Implementing Methods Research

Presented, on behalf of the TMRP Working Groups, by:
Katie Gillies and Taylor Coffey (University of Aberdeen)

04 May 2023

The slides are available below.
For any queries, please contact uktmn@nottingham.ac.uk

https://youtu.be/vntw-Bv3zsc
Implementing findings from trial methods research: what needs to change?

Taylor Coffey, Katie Gillies, & Paula Williamson, on behalf of the TMRP Working Groups
Introduction

• Advances in trials methods research aim to improve the ‘doing’ of trials.

• Significant variability in whether/how findings influence ‘practice’ in trials.

• Critical to identify challenges to implementing findings

Improving trials → Improves evidence → Improves health
Aim

• To generate evidence on what obstacles and facilitators trialists experience when implementing trials methods research findings

• Specific objectives
  • leverage existing professional networks to scope completed trials methods research
  • determine the obstacles/facilitators to implementation of trial methods research
  • Identify potential solutions and areas for future research
Study description

1. Mapping
2. Survey
3. Interviews
Our approach

- Implementation science + behavioural theory
  - rigorous method of investigating the individual/organisational factors

- Why use a behavioural approach?

Diagram:
- Behavioural specification: defining the problem
- Behavioural investigation: diagnosing the problem
- Behavioural solutions: treating the problem
Frameworks

Consolidated Framework for Implementation Research (CFIR)
- Structural characteristics
- Culture
  - Inner domains
    - Implementation climate
    - Networks and communications

Capability, Opportunity, and Motivation Behaviour Model (COM-B)
- Capability
- Motivation
- Opportunity
- Behaviour
Mapping phase

1. Design

Open Access

**BMJ Open**

Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies

Kerry N L Avery, Paula R Williamson, Carrol Gamble, Elaine O’Connell Francischetto, Chris Metcalfe, Peter Davidson, Hywel Williams, Jane M Blazebry, members of the Internal Pilot Trials Workshop supported by the Hubs for Trials Methodology Research

2. Conduct

Clinical Trials

A proposed charter for clinical trial data monitoring committees: helping them to do their job well

DAMOCLES Study Group

3. Analysis

**JAMA | Special Communication**

Guidelines for the Content of Statistical Analysis Plans in Clinical Trials

Carrol Gamble, Ashna Krishan, BSc; Deborah Stocken, PhD; Steff Lewis, PhD; Edmund Juszczak, MSc; Caroline Dove, BSc; Paula R. Williamson, PhD; Douglas G. Altman, DSc; Alan Montgomery, PhD; Pia Lim, PhD; Jesse Berlin, ScD; Stephen Senn, PhD; Simon Day, PhD; Volantia Barbachino, PhD; Elizabeth Loder, MD, MPH

4. Reporting

**BMJ Open**

Dissemination of trial results to participants in phase III pragmatic clinical trials: an audit of trial investigators intentions

M Zulfiqar Raza, Hanne Bruhn, Katie Gillies
Survey - Methods

- Questions based on the Inner domains of the CFIR adapted to trial context
Survey - Findings (n=27)

Age of CTU
- < 5 yrs: 4%
- 5-10 yrs: 11%
- 10-20 yrs: 55%
- 20+ yrs: 30%

Staff Numbers
- Less than 50: 37%
- 50 - 99: 26%
- 100+: 37%
<table>
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<tr>
<th>Site</th>
<th>Stability</th>
<th>Communication Effective</th>
<th>Important to Implement</th>
<th>Findings are relevant</th>
<th>We clearly communicate the goals of implementing the findings</th>
<th>We solicit and incorporate feedback</th>
<th>We ask other members for help</th>
<th>Senior members are integral partners in implementing the findings</th>
<th>Staff feel they are involved in the process</th>
<th>The CTU has the appropriate amount of:</th>
<th>Senior members of the CTU are actively involved</th>
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Implementation rates of case studies

1. Design - Progression criteria
   - Yes: 10
   - Partially: 8
   - No: 9

2. Conduct - DAMOCLES
   - Yes: 5
   - Partially: 1
   - No: 21

3. Analysis - Statistical analysis plans
   - Yes: 5
   - Partially: 1
   - No: 21

4. Reporting - RECAP
   - Yes: 2
   - Partially: 5
   - No: 20
## Facilitators/obstacles to implementing case studies

<table>
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<tr>
<th>Total sites (N=27)</th>
<th>Progression criteria</th>
<th>DAMOCLES</th>
<th>Statistical analysis plans</th>
<th>RECAP</th>
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<tr>
<td><strong>Facilitators</strong></td>
<td>Funder expectations (n=8)</td>
<td>Clear guidance with useful templates (n=8)</td>
<td>Standardisation (n=9)</td>
<td>Best practice* (n=5)</td>
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<tr>
<td><strong>Obstacles</strong></td>
<td>No expertise/not typically involved in area (n=8)</td>
<td>Time/resource limitations (n=2)</td>
<td>Other SOP already in use (n=5)</td>
<td>Lack of awareness (n=13)</td>
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*=potential facilitator as study has not been implemented widely*
Interviews - Methods

- Interview guide developed using the COM-B
- Senior trial staff (e.g., directors, head statisticians, etc) interviewed
- Transcripts coded into behavioural sub-domains of the COM-B

Adapted from Michie et al. 2014
Most participants (n=11) have worked in trials 20-29 years

Half have been in their current role less than 5 years
Interview - Findings

Research Findings
- Perceived value of implementation
- Relevance and feasibility of findings

Internal
- Interpersonal communication
- Existing work commitments
- Cultural drivers of implementation

External
- The influence of funders
- The visibility of findings
Perceived value of implementation

- Implementing findings improves our practices (+)
- Implementation of findings leads to improvements in the trials (+)
- We had established good practices and findings help to reassure those practices (̅)
- Implementation research is important (+)
- Implementation signals that the CTU is innovative and adhering to best practices (+)

Relevance and feasibility of findings

- You should be able to adapt findings to your CTU (-)
- We have to prioritise what’s relevant to the trials our CTU delivers (-)
- The resources that findings are packaged with help make them more implementable (+)
“Talking about the SAPs one, it was. Well, we made it a priority because, again, we sort of believed in that piece of work. We thought that was something we ought to try and implement as quickly as we could. I’d say where we become aware of a piece of trial’s methodology research is clearly important because it’s got wide influence, you know, across CTUs and across... it’s applicable to all or most of the trials that we do so we’d try and prioritise.” - Site 10
Internal level themes & beliefs

Interpersonal communication
- We, as a unit, are open to new ideas (+)
- We try to have open communication at our CTU (+)
- Encountering resistance to change can be frustrating and draining (-)
- We have internal training/meetings that support implementation (+)
- We, as a unit, are open to new ideas (+)

You have to communicate the importance of implementation efforts convincingly (-)

Existing work commitments
- The design of new trials and delivery of ongoing trials takes priority (-)
- Implementing findings requires effort from CTU staff (-)
- We lack the resources to implement findings (-)

Cultural drivers of implementation
- You need to set out expectations around implementation and offer support for it to happen
- Having someone within the unit to keep on top of and champion implementation findings is key (+)
- The CTU would like to improve its uptake/generation of findings (~)
- Career development opportunities could aid implementation efforts (~)
- Our CTU has the expertise to generate/implement findings (+)
- I am trying to create a culture at my CTU that encourages and supports research (+)
Internal level findings - Theme 1

**Interpersonal communication**

- Certain CIs can be difficult to convince to implement findings (~)
- You have to communicate the importance of implementation efforts convincingly (-)
- We try to have open communication at our CTU (+)
- We have internal training/meetings that support implementation (+)
- Encountering resistance to change can be frustrating and draining (-)
- We, as a unit, are open to new ideas (+)
“I’m a very persistent person. I think... if I think something is right, I tend to just keep it in my mind and keep going and not give up when there’s a barrier. [..........]

Also good communication skills,[..........], **being able to communicate things in simple words and trying to get the perspectives that are involved are very different when you’re trying to put a case in favour of a particular improvement.** I think that’s really, really useful because if you cannot communicate, or engage with everyone, it’s very difficult to get people onboard with that particular improvement..” – Site 21
Internal level findings - Theme 2

- The design of new trials and delivery of ongoing trials takes priority (-)

- Implementing findings requires effort from CTU staff (-)

- We lack the resources to implement findings (-)

Existing work commitments
“So, our focus is on doing the trials, but of course we should always be trying to have an eye on what is the evidence that it’s underpinning what we do in those trials. We should. But with the best will in the world, it’s writing applications, responding to board comments, getting contracts done once things are funded, getting trials underway. **The focus is just constantly on that work of trying to win funding and delivering on what you said you were going to deliver**, in amongst all the other business of running a CTU or recruiting staff, managing funding contracts, dealing with our institutions, our universities, our local trusts. All the efforts that go into getting trials underway in terms of writing documents and approvals and recruiting sites, you know?” – Site 10
You need to set out expectations around implementation and offer support for it to happen (+)

Having someone within the unit to keep on top of and champion implementation findings is key (+)

I am trying to create a culture at my CTU that encourages and supports research (+)

Our CTU has the expertise to generate/implement findings (+)

The CTU would like to improve its uptake/generation of findings (~)

Career development opportunities could aid implementation efforts (~)

Cultural drivers of implementation
“I hope that within the Trials Unit, I also create an environment where I’m trying to encourage people to not always work to capacity, so they do have the headroom to go away and explore things and to try things and to develop their own research ideas, so that we can say to people okay. Whether it’s looking at different patient information sheets, whether it’s looking at different recruitment strategies, whether it’s looking at different ways of doing data cleaning across sites, looking at different ways of delivering training to people for data entry because we’ve lots of different ways of delivering training and we still get a very high error rate. I’m sure there are other Trials Units that are doing the same thing, so we should be publishing and sharing that with Trials Units. I’m trying to create that environment.” – Site 1
External level themes & beliefs

**Influence of funders**

- Funders drive what we prioritise through shifts in research culture (~)
- Implementation efforts improve relations with funders and opportunities for funding (+)
- Funders drive what we prioritise through funding (~)

**Visibility of findings**

- Dedicated channels for dissemination, like network events and conferences, are helpful (+)
- Involvement in trials methods projects support implementation (+)
- It’s difficult to know what research is out there (-)
- Conferences and network events are a great opportunity to share implementation research and experience (+)
“Very often, a Trials Unit cost is seen as a big part of the trial budget that goes in, so having to justify it and demonstrate it, so anything that we can do to say the activity that the Trials Unit is giving you will increase your chance of meeting your recruitment target, keeping patients in the trial, getting good clean data when you need it, and being able to do the analysis, that will protect the reputation of the Chief Investigator and also the Trials Unit. They’re more likely to come back to you, the funder will come back to you, we will be on their publications.” - Site 1

“I mean probably the greatest competing demand is being up to speed on what's coming out that's new. That's probably where I would feel that... yes, trying to... I know everyone feels like they don’t have enough time to just read and be aware of the stuff coming out, so that’s... I'm more anxious, and I know others are, that there’s stuff being done that we don’t even know about to try and implement, so in some ways we might almost be repeating the wheel of trying to improve best practice in a topic area, and actually someone’s done loads of work on it.” - Site 3
Conclusions

• CTU staff face persistent challenges in implementing trials methods research findings

• Resource issues were reported as the most pervasive
  • Time:
    • To find
    • To implement
  • Funding:
    • Does not prioritise implementation
    • Does not allow staff protected time away from delivering trials
Questions to the group

- These questions will appear in the Teams chat function as a poll
  - Y/N responses are submitted in the Poll
  - Further comments can be entered in the chat

Q1. Do these findings make sense?
   Y/N
   What doesn’t make sense?

Q2. Do you think these findings are important?
   Y/N
   How could they be made more relevant?

Q3. Do you feel there’s something important that’s not reflected in our findings?
Future directions

• Potential strategies based on selected intervention functions of the Behaviour Change Wheel

• Linked to the behavioural domains of the COM-B

• Enhance facilitators, reduce obstacles
Potential strategies

1. Conference sessions on new trials methods research findings - at both clinical and methods conferences
2. Establish/modify internal meetings to focus on implementation
3. Establish role/group of implementation champions
4. Reward staff for successful integration/adherence to changes in practice
5. Produce recommendations on how to best package findings to make them easier to implement
6. Funders host findings on website, provide resources/training on implementation into methods practice
7. Petition funders to provide dedicated funding to CTUs for implementation efforts
8. Review of current dissemination channels and their level of engagement

• **Enhance facilitators**

• **Reduce obstacles**
Thank you

- Taylor Coffey (taylor.coffey1@abdn.ac.uk)
- Katie Gillies (k.gillies@abdn.ac.uk)
- Paula Williamson (prw@liverpool.ac.uk)

TRIP project page

https://tinyurl.com/HSRU-TRIP

