Involving people in developing interventions for trials

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Overview

• What approaches are there to intervention development?
• What methods do we use to involve others in the process?
• What are the strengths and limitations of these methods?
• How do research teams make decisions?
Identifying and critiquing different approaches to Developing complex interventions.

CI: Alicia O’Cathain, Sheffield; Team from Stirling, Bristol and Southampton

BMC: Pilot and Feasibility Studies – special series on Intervention Development

http://www.pilotfeasibilitystudies.com/series/InterventionDevelopment

Complex Intervention Development

• Important because we need interventions that are:
  – effective/cost-effective
  – implemented in practice
  – sustainable
  – acceptable to taxpayers

• Yet
  – methods are poorly reported
  – there is considerable research waste

Rationale for involving other people

• Moral and ethical imperative where services are publicly funded

• To improve the research through 3 key functions:
  – Research decision making
  – Advancing understanding
  – Capturing knowledge - facts, experiences, tacit understanding, awareness……..opinion, beliefs…….. Data?
Some approaches to intervention development

• Evidence based – NICE or systematic reviews
• Theory-based – e.g. COM-B; Theoretical domains Framework
• Logic-based – inductive, deductive, models
• Person-based – e.g. e-health
• Paradigm-based – e.g. participatory research
• Methods-based – e.g. qualitative research, mixed methods
Participatory approaches to intervention development

- Language differs across disciplines and a common definition is hard to pin down

- Co-design, Co-production, Co-creation…
- Action Research
- Community Development Approaches
Participatory Approaches

They all share key tenets:

– *a democratic impulse*

– *iterative data collection and analysis*

– *simultaneous contributions to science, improvement and change*


The integration problem

The real world

The trial world

Recruitment

Fidelity

Retention

Implementation
QR and PPI - definitions

- In qualitative health research people and situations provide or are a source of data for developing an enhanced understanding of perceptions, experiences and behaviour.

- In PPI people including patients/carers discuss and sometimes share decisions in order to enhance research design and conduct.
PPI and qualitative research

- Both are increasingly used in trials
- They are different, although they are sometimes conflated in grant applications and reports
- They can be complementary and synergistic
When designing an intervention - what are the strengths and limitations of:
1. Qualitative research
2. PPI
3. Participatory approaches?
How are people selected?

<table>
<thead>
<tr>
<th>Qualitative research</th>
<th>PPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systematic sampling strategy</td>
<td>Variable. Selection not always transparent</td>
</tr>
<tr>
<td>Single or serial interviews</td>
<td>Continuity over years; “in the team”. Group think?</td>
</tr>
<tr>
<td>Participants usually have no research experience</td>
<td>Single or multiple topics/projects</td>
</tr>
<tr>
<td>Purposive, theoretical, diversity, snowball for hard to reach, disconfirming data</td>
<td>Trained? Professionalised?</td>
</tr>
<tr>
<td>How many?</td>
<td>How representative?</td>
</tr>
<tr>
<td>Saturation for key themes</td>
<td>How many?</td>
</tr>
<tr>
<td>Rigour</td>
<td>1-2, sometimes a group, outreach, charities, social media</td>
</tr>
</tbody>
</table>
How do people contribute?

Qualitative
Skilled staff collect data (interviews, focus groups, observations…..)
Ethics approval
Discipline/epistemology driven
COnsolidated criteria for REporting Qualitative research (COREQ) http://www.equator-network.org/

Power relations:
The researcher and the researched

PPI
Team meetings, email. Task orientated – leaflets, outcome measures, dissemination
No ethics approval required
Drivers not always transparent
GRIPP (Guidance for Reporting Involvement of Patients and Public). Staniszewska et al. (2011)

Power relations:
Patient and public involvement as equals?

Participatory Approaches
Breastfeeding
Breastfeeding in Scotland 6-8 weeks, Health Visitor “Baby Check”

Source: ISD Scotland, CHSP Pre-School Aug 2016
www.isdscotland.org/Health-Topics/Child-Health/Infant-Feeding/
Global evidence - UK idiosyncrasy

Cochrane Systematic Reviews:
Any additional support – professional or lay increases breastfeeding duration and exclusivity. (Renfrew et al 2012)

But not in the UK! (Hoddinott et al 2010, 2011; Jolly et al. 2012)

Some things…
…..work in some places
…..for some people
…..at some times
…..under some circumstances

How do we change “some” to “most” … in an efficient and sustainable way?
A cautionary tale

- Qualitative research on infant feeding decision making
- An action research breastfeeding coaching intervention (Before and After Cohort Design).
  Significant increase in breast feeding at 6 weeks
- The Breastfeeding in Groups Trial (BIG).
  Cluster RCT embedded in qualitative research
  - no effect
  - action research was probably the effective component

References: (Hoddinott et al.: BMJ, 1999; Birth, 2006; Family Practice, 2007; BMJ, 2009; Social Science and Medicine, 2010)
Consider how you could use PPI, qualitative research and/or participatory methods to strengthen the design of an intervention to meet the commissioning brief below.

Facilitating the return to work of NHS staff with common mental health disorders (Adapted from NIHR/HTA Commissioning Brief 2015)
THANK YOU

• Colleagues, patients and lay representatives who have contributed to this talk
• NMAHP-RU receives funding from the Chief Scientist Office of the Scottish Government Health and Social Care Directorates.

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