

The new kid on the block:

Design & conduct of 'hybrid' effectiveness-implementation trials to advance population health and healthcare delivery

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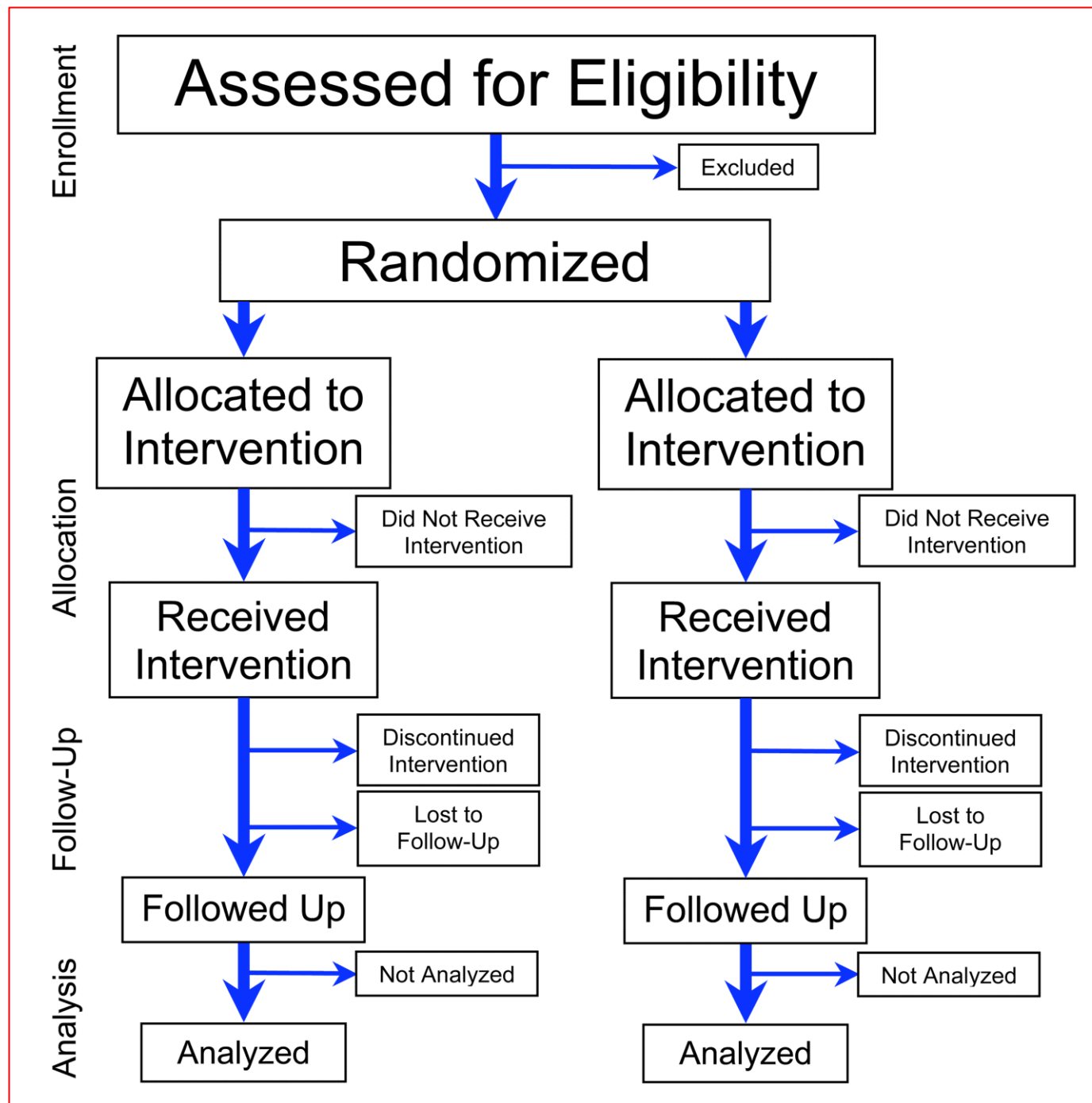
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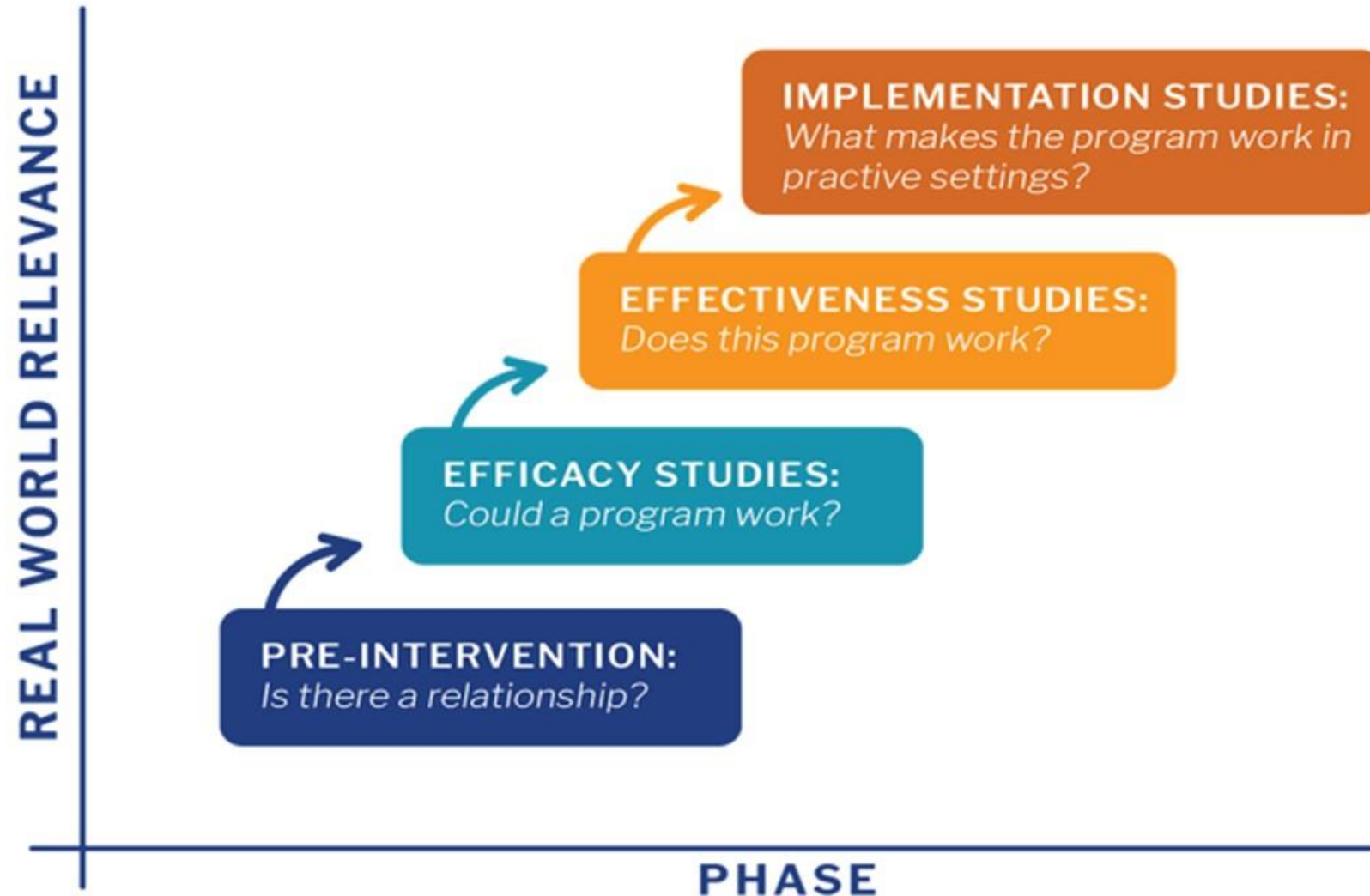


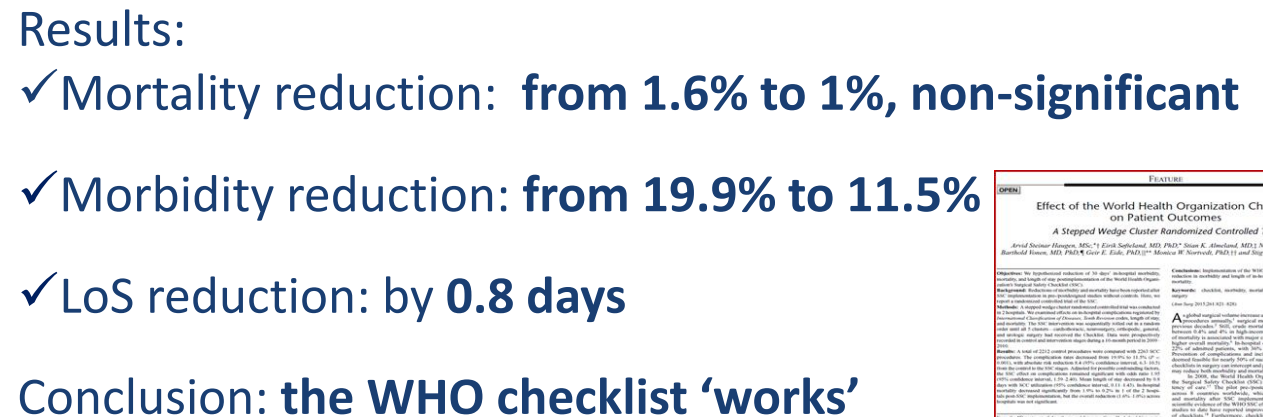
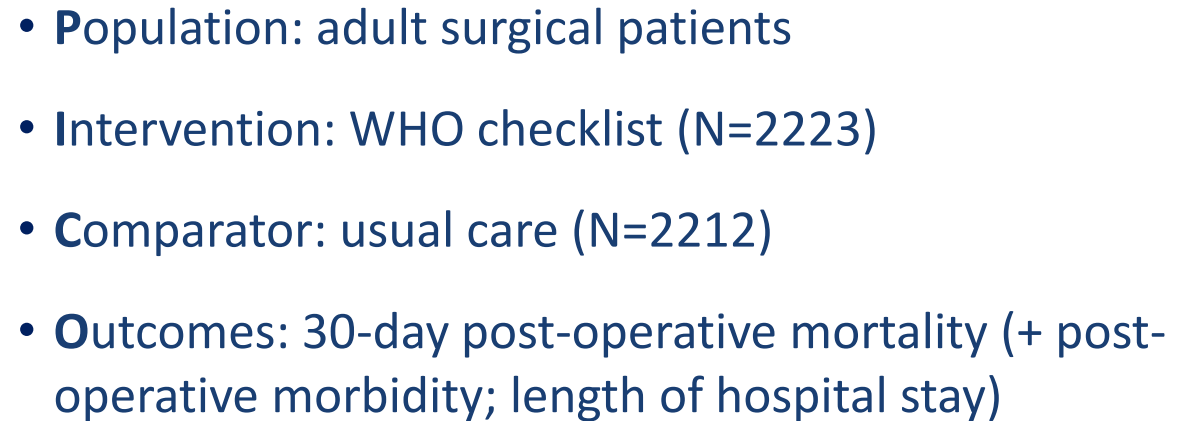
My aims today

- To introduce the concept of ‘hybrid’ trials as a novel method to accelerate the translation of research evidence into clinical practice and policy
- To offer some examples
- To generate discussion of how these may be used within your research and consider collaborative studies

Acknowledgment: slide materials informed by Dr Ioannis Bakolis (KCL, UK) and Professor Geoffrey M. Curran (UAMS, USA)

Translational pathway for research



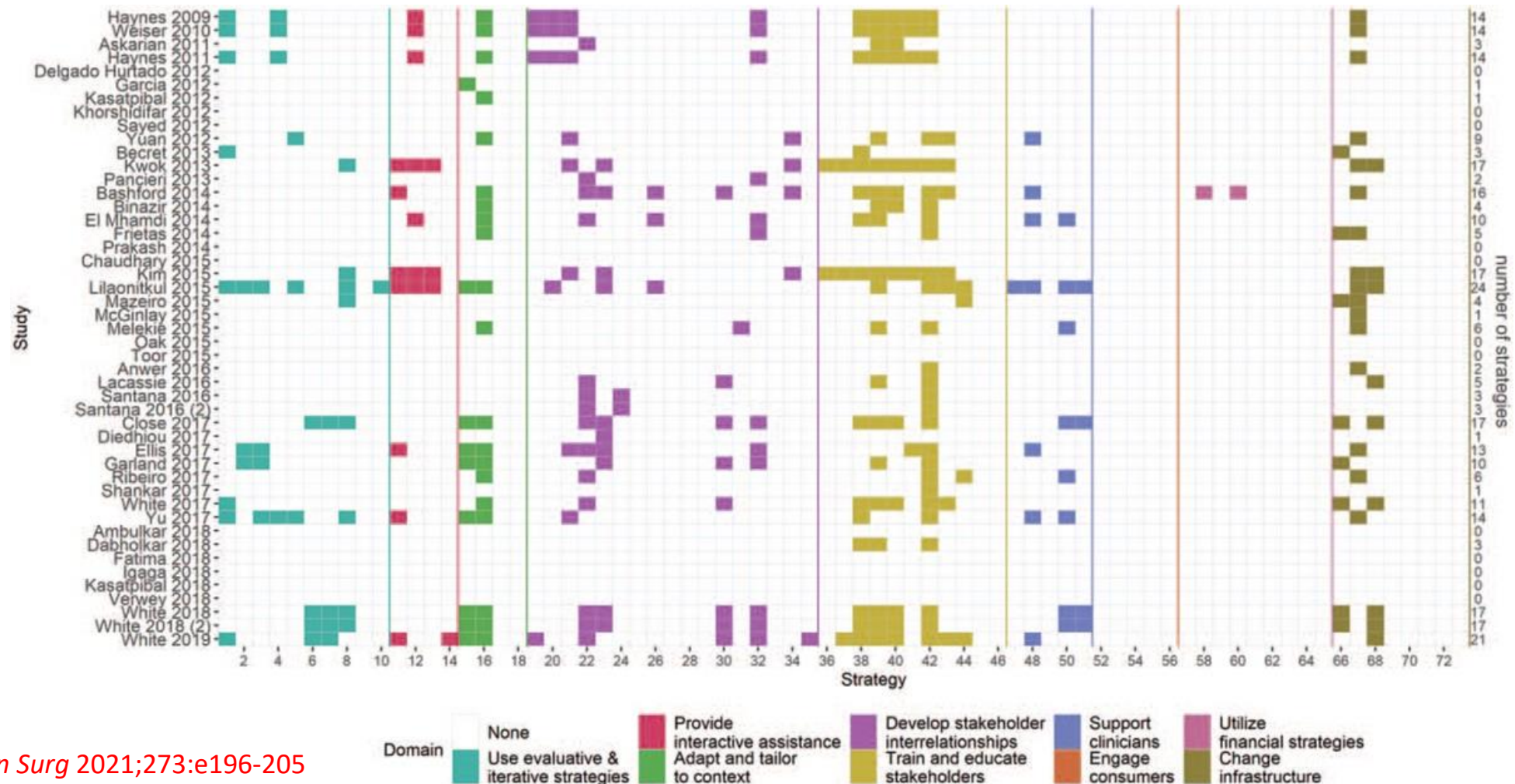
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*OK, so now we **DO** know that the checklist improves the outcomes for the patients IF used and applied as we did in this study...*

*But we did **NOT** study explicitly how best to implement it (even in the study hospitals) – so we do **NOT** know what implementation approaches might ‘work’ best...*

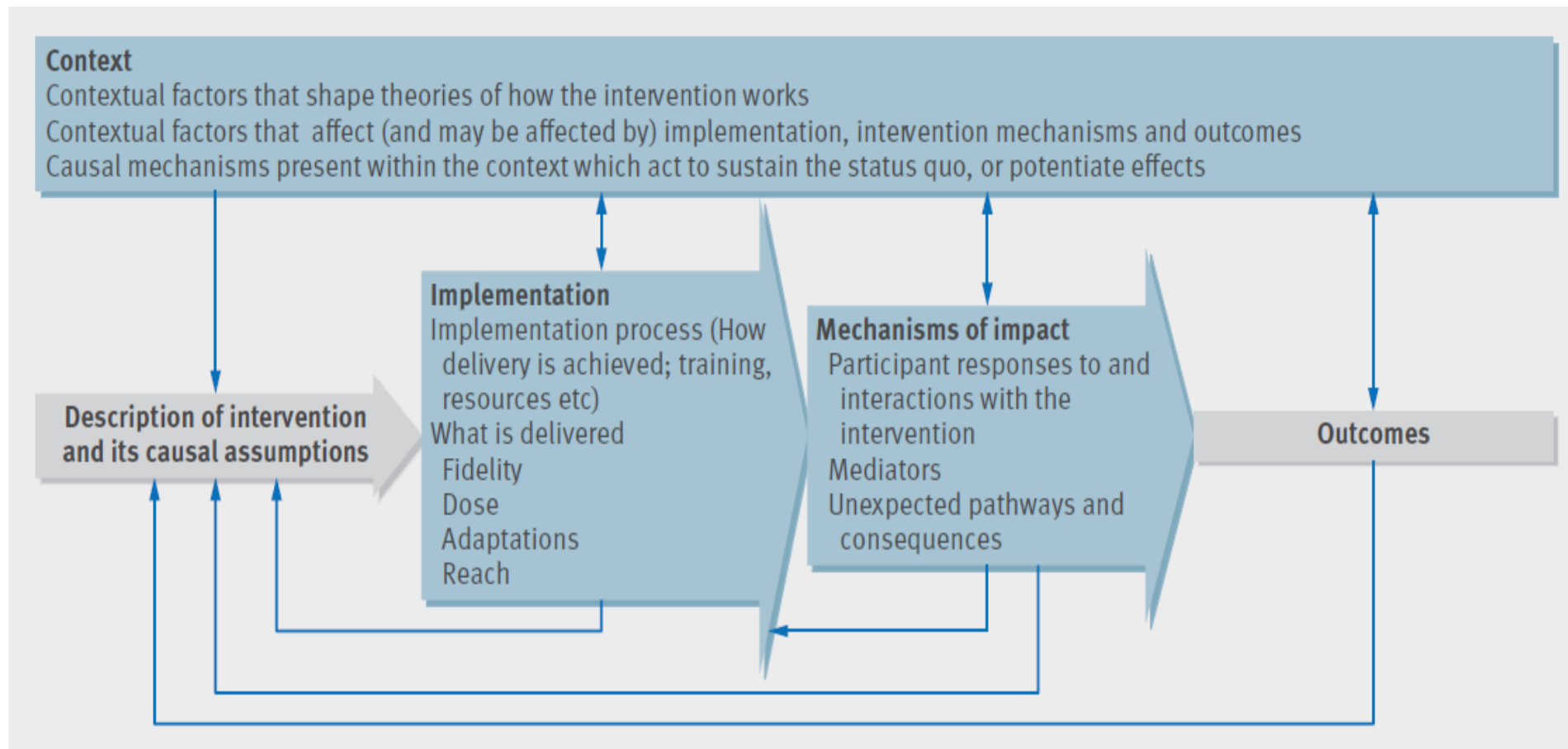


Approaches used in WHO Checklist implementation globally: variation & lack of definitive prescription

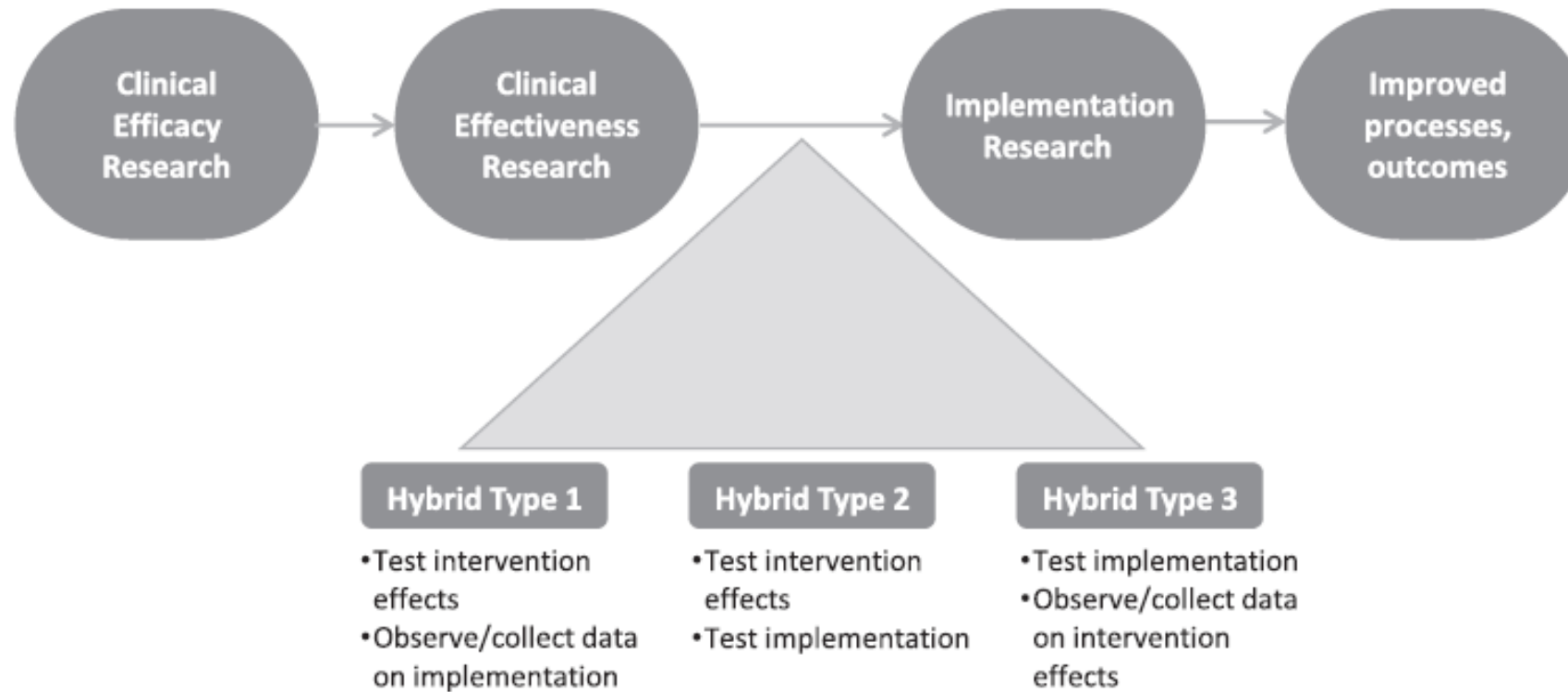


Implementation aspects of RCTs: an established framework

- FOR: RCTs assessing complex interventions
- BY: clinical, health and behavioural scientists supported by the UK's Medical Research Council (20+ years)

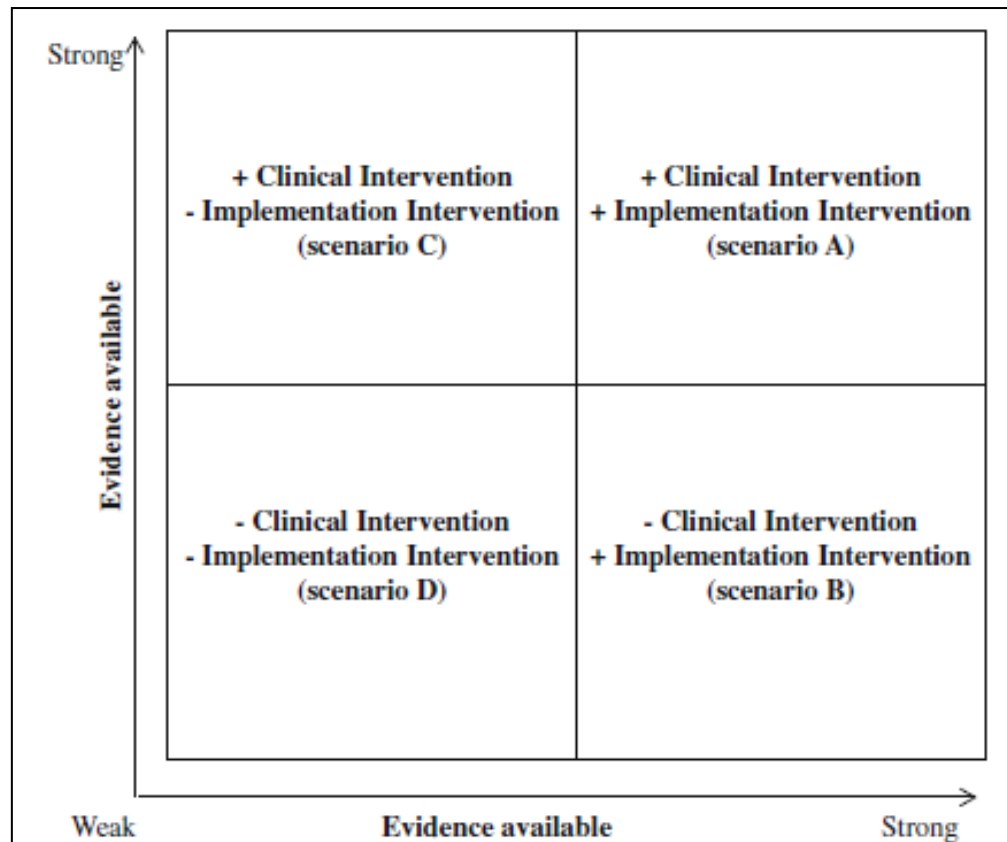


The concept of 'hybrid' RCTs



Curran et al, *Med Care* 2012;50:217-26
Schliep et al, *Evid Based Commun Assess Interv* 2017;11:82-98

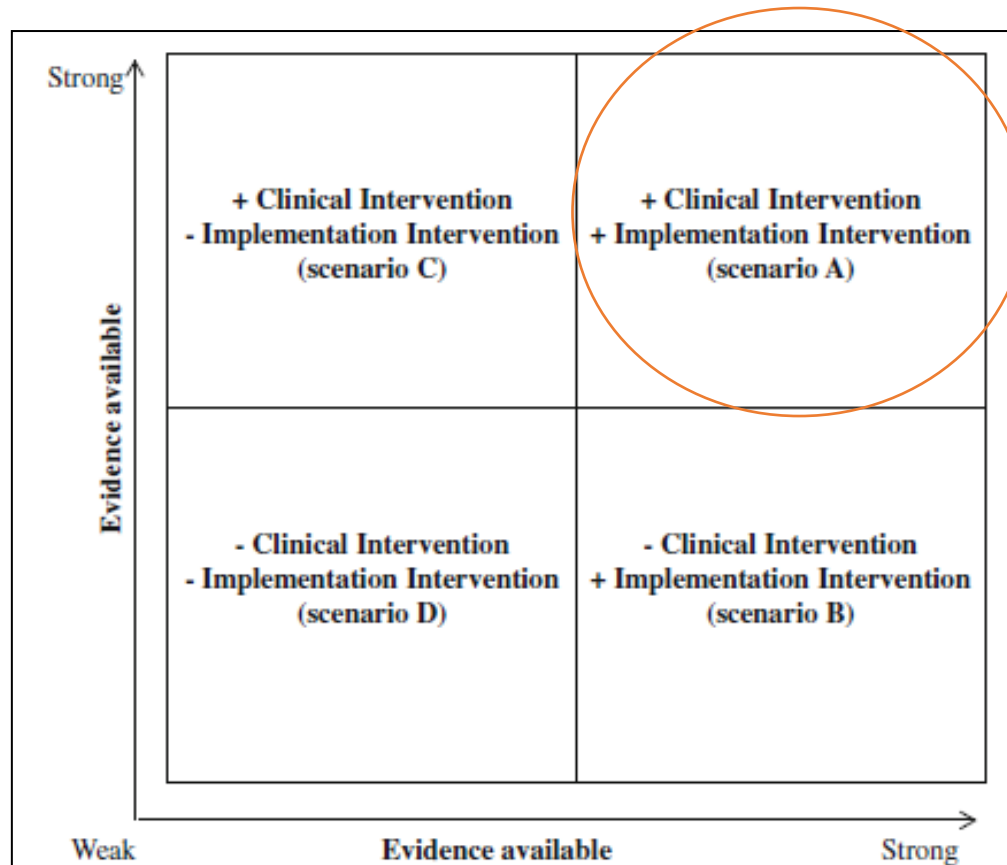
A practical design angle on 'hybrid' RCTs



• ALWAYS considering 3 things:

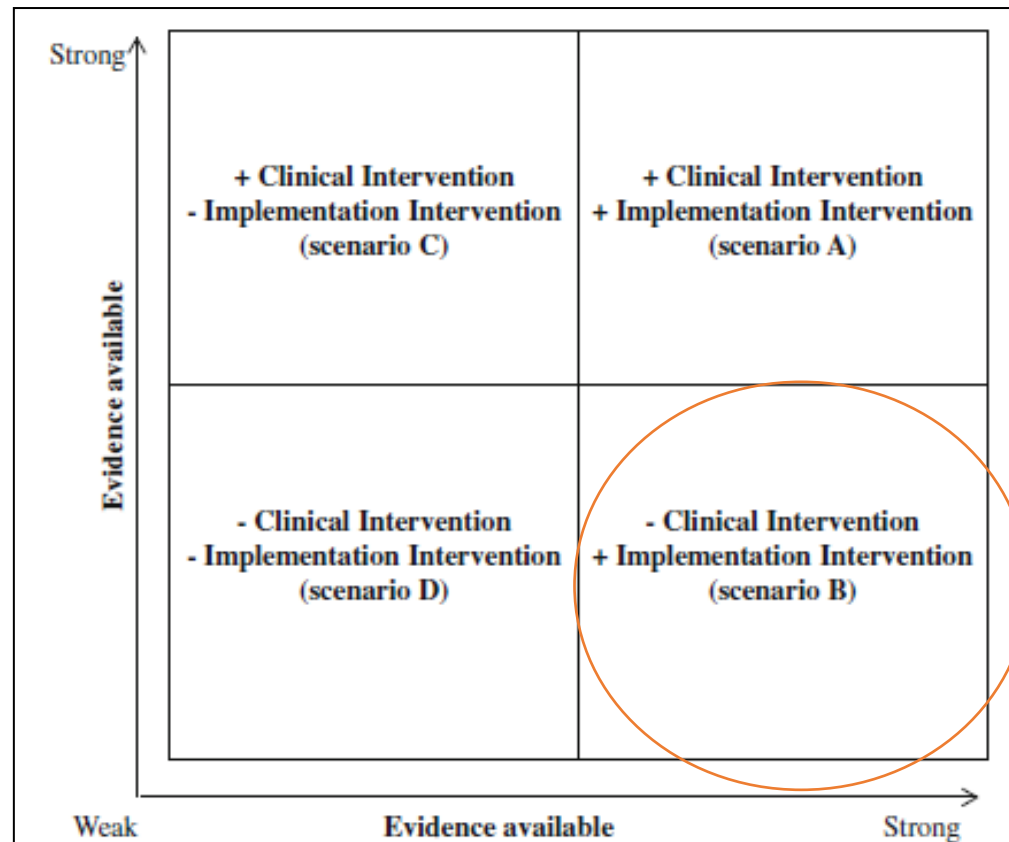
1. The **clinical or health service or public health intervention**
2. The **implementation intervention (i.e. strategy or approach)** used to implement the above
3. The **evidence base** available to support (1) and (2) above

Strong evidence all round



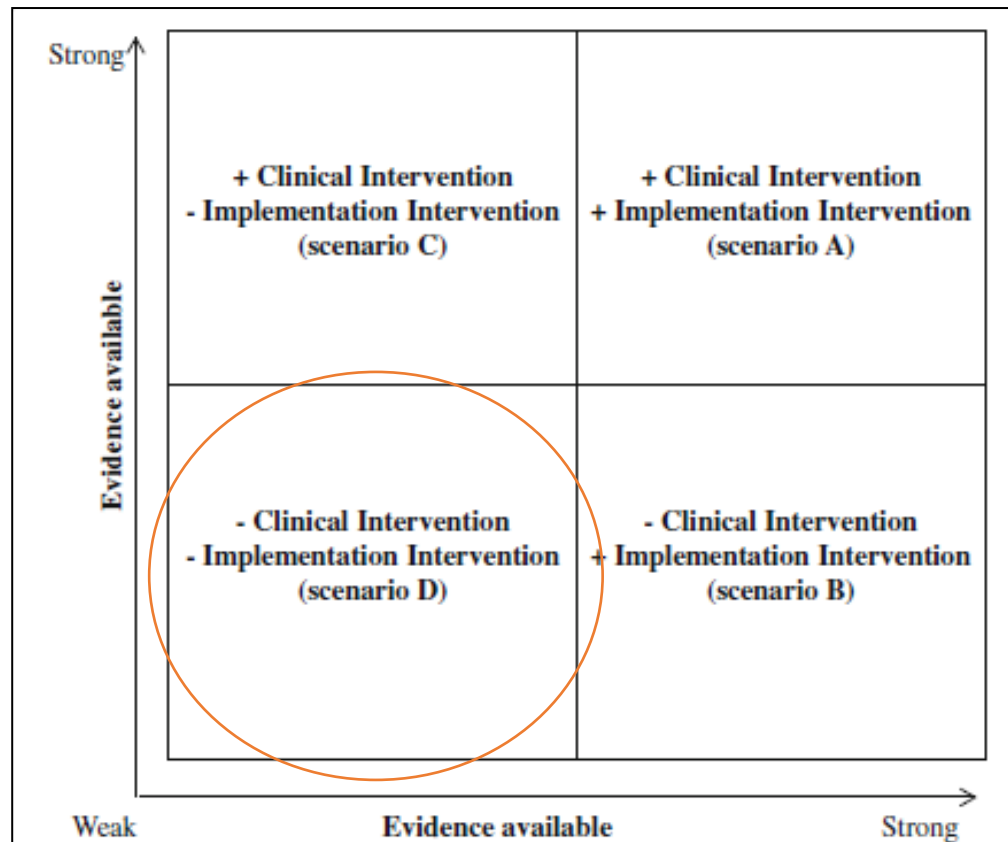
- ✓ Strong evidence on both clinical and implementation fronts
- ✓ Potentially no need for research
- ✓ BUT: if your setting/context is different from where the evidence comes from...:
 - you have CONTEXTUAL EQUIPOISE
 - you decide what type of study to do (see coming slides)

Strong implementation evidence, lacking clinical evidence



- ✓ Strong evidence on the implementation front but weak clinical evidence
- ✓ Need for clinical RCT
- ✓ It can be an unusual scenario; sometimes present in health services, with novel services lacking in effectiveness data

Generally lacking evidence: Hybrid I

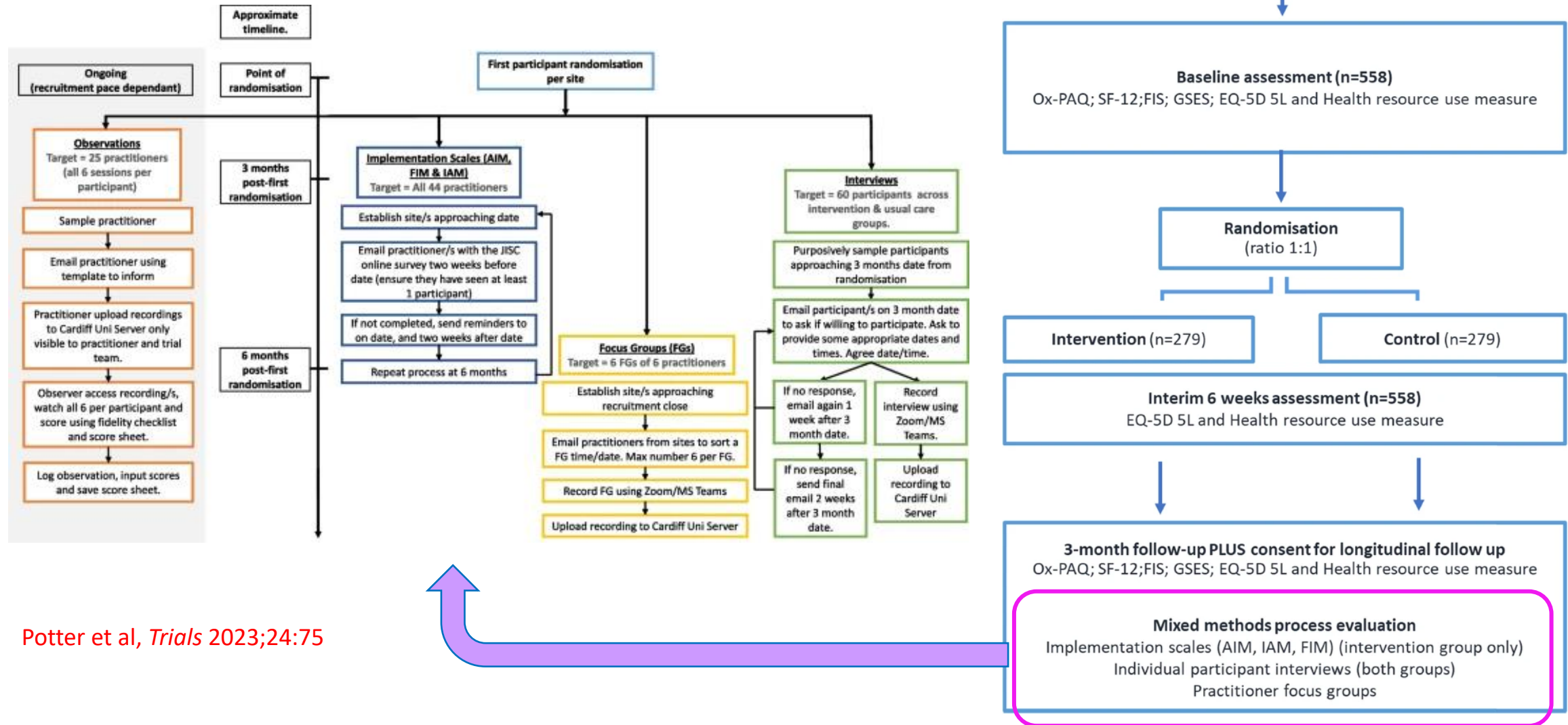


Eldh et al, *BMC Health Serv Res* 2017;17:16

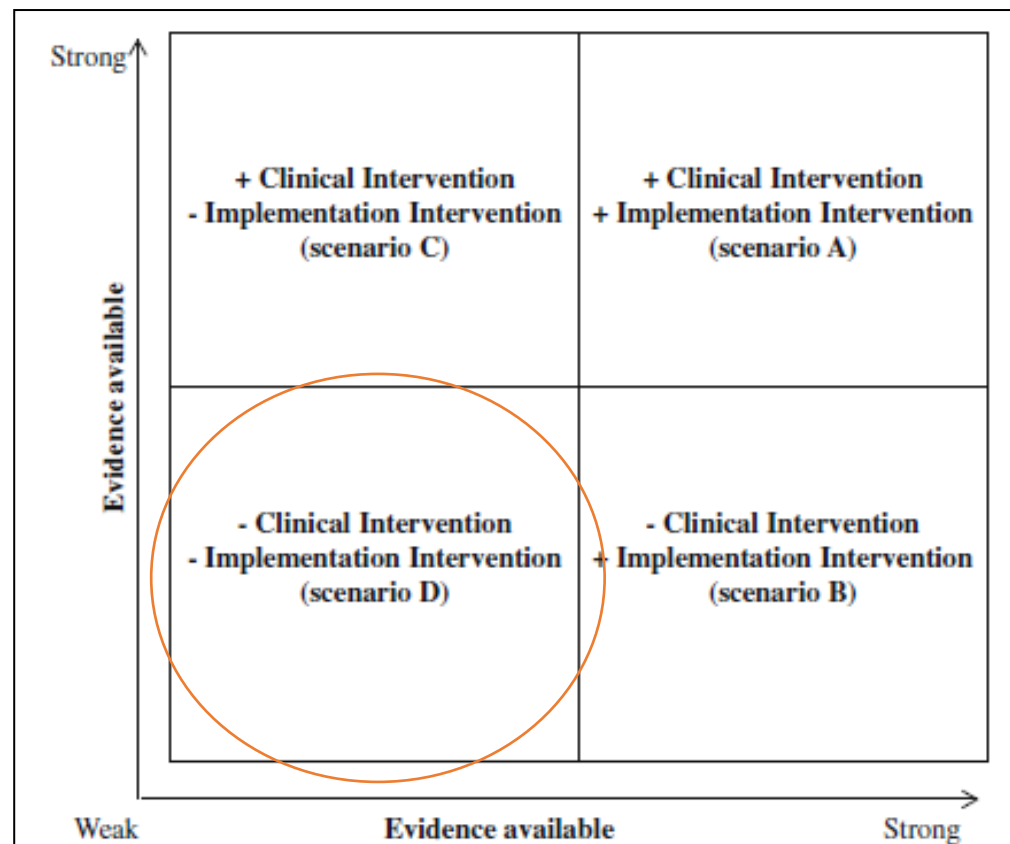
- ✓ Not much evidence on either clinical or implementation fronts
- ✓ Need for BOTH to be studied
- ✓ First option: conduct a RCT with an embedded **PROCESS EVALUATION**
- ✓ A process evaluation assesses the implementation and sustainability of a complex healthcare intervention within a clinical trial
- ✓ Typically descriptive (often qualitative)

Murdoch, *BMC Health Serv Res* 2016;16:407

Hybrid I example: LISTEN RCT on long COVID



When you wish to study implementation in more depth: Hybrid II



- ✓ Not much evidence on either clinical or implementation fronts
- ✓ Need for BOTH to be studied
- ✓ Same scenario – different option
- ✓ Second option: conduct a RCT which includes **randomisation of implementation strategies (ideally) OR a pilot evaluation of them**
- ✓ These studies can be hard to do – but yield very useful results!

Hybrid II: examples

TBM

ORIGINAL RESEARCH



Evaluating the effectiveness of physician counseling to promote physical activity in Mexico: an effectiveness-implementation hybrid study

Karla I. Galaviz,¹ Paul A. Estabrooks,² Edna Jauregui Ulloa,³ Rebecca E. Lee,⁴ Ian Janssen,⁵ Juan López y Taylor,⁶ Luis Ortiz-Hernández,⁷ Lucie Lévesque⁸

Rich et al. *BMC Public Health* (2018) 18:29
DOI 10.1186/s12889-017-4584-1

BMC Public Health

STUDY PROTOCOL

Open Access

Implementation-effectiveness trial of an ecological intervention for physical activity in ethnically diverse low income senior centers



Porchia Rich^{1*}, Gregory A. Aarons², Michelle Takemoto¹, Veronica Cardenas³, Katie Crist¹, Khalisa Bolling¹, Brittany Lewars¹, Cynthia Castro Sweet⁴, Loki Natarajan^{1,3}, Yuyan Shi¹, Kelsie M. Full¹, Eileen Johnson¹, Dori E. Rosenberg⁵, Melicia Whitt-Glover⁶, Bess Marcus¹ and Jacqueline Kerr^{1,3}

Open Access

Protocol

BMJ Open Effectiveness of implementing a best practice primary healthcare model for low back pain (BetterBack) compared with current routine care in the Swedish context: an internal pilot study informed protocol for an effectiveness-implementation hybrid type 2 trial

Allan Abbott,¹ Karin Schröder,¹ Paul Enthoven,¹ Per Nilsen,² Birgitta Öberg¹

Rogers et al. *Addiction Science & Clinical Practice* 2013, **8**:7
<http://www.ascjournal.org/content/8/1/7>



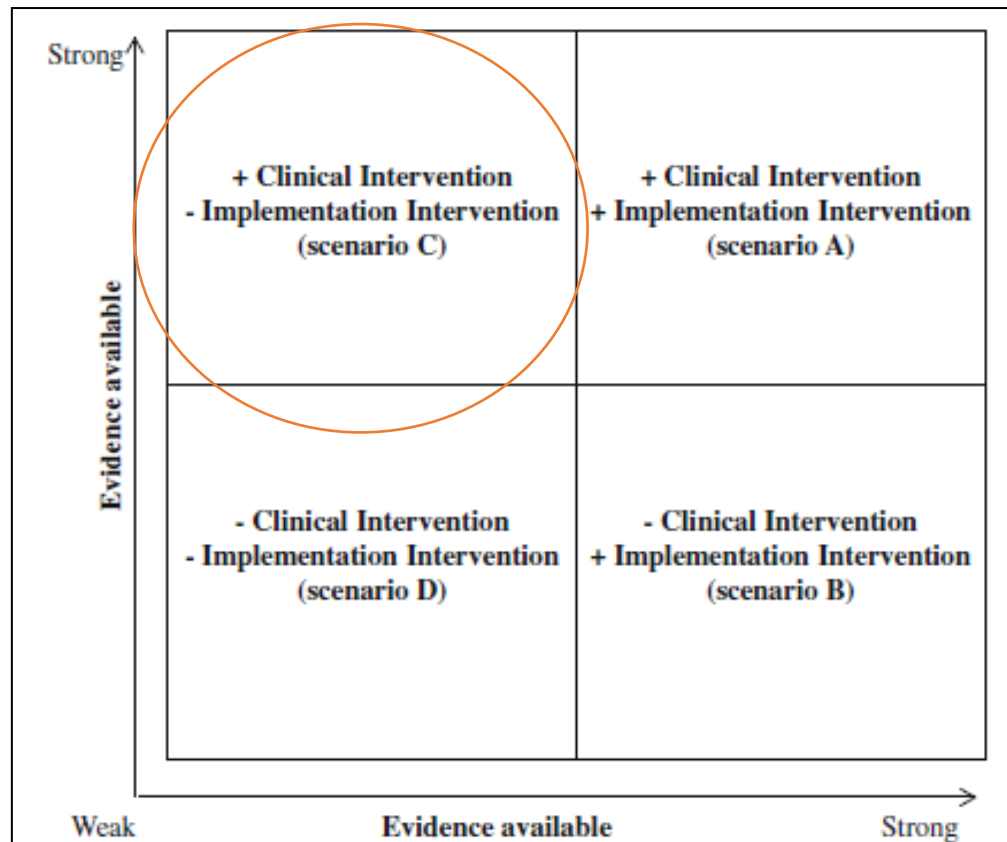
STUDY PROTOCOL

Open Access

Telephone care coordination for smokers in VA mental health clinics: protocol for a hybrid type-2 effectiveness-implementation trial

Erin Rogers^{1,2*}, Senaida Fernandez⁸, Colleen Gillespie², David Smelson^{4,5}, Hildi J Hagedorn^{6,7}, Brian Elbel³, David Kalman^{4,5}, Alfredo Axtmayer¹, Karishma Kurowski^{1,2} and Scott E Sherman^{1,2}

When you wish to study implementation alone: Hybrid III



- ✓ Well-established clinical evidence, beyond equipoise
- ✓ Lacking implementation evidence
- ✓ Conduct a RCT with sole implementation focus – i.e. an **IMPLEMENTATION TRIAL**

Hybrid III example: the OASI2 implementation RCT

CARE BUNDLE

1. Inform the woman about OASI and what can be done to minimise her risk.
2. Documented use of **manual perineal protection (MPP)**:
 - For spontaneous births, MPP should be used unless the woman objects, or her chosen birth position does not allow for it.
 - For operative vaginal births MPP should always be used.
3. When indicated, **episiotomy** should be performed **mediolaterally** at a **60-degree angle** at **crowning**.

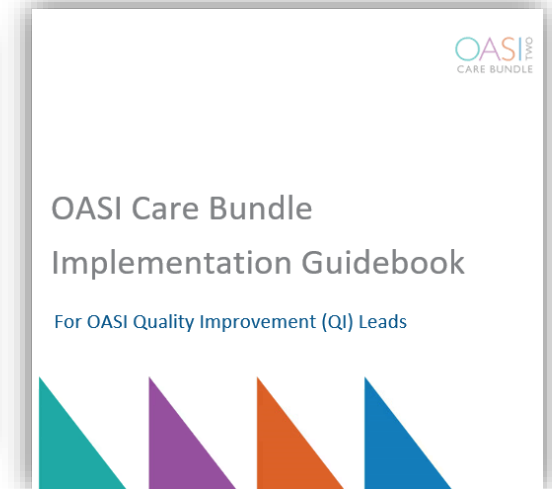
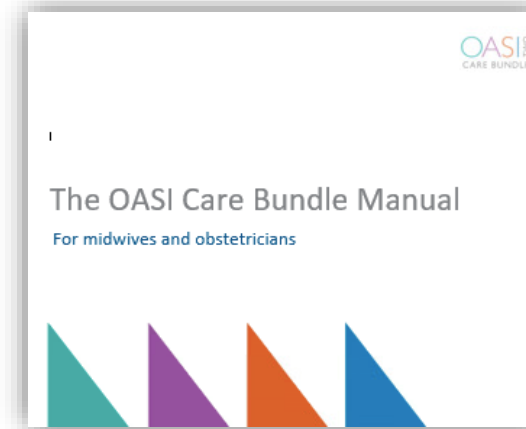
Following birth, the **perineum** should be **examined** and any tears graded according to the RCOG guidance. The examination should include a **per rectum** check even when the perineum appears intact.

Study protocol

OASI2: a cluster randomised hybrid evaluation of strategies for sustainable implementation of the Obstetric Anal Sphincter Injury Care Bundle in maternity units in Great Britain

Jurczuk et al, *Implement Sci* 2021;16:55

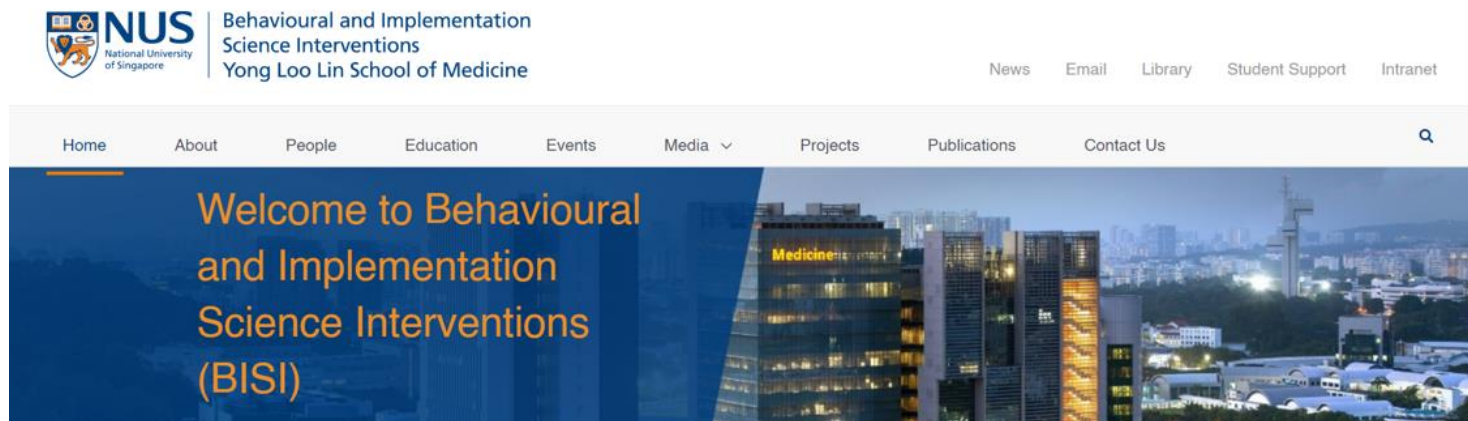
IMPLEMENTATION MANUALS



- Prior clinical RCT in 16 units, 55,000 live births: reduced OASI rate from 3.3 → 3%
- OASI2 RCT: level of implementation support
 - ✓ ALL units receive the bundle
 - ✓ Lean units (N=10): receive booklets
 - ✓ Peer-supported units (N=10): receive booklets + external facilitation (monthly)
- Primary outcome: level of adoption of the bundle

Summary and points for discussion

- Hybrid RCTs systematise the study of implementation within the ‘traditional’ clinical trial setting
- This typology offers a range of designs to help analyse and understand the process of implementation – from descriptive studies to controlled ones
- The ultimate objective remains to accelerate translation of effective clinical, health service and public health interventions into practice – routinely and sustainably
- Scientifically, there is a need to better specify these designs – at BISI, we are keen to explore these with those of you keen on trials!



*Thank
you*



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<https://medicine.nus.edu.sg/bisi/>