MiRoR
Methods in
Research on Research

European
Commission

# MIROR TRAINING EVENT

## 28-30 March 2017

## Liverpool, UK

# Introduction to qualitative research

Darko Hren, Faculty of Humanities and Social Sciences,
University of Split

Bridget Young, Department of Psychological Sciences,
University of Liverpool, UK

# Outline of session

**Value of Qualitative Research**

**Introduction to Qualitative Research**

- **Reflexivity**
- **Planning and Designing a Qualitative Study**

**10:55** **Coffee break** (15 mins)

**Qualitative Research Methods**

- **Collecting Data**
- **Open/Closed Questions**
- **Do's and Don'ts of Phrasing Questions and Conducting Interviews**
- **Writing an Interview Guide**

**12:30** **Lunch break** (60 mins)

**Conducting an Interview**

**Qualitative Analysis**

- **Analyzing Transcribed Interview Data**

**15:20** **Coffee break** (15 mins)

**Quality in Qualitative Research**

**16:30 Close**

# What does qualitative research contribute to clinical trials?

- **Discover if a trial is feasible or not**
- Enhance recruitment
- Develop/refine interventions
- Identify issues influencing the effect of an intervention
- Inform outcome measurement
- Enhance retention
- Inform understanding of poor reporting

# Recruitment problems in trials

| Author | Year | Data source | Findings |
|---|---|---|---|
| Charlson | 1984 | 41 RCTs (≥ 250 patients) identified via NIH inventory; investigator survey was principal data source | A third of RCTs recruited fewer than 75% of their planned sample size |
| Easter-brook | 1992 | 720 research protocols (N = 137 RCTs) approved by REC (UK); investigator survey was principal data source | Main reason (28%) for study discontinuation was slow recruitment of patients |
| McDonald | 2006 | 114 RCTs funded by UK MRC and HTA; full applications and subsequent trial reports were principal data source | Less than a third of the trials reached original recruitment target |
| Toerien | 2009 | 133 publications of RCTs identified by a systematic literature review (restricted to six major journals) | Of trials reporting sample size calculation, 21% did not achieve recruitment target at randomisation and 48% at outcome assessment |
| Sully | 2013 | 73 RCTs funded by UK MRC and HTA; trial protocols, and subsequent online reports were principle data sources | 45% of trials did not reach original recruitment target |

Sources: Kasenda et al. (2012) *BMC medical research methodology* 12.1 (2012): 131; Sully et al (2013) *Trials* 14;166;

Open Access Research

BMJ Open

# Doing challenging research studies in a patient-centred way: a qualitative study to inform a randomised controlled trial in the paediatric emergency care setting

Woolfall et al *BMJ open* 2014 4.5: e005045

- Qualitative interviews as part of feasibility study for a proposed trial (EcLiPSE)
- EcLiPSE involves 'deferred consent' where consent (to remain in trial) is sought **after** administration of the treatments being investigated
- Interviewed parents supported the use of deferred consent in this situation, providing a child's safety was not compromised by the trial

For overview of use of qualitative research to inform trials and guidance see: O'Cathain et al. *BMJ open* (2013) 3.6. and O'Cathain et al *Pilot and Feasibility Studies*.2015, 1:32

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# Enhance recruitment

ProtecT trial comparing monitoring, radiotherapy and surgery for prostate cancer

In early months only 40% of eligible patients agreed to randomisation

Qualitative study of recruitment consultations to identify communication strategies to enhance communication

After clinicians were trained in the communication strategies recruitment rose to 70%

(Donovan et al. *BMJ* 2002; 325: 766-770)

The NEW ENGLAND JOURNAL of MEDICINE



ORIGINAL ARTICLE

# 10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer

Freddie C. Hamdy, F.R.C.S.(Urol.), F.Med.Sci., Jenny L. Donovan, Ph.D., F.Med.Sci., J. Athene Lane, Ph.D., Malcolm Mason, M.D., F.R.C.R., Chris Metcalfe, Ph.D., Peter Holding, R.G.N., M.Sc., Michael Davis, M.Sc., Tim J. Peters, Ph.D., F.Med.Sci., Emma L. Turner, Ph.D., Richard M. Martin, Ph.D., Jon Oxley, M.D., F.R.C.Path., Mary Robinson, M.B., B.S., F.R.C.Path., John Staffurth, M.B., B.S., M.D., Eleanor Walsh, M.Sc., Prasad Bollina, M.B., B.S., F.R.C.S.(Urol.), James Catto, Ph.D., F.R.C.S.(Urol.), Andrew Doble, M.S., F.R.C.S.(Urol.), Alan Doherty, F.R.C.S.(Urol.), David Gillatt, M.S., F.R.C.S.(Urol.), Roger Kockelbergh, D.M., F.R.C.S.(Urol.), Howard Kynaston, M.D., F.R.C.S.(Urol.), Alan Paul, M.D., F.R.C.S.(Urol.), Philip Powell, M.D., F.R.C.S., Stephen Prescott, M.D., F.R.C.S.(Urol.), Derek J. Rosario, M.D., F.R.C.S.(Urol.), Edward Rowe, M.D., F.R.C.S.(Urol.), and David E. Neal, F.R.C.S., F.Med.Sci., for the ProtecT Study Group*

N Engl J Med 2016; 375:1415-1424 | October 13, 2016 | DOI: 10.1056/NEJMoa1606220

Donovan, J et al **Improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT study**

(2002) *BMJ*, 325 (7367), 766-769.

Switched from using “watchful waiting” to “active monitoring” for non-radical treatment arm

Found recruiters gave more detail about radical treatments – advised to explain each arm of trial in same level of detail

# Key communication strategies

1. Exploration and acknowledgment of preferences
2. Information to balance patients' views
3. Emphasise keeping an open mind/weighing up all treatments
4. Patient friendly language
5. Beware inadvertent messages/difficulties in communicating equipoise despite best intentions

- **Strategies help to promote informed decision-making, as well as increasing recruitment rates**

(Mills et al *Trials* 2014, 15:323; Rooshenas et al *PLoS Medicine* 2016, 13;10)

# What does qualitative research contribute to clinical trials?

- Discover if a trial is feasible or not
- Enhance recruitment
- **Develop/refine complex interventions**
- **Identify issues influencing the effect of such interventions**
- Inform outcome measurement
- Enhance retention
- Inform understanding of poor reporting

# Complex interventions

- Integrated care programme interventions for risk reduction in cardiovascular disease
- Community based health promotion
- Stroke units
- Strategies for implementing clinical guidelines
- Adolescent sexual health intervention
- Psychological therapies

# Postnatal women's experiences of management of depressive symptoms: a qualitative study

*Pauline Slade, C Jane Morrell, Anna Rigby, Karen Ricci, Janet Spittlehouse and Traolach S Brugha*

## ABSTRACT

**Background**

Postnatal depression is a public health problem requiring intervention. To provide effective care, information is needed on the experiences of those with high levels of depressive symptoms who are offered and accept, or decline, psychological intervention postnatally.

**Aim**

To provide the first integrated in-depth exploration of postnatal women's experiences of the identification and management of symptoms of depression and the offer and acceptance of postnatal care by health visitors taking part in the PoNDER trial.

**Setting**

General practice: primary care within the former Trent regional health authority, England.

**Method**

## INTRODUCTION

Postnatal depression is a public health issue affecting 10–13% of women,[1] and influencing the woman herself, her partner,[2] her relationship with her infant,[3] and consequent child development.[4] Support for women is provided mainly within primary care. Health visitors have been encouraged to see identification of postnatal depression and subsequent provision of support as a part of their role.[5] The most commonly used method for identifying symptoms is the Edinburgh Postnatal Depression Scale (EPDS),[6] alongside a health visitor's clinical judgement.

Postnatal women with depressive symptoms are reluctant to seek help, partly because of the perceived stigma and wishing to be seen as 'good mothers'.[7]

Slade, P et al British Journal of General Practice 2010; 60: 440-8

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BMJ

RESEARCH

# Frequency and reasons for outcome reporting bias in clinical trials: interviews with trialists

R M D Smyth, research associate,[1,2] J J Kirkham, research associate,[1] A Jacoby, professor of medical sociology,[2] D G Altman, professor of statistics in medicine,[3] C Gamble, senior lecturer,[1] P R Williamson, professor of medical statistics[1]

[1]Centre for Medical Statistics and Health Evaluation, University of Liverpool, Liverpool, UK

[2]Division of Public Health, University of Liverpool, Liverpool, UK

[3]Centre for Statistics in Medicine, University of Oxford, Oxford, UK

**Correspondence to:** P R Williamson
prw@liv.ac.uk

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doi:10.1136/bmj.c7153

## ABSTRACT

**Objectives** To provide information on the frequency and reasons for outcome reporting bias in clinical trials.

**Design** Trial protocols were compared with subsequent publication(s) to identify any discrepancies in the outcomes reported, and telephone interviews were conducted with the respective trialists to investigate more extensively the reporting of the research and the issue of unreported outcomes.

**Participants** Chief investigators, or lead or coauthors of trials, were identified from two sources: trials published

PubMed trials, there was at least one unreported efficacy or harm outcome. More than a quarter (6/21, 29%) of these trials were found to have displayed outcome reporting bias.

**Conclusion** The prevalence of incomplete outcome reporting is high. Trialists seemed generally unaware of the implications for the evidence base of not reporting all outcomes and protocol changes. A general lack of consensus regarding the choice of outcomes in particular clinical settings was evident and affects trial design, conduct, analysis, and reporting.