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What use is an external pilot study?

Sandra Eldridge¹, Christine Bond², Mike Campbell³, Claire Chan¹, Sally Hopewell⁴, Gill Lancaster⁵, Lehana Thabane⁶

¹Queen Mary University of London, United Kingdom; ²University of Aberdeen, Aberdeen, United Kingdom; ³University of Sheffield, Sheffield, United Kingdom; ⁴University of Oxford, Oxford, United Kingdom; ⁵Keele University, Keele, United Kingdom; ⁶McMaster University, Hamilton, Canada

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The past 15 years have seen an exponential rise in published studies in health research described as pilot or feasibility studies. Many of these published studies are in preparation for larger randomised controlled trials evaluating efficacy or effectiveness. The vast majority of these studies are external pilot or feasibility studies conducted separately from the future larger randomised trial, and the data they produce is used only to make decisions about whether and how to go on to a larger study. However, there has also been a rise in the number of effectiveness or efficacy randomised controlled trials in which the first part of the trial is a pilot phase used to test out the feasibility of trial processes such as recruitment and retention. These pilot phases are usually called internal pilot studies. A pilot or feasibility phase for trials of complex interventions is widely recommended, for example by the UK MRC framework for the development and evaluation of complex interventions and is expected by funders such as the UK NIHR. However, researchers still face the question about whether and what sort of external pilot work is needed in relation to their own research area. In this talk, we will use some examples of external pilot and feasibility studies to reflect on when external pilot studies are particularly useful, and how to make judgements about their objectives, design and conduct. The examples cover a range of different health issues. We suggest that the usefulness of an external pilot study in advance of a larger randomised controlled trial may be best assessed on a case by case basis.