What worked for us in which circumstances, and what didn't

reflections upon incorporating a realist evaluation within a clinical trial.

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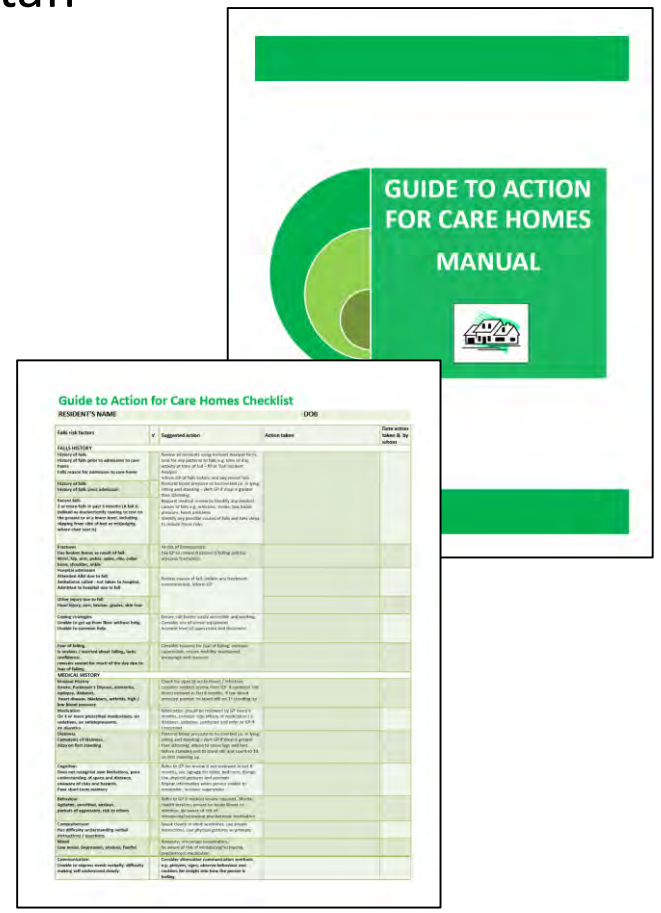
Overview

- The Good, the Bad and the Ugly of a nested realist, process evaluation …
    - The good (?) – what we learned and can support future implementation.
    - The bad (?) – methodological compromises made along the way.
    - The ugly (?) – moments of stress, anxiety, misunderstandings and poor communication.

The Falls in Care Homes (FinCH) Trial.

- The Guide to Action in Care Homes tool.
  - A falls management tool for the residents of care homes.
  - A complex intervention – tool, training, staff support.
  - Evidence based.

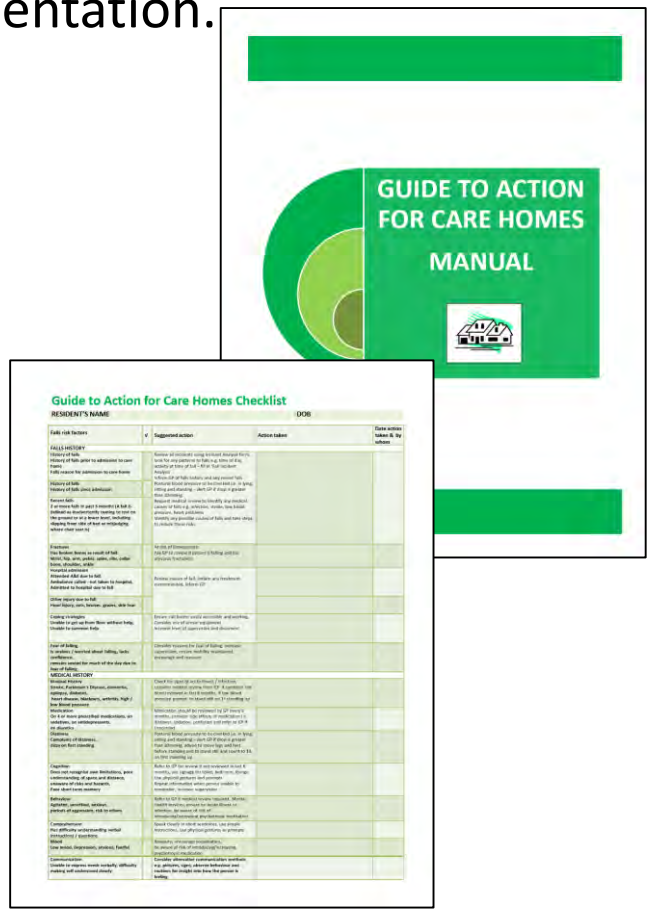


- Trial design.
  - Cluster RCT.
  - 87 care homes – nationwide sample.
  - 1698 residents recruited.
  - Primary Outcome - Rate of falls per participant.
    - Secondary outcomes – falls injuries, fractures, functional ability.
  - Nested process evaluation.

The Falls in Care Homes (FinCH) Trial.

- Process evaluation.
  - To review how GtACH was actually used in care homes.
  - To support recommendations for implementation.
    - More/less appropriate settings?
    - Further adaptations to support use?

- Process evaluation.
  - Realist evaluation design.
  - 6 care homes – all in receipt of GtACH.
    - 129 residents.
  - Data collected - observation of training, focus groups, interviews, observation of practice, review of internal documents.
    - 11 focus groups; 44 staff interviews.
  - Additional data - trial outcome data.



Realist evaluation.

- Key Characteristics - approach.
  - GtACH in itself does little to reduce fall rates.
    - GtACH is a resource that enables change to happen.
    - **Mechanisms** for change are actually 'unseen' – (individual) awareness, different attitude, more knowledge, etc. (collective) more resources, higher priority, more open, etc.
  - GtACH will not work in all places.
    - GtACH will impact differently in different **Contexts**, depending upon which mechanisms are triggered.
    - GtACH will be used in different contexts, used differently in different contexts (calling upon different mechanisms), with different **Outcomes**.
  - **Trials method = uniformity.**
  - **Realist method = variation.**

Realist evaluation.

- Key Characteristics - practice.
  - Programme theories & testing of programme theories.
    - Formal description of how GtACH 'should' work.
    - Testing of this 'theory' in specific contexts.
    - Iterative development of the programme theories.
  - Theoretical sampling & emergent issues.
    - Choosing evaluation settings to test specific things….
      - Size of home? Nursing or residential? Ownership of home?
    - Looking for different things as the evaluation progresses…
      - As our understanding improves we might ask different questions of subsequent settings.
      - Training? Fidelity? Adherence? Acceptability?
  - **CMO – CONTEXT + MECHANISM = OUTCOME**

What we found…

- Trial 'outcomes'…
  - At 6 months post-training falls rate where GtACH had been delivered were 40% lower than in control care homes.
  - But, difference was not maintained at 12 & 18 months.
  - Fewer fractures and other injuries in GtACH care homes.

- Process Evaluation insight:
  Different 'outcomes' in different settings. …
  - In two care homes - rate of falls decreased. ✓
  - In two care home – rate of falls remained stable. ✓

    [as population ages we might expect more falls?]
  - In one care home – rate of falls increased.
  - In one care home – rate of falls increased markedly. *x*

What we found…

- 81 CMO configurations recognised across the settings to help describe/understand these differences ...

  e.g. ….

  - (Independent setting + small staff team) + Insufficient resource = Partial adoption (training ✓ forms *x*)

  - (Corporate setting + external reward systems) + Lack of incentive = Limited change to practice

  - (Large Setting + knowledgeable staff) + Inertia = Persistence of prior practice.

What we found…

- Recurrent Patterns in the CMOs (demi-regularities)...

1. Where existing falls management systems are in place inertia means that GtACH is only partially adopted.

2. Where staff are already knowledgeable about falls there is limited motivation to change practice.

3. Where staff structures are inflexible the scope of GtACH adoption is limited.

4. Where organisational culture is fixed the scope of GtACH adoption is limited.

5. Where the implementation of GtACH is not actively supported by local management success is limited.

What we found…

- Lessons for future implementation …
  [through the lens of *Normalisation Process Theory*] …
  - GtACH needs to be clearly distinguished from other falls initiatives to support its adoption and maintenance. [COHERENCE]
  - The appropriateness of GtACH for all residents (inc. those with dementia) needs to be communicated to support adoption and maintenance. [COGNITIVE PARTICIPATION]
  - Whilst all stay may recognise the importance of reducing resident falls, not all will want to do paperwork. This needs to be negotiated in future implementation. [COLLECTIVE ACTION]
  - GtACH targets (use of tool, remedial actions taken & falls reduction) need to be built into care home routine monitoring to ensure long-term maintenance of use. [REFLEXIVE MONITORING]

Methodological challenges…

- Care Home research is challenging …
  - Care homes are complex places to collect data.
    - Access to staff inhibited by provision of normal care. (staff *persuaded* to take part; staff giving up breaks to take part)
    - Access to staff inhibited by incidents / exceptional circumstances. (homes closed to visitors; unwell residents).
    - Access to private space for data collection.
    - Staff/organisations less familiar with research processes.

  - Our Solution…
    - All researchers were experienced!!
    - All researchers had worked in care homes!

Methodological challenges…

- *Refining (Realist) Evaluation without influencing the rest of the trial?*
    - Realist Evaluation is emergent in where to look & what to look for.
    - RCT less fluid in focus –
      does interim insight interrupt this focus / affect how the trial is delivered?

- Our Solutions…
    - Realist Evaluation delivered by a separate team.
    - Interim findings not reported to Trial management group.
    - Realist Evaluation revised focus (substantive and geographic) not reported to TMG in detail.

Methodological challenges …

- *Finding the right home, at the right time, hoping it is randomised to intervention, hoping it has consented to process evaluation …*
    - Always looking for specific **Contexts** to test emergent ideas.
    - But, available settings (contexts) limited to those care homes recruited at that moment in time.

- Our Solution …
    - Sampling compromise – to fit within broader RCT recruitment processes.
        - Less precise – no falls history, no assessment of falls processes, etc. …
        - More generic criteria - Size, geography, type of care home (residential/nursing), ownership of care home (independent/corporate).

Methodological challenges …

- *Realist evaluation was a new way of working for most people involved in the process evaluation ...*
    - Really 'Realist interviews' or just process evaluation interviews and focus groups?
    - Is GtACH **context** or **mechanism** or neither?

- Our Solution …
    - Get the data, worry about 'realist' later… perhaps more 'realist in analysis' than in data collection processes.
    - [it's neither] our analysis looked to identify local **mechanisms** in the equation:

Context + GtACH + ? = Outcome

(mechanism)

Methodological Failings (?)…

- *Realist evaluation was a new way of working for most people involved in FinCH …*
    - Issue - Expectation for Protocols, Standard Operating Procedures, & Statistical Analysis Plans…
        - Resolution – analysis plan reviewed by a statistician with no knowledge of Realist methods.
        - Resolution – analysis plan that perhaps wasn't an accurate/adequate reflection of what we actually ended up doing.
    - Issue – Unrealistic timescales.
        - Practical delays in completion of individual evaluations.
        - Difficulties consenting homes prior to completion of GtACH training.
        - Difficulties accessing outcome data in appropriate timescale.

Methodological Failings (?)…

- *Access to Outcome data …*
    - Issue – Evaluation timings not well aligned with trial processes.
      (PE months 0-6) (primary outcome at month 6 - but reviewed later)
        - Resolution - Softer outcomes incorporated into CMOs - *Fidelity*, *acceptability* and observational notes on *GtACH use*.
        - Softer outcomes used in evaluation processes – refining focus and sampling.
    - Issue – Hospital Episode Statistics not gathered until the end of the study.
        - Resolution – as above.

Methodological Failings (?)…

- *Process evaluation blind to Hard Outcomes …*
    - Issue – All assessment based upon softer / subjective assessment of GtACH and its use.
        - Resolution – Evaluation recognised many of the problems with GtACH without realising the (short-term) benefit it was generating.
        - Resolution – [in hindsight] has helped us to understand the different components of GtACH…

          no one liked the paperwork, yet training / peer support still made a difference….

Reflections on Method …

- Has the evaluation worked - No?
  - Outcome data has challenged completeness of CMOs
  - Failure to iteratively sample care home settings has challenged the realist process.
  - More context than mechanism?

- Has the evaluation worked? Yes?
  - Systematic and rigorous approach to the evaluation.
  - Identified some of those mechanisms which have impacted upon GtACH implementation.
  - Identified some of those contextual features which are pertinent in this.

Reflections on Method …

- A new way of working for most involved …
  - Naïve assumptions – *it will just work.*
  - More explicit and detailed discussion at the protocol stage would have helped – esp. outcome data and sampling processes.
- Realist principles and RCT principles do not always sit well together.
  - But, methodological compromise can make it work…
    [Better to generate meaningful data than to be methodologically pure]
- [Despite compromises] realist methods still offer important insight.Context helps us to understand that not all settings are the same.
  - Reasoning and responses to GtACH helps us to consider HOW it works.

Comments / Questions …