

ORAL PRESENTATION

Open Access

ADePT (algorithm for decision-making after pilot and feasibility trials): a decision aid for progression from feasibility study to main trial

Carol Bugge^{1*}, Brian Williams², Suzanne Hagen³

From 2nd Clinical Trials Methodology Conference: Methodology Matters
Edinburgh, UK. 18-19 November 2013

Background

Complex intervention guidance advocates pilot trials and feasibility studies as part of a phased approach to development, testing and evaluation of healthcare interventions. In this paper an example of a feasibility study and pilot trial for a randomised controlled trial (RCT) of pelvic floor muscle training for prolapse is used to explore challenges for progression to main trial.

Methods

A four-centre feasibility study including pilot trial aiming to randomise 50 women with prolapse of any type or stage and who had had a pessary successfully fitted. We used published methodological categories to classify and analyse the problems that arose in our feasibility study. Subsequently we sought to locate potential solutions that might minimise the trade-off between an explanatory and pragmatic main trial.

Results

The feasibility study pointed to significant potential problems in relation to participant recruitment, features of the intervention, acceptability of the intervention to participants and outcome measurement. Finding minimal evidence to support our decision-making regarding the transition from feasibility work to a trial, we developed an algorithm (ADePT; Algorithm for Decision-making after Pilot and feasibility Trials) which we subsequently used as a guide. The algorithm sought to: 1) encourage systematic identification and appraisal of problems and potential solutions; 2) improve transparency of decision-making processes; and 3) reveal tensions that exist

between choices which lead to a pragmatic versus explanatory trial.

Conclusions

We have developed a decision-support tool that may aid future researchers to identify the most appropriate solutions to problems identified within pilot and feasibility studies.

Authors' details

¹University of Stirling, Stirling, UK. ²Nursing, Midwifery and Allied Health Professions Research Unit, University of Stirling, UK. ³Nursing, Midwifery and Allied Health Professions Research Unit, Glasgow Caledonian University, UK.

Published: 29 November 2013

doi:10.1186/1745-6215-14-S1-O19

Cite this article as: Bugge et al.: ADePT (algorithm for decision-making after pilot and feasibility trials): a decision aid for progression from feasibility study to main trial. *Trials* 2013 **14**(Suppl 1):O19.

Submit your next manuscript to BioMed Central and take full advantage of:

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

Submit your manuscript at
www.biomedcentral.com/submit



¹University of Stirling, Stirling, UK
Full list of author information is available at the end of the article