Planning complex interventions using pilot and feasibility studies: what is good practice?

Dr Gillian Lancaster

Postgraduate Statistics Centre
Lancaster University

g.lancaster@lancaster.ac.uk
Design and Analysis of Pilot Studies: recommendations for good practice

Cited over 400 times
Trials in primary care: statistical issues in the design, conduct and evaluation of complex interventions

GA Lancaster
MJ Campbell
S Eldridge
A Farrin
M Marchant
S Muller
R Perera
TJ Peters
AT Prevost
G Rait

1. What makes an intervention complex?

- Interactions between components in experimental and control arms
- Difficulty of behaviours required by those delivering or receiving the intervention
- Organisational levels targeted by the intervention
- Variability of outcomes
- Degree of flexibility/tailoring of intervention permitted
- Will it work in everyday practice?

NB. taken from MRC guidelines
Guidance

- MRC document
  ‘Developing and Evaluating Complex Interventions’
  www.mrc.ac.uk/complexinterventionsguidance

- BMJ paper (Campbell NC et al., 2007)
  ‘Designing and Evaluating Complex Interventions to improve health care’

- Case studies
### Key statistical design issues

<table>
<thead>
<tr>
<th>Phases given in MRC guidance framework</th>
<th>Key elements in designing and evaluating complex interventions</th>
<th>General points to consider</th>
<th>Key statistical design issues addressed in our SMMR paper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Background and context (For more information and examples see MRC and Campbell et al.)</td>
<td>Socio-economic background; Underlying cultural assumptions; Health service system; Government initiatives; Preventative policies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Defining and understanding the problem (See above docs)</td>
<td>Prevalence of condition; Population most affected; How condition is caused/sustained; Potential for intervention and improvement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Conceptualising the problem (See above docs)</td>
<td>Levels of complexity of health problem and co-morbidity; Risk factors and factors influencing changes over time; Patient beliefs, symptoms and adherence to treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gathering evidence</td>
<td>Systematic reviews; Epidemiological research; Qualitative research; Expert opinion</td>
<td>Using evidence from primary studies, systematic reviews and qualitative studies to inform study design</td>
</tr>
<tr>
<td></td>
<td>Developing the intervention</td>
<td>Identify key processes and mechanisms for delivery; Potential beneficial effect; Define target group; Optimise best treatment combinations</td>
<td>Conducting primary care research in the UK: complying with research governance and assessing quality of care using eg. Quality and Outcomes Framework, HES</td>
</tr>
</tbody>
</table>
## Key statistical design issues II

<table>
<thead>
<tr>
<th>Phases given in MRC guidance framework</th>
<th>Key elements in designing and evaluating complex interventions</th>
<th>General points to consider</th>
<th>Key statistical design issues addressed in our SMMR paper</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Evaluation</strong></td>
<td>Developing and optimising trial parameters</td>
<td>Testing the feasibility and integrity of the trial protocol; Consideration of appropriate primary/secondary endpoints; Recruitment and retention strategies; Method of randomisation to minimise imbalance; Sample size considerations</td>
<td>Pilot studies and pre-trial modelling; Selection of outcome measures for effectiveness and quality; Recruitment of practices and participants; Choosing the method of randomisation; Sample size and between practice variation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Data collection and analysis</strong></td>
<td></td>
<td>Data collection forms; Design of database; Monitoring procedures; Awareness of issues of data analysis for different study designs</td>
<td>Choosing the method of analysis: cluster specific versus marginal models</td>
</tr>
<tr>
<td><strong>Implementation</strong></td>
<td>Getting evidence into practice (See new MRC guidance document)</td>
<td>Publication and dissemination strategy; Stakeholder involvement; Benefits, harms, costs for decision making; Recommendations</td>
<td></td>
</tr>
</tbody>
</table>
2. Using evidence from primary studies, systematic reviews and qualitative studies in the design

- Much high quality research lacks generalisability (external validity)
- Strong argument for carrying out research in the most appropriate context and setting

Eg. Can we trust estimate of effect size when intervention studies to lower BP after stroke are mostly carried out in secondary care? (Mant et al BMJ 2006)
Systematic reviews of RCTs

- Useful because based on clearly formulated research questions and methodology
- Quality of included papers has been appraised
- Summary (pooled) estimate of effect size
- Feasibility, acceptability and uptake of intervention can be measured by level of attrition of participants

Eg. ‘Relative attrition’ has been used to compare levels of attrition across oral anticoagulation and Diabetes type II trials (Hennekens et al. BMC Res. Methods 2007)

- Systematic reviews of diagnostic test and method comparison studies also useful for selecting an appropriate measurement method or technique
Qualitative studies

- Especially useful when planning or evaluating a complex intervention

Can be used:

- **Before** the trial to explore issues of design eg. barriers to recruitment; acceptability of randomisation from a patient’s perspective

- **During** the trial to understand and unpack the processes of implementation and change

- **After** the trial to explore reasons for the findings eg. are findings in line with underlying theory; acceptability to deliverers and receivers; the value of the intervention – as an evaluative assessment and to aid interpretation
Awareness of research potential of existing data sources

- Eg. Using QOF indicators in research to assess differences in quality of care:
  - Exclusions eg. failure to attend for assessment, frailty of condition, refuse treatment
  - Differences between GP Practices eg. how conditions are recorded, how interventions are assessed, composition and skills of practice staff

- Hospital Episode Statistics and disease registers – quality and consistency of coding, abstraction

- Usually not created for research purposes

- Research databases have been created eg. CPRD, Qresearch.
3. Use of pilot studies

- Important pre-requisite for funding
- Often ad-hoc small stand-alone studies
- Subject to publication bias
- Is there a difference between a feasibility and a pilot study?
- Pilot studies address the integrity of the study protocol
- Need clear list of key objectives
- May lead to changes in study design
Pilot studies

• NIHR definition: “Smaller version of main study” (encourages mini RCTS)
• Better to say: “To test the integrity of the main study protocol”
• Important if multi-centre or cluster RCT
• Focus on ensuring processes of main study are understood and well-organised
• Internal or external pilot – needs to be specified beforehand
• Internal pilots are part of the main study and should be planned as such

http://www.netscc.ac.uk/glossary/#glos6
Table 1: Pilot studies published in 2000-2001 in selected journals*

<table>
<thead>
<tr>
<th>Pilot study</th>
<th>BMJ</th>
<th>Lancet</th>
<th>JAMA</th>
<th>NEJM</th>
<th>BJC</th>
<th>BJOG</th>
<th>BJS</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pilot in preparation for a trial</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3 (3)</td>
<td>1 (1)</td>
<td>4 (4)</td>
</tr>
<tr>
<td>Piloting new treatment, technique, combination of treatments, Phase I/II trials</td>
<td>5 (3)</td>
<td>11 (8)</td>
<td>4 (1)</td>
<td>3</td>
<td>28 (25)</td>
<td>5 (1)</td>
<td>7 (1)</td>
<td>63 (39)</td>
</tr>
<tr>
<td>Piloting screening programme</td>
<td>1</td>
<td>3 (2)</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>5 (2)</td>
</tr>
<tr>
<td>Piloting guidelines, educational package, patient care strategy</td>
<td>5 (1)</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>11 (1)</td>
</tr>
<tr>
<td>Laboratory testing of activity of compounds eg. in vivo or in vitro assays</td>
<td>0</td>
<td>2 (1)</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>7 (1)</td>
</tr>
<tr>
<td><strong>Total pilot studies</strong></td>
<td>11 (4)</td>
<td>17 (11)</td>
<td>7 (1)</td>
<td>3</td>
<td>33 (25)</td>
<td>10 (4)</td>
<td>9 (2)</td>
<td>90 (47)</td>
</tr>
<tr>
<td><strong>Total number of research papers</strong></td>
<td>372</td>
<td>1115</td>
<td>619</td>
<td>434</td>
<td>1132</td>
<td>381</td>
<td>396</td>
<td>4449</td>
</tr>
</tbody>
</table>

*Numbers in parentheses refer to the number of studies that mentioned the need for further study as a result of the findings of the pilot study.

**This is an approximate total, referring to a search of the total number of journal articles containing an abstract, excluding reviews, using PubMed (National Center for Biotechnology Information 2002).
Key objectives

i. Test integrity of study protocol

ii. Sample size calculation

iii. Pilot data collection forms/questionnaires
   - Prepare and plan data collection and monitoring

iv. Acceptability of the intervention
   - Develop and test implementation and delivery of the intervention
   - Train staff in delivery and assessment

v. Selection of most appropriate outcome measures (endpoints)

vi. Recruitment and consent rates

vii. Randomisation procedure
(i) Integrity of study protocol

• Eg. In preparation for large multi-centre trial
• Randomised pilot study
• Enables all procedures to be put in place and tested
  – inclusion/exclusion criteria
  – drug preparation (if applicable)
  – storage and testing of equipment and materials
  – training of staff in administration
  – assessment of the intervention enrolment procedure
  – determine the number of research assistants necessary to provide 24 hour on-call cover
(ii) Sample size calculation

- Common reason for pilot study
- Need estimates for control group:
  - location (mean) and variability (sd)
  - proportion of primary outcome/endpoint
- Rule of thumb: need at least 30 patients (Browne 1995)
- Use confidence interval when estimating a standard deviation eg. 80% upper one-sided confidence limit, rather than the estimate itself (Browne 1995).
Sample size cont.

• Vickers (JCE, 2003)
• Reviewed 30 endpoints from 28 RCTs in four major journals
• Trials could be underpowered if used estimate of SD without confidence interval
• Actual study SD was greater than predicted SD in 80% of endpoints
• Around quarter of trials required 5 times as many patients as specified in sample size calculation, to have sufficient power
• SDs from small studies tend to be under-estimates – table of correction factors
Sample size for Cluster RCT

- Identify primary outcome measure and calculate sample size for individual trial
- Find estimate of Intra-cluster Correlation Coefficient (ICC)
- Multiply (inflate) sample size by design effect
  - $1 + (m-1) \times ICC$ where $m$ is cluster size assuming all cluster sizes are equal
- How do we accurately measure this variation?
  - Need good quality data from large datasets eg. CPRD, Mediplus, MIQUEST, ?QOF
  - Primary research
- Trade off between bias and precision
(iii) Testing data collection forms and questionnaires

- Particularly important when the patient has to self-complete a form or when several different assessors
- Ensures form is comprehensible and questions are well-defined, clearly understood and presented in a consistent manner
- Other forms such as patient information documents and consent forms can also be tested

NB. Testing administration of a questionnaire is not the same as validating the instrument (see point v)
(iv) Acceptability of intervention

• When intervention may not appeal to all patients, it is wise to determine its acceptability.
  eg. known side effects, difficult to administer, complementary therapy.

• Of particular benefit in a paediatric population when drugs may be licensed and tested in adults but not necessarily in children, or when children need to stick to a dietary regime.
### Example 1 – PANDAs trial

- **Patients ANd Decision Aids trial**
- **To test the acceptability and feasibility of developing and implementing the intervention**
- Planned as cluster randomised trial to help patients with Type 2 diabetes decide when they should go on to insulin

#### Findings:
- General practitioners found the PDA acceptable
- There were sufficient eligible and willing patients in the practices to devise a cluster trial of the intervention against usual care in one city using 30 practices.

> PhD thesis – pilot work (Ng)
> Trial went ahead and is now completed (Mathers et al., 2012)
Example cont.

Methods:
(i) Expert Panel set up - GPs, nurses, a diabetologist, patients, statistician, clinical decision experts;
(ii) Needs assessment exercise involving a Review Panel of 14 GPs and nurses and nine patients with Type 2 diabetes;
(iii) Systematic review of evidence for insulin therapy;
(iv) Drafting of the decision support intervention using the Ottawa Guidelines;
(v) Review of the intervention by the Review Panel;
(vi) Pilot study to test the decision aid for acceptability and feasibility;
(vii) Sample size calculation: 30 practices (15 to receive the PDA and 15 to receive usual care) and with 15 patients per practice to have 80% power to detect a difference of 0.5% HBA1c at the 5% significance level.
Example 2 – Antibiotics use

- Optimising antibiotic use in nursing homes (Loeb, 2002)
- To develop diagnostic and treatment algorithms for use in delivering the intervention in nursing homes
- Multifaceted intervention to reduce prescriptions for antimicrobials for suspected urinary tract infections
- Randomised matched-pairs design
- Systematic review of literature, qualitative study to assess attitudes and perceptions
Example cont.

- Findings:
  - Poor adherence to the algorithms in the nursing homes
  - Changed ‘training the trainer’ approach – used standardised training by research team rather than infection control practitioners to train nursing staff
  - Introduced regular on-site visits by research team to aid adherence to treatment algorithms

- Developed the study protocol following the MRC complex intervention guidelines
- Protocol was published in BMC Health Services Research
(v) Selection of appropriate outcome measure(s)

- Distinguish between primary and secondary outcome measures
- **Valid and reliable** (repeatable & reproducible)
- Directly measured vs patient-reported
  - Include additional objective measures when self-reporting may be unreliable eg. self-assessed smoking cessation and biochemical measure
  - HRQL – use generic and disease-specific measure
- Individual level vs group (cluster) level
- Select most appropriate outcome for evaluating the **effectiveness of the intervention**
  - eg. level of knee pain, knee function, ability to work, satisfaction with treatment
(vi) Recruitment

- Successful recruitment requires a co-ordinated approach and good pilot work
- Need to find efficient ways to identify the sample and gain consent
- Complex interventions can have different levels of recruitment (eg. practices & patients)
- Failure to recruit sufficient numbers reduces statistical power, and is one of the main reasons for abandoning a trial early

(Ross et al 1999)
Principles of good recruitment

- Engage with all stakeholders (Clinicians, GPs, practice staff and participants)
  - Brand for trial (eg. BEAM, PANDA, SCAMPS)
  - Well-developed marketing strategy, good PR
    - eg. Bell’s Palsy trial used local celebrity in media
  - Well-written patient information documents
- Invitation to take part coming from own doctor
- Use trained staff other than doctor/GP to identify and consent participants eg. practice nurses
- Provide staff training in disease topic and research
- Get support from local research network eg. PCRN
  - ‘Research Ready’ accreditation scheme for GP practices
  - ePCRN (evolved into www.transformproject.eu)
(vii) Method of randomisation

- Test out randomisation procedure
  - By individual or by cluster eg. GP practices, households, nursing homes
  - relative costs and justification

- If CRT usually have relatively fewer clusters than individuals ➔ higher prob. of imbalance
  - in the size of each treatment arm
  - in baseline covariate distributions at individual level

- Complex interventions may have multiple components
  eg. simple parallel design vs factorial design
Randomisation procedure

- Test how the randomisation procedure is to work
- Preparation and storage of sealed envelopes
- **Administration** eg. through a hospital pharmacy where each envelope could be signed for at the pharmacy window to maintain objectivity
- Use of a specialist clinical trials unit to provide 24-hour randomisation service, or to provide phone coverage from 9am to 5pm
- Test **acceptability of the concept** of randomisation to the patient and best way of providing a suitable explanation and eliciting informed consent
Example 3 – UK BEAM trial

- UK Back Pain, Exercise, Active management and Manipulation trial (Farrin et al. 2005)
- To test the integrity of the study protocol using a series of sub-studies
- Planned as cluster randomised trial
- 3 treatments – active management (practice level); spinal manipulation and exercise (patient level) – 3 x 2 x 2 factorial design
- Qualitative and quantitative pilot work
  - Views, acceptability and needs of support staff
  - Sample size, staff training, data collection processes, treatment delivery
Example cont.

Findings:

- Majority of methods were successful but highlighted where changes were needed
- Problem with differential recruitment between practices
- Twice as many recruited to intervention arm (active management) than control
- Less severe back pain, less depression, higher education, more in full-time work in intervention group than control at baseline

→ changed to non-clustered design
4. Analysis of a pilot study

• Analysis should be mainly descriptive or should focus on confidence interval estimation

• An external pilot is treated as a stand-alone study, and it is questionable as to whether it should be analysed using hypothesis testing

• Internal pilot studies are designed and planned as part of the main study – interim analyses should be specified in main study protocol
Hypothesis testing

• Inappropriate to place undue significance on results from hypothesis tests, since no formal power calculations have been carried out
• Likely to be imbalance in pre-randomisation covariates - need adjustment in the analysis
• Confidence intervals likely to be imprecise even when there are significant differences
• Results from hypothesis testing should be treated as preliminary and interpreted with caution
• Avoid temptation not to proceed with the main study when significant differences are found
Has anything changed?

**Design and analysis of pilot studies: recommendations for good practice**

Gillian A. Lancaster MSc PhD¹, Susanna Dodd MSc², Paula R. Williamson PhD³

Article first published online: 4 JUN 2004
DOI: 10.1111/j.2002.384.doc.x

**2001/2**

**Correspondence**

**What is a pilot or feasibility study? A review of current practice and editorial policy**

Mubashir Arain¹, Michael J Campbell*¹, Cindy L Cooper¹ and Gillian A Lancaster²
Editorial Policy

• Editor 1: “…..it might be more convincing if reported in more conventional style with p values, appropriate attention to the calculation of sample size and both intention to treat and per protocol analyses”

• Editor 1: “….the fact remains that studies with results that are definitive and clinically directive will always have a better chance”

• Editor 2: “…..the lack of objective outcomes and the incomplete matching between groups”

• Editor 3: “We do appreciate the effort behind the study, and its value to the scientific community, but it can unfortunately not achieve sufficient priority to be considered”

(Arain et al, 2010)
Number of studies with "pilot" OR "feasibility" in the title and "trial" in the title or abstract between 1970 and 2013

Number of studies with "pilot" AND "feasibility" in the title and "trial" in the title or abstract between 1970 and 2013

(Eldridge and Coleman)
5. Conclusion I

• Specific **objectives** of feasibility/pilot study (not main study) should be **clearly presented**

• Methodologically rigorous framework safeguards against pilot studies being conducted simply because of small numbers
  – multi-centre trial may be more appropriate
  – strong ethical argument

• Be consistent - **get message across**
Conclusion II

- Pilot studies are prone to publication bias
- To publish - Need a clear message
- Balance methodological issues and more practical issues of ‘real-life’ research
  - quote existing MRC framework, guidance
  - emphasise innovative methodology
- Need CONSORT extension guidelines for reporting feasibility/pilot studies
Developing CONSORT Guidelines for Reporting of Pilot/Feasibility Studies for Randomized Controlled Trials

Sandra Eldridge, Gillian Lancaster, Mike Campbell, Lehana Thabane, Christine Bond, Sally Hopewell
Welcome to the CONSORT Website

CONSORT stands for Consolidated Standards of Reporting Trials and encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising from inadequate reporting of randomized controlled trials.

The CONSORT Statement

The main product of CONSORT is the CONSORT Statement, which is an evidence-based, minimum set of recommendations for reporting randomized trials. It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and
**CONSORT: checklist (25 items)**

**CONSORT 2010 checklist of information to include when reporting a randomised trial**

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item No</th>
<th>Checklist item</th>
<th>Reported on page No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td>1a</td>
<td>Identification as a randomised trial in the title</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)</td>
<td></td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Background and objectives</strong></td>
<td>2a</td>
<td>Scientific background and explanation of rationale</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>Specific objectives or hypotheses</td>
<td></td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trial design</strong></td>
<td>3a</td>
<td>Description of trial design (such as parallel, factorial) including allocation ratio</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3b</td>
<td>Important changes to methods after trial commencement (such as eligibility criteria), with reasons</td>
<td></td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td>4a</td>
<td>Eligibility criteria for participants</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4b</td>
<td>Settings and locations where the data were collected</td>
<td></td>
</tr>
<tr>
<td><strong>Interventions</strong></td>
<td>5</td>
<td>The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</td>
<td></td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td>6a</td>
<td>Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
<td></td>
</tr>
<tr>
<td><strong>Sample size</strong></td>
<td>7a</td>
<td>How sample size was determined</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
<td></td>
</tr>
<tr>
<td><strong>Randomisation:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sequence generation</strong></td>
<td>8a</td>
<td>Method used to generate the random allocation sequence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8b</td>
<td>Type of randomisation; details of any restriction (such as blocking and block size)</td>
<td></td>
</tr>
<tr>
<td><strong>Allocation concealment</strong></td>
<td>9</td>
<td>Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned</td>
<td></td>
</tr>
<tr>
<td><strong>Implementation</strong></td>
<td>10</td>
<td>Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
<td></td>
</tr>
<tr>
<td><strong>Blinding</strong></td>
<td>11a</td>
<td>If done, who was blinded after assignment to interventions (for example, participants, care providers, those</td>
<td></td>
</tr>
</tbody>
</table>
Previous papers
- Society for Academic Primary Care workshop 2011

Preliminary work
- Delphi user-testing April 2013
- Society for Clinical Trials workshop Boston May 2013

Main Delphi study
- Edinburgh MRC Methodology Hubs, open meeting Nov 2013

Team meeting
- Heathrow airport February 2014
- Consensus meeting Oxford October 2014

Decision to embark on programme of work
- Started with NIHR definitions

Pilot/feasibility studies mutually exclusive???
- One reporting checklist or two??

Pilot/feasibility studies cannot be viewed as mutually exclusive????
- One checklist for pilot randomised trials
Publish your research in

PILOT AND FEASIBILITY STUDIES

Editor-in-Chief: Gillian Lancaster (UK)

• Only journal dedicated to pilot and feasibility studies
• Rapid and thorough peer review
• High visibility – permanent, unrestricted online access
• Highly-respected Editorial Board

New Journal
Launched January 2015
Pilot and Feasibility Studies is an open access, peer-reviewed, online journal that encompasses all aspects of the design, conduct and reporting of pilot and feasibility studies in biomedicine. The journal publishes research articles that are intended to directly influence future clinical trials, as well as protocols, commentaries and methodology articles. The journal also ensures that the results of all well-conducted, peer-reviewed, pilot and feasibility studies are published, regardless of outcome or significance of findings.

Editor in Chief
Gillian Lancaster, University of Lancaster

Editorial Board | Instructions for authors | FAQ
References - pilot studies


Presentations and summaries of discussions from meetings of the PHCSG: Primstat data archive www.jiscmail.ac.uk/primstat

Lots of Examples – www.pilotfeasibilitystudies.com

g.lancaster@lancaster.ac.uk