

# Research Design Service London NEWSLETTER

Issue 17  
Spring 2017

Welcome to RDS London's newsletter: inside you'll find a **Guide to Feasibility Studies** - a topic we regularly advise clients on, which we hope many readers will find useful.

## Successful grant applicants share their experiences and tips for working with us

The most frequent tip from our successful clients was to get in touch with RDS London early in the process of developing a grant application - something we certainly encourage everyone to do to get the most out of our free advice service. We really appreciate it when researchers take the time to give us feedback, and congratulations to all the researchers featured below on their successful funding applications:



"I would recommend the RDS service to all the colleagues considering writing grants without any reservations. My only request to those applying for grants is to contact RDS well in advance of the deadline, the earlier the better."

- **Dr Manu Shankar-Hari**, Consultant in Intensive Care Medicine, Guy's and St Thomas' NHS Foundation Trust, received an **NIHR Clinician Scientist Award**.

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*What support did RDS London provide?* "Detailed feedback on all aspects of the application, including making the case for the need for the research, design and PPI. The RDS input helped to focus and refine our proposal."

*Would you recommend RDS London to colleagues?* "Yes, I would thoroughly recommend the service. I would advise getting in contact with RDS as early as possible in developing your grant and staying in touch regularly during the process as you develop your ideas."

- **Professor Christine Norton**, Professor of Nursing at King's College London, received an **NIHR Programme Grant for Applied Research** (and previously an **RfPB** grant).



*What support did RDS London provide?* "Excellent support for study design, statistics, health economics, qualitative assessment and PPI. Also very useful comments through having attended RfPB committee meetings."

*How did RDS London's support improve your grant application?*

"Much clearer design, aims and outcomes. More convincing PPI."

*Would you recommend RDS London to colleagues? Any advice for colleagues using RDS?* "Yes. Probably best to meet the advisers in person, not just get written feedback."

- **Professor Pippa Oakeshott**, Professor in General Practice at St George's University of London, received an **NIHR Research for Patient Benefit grant**.

The Research Design Service (RDS) provides free expert advice and support for health researchers to develop and submit high quality applied health and social care grant applications to NIHR and other open, national, peer-reviewed funding programmes. The RDS is funded by the National Institute for Health Research (NIHR).

# Feasibility studies guide: Preliminary research to identify any challenges and risks to the conduct of your main trial

by **Lauren Bell**  
Biostatistician



Ensuring a randomised controlled trial runs smoothly can be a challenge, even for the most competent of research teams. Trials can involve complex protocols, require the collection of intricate clinical data, and may involve recruiting from a population of patients at a sensitive time in their lives. Feasibility studies are thought of as an investment towards a main trial; they aim not only to determine if your main trial can be done, but to contribute meaningful insight of any challenges so that you can then mitigate for such risks in the design of the main trial. Feasibility studies explore issues which can either: relate to, for example, the refinement and delivery of the intervention, the setting, conduct, and length and nature of information asked in a trial; or to ensure the main trial has the potential to change practice and is acceptable to patients and health care professionals.

Often the first question to ask is: Is a feasibility study required? Before rushing into an application for funding for a feasibility study, think carefully about what your main trial might look like. In a grant application, it is beneficial to state the main research question, if possible using PICO (Population, Intervention, Control, Outcomes), and list any main trial assumptions and gaps in the plan for the trial. You should review the literature for previous trials similar to your intended main trial to understand if there were any issues with the conduct of the trial. Did previous trials complete on time? Did they have any major protocol amendments or

require further funding? What were the discussed challenges, and what kind of solutions may overcome these? If there is remaining uncertainty necessitating a feasibility study, it is the gaps in the plan for the main trial that will form the basis of the feasibility study aims and objectives.

As NIHR's Research for Patient Benefit funding programme guidance notes point out, feasibility studies should not attempt to evaluate the effectiveness of an intervention. This is the primary question for the main trial to answer. The argument is that feasibility studies will be too small to give any definitive evidence of effectiveness or efficacy. The discussion of any observed effectiveness from the feasibility study could be misguided, and undermine the need for a sufficiently powered and well-designed main trial.

It's not always obvious which aspects your feasibility study may examine. Feasibility research may encompass a broad range of issues from recruitment to follow-up, for example:

- estimating rates of recruitment

and retention, and adherence to treatment;

- investigating the feasibility of recruitment and consent processes;
- exploring patients' and health professionals' perspectives and willingness to be involved;
- weighing the burden of participation and acceptability of assessments;
- estimating parameters such as standard deviations of outcome measures to allow sample size calculation for a full-scale trial.

But every study is different, and you should consider each on its own terms. Here are two examples of feasibility studies that were supported by public funding:

## 1. The PROTECT study

The PROTECT study ([www.dx.doi.org/10.3310/hta7140](http://www.dx.doi.org/10.3310/hta7140)) explored the feasibility of conducting a main trial to evaluate three treatments for prostate cancer. The treatments for consideration were: 1) radical prostatectomy 2) radical



radiotherapy and 3) non-radical option involving monitoring that is variously called ‘watchful waiting’, ‘conservative management’, ‘monitoring’ or ‘surveillance’.

Previous trials, for example the US Prostate Cancer Intervention Versus Observation Trial (PIVOT) and UK MRC PR06 studies, experienced considerable challenges, including the source of patients with true localised disease, the patient preference for particular treatments, and the high rate of 10-year survival in men with local prostate cancer. This established the need for the PROTECT feasibility study to 1) explore the feasibility of ‘case-finding’ in the community as a source of patients, 2) determine the most efficient and effective design for a main trial of treatments, 3) undertake a randomised feasibility study of potential recruitment strategies and 4) pilot outcome measures and procedures for the main trial. They evaluated the acceptability of randomising participants into either a 2 or 3 arm RCT, developed and selected the most suitable outcome measures, compared the recruitment rates of research nurses and consultant urologists, considered if sufficient numbers of recruits could be secured by a programme of ‘case-finding’ in the community, and tested procedures for conducting the major multicentre trial. The PROTECT study gave a comprehensive analysis of the feasibility of the RCT across a number of issues. An example of the PROTECT findings is that ‘watchful waiting’ to describe one treatment protocol had unexpected negative connotations to participants, and ‘active monitoring’ gave participants more confidence they would not be neglected if randomised to this treatment arm.

## 2. The KORAL study

The KORAL feasibility study (<https://www.journalslibrary.nihr.ac.uk/hta/hta14050#/abstract>) focused on one particular objective, which is the acceptability of placebo surgery as the comparator treatment in a large definitive

trial. The main randomised controlled trial would evaluate arthroscopic lavage (a surgical technique to wash out contents in a joint space) for the management of osteoarthritis of the knee. A placebo surgery, or ‘sham surgery’, was considered the most ideal control treatment to minimise bias in the trial, but posed challenges with the acceptability and feasibility of randomising patients to sham surgery. KORAL undertook focus groups and also surveyed surgeons and anaesthetists. They concluded that a main definitive trial with a sham surgery arm would be extremely difficult to undertake. The recommendations from the KORAL feasibility team suggest further research into 1) the usefulness of decision aids to support informed consent for such a placebo-controlled surgical trial, 2) the effects of different terminology for describing the control treatment, such as placebo, sham and dummy, 3) the surgeon–anaesthetist partnerships when planning clinical trials, especially trials including a placebo surgical arm and 4) the influence of ethical perspective of individuals participating in the trial. The findings from this feasibility study have also informed the best practise for trials in other populations where sham surgery as a control arm is considered.

## Which NIHR programmes fund feasibility studies?

The Research for Patient Benefit (RfPB) programme will fund feasibility studies that cost up to £250,000. Other NIHR programmes including Health Technology Assessment (HTA), Efficacy and Mechanism Evaluation (EME) and Public Health Research (PHR) will also fund more expensive feasibility studies, if the next proposed study is within remit of the programme and there are clear progression criteria. A feasibility study might also be a Work Package within a wider programme funded by a Programme Grant for Applied Research (PGfAR) or a Programme Development Grant (PDG). The Public Health Intervention Development Scheme (PHIND) within the Medical Research Council funds the development of public health interventions, including developing theory, modelling process and outcomes, and developing procedures and protocols, though they recommend that “pilot testing or stand-alone feasibility studies” be submitted to the relevant NIHR programme.

*by Lauren Bell, with input from Dr Richard Hooper and Claire Chan, from Queen Mary University of London*

### *How did RDS London’s support improve your grant application?*

“The statistician was super astute in picking up the weakest link in my initial proposal draft in terms of trial design and analysis plan and advised further along my application writing in the next few months. The RDS also organised a mock interview for me and other shortlisted candidates they supported once we found out we got shortlisted.”

### *Would you recommend RDS London to colleagues? Any advice for colleagues using RDS?*

“Given my very positive experience in receiving support from RDS London ... I could not recommend the service any better. Get in touch early and don’t be shy to show the advisers your developing drafts of study proposal to get the most of the comprehensive advice they can offer.”



*- Dr Jacqueline Sin, NIHR Post Doctoral Research Fellow, St George’s University of London, received an NIHR Post Doctoral Fellowship.*

# Ethical approval – getting it right the first time

by Jennifer Bostock, Ethics Lead

It may surprise you to learn that a recent Health Research Authority review found that only 15% of ethics applications pass at first review ([www.bit.ly/HRA2017](http://www.bit.ly/HRA2017)). As an NHS Research Ethics Committee (REC) Vice Chair, I see many research proposals that have achieved funding, gone through R&D, employed staff, and then either stall or fail at the REC.

Some are given unfavourable opinions (4%) or conditional approvals (18%), but the majority are given provisional opinions (61%). This means that applicants must respond to the REC in writing or in person for the committee to consider changes. This costs the REC time and money, other applicants have their reviews pushed back, and most crucially it results in delays for the researchers. These delays are frustrating and can have knock-on effects, such as delayed contractual agreements, extensions being sought from funders and delayed recruitment.

In my experience on RECs and funding panels, the types of studies that most commonly have ethical issues include: mental health studies; studies where participants lack capacity; studies involving vulnerable populations (e.g. prison, forensic, learning disability and care home environments); methodologies such as ethnography; interviews and questionnaires; placebo studies; and studies in general practice. Studies also often have difficulties with qualifying for the Proportionate Review Service (accelerated review of research studies which raise no material ethical issues).

## Tips:

- Think about the overarching aim of the study - what will be the ultimate benefit to patients or the public? Prepare a clear, coherent and honest answer for the REC interview.
- Think about whether you would be happy to participate or if you would want your mother or child to do so. If not, why not?
- Qualitative questionnaire/interview/ethnographic studies should be careful not to include unnecessarily intrusive methods or questions, which could be seen as fishing exercises.
- Patient information sheets, consent forms and recruitment strategies are frequent 'offenders' when it comes to provisional opinions. Always get a lay person, who is outside of academia or healthcare, to read study documents. If possible, have a relevant PPI group review the documents and ask for honest critical feedback.
- If study participants are likely to lack capacity at any stage, you must adhere to the Mental Capacity Act.
- Remember that the primary job of the REC is to protect participants, not to approve research.

As part of RDS London's free support, I can provide expert ethical input into your funding applications to highlight and mitigate against ethical issues that may result in delays in achieving ethical approval. Speak to your RDS advisor if you feel your application could benefit from ethics input.

# Patient and Public Involvement (PPI) update

by Jonathan Paylor, PPI Advisor

RDS London have been working with our Public Advisory Group to develop ways to better embed PPI in our activities. This has led to members of the group offering their advice to researchers who present at our Proposal Feedback Forums.

We have also been working with INVOLVE and RDS East of England on a research project that explores how the concept of co-production can be used to inform and advance PPI in health research. The project consists of a roundtable event, a literature review, interviews and a workshop and will ultimately inform INVOLVE's guidance on co-production.

Finally, we are excited to announce that Charlotte Kühlbrandt will be joining us in June as the PPI lead for RDS London. Charlotte brings a wealth of expertise in ethnography and patient and community involvement in healthcare settings.

Email: [PPI@rdslondon.co.uk](mailto:PPI@rdslondon.co.uk)



"RDS London improved my fellowship application by making helpful suggestions to make the proposal clearer. The mock

interview was particularly excellent and helped me to feel more prepared and confident going to my interview.

"My advice would be to contact them as early as you can to make sure you receive a thorough review of your proposal."

- *Serena Luchenski, PhD candidate, University College London, received an HEE/ NIHR ICA Programme Clinical Doctoral Research Fellowship.*

## Contact Details

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