

HRM 733 (Winter 2023) | Session 1

Last Updated: December 15, 2022

Health Research Methodology (HRM) Program

Title: Course overview, trial design, and pilot and feasibility trials

Date: January 9, 2023

Instructor: Lehana Thabane

Objectives:

1. Review the course material, expectations and methods of evaluation
2. Revise important terminologies in clinical trials and discuss concepts related to design
3. Discuss how often the various designs are used in practice

Objectives (pilot and feasibility trials):

4. To understand the rationale for conducting a pilot/feasibility trials
5. To understand how to develop feasibility objectives and outcomes
6. To understand how to report pilot and feasibility trials

Readings (references) for this session:

1. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, Lancaster GA, group Pc: CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* 2016, 355:i5239.
<https://www.ncbi.nlm.nih.gov/libaccess.lib.mcmaster.ca/pubmed/27965879>
2. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, Robson R, Thabane M, Giangregorio L, Goldsmith CH: A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol* 2010, 10:1.
<https://www.ncbi.nlm.nih.gov/libaccess.lib.mcmaster.ca/pubmed/20053272>
3. Arain M, Campbell MJ, Cooper CL, Lancaster GA: What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Med Res Methodol* 2010, 10:67.
<https://www.ncbi.nlm.nih.gov/libaccess.lib.mcmaster.ca/pubmed/20637084>
4. Mbuagbaw L, Kosa SD, Lawson DO, et al. The reporting of progression criteria in protocols of pilot trials designed to assess the feasibility of main trials is insufficient: a meta-epidemiological study. *Pilot and Feasibility Studies*. 2019;5(1):120.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6827233/>
5. Eldridge SM, Lancaster GA, Campbell MJ, Thabane L, Hopewell S, Coleman CL, Bond CM. Defining feasibility and pilot studies in preparation for randomised controlled trials: development of a conceptual framework. *PLoS One* 2016, 11(3):e0150205.