

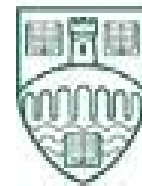
Opportunities, pitfalls and practicalities

A real world approach to combining qualitative research and trials

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Improving health through research  CHIEF SCIENTIST OFFICE

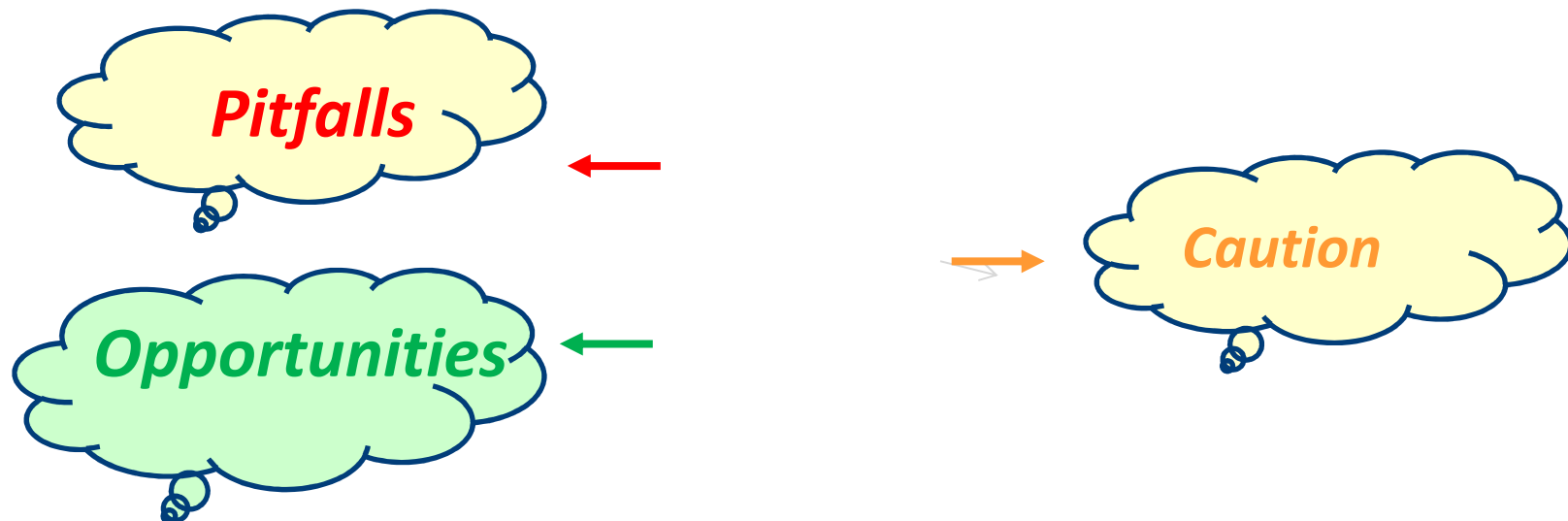


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Overview

- **Conceptualising complex interventions**
- **The Breastfeeding in Groups (BIG) trial**
- **The FEeding Support Team (FEST) feasibility and pilot trial**



How out of control can a RCT be?

- **Interventions as events in complex systems**

Hawe P, et al: *BMJ* 2004, 328:1561-1563

Hawe P, et al: *Am J Community Psychol.* 2009;43(3-4):267-76.

- **Realist causal explanation**

Pawson R, *Evidence-based policy*: Sage; 2006

- **A social model of RCTs - processes**

Oakley A, et al. (2006): *BMJ* 332(7538), 413–416

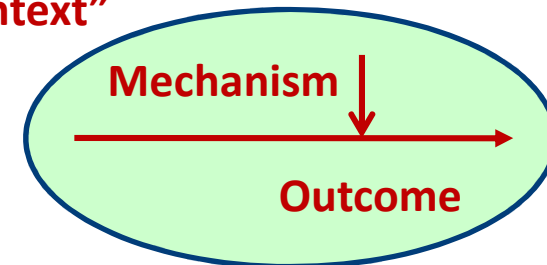
- **MRC guidance – iterative designs**

Craig P, et al. *BMJ* 2008, 337:a1655

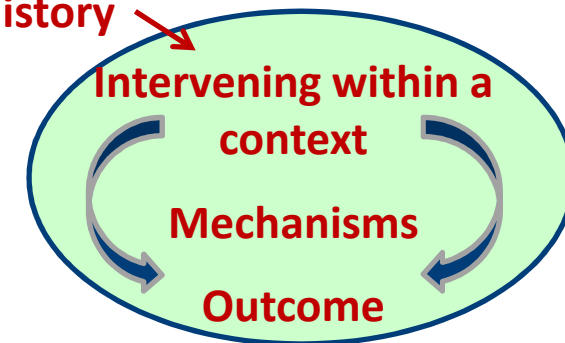
- **“Context” as integral to the intervention – not background**

Wells M, et al. (2012) *Trials* 2012, 13:95

“Context”



History



Conceptualising complex interventions

What does “intervention” mean to stakeholders?

- **Participants** – what happens to me
- **NHS staff** – what is going on that is different to usual and how does it affect me and my work
- **Researchers** – replicable, precisely defined, stable components

Context



Room 101

Fixed and dynamic components

Intervention categories

fix, attempt to standardise

Things

People – *number, training*

Setting – *local < international*

Actions – *doing or not doing, rituals*

Talk – *non-standardised < standardised*

Intervention situations

constantly changing

Systems

Organisations

Cultures

Ambience

Meanings: *personalities, associations*

Sensations: *visual, comfort, smell*

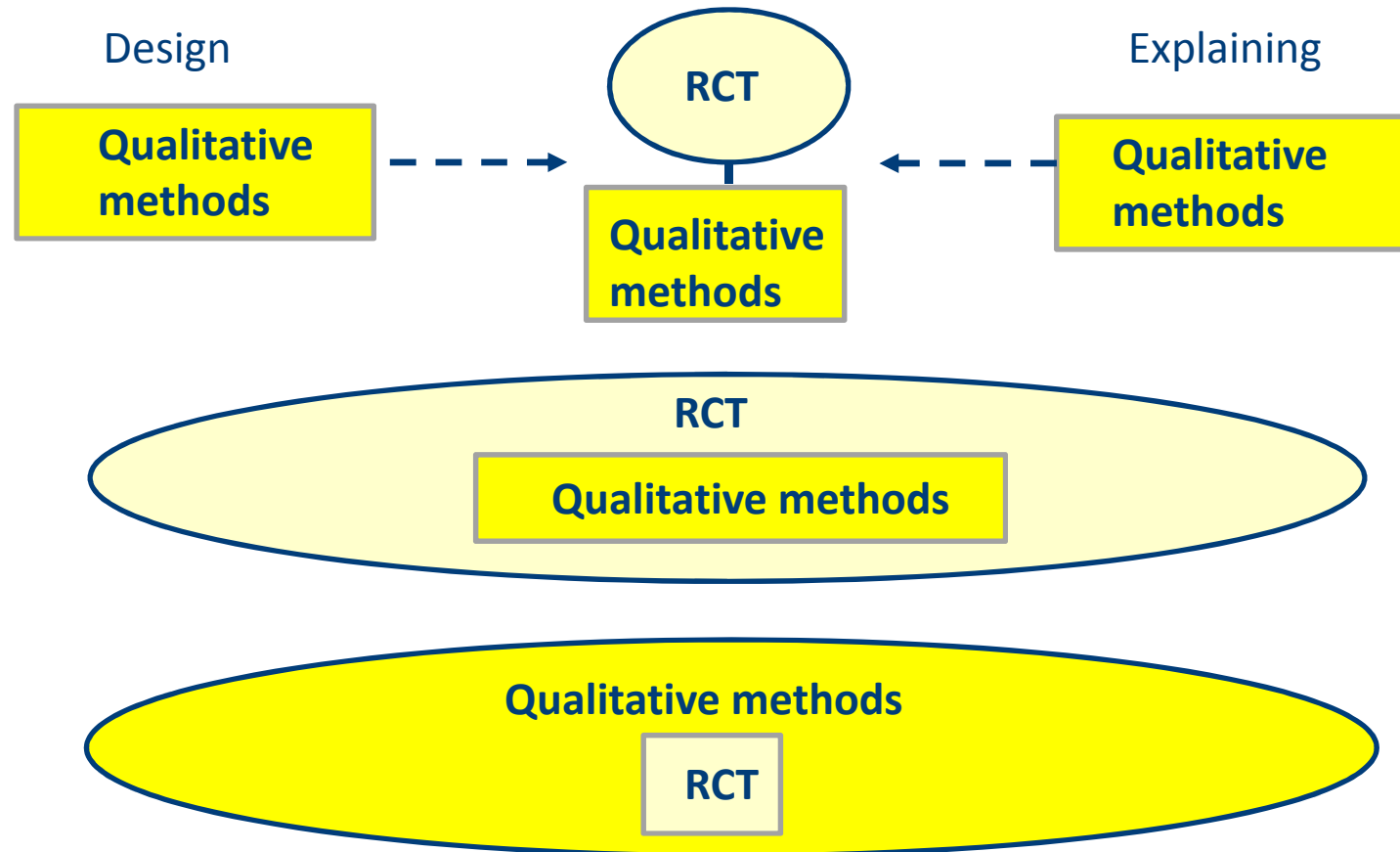
Complex intervention trials

Should we conceptualise as an “intervention” (noun) or “intervening” (verb)?

Depends.....

Integration and reflexivity

Intervening: everything that happens



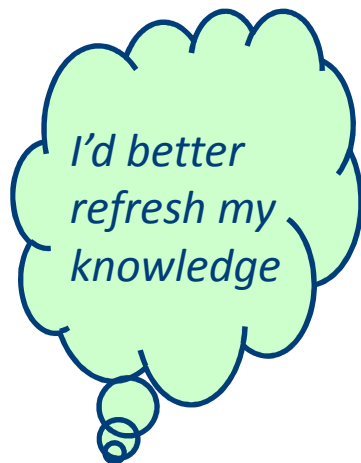
When does an intervention start?

- **Researchers** – first patient receives “the intervention”?
- **Participants** – request to participate?
- **NHS staff** – first hearing about the trial?

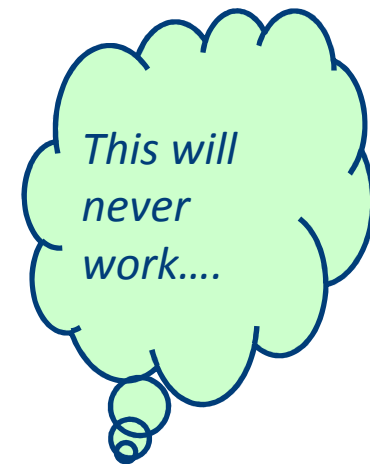
Resistance

Getting the house in order

Anticipation....



This is just what we need to get us working together

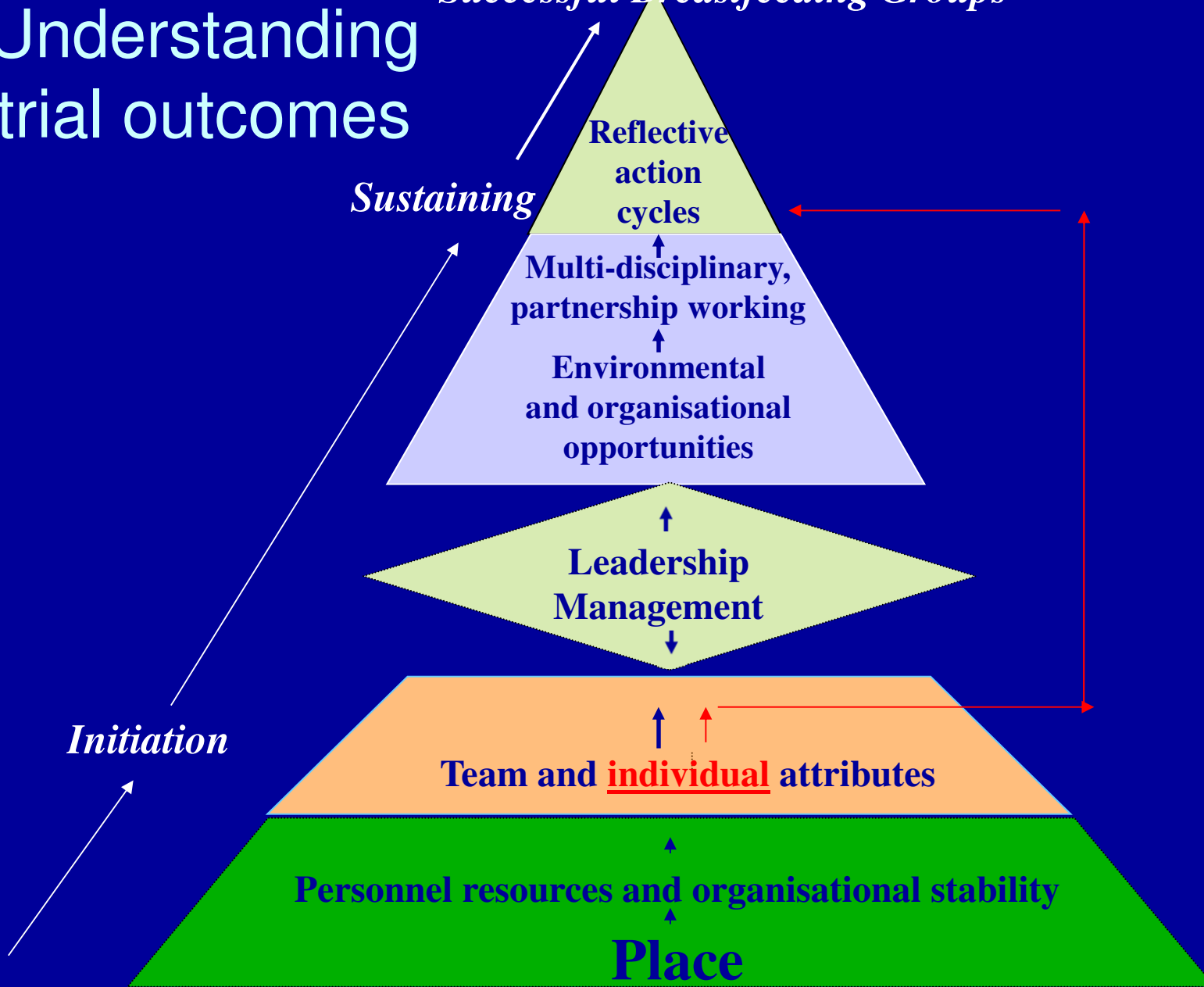


Recruitment : climbing mountains for the view at the top or pushing boulders uphill? Ethnographic approach to recruitment processes (after Donovan et al, ProtecT trial *BMJ* 2002;325:766–70)



Understanding trial outcomes

Successful Breastfeeding Groups



Prospective model explained outcomes

Why did breastfeeding rates increase in 3 sites, decrease in 3 sites and remain the same in 1 site?

Prospective mixed methods process evaluation

- Interviews with women (after exit)
- Intervention area focus groups with group facilitators (during trial)
- Interviews with managers (after trial end)

First sentence of manager interviews

- **Manager (Breastfeeding ↑):** *“For us I think it’s been really positive....raised the issue on the agenda as something that both midwives and health visitors need to do jointly”*
- **Manager (Breastfeeding ↓):** *“Sorry to start with negative stuff..... staffing shortages and caseloads which led to operational difficulties in terms of actually covering.....”*

**The Breastfeeding
in Groups (BIG)
trial: why did the
preliminary
intervention work
and not the trial?**

Intervention-context fit

Preliminary intervention	BIG trial
PI's own patch – understood intervention-context fit. Action research	Process evaluation - observed intervention-context fit
Community maternity unit groups – Midwives and Health Visitors in same building - partnership	Centralised maternity units – Midwives and Health Visitors strangers. Travel to groups.
Midwives – high engagement 6x more pregnant women attending 4x more women attending	Midwives did not engage, few pregnant women attended
Pregnant women shared experiences with breastfeeding mothers	Mothers first attendance – median 5 weeks after birth – too late!

RCT design – what to fix and how do you decide?

The FEeding Support Team (FEST)
randomised, controlled feasibility trial
of proactive and reactive telephone
support for breastfeeding women living
in disadvantaged areas

FEST Study Design

- Preliminary qualitative research
- Intervention vignettes
- What do women want?

Fixed and flexible intervention components – FEST

Fixed components:

Intervention: Proactive and reactive daily calls < day 14

Control: Reactive calls only

Fixed process components:

- Feeding team on ward: 1-8pm, 7 days/week
- Watch a complete breastfeed
- No additional staff training
- Woman-centred care
- Web randomisation after discharge

Flexible process components

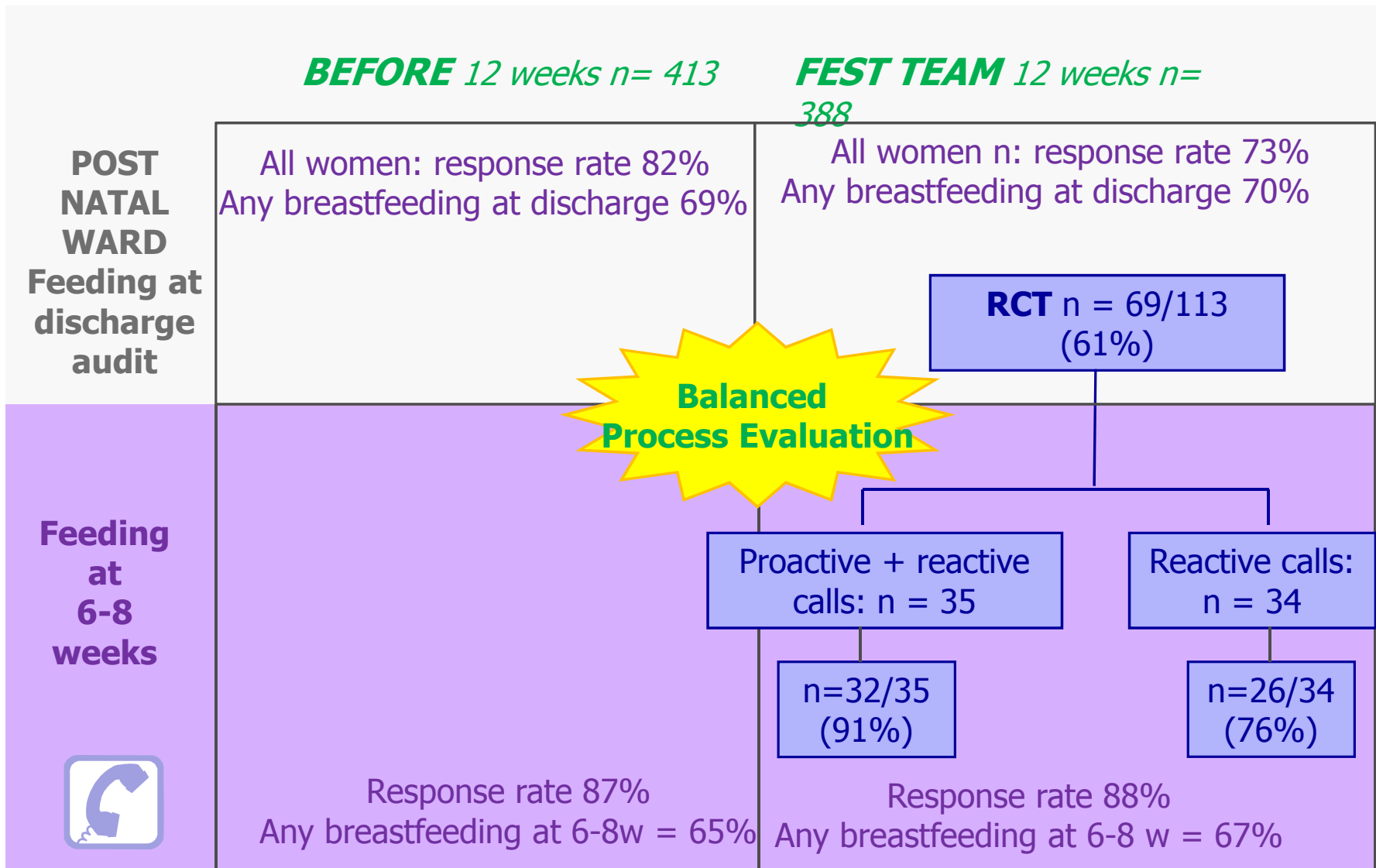
Multi-disciplinary steering group (observed and recorded): monthly to reflect and decide on:

- The feeding team roles and responsibilities:
- The content and delivery of FEST care
- How FEST integrated with existing services

The FEST team

- A band 7 midwife team leader
- Two band 4 staff

FEST study design



Fidelity, content, implementation, integration, unintended consequences

- **recorded steering group meetings** (n=9)
- postnatal ward **observations** 2 weeks before and 2 weeks after (medical student)
- **recorded telephone calls** made by the FEST team (n=16)
- interviews with **the FEST team, managers**, ward and community staff **after study** (n=17)
- FEST team case notes for randomised women (n=69)
- audit questionnaire (pre-randomisation) at hospital discharge
 - feeding outcomes
 - baseline characteristics (from computer)
 - was an entire breastfeed observed?

Participant perspectives

minimise interference – intervention and outcomes

- interviews with women **prior to randomisation and after exit**

Stage	Women interviewed in hospital (prior to randomisation)	Women interviewed after 6-8 week outcomes collected
Before intervention	13	3
After - not randomised	3	N/A
After - intervention arm	13	11
After - control arm	11	9

- an open question at the end of the structured 6-8 week breastfeeding outcome telephone interview (n=372)

Results

Some breast milk at 6-8 weeks: 22 intervention women compared to 12 control women (RR 1.49, 95% CI 0.92 to 2.40)

Effective processes:

- Proactive daily calls
- Continuity of woman centred care
- Dedicated unrushed team

Intervening: ways forward

- Integration: systematically collecting multiple perspectives
- Training, mutual respect and rigour
- Reflexivity – reporting what goes wrong and why
- Qualitative trialists?
- Ethnographic trials?
- There is no one holy grail....
- Checklists, guidelines.....
....the tail wagging the dog? (Barbour R, *BMJ* 2001;322:1115)

References

Preliminary before and after study for the BIG Trial

Effectiveness: Hoddinott P. et al, *Birth*. 2006;33(1):27-36

Women's perceptions: Hoddinott P. et al, *Birth*. 2006;33(2):139-146.

Understanding outcomes: Hoddinott P et al, *Family Practice*. 2007;24:84-91

The BIG Trial

Recruitment: Hoddinott P. et al, *Contemporary Clinical Trials*. 2007;28:232-241.

Effectiveness: Hoddinott P. et al, *BMJ* 2009;338:a3026.

Why do interventions work in some places and not others? Hoddinott P et al, *Social Science and Medicine*. 2010;70(5):769-778.

FEST Trial

Preliminary qualitative research: Hoddinott P. et al. NHS Health Scotland. 2010.
<http://www.healthscotland.com/documents/4720.aspx>

Outcomes: Hoddinott P. et al, *BMJ Open*. 2012.
<http://bmjopen.bmj.com/content/2/2/e000652.full>

Process evaluation: Hoddinott P. et al, *BMJ Open*. 2012.
<http://bmjopen.bmj.com/content/2/2/e001039.full>