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Trial Design Considerations and the Management of Operational Complexity.

RCT in Social Sciences Conference

Date: 7th September 2017

Presenter: Mark Langdon

Summary...



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- **This presentation will give an overview of some of the considerations regarding organisational complexity and how this has been reflected in our trial decisions for the Group Work (JOBS II) trial.**
- **I will give a brief overview of what JOBS II is and why we are testing it**
- **I will highlight of the potential issues with a number of trial design options and the extent to which organisational complexity is addressed.**
- **I'll then outline how our selected methodology (Zelen) addresses more of the complexity issues compared to other design options (in the context of the Group Work trial).**
- **I will then make the case for the need to include qualitative process evaluation in order to support the overall evidence base and interpretation of results.**
- **But before I do that, lets just quickly review the context within which we work.**

The context within which we work...



We don't work here...



We work here...



The context within which we work...



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- Deaton and Cartwright (2016) - the claim of RCTs being the gold standard of research rest on the fact that the ideal RCT is a deductive method: if the assumptions of the test are met, a positive result implies the appropriate causal conclusion.
- However, in the social policy context the *ideal* RCT is difficult to achieve
- Pawson (2013) - there are a number of 'complexity' factors which can erode the robustness of an RCT when conducting 'real world' research. Such complexities can undermine the robustness of conclusions drawn from analysis.
- Pawson's main argument lies in the doctrine that a trial should not be seen in isolation of the context within which it was implemented.

The context within which we work...



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- John (2017) – when considering experiments in the welfare and employment context, states “*in spite of these complexities, what is remarkable is the number of successful trials that have been done for these interventions – especially in the US and the UK – but the conditions need to be right for them to work*” (p111)
- The question here is can the trial design go some way to helping to achieve the ‘right’ conditions and thus increase the likelihood of a successful trial.

What are these complexities?



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Complexity within organisations and service delivery

- Poor Alignment with Operational Processes
- Operational Pressures
- Service Delivery buy-in
- Rivalry – competing/interact with other support options
- Temporal – organisational memory, recollection of (perceived) similar interventions
- Challenge to equipoise (social justice)*

Behavioural and Cognitive considerations within participants

- Innovation Bias (Challenge to equipoise)*
- Resentment Bias*
- Reactance Bias
- Volitions throughout the programme 'active' participation

* Bias usually managed through blinding of either trial participants and/or trial administrators

Group Work (JOBS II)

Why are we testing Group Work



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Tested via RCT in the USA (twice) and Finland

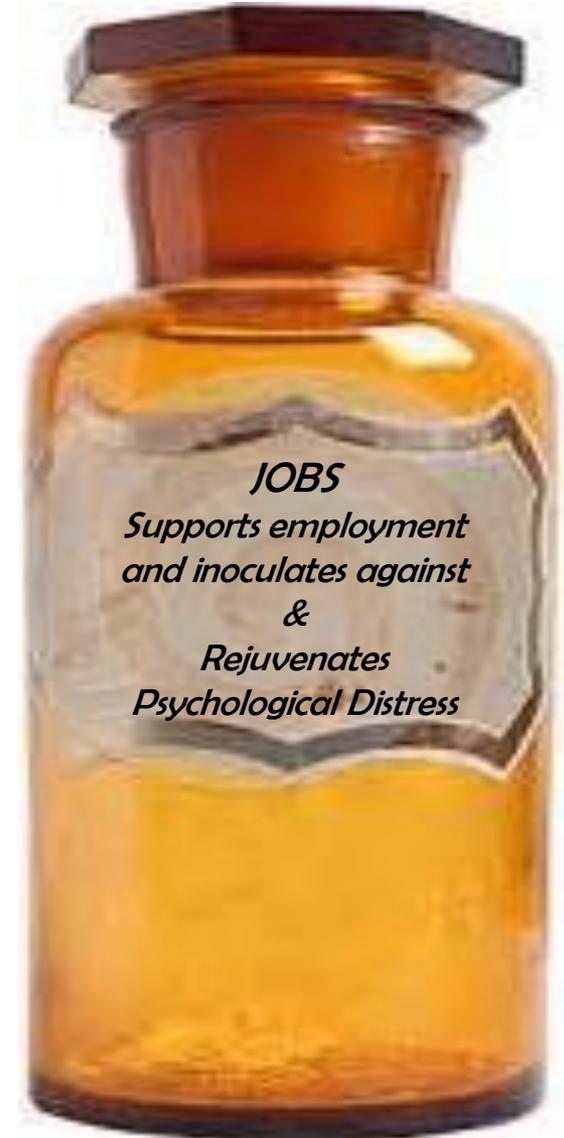
Found +ve impact on employment and
Psychological State.

Sustained differences up to 2 years following
participation.

Also '*tested*' in Ireland and China

But how does it work?

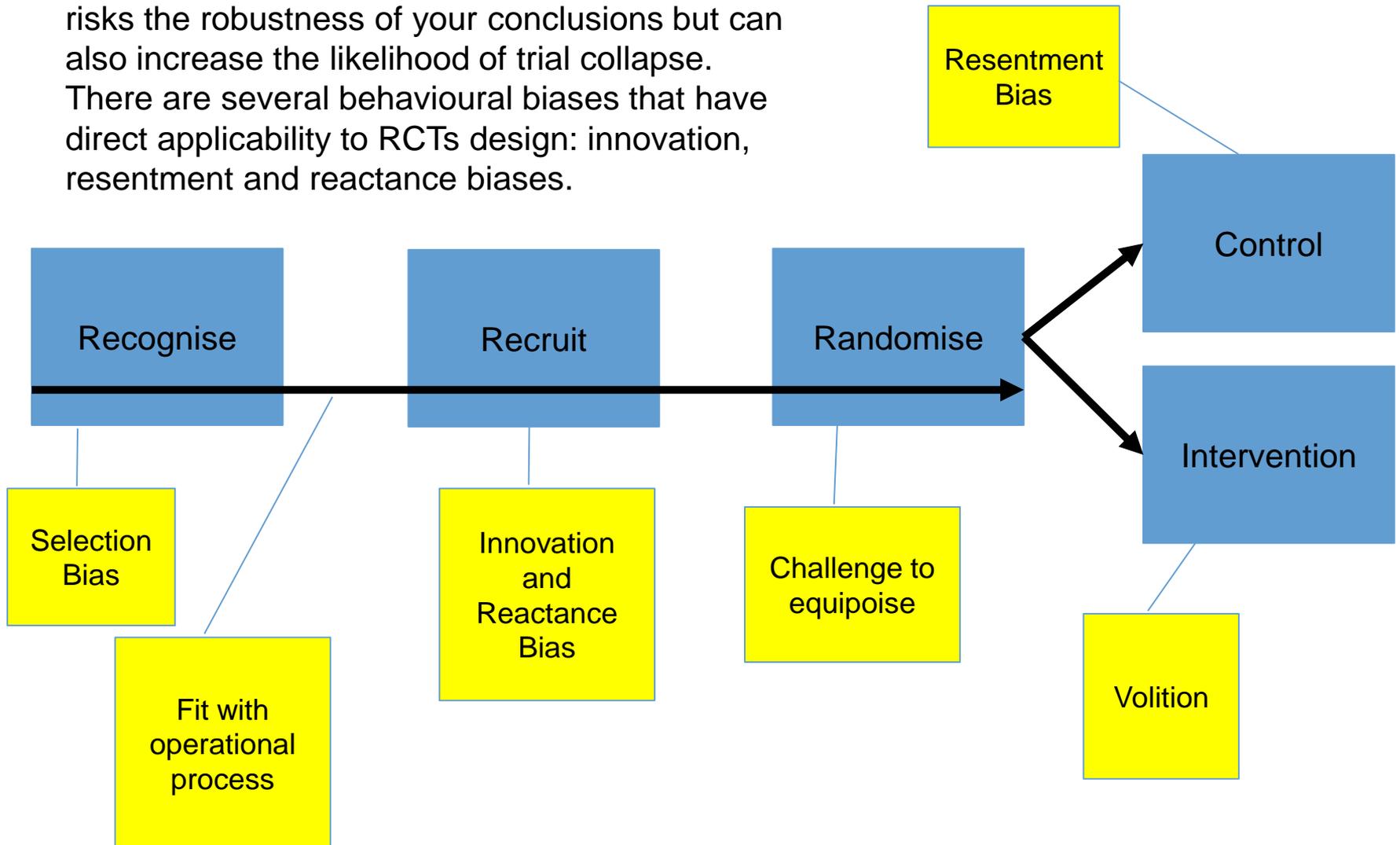
Careful design; the facilitators behaviours,
structure to claimant day, shared problem solving,
shared group experiences, job search skills and
resilience building.





A Simple Parallel Designed RCT

Failure to consider the complexities not only risks the robustness of your conclusions but can also increase the likelihood of trial collapse. There are several behavioural biases that have direct applicability to RCTs design: innovation, resentment and reactance biases.



Clustered RCT



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Complexity within organisations and service delivery

Is not able to manage:

- Poor Alignment with Operational Processes – identification of the control group often requires additional work
- Service Delivery buy-in – particularly difficult to maintain for control group sites, limited rewards

But is able to manage:

- Challenge to equipoise (social justice)

Behavioural and Cognitive considerations within participants

Is able to manage:

- Resentment Bias
- Innovation Bias (Challenge to equipoise)

Is not able to manage:

- Reactance Bias
- Volitions throughout the programme 'active' participation

Pair – Wise Randomisation



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Complexity within organisations and service delivery

Is not able to manage:

- Poor Alignment with Operational Processes – difficult to do in real time service delivery
- Service Delivery buy-in – Service Delivery staff need to understand who is in which group in real time.

But is able to address:

- Challenge to equipoise (social justice)

Behavioural and Cognitive considerations within participants

Is able to manage:

- Resentment Bias
- Innovation Bias (Challenge to equipoise)

Is not able to manage:

- Reactance Bias
- Volitions throughout the programme 'active' participation

Delayed Onset

Complexity within organisations and service delivery

Is not able to manage:

- Challenge to equipoise (social justice)

But is able to address:

- Alignment with Operational Processes – difficult (but not impossible) to do in real time service delivery
- Service Delivery buy-in – Only if the delay in provision isn't too long from the point of randomisation.

However, given that employment programme outcome measures are based on number of days off-benefit over 12 months, how long can we ethically delay the intervention?



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Behavioural and Cognitive considerations within participants

Is able to manage:

- Resentment Bias
- Innovation Bias (Challenge to equipoise)

Is not able to manage:

- Reactance Bias
- Volitions throughout the programme 'active' participation

I selected a Zelen Design RCT

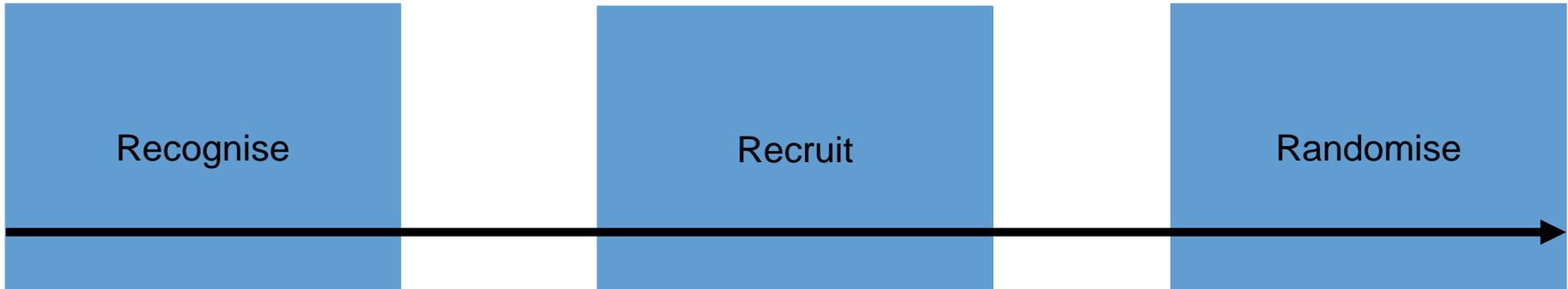


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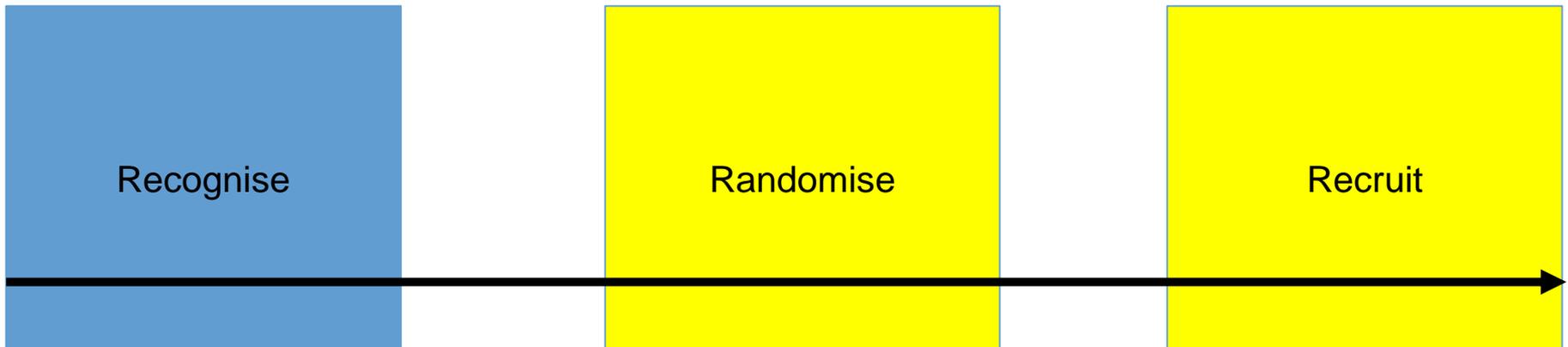


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First reported in 1970 – Marvin Zelen: changing the standard parallel design process from this...



To this...



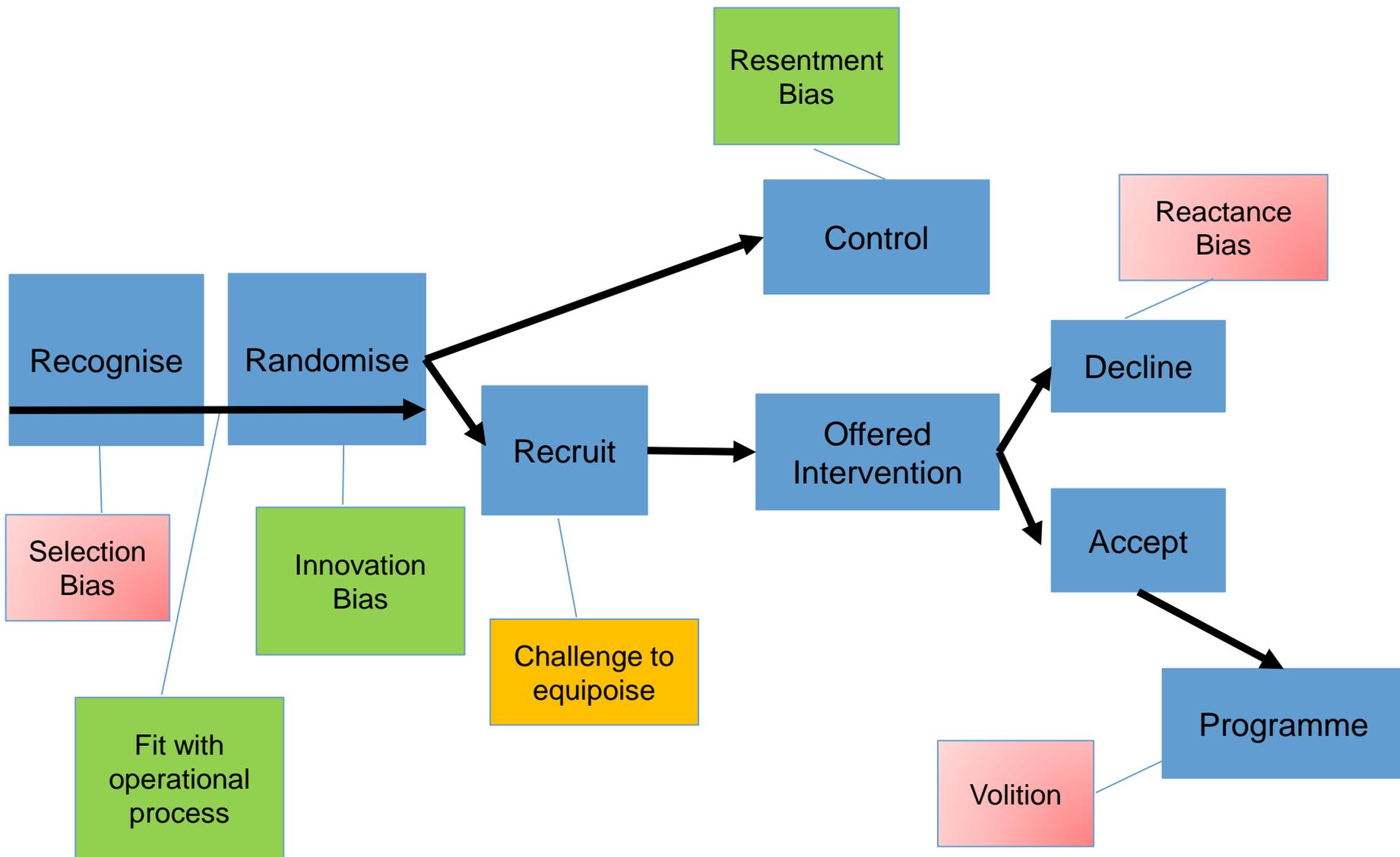
What complexities can/can't be overcome with the Zelen designed RCT



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No trial design can manage all challenges...



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Good communications and Trial Compliance Management can help address some issues

- Service Delivery buy-in
- Selection bias
- Challenge to equipoise (social justice)
- Adherence to the process

However, good qualitative process evaluation can help us understand issues around...

- Operational Pressures
- Rivalry – competing/interact with other support
- Temporal – organisational memory, recollection of (perceived) similar interventions



Questions for discussion...



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- What steps have you taken to ensure successful trial delivery?
- What complexities have you faced and how have they been managed?

Thank you!

References...



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