



Undertaking Qualitative Research in Trials.

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Workshop overview

- ▶ Why do qualitative research in trials
- ▶ Overview of qualitative approaches
- ▶ Opportunities and challenges of using qualitative research in trials –discussion
- ▶ Take home messages



RESEARCH

There is ongoing work contributing to evidence around important questions such as:

- What is the best approach to qualitative research in informing choice of outcomes in trials?
- How best to integrate the findings from qualitative and quantitative components of trials?

Firstly....

- **What can qualitative research do for a trial?**
- **What characteristics does that qualitative research require?**

Why Qualitative Research in Trials?

- Reducing research 'waste' (recruitment, retention, dissemination, application)
- Using novel, appropriate methods - HRB Strategy 2016-20, MRC (2000, 2008) Strategies for Complex Interventions.
- Need to improve how trials are prioritised, conducted, analysed, interpreted and results presented to decision makers.

Why Qualitative Research in Trials?

- Answers questions about recruitment and ethics
- Explores feasibility and acceptability of interventions
- Provides a voice for participants, recruiters, stakeholders, makes trials sensitive to “human beings”- PPI
- Provides crucial “real world evidence”
- Can increase cost effectiveness

(DeSalis et al. 2008, Plano Clarke et al. 2013, Rapport et al. 2013, Cooper et al. 2014, O’Cathain et al. 2014)

- Fully integrated structurally and culturally”
- Consider qualitative component at pre-trial, feasibility and pilot stage (O’Cathain et al. 2014)
- Embedding qualitative research within RCTs: embedding secondary aims that are bounded yet contextualised by the primary aims (Plano Clark et al. 2013)...

A Range of Approaches

- All about Recruitment- Explicitly about understanding recruitment issues (**Donovan QuinteT**)
- Broader (but **Lawton** ends up focused on recruitment)
Interpretation of trial findings, inform recommendations
- Specifically getting in pre and post to influence and explain the results **O'Cathain**

Potential Pitfalls (Cooper et al. 2014)

- Reporting qualitative findings before trial completion brings issues of confidentiality for participants (Before-During-After-Blinding?)
- Modifications may be made during full trial based on feedback, threatening trial integrity or increasing the need for flexibility
- Reporting on qualitative findings before completion of trial can impact on recruitment, retention and outcome measurements

Quality Beats Mere Description

- Extract and Explain, so that you can Contend, Defend, and Extend to bring (your research) to a conclusion” (Bazeley, 2013)

Characteristics Richards (2005)

- Simplicity – a ‘small polished gem of a theory’, rather than ‘a mere pebble of truism;’
- Elegance and balance – it is coherent;
- Completeness – it explains all;
- Robustness – it doesn’t fall over with new data; and
- It makes sense to relevant audiences.

ENHANCES THE TRIAL ACROSS ITS COURSE

Examples

- **Research:**
 - **DARES**
 - **SWAT- KARMA Dep (II)**
 - **STEER study**

DARES

- Exploration and Explanation of How, rather than Why
- Dissemination/Publication opportunities

Dementia education programme incorporating Reminiscence for Staff (DARES)

- A clustered randomised control trial with an embedded qualitative component.
- Evaluate the impact of a structured education reminiscence-based programme for staff (SERPS) on the quality of life of residents with dementia.
- Staff (nurses and health care assistants) within clusters allocated to the intervention arm will receive the SERPS.
- Staff within clusters allocated to the control arm will deliver usual care.

Sample Size

- 18 long-stay units (17 residents with dementia per unit)
- Total 304 residents with dementia
- Blinded outcome measurement undertaken at baseline and at 22-25 weeks post randomisation.

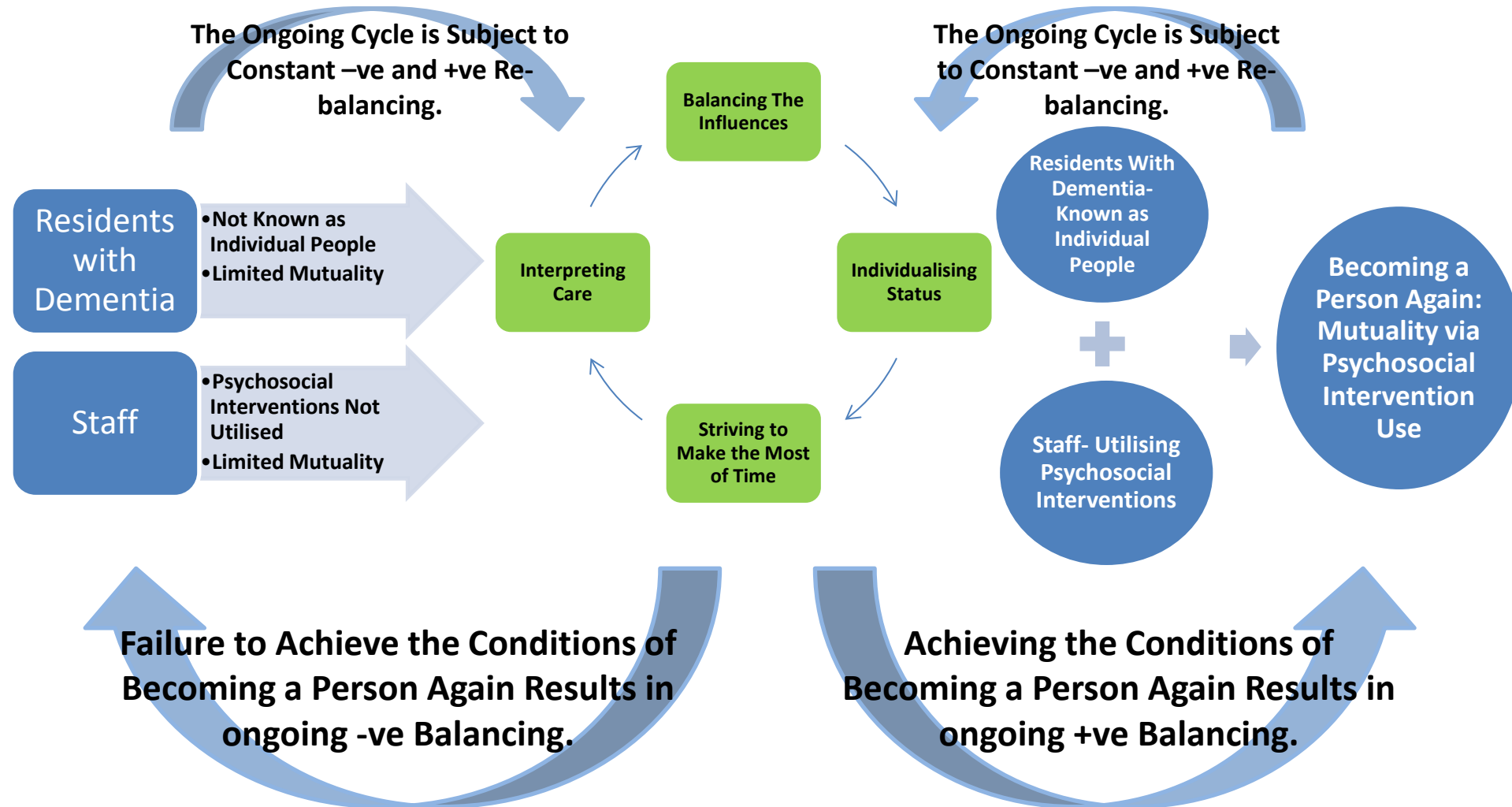
DARES Outcomes

- **Primary:**
- Quality of life (Quality of life-AD, QOL-AD)
- **Secondary:**
- Agitation (the Cohen Mansfield Agitation Inventory, CMAI)
- Depression (the Cornell Scale for Depression in Dementia, CSDD)
- Staff attitudes to residents with dementia and perceived care burden (Strains in Dementia Care Scale, SDC-scale)

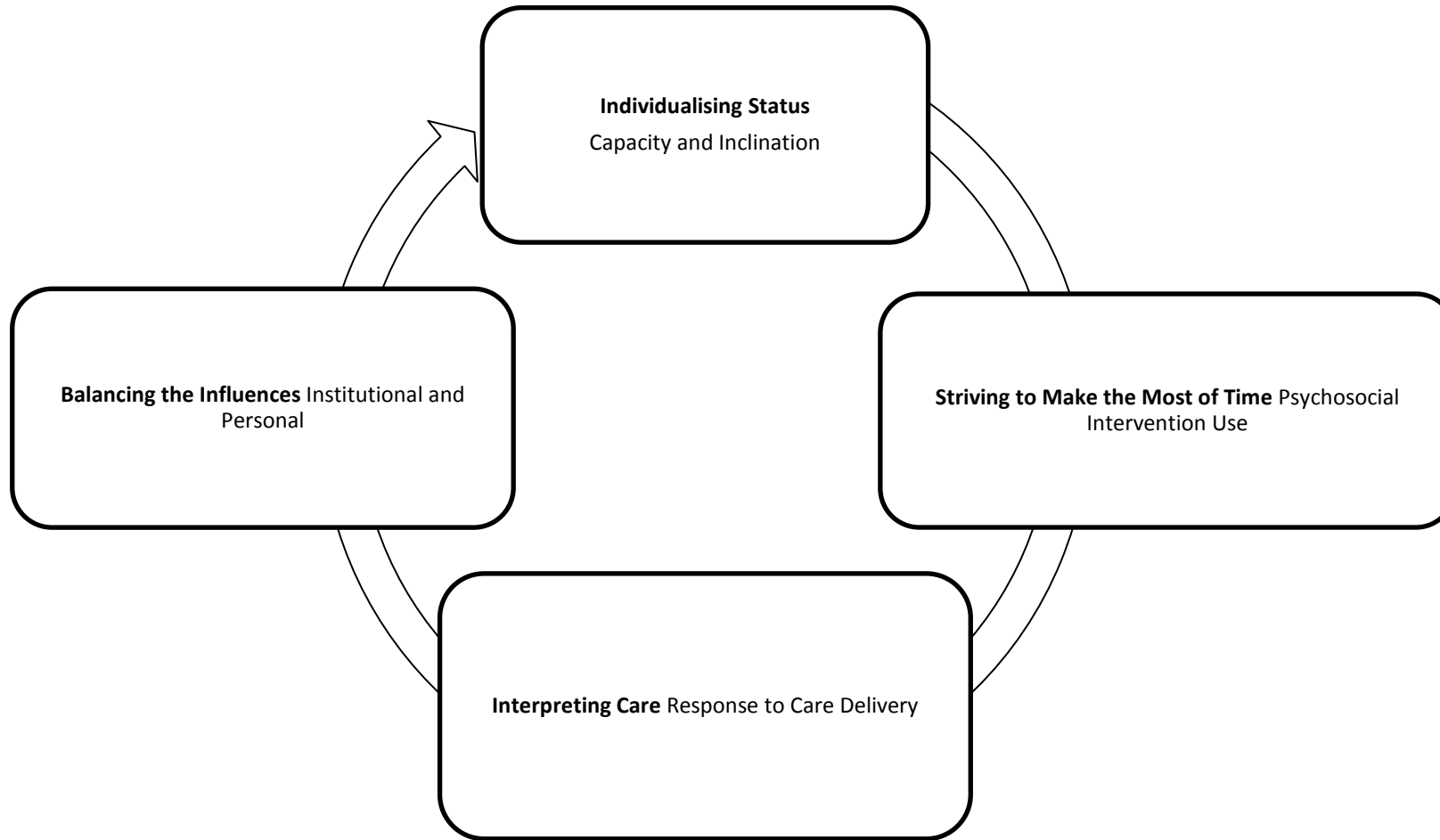
DARES Qualitative Component

- 2 Complimentary Qual Threads
- Understanding Context (Pilot)
- Designing the Intervention (Expert Interviews)
- Modelling the Intervention Process
- Explaining the Unexpected (burden and depression examples)

Becoming a Person Again: Cyclical Interaction of Concepts Accounting for Mutuality and Psychosocial Intervention Use Over Time



The conceptual stages of Becoming a Person Again



Dissemination

Hunter, A, Murphy K., Grealish A., Casey D. and Keady J (2016) Psychosocial Intervention Use in Long-Stay Dementia Care: a classic grounded theory Qualitative Health Research DOI: 10.1177/1049732316632194 1(11)

Hunter A. (2015) Positive Relationships in Residential Dementia Care Book Chapter in Improving the Quality of Life of Older Adults Across Environments of Care

Cooney, A., Hunter, A., Murphy, K., Casey, D., Smyth, S., Devane, D., Dempsey, L., Murphy, E., Jordan, F. & O'Shea, E. (2014) "Seeing me through my memories": a grounded theory study on using reminiscence with people with dementia living in long-term care. Journal of Clinical Nursing. 23 (23-24) 3564–3574

O'Shea E., Murphy K., Cooney A., Devane D., Smith S., Dempsey L., Casey D., Jordan F., and Hunter A (2014) The impact of reminiscence on the quality of life of residents with dementia in long-stay care International Journal of Geriatric Psychiatry 29(10) 1062-1070

Murphy K, Cooney A., Casey D., Jordan F., Hunter A (2014) Articulating the strategies for maximising the inclusion of people with dementia in qualitative research studies. Dementia 0(0) 1–26

Dempsey L., Murphy K., Cooney A., Casey D., O'Shea E., Devane D., Jordan F., and Hunter A. (2014) Reminiscence in dementia: A concept analysis Dementia Vol. 13(2) 176–192

Cooney A., O'Shea E., Devane D., Casey D., Jordan F., and Hunter A and Murphy K (2013) The systematic development of a structured education programme for carers of people with dementia in long-stay care Journal of Clinical Nursing 22 (13-14):1977-1987

Haughton C., Hunter A., and Meskell P. (2012) Linking Aims, Paradigm and Method in Nursing Research: Three Practical Examples Nurse Researcher. 20(2) 32-29

O'Shea E., Devane D., Murphy K., Cooney A., Casey D., Jordan F., Hunter A. and Murphy E (2011) Effectiveness of a structured education reminiscence-based programme for staff on the quality of life of residents with dementia in long-stay units: A study protocol for a cluster randomised trial Trials, 12:41

Hunter, A, Murphy K., Grealish A., Casey D. and Keady J. (2011) Navigating the Grounded Theory Terrain (Part 1): a neophyte researcher's journey around the headlands of grounded theory Nurse Researcher 18, 4, 6-10

Hunter, A Murphy K., Grealish A., Casey D. and Keady J (2011) Navigating the Grounded Theory Terrain (Part 2): justification for and application of Classic Grounded Theory Nurse Researcher 19, 1, 6-11

SWAT- KARMA Dep (II)

<https://priorityresearch.ie/>

- PRioRiT_y question 1:

How can randomised trials become part of routine care and best utilise current clinical care pathways?

- PRioRiT_y question 5:

What are the barriers and enablers for clinicians/healthcare professionals in helping conduct randomised trials?

SWAT- KARMA Dep (II)

- Framework analysis
 - Refusers
 - Acceptors (intervention and control)
 - Trialists
-
- Findings fed back to the host trail team to support ongoing recruitment and retention as well as addressing PRioRiT_y questions 1 and 5.

Systematic Techniques to Enhance Retention in Randomised controlled trials

- Develop and pilot theoretically informed, participant-centred, evidence-based behaviour change interventions to improve retention in trials.

STEER: stakeholder semi-structured interviews and workshops

1. Identify stakeholders' views and experiences of non-retention to determine 'who needs to do what differently?'
2. Use a theoretical framework to identify which barriers and enablers to retention in trials need to be targeted)
3. ID which behaviour change techniques could overcome the modifiable barriers and enhance the enablers of trial retention
4. Evaluate feasibility and acceptability of the selected interventions from the perspective of stakeholders and how retention interventions can be implemented

References

- Cooper, C., O’Cathain, A., Hind, D., Adamson, J., Lawton, J., Baird, W. (2014) Conducting qualitative research within Clinical Trials Units: Avoiding potential pitfalls. *Contemporary Clinical Trials* **38**, 338-343.
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Qualitative Research Designs

- ▶ Phenomenology
- ▶ Ethnography
- ▶ Grounded Theory
- ▶ Case study
- ▶ Qualitative descriptive
- ▶ Interpretive descriptive



The questions I get asked!

- ▶ How do I know which methodology to choose?
- ▶ How big should my sample size be?
- ▶ How do I fill in an ethics application for interviews, as surely there are minimal risks?
- ▶ How do I know which analysis approach to use?
- ▶ Can you just tell me how to actually analyse?

... And the questions I wish I was asked more often...

- ▶ How do I know my qualitative research has been done well?
- ▶ How can I make my qualitative research have impact?

How do I know which
methodology to choose?

Working example



Exploration of Research nurses experiences of working in a Clinical Research Facility in Ireland

Different approaches

- ▶ Research nurses' lived experiences of working in a clinical research facility
- ▶ Culture of teamwork in clinical research facilities
- ▶ “one uniform, many hats” a theory of multiple obligations for nurses/midwives working in a clinical trial
- ▶ Factors that impact on how research nurses experience involvement in a clinical trial

Importance of the question

- ▶ Research nurses' lived experiences of working in a clinical research facility
- ▶ Culture of teamwork in clinical research facilities
- ▶ "one uniform, many hats" a theory of multiple obligations for nurses/midwives working in a clinical trial
- ▶ Factors that impact on how research nurses experience involvement in a clinical trial
- ▶ Phenomenology
- ▶ Ethnography
- ▶ Grounded Theory
- ▶ Qualitative Descriptive or Interpretive descriptive

How do I know which
methodology to choose?

Sample Size

- ▶ Quick answer is **data saturation** but that is now contested
- ▶ Quality of data
- ▶ Depth and richness
- ▶ Are comparisons being made?
- ▶ Unique cases?
- ▶ Multiple interviews?
- ▶ Researcher expertise (Cleary et al. 2014)
- ▶ Feasibility and resources
- ▶ **FOCUS GROUPS**

Method specific considerations

- ▶ Ethnography
 - ▶ talk to many relevant people but few **key informants**
 - ▶ Sampling **observations** also-time, context, people (Higginbottom 2004)
- ▶ Phenomenology
 - ▶ Typically less than ten
 - ▶ Individuals with **lived experience**
- ▶ Grounded Theory
 - ▶ Start with broad **maximum variation**
 - ▶ Then **theoretical sampling**
 - ▶ **Confirming** and **disconfirming** cases

How do I fill in an ethics application for interviews, as surely there are minimal risks?



Qualitative Research Ethics

- ▶ Informed consent:
 - ▶ Evolving nature (Houghton et al. 2010)
 - ▶ “informed process consent” (Munhall 1988)
- ▶ Risk-benefit:
 - ▶ Potential for distress
 - ▶ researcher-participant relationship
- ▶ Data Protection:
 - ▶ Confidentiality versus anonymity



How do I know which analysis approach to use?

Can you just tell me how to actually analyse?

Qualitative research

- ▶ The right question
- ▶ The right methodology
- ▶ Sampling
- ▶ Data collection
- ...
- ▶ All lead towards good analysis!

“For example, if interview questions are asked in such a way as to prompt superficial answers, there is not even a starting point for meaningful analysis” (Bazeley, 2009)

Qualitative Data Analysis

- ▶ “Qualitative data analysis ... is a **complex, creative process** that is ongoing, interactive, inductive and reflexive. It occurs throughout the study from the initial conception of the idea to the production of the final report or account. While it can be quite different from the processes used to analyse quantitative data, nevertheless it still needs to be rigorous, systematic and transparent” (Lathlean 2010, p 435)
- ▶ Thorne (2000, p.68) “unquestionably, data analysis is the most **complex and mysterious** of all the phases of a qualitative project”
- ▶ Basit (2003, p. 143) “it is **dynamic, intuitive, and creative process** of thinking and theorizing”
- ▶ “Analysis brings **moments of terror** that nothing sensible will emerge and times of exhilaration from the certainty of having discovered ultimate truth. In between are long periods of hard work, deep thinking, and weight-lifting volumes of material” (Halcom’s Iron Laws of Evaluation Research, cited in Patton 2002)
- ▶ Some authors use language that accentuates the air of mystery-“emerging” from the data (Thorne 2000).

Qualitative Data Analysis

- ▶ No formula, just guidance and direction, final destination is unique to each researcher.
- ▶ No abstract process of analysis, no matter how eloquently named or finely described can substitute for the skill, knowledge, experience, creativity, diligence, and work of the qualitative analyst (Stake 1995)
- ▶ Qualitative analysis and writing involve us not just making sense of the world but also making sense of our relationship to the world and therefore discovering things about some phenomenon of interest (Richardson 2000).
- ▶ Patton (2002) "Do your very best with your full intellect to fairly represent the data and communicate what the data can reveal given the purpose of the study"

What does all that mean?



Types of Analysis

- ▶ Phenomenological analysis
- ▶ Ethnographic analysis
- ▶ Grounded theory analysis
- ▶ Content analysis
- ▶ Thematic analysis
- ▶ Framework analysis



Think of a family... but consider theoretical underpinning!

Braun and Clarke (2006)

- ▶ Familiarising yourself with your data
- ▶ Generating initial codes
- ▶ Searching for themes
- ▶ Reviewing themes
- ▶ Defining and naming themes
- ▶ Producing the report



6 steps to success

How do I know my qualitative research has been done well?

How can I make my qualitative research have impact?

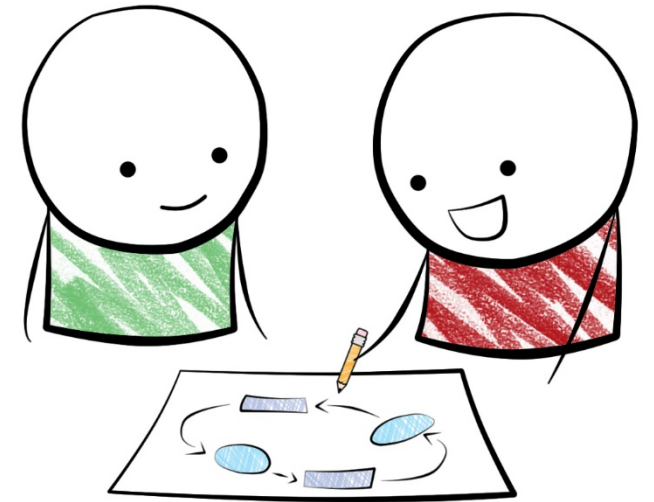
Why is rigour important?

- ▶ Findings are "worth paying attention to" (Lincoln and Guba 1985)
- ▶ Findings may inform changes to an intervention
- ▶ Findings may inform policy and practice
- ▶ Ultimately! May impact on health care and PEOPLE
- ▶ Ethics throughout the whole research process
- ▶ "The Big 8"

Critical friends

- ▶ Inter-rater reliability or Peer debriefing
- ▶ NB: time to consider Paradigm!

E.g. Andrew and Catherine coding...



Audit trail

- ▶ Audit Trail
 - ▶ Decisions
 - ▶ Rationale
 - ▶ Trustworthiness



Broad coding

SAMPLE 1

So the first question is about the skills lab, can you tell me about your experience in the skills lab, how you found it and how you learned in the skills lab?

1. ① [Well, we have a new skills lab in XXXX and it's really like the same layout as a hospital ward almost. So it's really kind of like a good example of what we will be working in. So we just have lectures in there on the skills and then we perform them. Yeah I think it's really good but it is nothing like the real thing...but that can't be helped.

I thought they were good for giving injections and stuff like that, but yeah, they're okay, but for stuff like wound care, they're obviously nothing like it. They're good practice, practice for moving and handling and stuff like that as well...

find that it's like, you're trying to remember, 'oh what's the technical way I'm meant to move this person?' and then when you do it, there was an easier way, and you're like, 'oh' and next time you do it and you remember it and you do it that way and it's much easier. Like the way they teach you in the college are really good and way easier than some of the stuff we do here, it's like, 'ah move quickly here' and stuff like that but they're really good but it's hard to remember that one. We didn't actually use the mannequins for that, we got our lecturers to sit on the bed and move them about [both laugh]. But yeah, moving and handling can be very different because you are totally restricted to place and a patient mightn't want to be touched on one side because they are sore, especially here on this ward because we have stroke patients and a lot of fallen and hurt themselves and that sort of thing, maybe a lot more sensitive and don't want to be moved and stuff like that and then it's really hard to move them without touching them too much and hurting them and stuff.

So can you tell me what you think are the good things about the way you were taught your skills in the skills lab?

The lecturers doing it first and like, telling you about their experiences and stuff like 'and my first time', and that kind of puts you at ease when like someone else mucks up and stuff; it's okay. And the way it is group, like then if someone makes a mistake, then everyone else is like, 'oh that's grand, you do it again'.

[illegible]

allowed to
make mistakes.
↓
literature
freedom to
make
mistakes.

Example of matrix query

	Participants who Accepted	Participants who Declined
1 : Feeling like a guinea pig	1	3
2 : Altruism	2	2
3 : Taking a gamble	0	3

Reflexivity



Dumbledore: *"I use the Pensieve. One simply siphons the excess thoughts from one's mind, pours them into the basin, and examines them at one's leisure. It becomes easier to spot patterns and links, you understand, when they are in this form."*

- ▶ As a group
- ▶ As an individual
- ▶ Why?

Other considerations

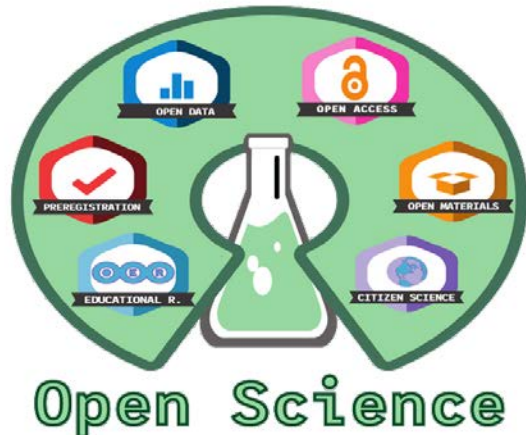
- ▶ Member checking
- ▶ Thick Descriptions
- ▶ Reporting guidelines: COREQ and SRQR



Open Science



- Open science platforms
- FAIR data management
- PPI ignite



Findable 
Accessible 
Interoperable 
Reusable 

Opportunities and challenges to undertaking qualitative research in trials

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Any Questions?