symposium at St. Michael's Hospital and that a draft grant submission has been prepared.</p>		
Meeting adjourned at 5:00 p.m.				
Next meeting: Wednesday, March 25 <sup>th</sup> , 2020; 4:00 p.m.-5:00 p.m. (virtual)				