



UTOPIAN Primary Care Trials Group – Session 8 Minutes

Thursday, October 22nd, 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) Luca Pisterzi (LP) Deepti Pasricha (DP) Carolyn Steele Gray (CSG)

Regrets: Payal Agarwal (PA)

Marjan Moeinedin (MM)

Eva Grunfeld (EG) Ross Upshur (RU)

Donatus Mutasingwa (DM)

Abhimanyu Sud (AS) Jennifer Rayner (JR) Rosemarie Lall (RL) Ann Burchell (AB) Sheila Dunn (SD) Tony D'Urzo (TD) Peter Selby (PS)

Stephanie Terenzi (ST)

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 June 18, 2020 draft meeting minutes (All)	Minutes of the previous meeting were approved by those present.	• Approved	• All

Discussion topic:	1. The need for a trial:
Suggestions on	
writing a grant	o <u>Steps</u> :
o support a RCT Andrew Pinto)	- What is the problem to be addressed?
Allulew Fillioj	- What is/are the principal research
	question(s) to be addressed?
	Why is a trial needed now?How will the results of this trial be useful?
	- Are there any risks to the safety of the participants involved in the trial?
	participants involved in the trial.
	o <u>Peer Review Committees - Evaluation</u>
	<u>Criteria:</u>
	- Present and future resource implications
	for Canadian healthcare and the economy
	in general.
	- Are the hypotheses to be tested and/or the
	study objectives specified and described clearly?
	- Is the trial addressing the right
	question(s)?
	- Is this the right time to conduct the trial
	with respect to current knowledge of the
	intervention and current use of existing
	technologies?
	- Are the reasons for the study and the
	changes that might be implemented as a
	result of the study adequately explained?
	- What evidence is available to inform the
	need for and design of this trial (e.g.:
	systematic reviews)? - Is the proposed research compatible with
	the extent of the available knowledge,
	nationally and internationally?
	- What impact will the results have on
	practice or our understanding of the
	proposed intervention or underlying
	condition?
	- Will the results of the trial be generalizable
	beyond the immediate research setting of
	the trial in a way that will maximize the impact of the results?
	impact of the results:
	2. The proposed trial:
	o Steps:
	- What is the proposed trial design?
	- What are the planned interventions?
	- What are the proposed practical
	arrangements for allocating participants to
	trial groups?
	- What are the proposed methods for
	protecting against sources of bias?
	- What are the planned inclusion /exclusion

What are the planned inclusion/exclusion

What is the proposed duration of treatment period?

criteria?

- What is the frequency and duration followup?
- What are the proposed primary and secondary outcome measures?
- How will the outcome measures be measured at follow up?
- What is the proposed sample size and what is the justification for the assumptions underlying the power calculations?
- If applicable, are health service research issues being addressed?
- What is the planned recruitment rate? How will the recruitment be organized? Over what time period will recruitment take place? What evidence is there that the planned recruitment rate is achievable?
- Are there likely to be any problems with compliance? On what evidence are the compliance figures based?
- What is the likely rate of loss to follow-up?
 On what evidence is the loss to follow-up rate based?
- How many centers will be involved?
- What is the proposed type of analyses?
- What is the proposed frequency of analyses?
- Are there any planned subgroups?
- Has any pilot study been carried out using this design?

• Peer Review Committee – Evaluation Criteria:

- Is the study design appropriate to answer the research questions posed?
- Has sufficient account been taken within the study design of the issues of generalizability and representativeness?
- What is the justification for the hypothesis underlying the power calculations?
- Are the outcomes, and their measures, clearly described and appropriate to the scientific hypothesis?
- Has the trial population been defined adequately in relation to the target population so that the results will have meaning?
- Have the measures been validated specifically for the target population(s)?
- Is the control group appropriate?
- How will sources of bias be avoided or taken account of?

3. Trial Management:

- Steps:
 - What are the arrangements for the day-today management of the trial?

		 What will be the role of each principal applicant and co-applicant proposed? Describe the trial steering committee and if relevant, the data safety and monitoring committee. 				
		 Peer Revie Committee – Evaluation Criteria: Does the proposed team of investigators have the necessary range of disciplines and experience necessary to carry out the study? Does the trial team include people with experience in successfully running large multi-center trials? Has adequate statistical advice been sought and incorporated? Has adequate advice been sought and incorporated on other health services research issues if they are to be addressed? How will the trial be coordinated? What are the roles of members of the trial team? 				
		Reference: https://cihr-irsc.gc.ca/e/39187.html				
5	Ongoing work (All)	 Ontario pRimAry Care LEarning (ORACLE) Network: 7 PBRN in Ontario have agreed to form a consortium Each will continue to exist and be based in the 6 schools of medicine in Ontario, plus the CHCs Looking for an overarching governance structure (i.e. a board with all 7 PBRNs represented) Objective: greater coordination, more standardized clinical research systems, more standardized data and collaboration across networks **Data2SaveLives: UTOPIAN session Wednesday, October 28th, 4-5pm; https://www.dfcm.utoronto.ca/event/data 2savelives-value-data-research-utopian-presentations DAC session Wednesday, November 4th, 4-5pm; 				
		https://www.dfcm.utoronto.ca/event/data 2savelives-value-data-research-dac- presentations				
Mee	l ting adjourned at !					
	Next meeting: November 18, 2020; 4:00 p.m5:00 p.m. (virtual)					