UTOPIAN Primary Care Trials Group – Session 10 *Minutes*

Thursday, December 3rd, 2020 from 4:00 p.m. to 5:00 p.m., Zoom teleconference

Attendance:

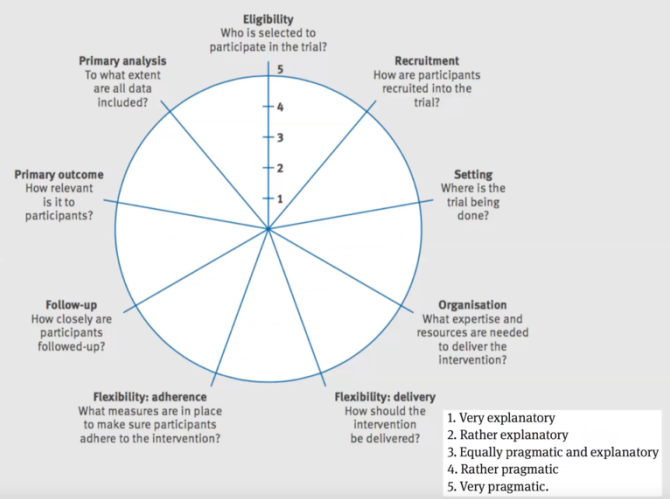
Andrew Pinto (AP) – Chair
Aashka Bhatt (AB)
Giles Pereira (GP)
Rahim Moineddin (RM)
Braden Gregory O'Neill (BGO)
Michelle Greiver (MG)
Sumeet Kalia (SK)
Noah Ivers (NI)
Noah Crampton (NC)
Chris Meaney (CM)
Joanna King (JK)
Peter Selby (PS)
Eva Grunfeld (EG)
Ross Upshur (RU)
Jennifer Rayner (JR)
Peter Juni (PJ)
Rosemarie Lall (RL)
Bernard Le Foll (BF)
Luca Pisterzi (LP)
Deepti Pasricha (DP)
Carolyn Steele Gray (CSG)

Regrets:

Payal Agarwal (PA)
Marjan Moeinedin (MM)
Donatus Mutasingwa (DM)
Abhimanyu Sud (AS)
Sheila Dunn (SD)
Ann Burchell (AB)
Stephanie Terenzi (ST)
Tony D'Urzon (TD)
Tara Kiran (TK)

Item	Topic	Minutes	Action	Responsible
1	Introductions (Andrew Pinto)	• Andrew Pinto introduced those present on the phone		
2	Review and approval of Nov 18, 2020 draft meeting minutes (All)	• Minutes of the previous meeting were approved by those present	Approved	All

3	Presentation: AHRC & Pragmatic Trials (Dr. Peter Juni)	**Applied Health Research Centre (AHRC):** • More than 70 staff members managing 150 studies • Worked with more than 200 PIs and 350 sites and site investigators • Enrolled more than 60,000 patients, globally Organized into Business Units: • Methods & Statistics • Clinical Trials Unit • Observational and Qualitative • Research informatics • Quality & Monitoring • Business & Contracts Productivity: • >700 peer reviewed publications since 2009 • >60 original journal articles in top 5 medical journals (9 N Engl J Med, 12 Lancet, 11 JAMA) • Currently >100 publications per year • CAD 45M research funding spent since 2009 • Recent CIHR success rate >30% vs. national average of 15% • More on AHRC here: http://www.hubresearch.ca/ **Pragmatic Trials:** PRECIS • A tool with 10 domains to help trialists design clinical trials on a continuum of explanatory attitude (ideal situation) to more pragmatic attitude (usual care). PRECIS-2: • An improved, validated version, which has been developed with the help of over 80 international trialists, clinicians, and policymakers • Has nine domains—eligibility criteria, recruitment, setting, organization, flexibility (delivery), flexibility (adherence), follow-up, primary outcome, and primary analysis—scored from 1 (very explanatory) to 5 (very pragmatic) to facilitate domain discussion and consensus.		

		 How to do an RCT: • Let chance decide who gets what • Avoid manipulation of the decision • Maintain chance allocation throughout • Do fair assessments • Make sure nobody is sloppy • Prevent cheating • Include everybody in the analysis		
3	Presentation: Recapping 2020 and Planning for 2021 (Andrew Pinto)	**Objectives of Primary Care Trials Network**: 1. To support primary care providers who conceive an intervention (emerging from real-world clinical work) to test it rigorously using an RCT design as PI 2. To support primary care providers be thoughtful site investigators for RCTs 3. To build a community of practice, and ultimately create more efficient and effective research **Recap of 2020:** • Monthly meetings, combining education, guests and discussing trial ideas • Very consistent network of colleagues, leading to collaborations (e.g. COVID related projects and proposals) – usually DFCM with some guests from NORTHH and AOHC • Response to COVID-19: gradually sorted out trials and linkage to studies • Defining PI and Site PI responsibilities • Defining readiness PI Responsibilities: o Include SI as member of study team o Include SI on grant(s), which may involve adding the SI to existing grants		

		○ Include SI in discussions around study design, analysis and interpretation of results ○ Invite SI to be co-author on paper(s) ○ Identify study resources available to site investigators, including staff and documents ○ Reach out and visit site and meet with staff – e.g. sponsor introductory lunch Site Investigator Responsibilities: ○ Confirm the study is relevant and applicable to primary care, and meets the policies of the DFCM (e.g. relationship to industry) ○ Champion the study at the site, including approaching site leadership + colleagues to confirm involvement ○ Manage REB at site if applicable, with the support of the PI and study staff ○ Manage Research Contracts at site if applicable, with the support of the PI and study staff ○ Manage Cost Centres/financial details at site if applicable, with the support of the PI and study staff ○ Advertise study to participants and support recruitment (e.g., posters, emails, use of EMR to identify potential participants) ○ Contribute to interpretation of results ○ Contribute to editing paper, meeting ICMJE criteria for authorship Site Preparation and Readiness Checklist: □ Site Investigator identified: Requires each site to be aware of the interests, availability and experience of each potential SI: □ Qualified Investigator Undertaking Form and Protocol Agreement signed □ CVs (signed) and licenses as required □ REB identified and forms available: requires knowledge of each REB process, incld. CTO □ Staff and HR policies (where applicable) □ Training for TCPS2, GCP, Health Canada Division 5 □ Contracts (where applicable) □ Medical directive/Delegated act process & establish delegation log □ Finances (e.g., research cost centre) □ Recruitment processes: posters, emails, staff, on-site, pre-authorization to be contacted □ Process to communication about the trail to the site □ Data storage & consent documentation □ Site Initiation Visit □ Drug storage: standard operating procedures, temp, monitoring, logs □ Insurance □ Process to address any new identified health concerns, crisis management		

		2021 (overlapping) Priorities: 1. Network growth: Ontario and beyond • Complete an assessment of each UTOPIAN site and divide into "ready" or "in development" o Work with site leadership re: the importance of engaging in research • Reach out to ORACLE network members • Reach out to colleagues in other provinces, building on PIHCIN programmatic grant sites 2. Education/training • Ongoing invitation to guests to present/give rounds • 2 articles for Annals of Family Medicine • Start to record short talks (e.g. how to write a CIHR grant for RCT) 3. Linkage with other clinical trials networks • Recent experience with call for "Network of Clinical Trial Networks" by CIHR • Strategically, begin to form connections with other clinical trial networks o Critical Care Trial Network o CTN (HIV< STI, blood borne diseases) o Canadian Cancer Clinical Trials Network o Canadian Nephrology Trials Network		
Meeting adjourned at 5:00 p.m.				
Next meeting: January 27, 2021; 4:00 p.m.-5:00 p.m. (virtual)				