**Development of a reporting guideline for pilot and feasibility studies**

(summary document)

**Background**

Pilot/feasibility studies are an essential part of trial preparation, and have been shown to be particularly effective in the planning of complex interventions. Pre-trial preparation may involve qualitative work, for example, to ascertain practitioner views on delivery of the intervention or patient views on randomization [1], and quantitative work, for example, to gain initial estimates for sample size calculation, to determine likely recruitment and consent rates [2], or to conduct pre-trial modelling to assess feasibility, effectiveness and cost [3,4]. However recent research has shown that pilot/feasibility studies suffer from publication bias and a lack of clarity in the objectives and methodological focus, suggesting that there is an urgent need for the development of new guidelines for reporting such studies [5-7].

Misunderstandings about the purpose of pilot/feasibility studies means that opportunities to answer the important research questions at the piloting/feasibility stage may be lost. As a result full phase trials may be less efficient, interventions less effective, and trials may run into serious problems with conduct that could have been avoided with proper piloting. The National Institute of Health Research and Medical Research Council [8] in the UK have produced definitions of feasibility and pilot studies to try and address some of these issues. Nevertheless, there remains considerable interest and debate in this area and further guidelines are needed.

**Objectives**

We are developing an extension to the current CONSORT guidelines for pilot randomised controlled trials conducted in advance of a randomized controlled trial of effectiveness. We plan that this CONSORT extension will have the potential to be adapted or extended to provide guidance for other types of pre-trial pilot and feasibility studies, to ensure consistency and clarity. We will also give a clear definition as to what constitutes a feasibility study and what constitutes a pilot study, specifically in preparation for a randomized controlled trial.

**Methods**

We have set up a working group of six members (led by Sandra Eldridge, Christine Bond, Mike Campbell, Gillian Lancaster, Lehana Thabane, Sally Hopewell) to carry out the development work. The proposed work has been structured into three phases.

1. Construction of initial definitions

We have drawn up an initial definition as to what constitutes a pilot study and what constitutes a feasibility study.

2. Delphi process and development of checklist items

Between July and October 2013, a Delphi consensus study, involving 93 participants, was conducted to develop draft reporting guidelines. Subsequently the results of the Delphi study were discussed in a Royal Statistical Society Meeting in Sheffield in October 2013 and the work of the group was presented at the MRC Clinical Trials Methodology conference in Edinburgh in November 2013 [9] and followed by an open meeting.

3. Consensus meeting

The next stage of the development is the proposed consensus meeting. We intend to invite a maximum of 30 stakeholder participants from a variety of backgrounds and with an interest in pilot/feasibility studies to a meeting in late 2014.

The consensus meeting aims to agree a set of items, based on the findings of the Delphi study, to be included in a CONSORT extension checklist for pilot trials, and discuss how this might be extended to other pilot studies and a broader set of recommendations for feasibility/pilot studies more generally. We also aim to generate support for the new guidelines from a range of stakeholder participants who will then become advocates and users of the guidelines in their respective study areas.

If you are interested in finding out more about our work and to be informed of future developments, please contact Professor Sandra Eldridge at [s.eldridge@qmul.ac.uk](mailto:s.eldridge@qmul.ac.uk) or Dr Gillian Lancaster at [g.lancaster@lancaster.ac.uk](mailto:g.lancaster@lancaster.ac.uk).

**References**

1. Mays N., Pope C. (2000) Qualitative research in health care: assessing quality in qualitative research.*BMJ,* 320, pp. 50-52.

2. Lancaster G.A., Campbell M.J., Eldridge S., Farrin A., Marchant M., Muller S., Perera R., Peters T.J., Prevost A.T., Rait G. (2010) Trials in Primary Care: statistical issues in the design, conduct and evaluation of complex interventions**.** *Statistical Methods in Medical Research*, 19, pp.349-377.

3. Eldridge S., Spencer A., Cryer C., Parsons S., Underwood M., Feder G. (2005) Why modelling a complex intervention is an important precursor to trial design: lessons from studying an intervention to reduce falls-related injuries in older people. Journal of Health Services Research and Policy, 10, pp. 133–142.

4. Taylor S.J.C, Sohanpal R., Bremner S.A., Devine A., McDaid D., Fernandez J-L., Griffiths C.J., Eldridge S. (2012) Self-management support for moderate-to-severe chronic obstructive pulmonary disease: a pilot randomised controlled trial. *British Journal of General Practice* 62 (603), pp. 687-695.

5. Lancaster G.A., Dodd S., Williamson P.R. (2004) Design and analysis of pilot studies: recommendations for good practice**.** *J Eval Clin Pract,* 10, pp. 307-12.

6. Arain M., Campbell M.J., Cooper C.L., Lancaster G.A. (2010) What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Medical Research Methodology*, 10: 67.

7. Thabane L., Ma J., Chu R., Cheng J., Ismaila A., Rios L.P., Robson R., Thabane M., Giangregorio L., Goldsmith C.H. (2010) A tutorial on pilot studies: the what, why and how**.** *BMC Medical Research Methodology,* 10: 1.

8. Craig P., Dieppe P., Macintyre S., Mitchie S., Nazareth I., Petticrew M. (2008) Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ,* 337**:** a1655. Full document available at: <http://www.mrc.ac.uk/complexinterventionsguidance>.

9. Eldridge S, Bond C, Campbell M, Lancaster G, Thabane L, Hopewell S. Definition and reporting of pilot and feasibility studies Trials 2013, 14(Suppl 1):O18