MRC-NIHR Trials Methodology Research Partnership: Webinar recording

Implementing Methods Research

Presented, on behalf of the TMRP Working Groups, by:
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04 May 2023

The slides are available below.

For any queries, please contact uktmn@nottingham.ac.uk

https://youtu.be/vntw-Bv3zsc

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
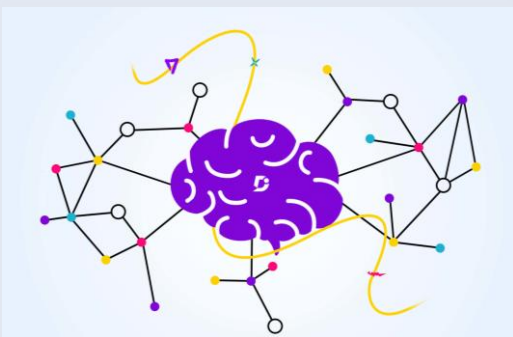
2. Survey

3. Interviews

Our approach

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

- ## Why use a behavioural approach?

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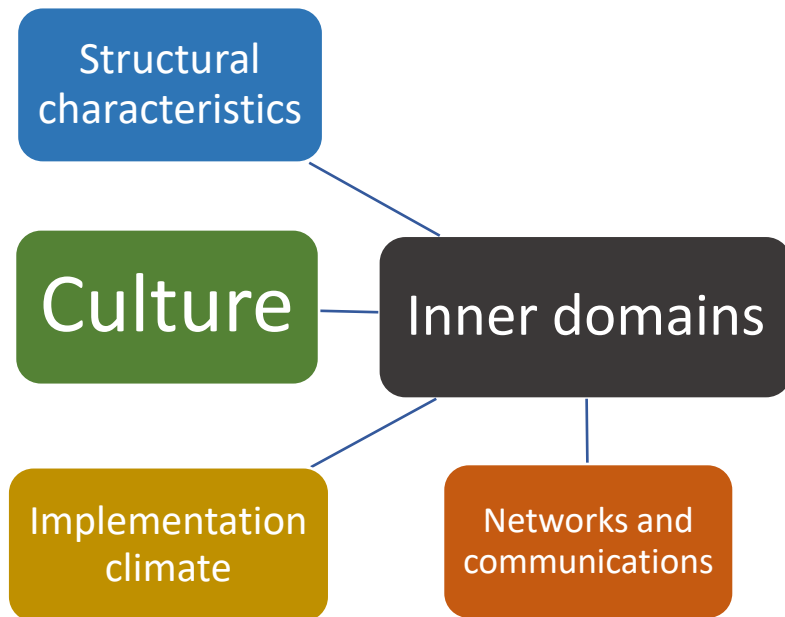
Capability, Opportunity, and Motivation Behaviour Model (COM-B)

Capability

Motivation

Opportunity

Behaviour
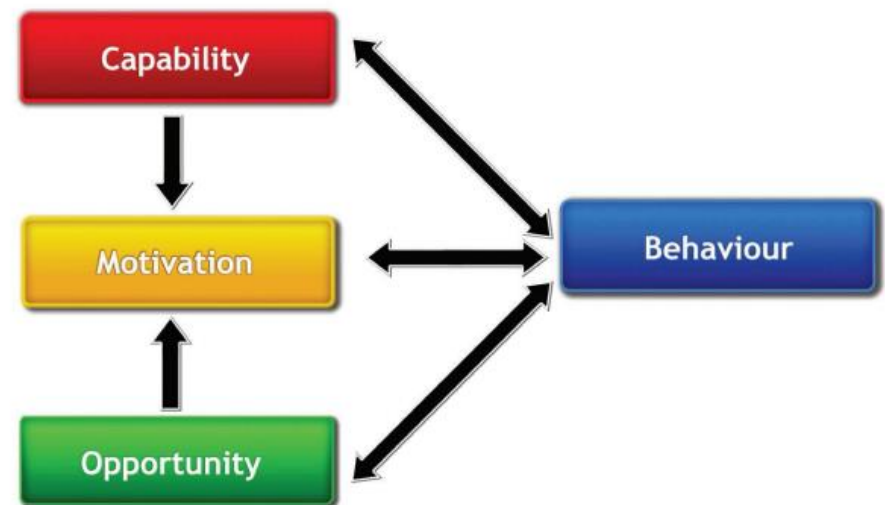
Mapping phase

1. Design

Open Access   **Research**

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

Kerry N L Avery,[1] Paula R Williamson,[2] Carrol Gamble,[2] Elaine O'Connell Francischetto,[1] Chris Metcalfe,[1] Peter Davidson,[3] Hywel Williams,[4] Jane M Blazeby,[1,5] 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, PhD; Ashma Krishan, BSc; Deborah Stocken, PhD; Steff Lewis, PhD; Edmund Juszczak, MSc; Caroline Doré, BSc; Paula R. Williamson, PhD; Douglas G. Altman, DSc; Alan Montgomery, PhD; Pilar Lim, PhD; Jesse Berlin, ScD; Stephen Senn, PhD; Simon Day, PhD; Yolanda Barbachano, 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

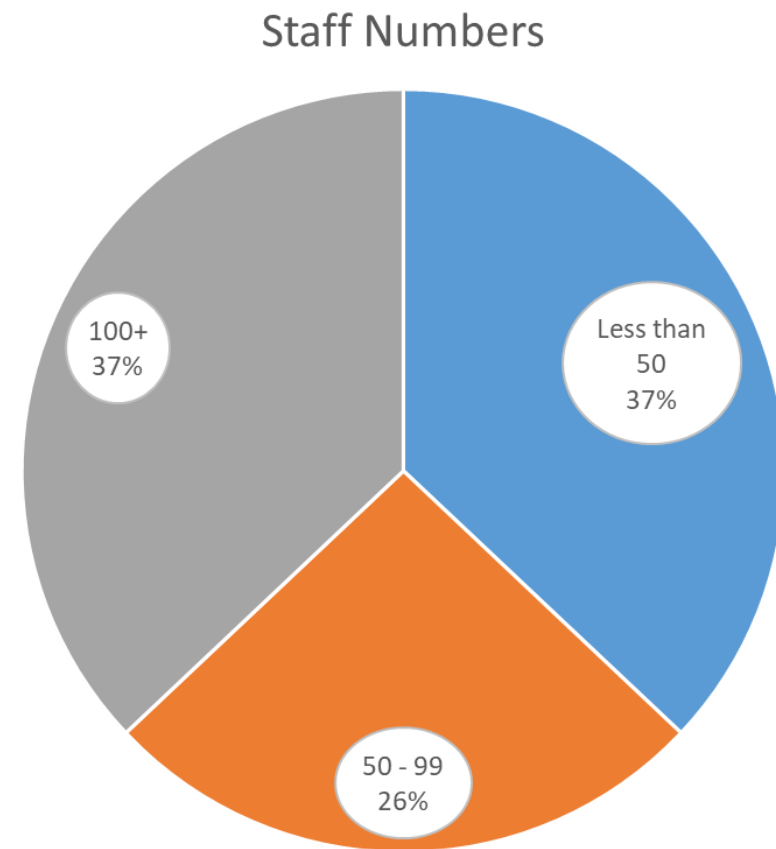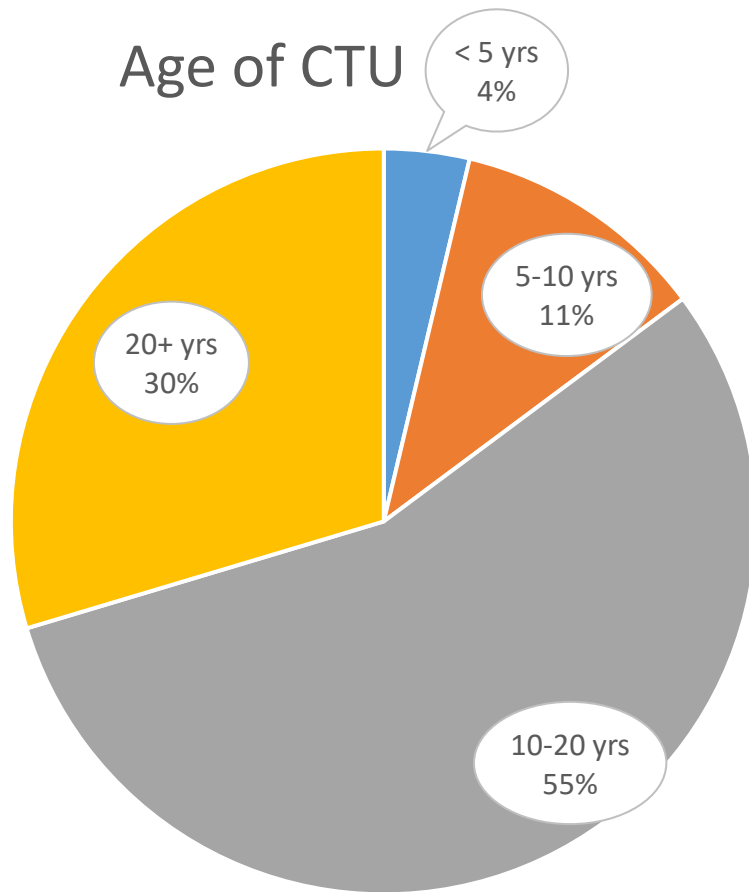- Questions based on the Inner domains of the CFIR adapted to trial context

Survey – Findings (n=27)

Site	Stability	Effective communication	Findings are relevant, it is important to implement	We clearly communicate the goals of implementing the findings	We solicit and incorporate feedback	Senior members ask other members for help	Staff feel they are integral partners in implementing the findings	The CTU has the appropriate amount of: Money	Training/ education	Time	Senior members of the CTU are actively involved	General implementation score (SD)
1	4	8	9	5	5	8	8	3	8	3	6	6.09 (2.21)
2	8	8	9	7	6	7	7	5	7	5	6	6.82 (1.25)
3	6	6	9	7	6	8	6	3	5	4	8	6.18 (1.78)
4	6	8	7	6	5	6	5	5	7	4	5	5.82 (1.17)
5	9	8	7	7	4	7	7	6	4	2	7	6.18 (2.04)
6	5	7	9	6	4	4	6	3	4	1	6	5.00 (2.14)
7	4	6	9	5	2	6	4	4	1	1	6	4.36 (2.42)
8	6	8	9	7	7	7	4	2	7	1	9	6.09 (2.66)
9	7	7	8	6	5	6	6	6	6	6	7	6.36 (0.81)
10	7	7	8	5	4	6	6	7	6	5	6	6.09 (1.14)
11	7	6	9	7	7	7	5	2	4	3	7	5.82 (2.09)
12	7	8	8	7	8	8	7	3	4	4	7	6.45 (1.86)
13	5	6	9	7	5	8	8	5	2	1	0	5.09 (2.98)
14	7	8	9	7	7	7	8	9	9	8	8	7.91 (0.83)
15	7	7	9	7	5	8	5	5	5	4	7	6.27 (1.56)
16	7	7	9	7	6	9	6	1	1	1	7	5.55 (3.08)
17	7	8	9	7	7	8	7	4	7	4	8	6.91 (1.58)
18	6	8	9	9	9	9	9	1	3	1	9	6.64 (3.35)
19	3	4	4	6	3	3	6	4	3	3	7	4.18 (1.47)
20	8	8	8	5	5	8	8	5	7	1	9	6.55 (2.34)
21	3	5	5	7	7	8	7	3	5	2	8	5.45 (2.11)
22	3	8	8	5	6	8	4	6	5	4	8	5.91 (1.87)
23	8	6	6	7	7	7	7	6	6	3	8	6.45 (1.37)
24	5	7	9	9	7	8	7	7	3	2	7	6.45 (2.25)
25	6	7	9	6	5	7	5	3	3	3	7	5.55 (1.97)
26	6	6	9	5	5	5	5	7	9	7	5	6.27 (1.56)
27	6	7	8	6	4	7	6	5	5	2	7	5.73 (1.68)
Mean	6.04	7.00	8.19	6.48	5.59	7.04	6.26	4.44	5.04	3.15	6.85	N/A

Implementation rates of case studies
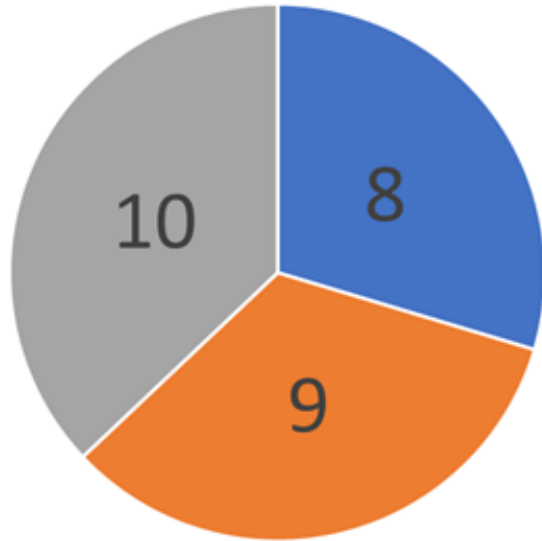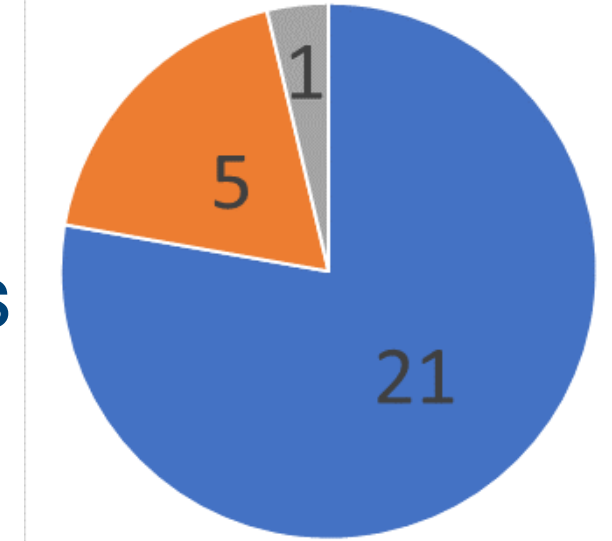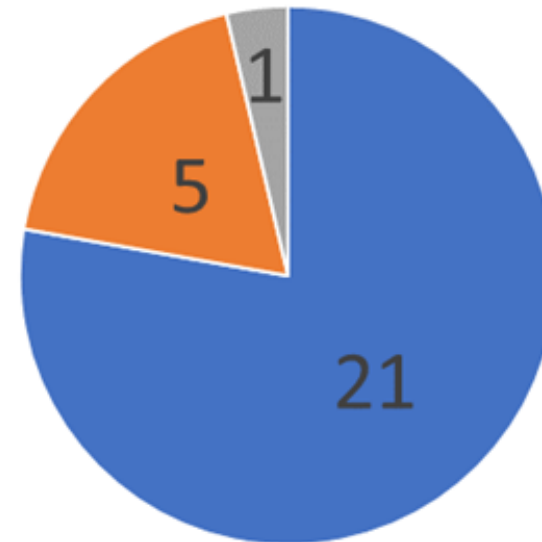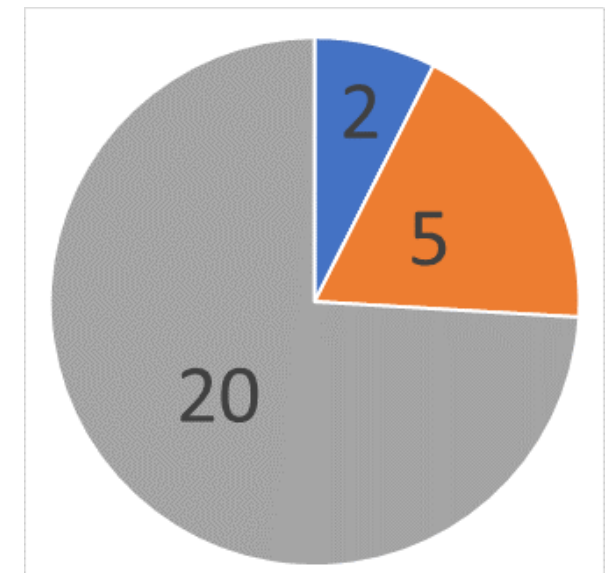
Facilitators/obstacles to implementing case studies

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Total sites (N=27)	Progression criteria	DAMOCLES	Statistical analysis plans	RECAP
Facilitators	Funder expectations (n=8)	Clear guidance with useful templates (n=8)	Standardisation (n=9)	Best practice* (n=5)
Obstacles	No expertise/not typically involved in area (n=8)	Time/resource limitations (n=2)	Other SOP already in use (n=5)	Lack of awareness (n=13)

*=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
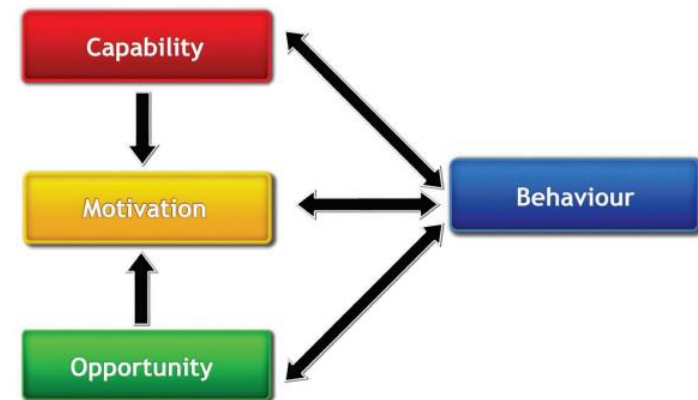
Interview – Participants

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Pie chart:
- CTU Director/co-director, 7
- Academic (e.g., methodologist, professor), 4
- Head/lead of group (e.g., trial management or stats lead), 5
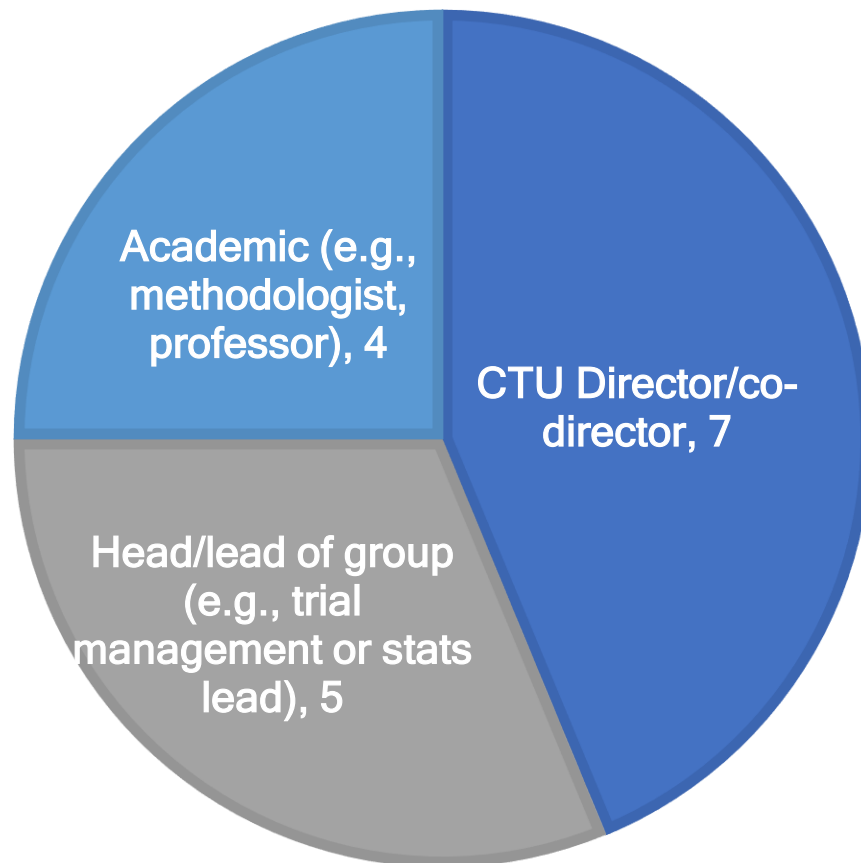
- **Most participants (n=11) have worked in trials 20-29 years**

- **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

Findings level themes & beliefs

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Perceived value of implementation

Implementing findings improves our practices (+)

Implementation of findings leads to improvements in the trials (+)

Implementation research is important (+)

Implementation signals that the CTU is innovative and adhering to best practices (+)

We had established good practices and findings help to reassure those 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 (+)

Sample quote

"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

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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 (-)
- You have to communicate the importance of implementation efforts convincingly (-)
- We have internal training/meetings that support implementation (+)
- We, as a unit, are open to new ideas (+)

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

Sample quote

"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,[,...........], <u>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</u>. 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 (-)

Existing work commitments

We lack the resources to implement findings (-)

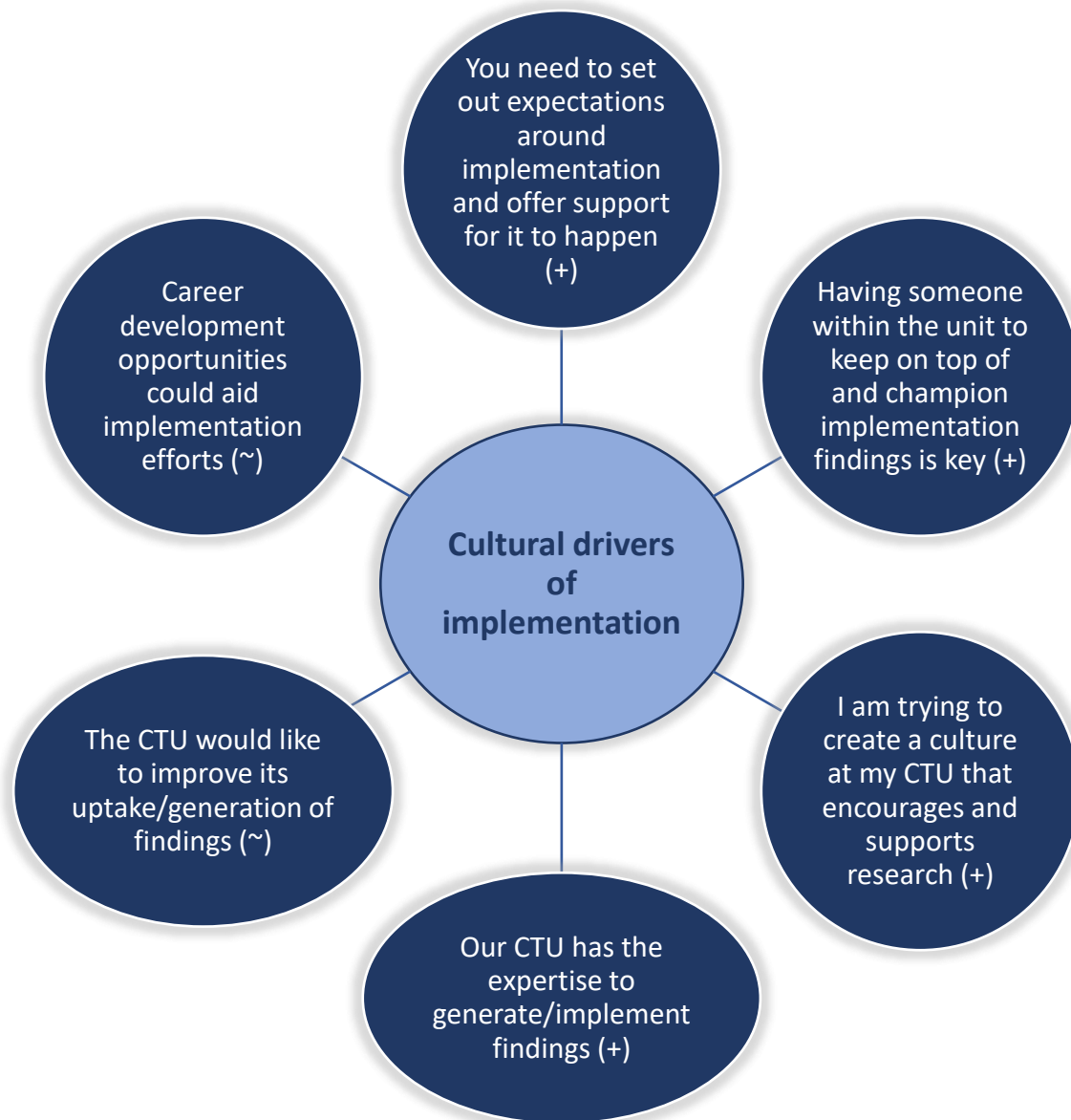Implementing findings requires effort from CTU staff (-)
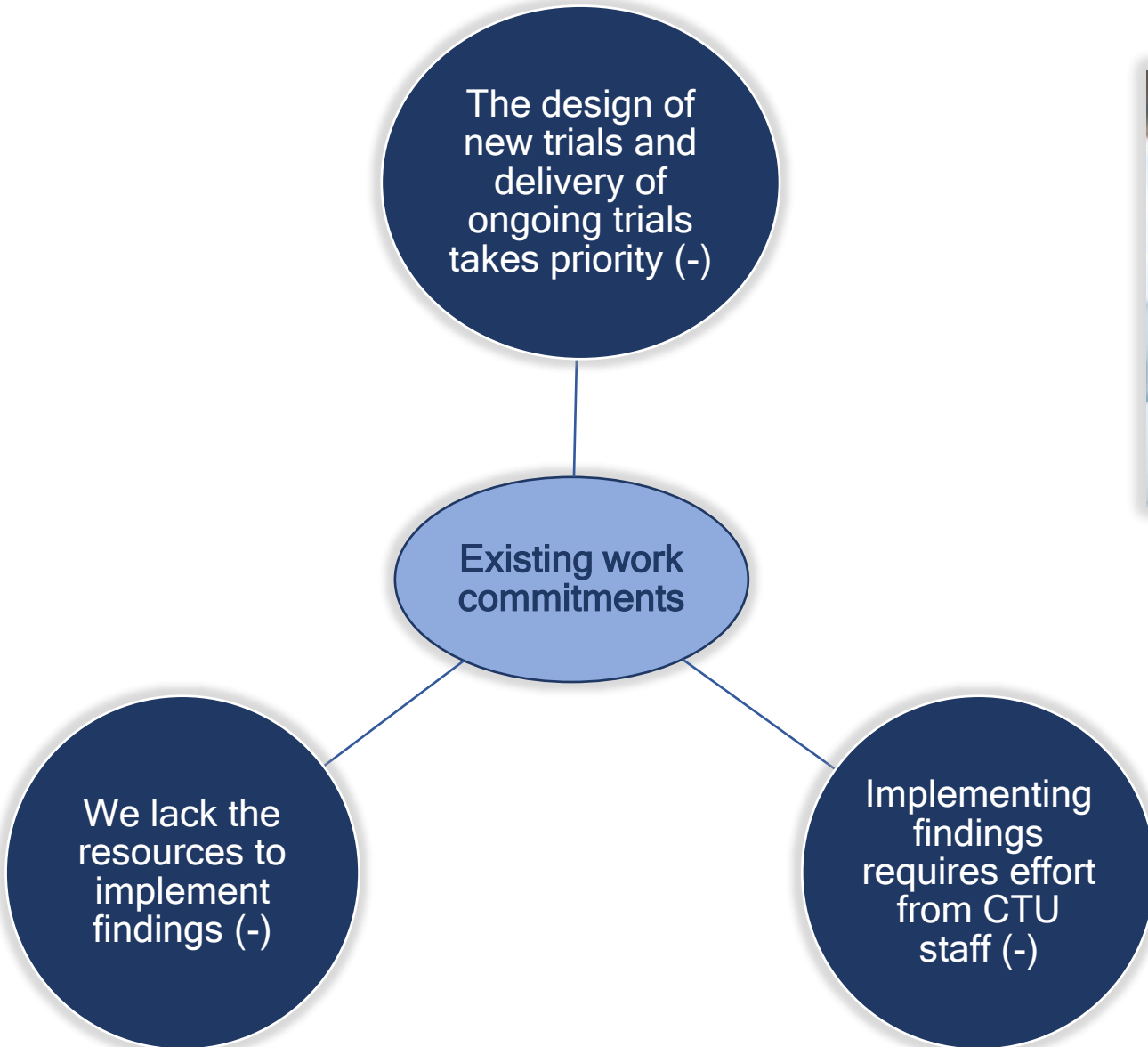
Sample quote

"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

Internal level findings – Theme 3

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 (+)
- Career development opportunities could aid implementation efforts (~)
- I am trying to create a culture at my CTU that encourages and supports research (+)
- The CTU would like to improve its uptake/generation of findings (~)
- Our CTU has the expertise to generate/implement findings (+)

Sample quote

> "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 (+)

Sample quote

"Very often, a Trials Unit cost is seen as a big part of the trial budget that goes in, <u>so having to justify it and demonstrate it</u>, 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, <u>the funder will come back to you</u>, we will be on their publications." - Site 1

"I mean probably the greatest competing demand <u>is being up to speed on what's coming out</u> that's new. That's probably where I would feel that... yes, trying to... I know everyone feels like <u>they don't have enough time to just read and be aware of the stuff coming out</u>, 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

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- **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

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✓ Enhance facilitators

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

✗ Reduce obstacles

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

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

www.abdn.ac.uk/hsru

Follow us on @hsru_aberdeen

References

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- Grimshaw JM, Shirran L, Thomas R, Mowatt G, Fraser C, Bero L: Changing provider behavior: an overview of systematic reviews of interventions. Medical care. 2001, 39 (8 Suppl 2): II2-45

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