Increasing the trial process evidence base without increasing research waste

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Trials Change Lives

“Clinical trials are the backbone of primary research that informs clinical practice in the NHS in the UK”

Prof Hywel Williams, Director, Health Technology Assessment Programme (NIHR)

Clinical Trials for the NHS

www.methodologyhubs.mrc.ac.uk/trials-change-lives/
'There is a peculiar paradox that exists in trial execution - we perform clinical trials to generate evidence to improve patient outcomes; however, we conduct clinical trials like anecdotal medicine.'*

SWATs– why bother?

It is essential that trials are done in the most effective and efficient ways and one way to do this is to use the same types of evaluation to investigate and improve the processes of how we do randomised trials.

Mike Clarke,
Belfast, UK
E.g. SWAT – financial incentives

No payment better recruitment

Payment better recruitment

GRADE LOW MODERATE HIGH
The key question now is–

Given what we know already, do we need to do another evaluation of a financial incentive?

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How to decide if a further Study Within A Trial (SWAT) is needed. DOI: https://doi.org/10.21203/rs.1.1/v1
Our five criteria

1. Cumulated evidence
2. GRADE
3. Context
4. Balance– participants
5. Balance– host trial
Our five criteria: #1

1. Cumulated evidence: the cumulative meta-analysis shows that the effect estimate for each outcome essential to make an informed decision has not converged.
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Criterion met
1. GRADE: the GRADE certainty in the evidence for all outcomes is lower than ‘high’.
Our five criteria: #2

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Criterion met
Our five criteria: #3

1. Context: the range of host trial contexts evaluated to date does not translate easily to the context of the proposed SWAT.
Six SWATs, all UK. Five done by the same group.
Five in primary care, one in community.
Three trials involved hypertension, one arthritis, one excess uric acid in urine, one smoking
Five done in drug trials (comparators were an active drug). Other done in mobile phone supported smoking cessation intervention trial, comparator no support.
All SWATs measured recruitment.
Five SWATs involved a £100 ($130) payment, higher than is usual in the UK at least.
Our five criteria: #3

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- Five in primary care, one in community.
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- Five SWATs involved a £100 ($130) payment, higher than is usual in the UK at least.

Criterion partially met, maybe
Our five criteria: #4

1. Balance– participants: the balance of benefit and disadvantage to participants in the host trial and/or the SWAT is not clear.
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Criterion partially met
1. Balance– host trial: the balance of benefit and disadvantage to the new host trial is not clear.
Our five criteria: #5

1. Balance– host trial: the balance of benefit and disadvantage to the new host trial is not clear.

Criterion not met
Do we need more evaluations of financial incentives for recruitment?

Users: trial teams
Outcome: recruitment

1. Cumulated evidence: Criterion met
2. GRADE: Criterion met
3. Context: Criterion partially met, maybe
4. Balance– participants: Criterion partially met
5. Balance– host trial: Criterion not met
Do we need more evaluations of financial incentives for recruitment?

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Outcome: recruitment

1. Cumulated evidence: Criterion met
2. GRADE: Criterion met
3. Context: Criterion partially met, maybe
4. Balance– participants: Criterion partially met
5. Balance– host trial: Criterion not met

On balance, yes, more evaluations needed
1. We need more trial process evidence.
2. SWATs are one way of filling evidence gaps.
3. ..but we need to stop once the gap has been filled.
4. Avoiding that needs criteria; now we have some.
5. We aim to use the criteria in Trial Forge. Others can too.
If you have any further questions please contact:

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