The Ottawa Hospital | L'Hôpital d'Ottawa

Research project summary

Developing a framework for the ethical design and conduct of pragmatic trials to improve the quality and value of health care systems and practices

- Principal Investigators: Monica Taljaard, Dean Fergusson, Terry Klassen, Charles Weijer
- Co-Investigators: Jamie Brehaut, Marion Campbell, Sarah Edwards, Sandra Eldridge, Christopher Forrest, Bruno Giraudeau, Corey Goldstein, Ian Graham, Jeremy Grimshaw, Karla Hemming, Spencer Hey, Austin Horn, Vipul Jairath, Alex London, John Marshall, Lauralyn Mcintyre, Joanne McKenzie, Alison Paprica, Merrick Zwarenstein
- Awarded $ 780,300 from the Canadian Institutes of Health Research (CIHR) in May 2017

The randomized controlled trial is the gold standard method for evaluating medical interventions. However, the majority of trials are conducted under laboratory-like conditions, which limits their applicability to the real-world clinical setting. There is therefore an urgent need for so-called pragmatic randomized controlled trials, which are undertaken in the routine clinical setting. Pragmatic trials can provide patients, doctors and policymakers with more reliable information as to which treatments and strategies are best for patients. But whilst ethical guidelines exist to protect participants in research - their applicability for pragmatic trials is not straightforward. This has led to confusion, where some trials have been carried out with inadequate protections, and in others, strict enforcement of current guidelines have posed unnecessary obstacles, undermining scientific quality and impeding improvements in the quality of healthcare. Our goal is to clarify this situation by developing novel ethics guidance to help researchers and research ethics committees conduct and review pragmatic trials. Questions addressed will include: Should pragmatic trials comparing accepted and routinely available medical treatments be classified as research and therefore receive extra scrutiny or should they be considered within the scope of usual medical care (as some have suggested) and fall under the rules of the doctor-patient relationship? Do patients always need to be informed about pragmatic trials and be required to provide informed consent? What information about risks and benefits should be disclosed to patients? We will answer these and other questions through extensive analysis of ethics documents and national and international regulations. We will also build a database of completed trials and examine practices; survey researchers, research ethics committees and patients; organize a consensus meeting to generate guidance; and disseminate our work to stakeholders.

Back to summary of all grants awarded to The Ottawa Hospital in this competition (May 2017)