Life in Perfect Frequency

Body Vibes contain frequencies believed to have various harmonizing effects on human bodies. Of course, not all human bodies are the same, so the effects may be different for each person. Through a proprietary technology, frequencies are recorded, condensed, and stored within the sticker, in much the same way that you would save a file to your computer's hard drive. When the sticker is properly applied to your skin, it begins broadcasting the stored frequencies, which may influence the cells in your body. This interchange of frequencies is believed to have balancing effects on particular systems within the body.

The stresses of daily life can throw off our bodies' ideal energetic frequency… These stickers can balance the energy frequency in our bodies.

They’re made from the same conductive carbon material NASA uses to line space suits

Come pre-programmed to an ideal frequency, allowing them to target imbalances

NASA spacesuits do not have any conductive carbon material.

Richard Eaton
Inventor of Good Vibes body stickers
~~Doctor~~
~~Scientist~~
~~Engineer~~
Wellness entrepreneur and marketing expert

Without going into a long explanation about the research and development of this technology, it comes down to this; I found a way to tap into the human body's bio-frequen
body is receptive to c
signature

Product research results are… CONFIDENTIAL

Peer-reviewed published research is… too expensive…

Clinical trials- who needs them?

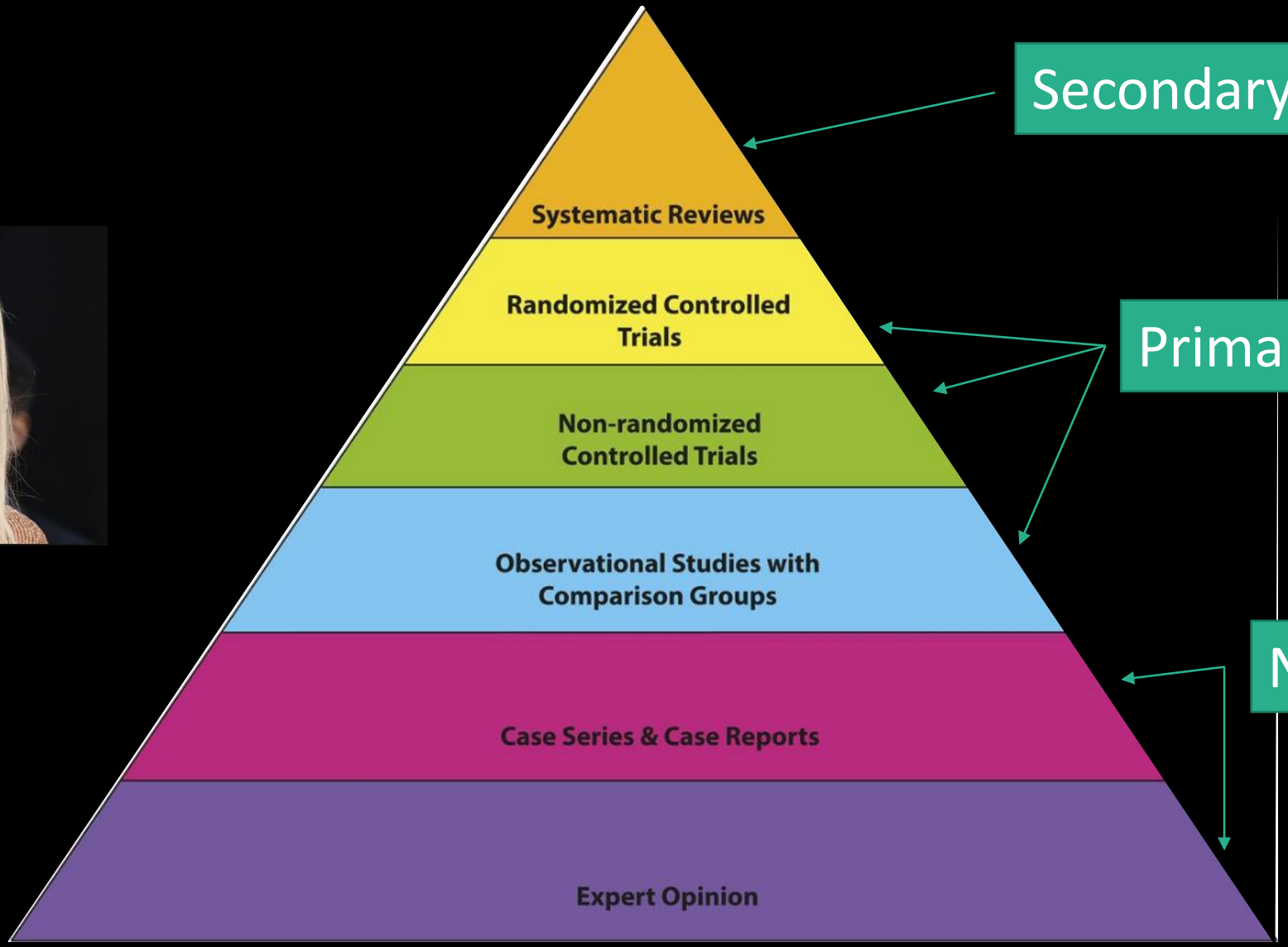
Felicity Fitzgerald

Felicity.fitzgerald@ucl.ac.uk
@flicfitzgerald (twitter)

UCL INSTITUTE OF CHILD HEALTH

SAMSON
Sub-Saharan African
MuScuIOskeletal Network

Grades of Evidence



Secondary appraisal

Primary Studies

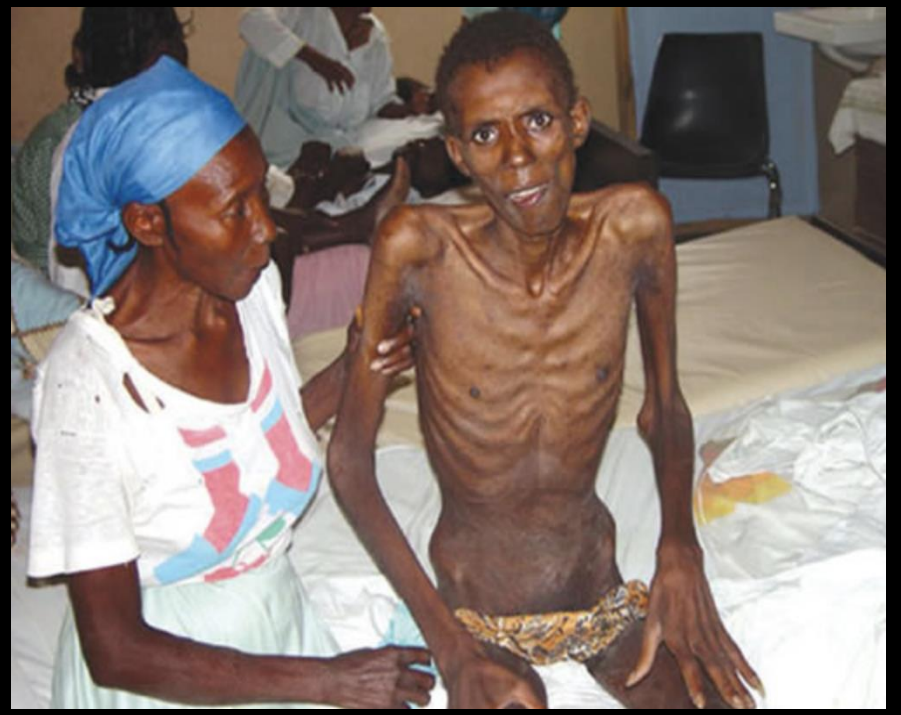
No Design

Why and when to intervene?

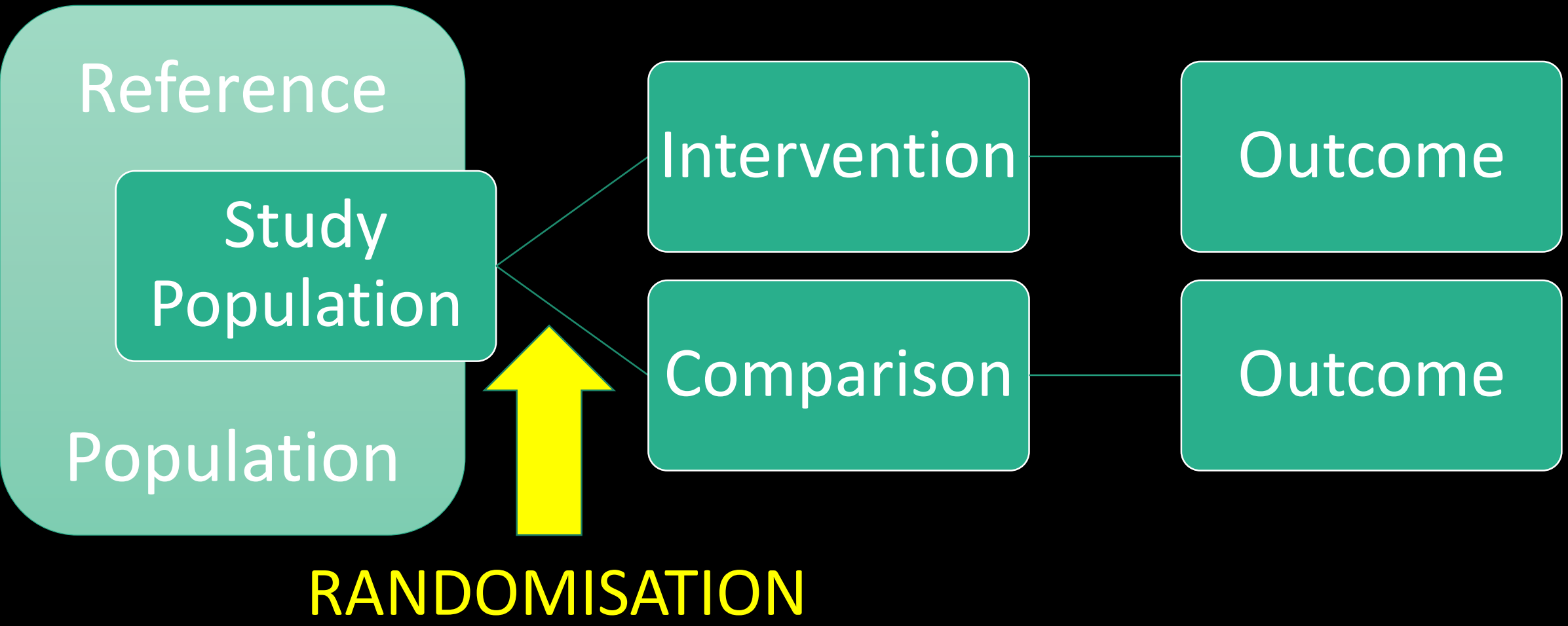
- Why?
  - Unanswered clinical question
  - Important for the reference population
    - E.g. Very high mortality for those starting ART at low CD4 counts

- When?
  - You are in EQUIPOISE about a potential intervention
  - You have a clear hypothesis about how the intervention MIGHT work
    - Epidemiological evidence
    - Laboratory studies
    - Animal models


A.I.D.S.: WE NEED
RESEARCH.
NOT HYSTERIA!



Randomised Controlled Trials



Ethics

- Has the question already been answered?
- Informed consent (Mandatory…?)
- Lack of coercion
- Confidentiality
- Long term plan….

AIMS OF EVALUATION

- Measure effect of intervention so results are BOTH:

- VALID
- PRECISE

Randomisation- what and why?

- Participants each have a known, usually equal chance of being allocated to either group
- CAN’T predict allocation
- Minimises bias and confounding
- Statistical theory based on random sampling

Allocation Concealment

- Person RANDOMISING doesn't know what's coming next…
- Different to double-blinding

Why is it important?

- If allocation known before to decision to recruit, can influence this decision
- Can lose benefits of randomization (i.e. similar characteristics in each group) with poor allocation concealment

When to Randomise?

- As late as possible

- AFTER:
  - Confirmed eligibility
  - Consented
  - Definitely Recruited
  - Baseline data collected- especially about variables that might influence outcome…

How to Randomise?

- Block (restricted) randomisation
- Stratified Randomisation
- Minimisation

Block Randomisation

1. AABB
2. ABAB
3. ABBA
4. BBAA
5. BABA
6. BAAB

e.g. sequence may be: ABBA/BABA/BAAB/ etc etc

Stratified randomisation

- Balancing for known potential confounders
- Divide into subgroups
- E.g. age, trial centre, disease severity
- Randomise within those subgroups

Minimisation

- Calculate the imbalance within each potential confounder should patient be allocated to treatment or control group
- Either add to one group/other directly or add random element
- Need sophisticated IT support

Participants

Health care professionals

Outcome Assessors

Non-differential

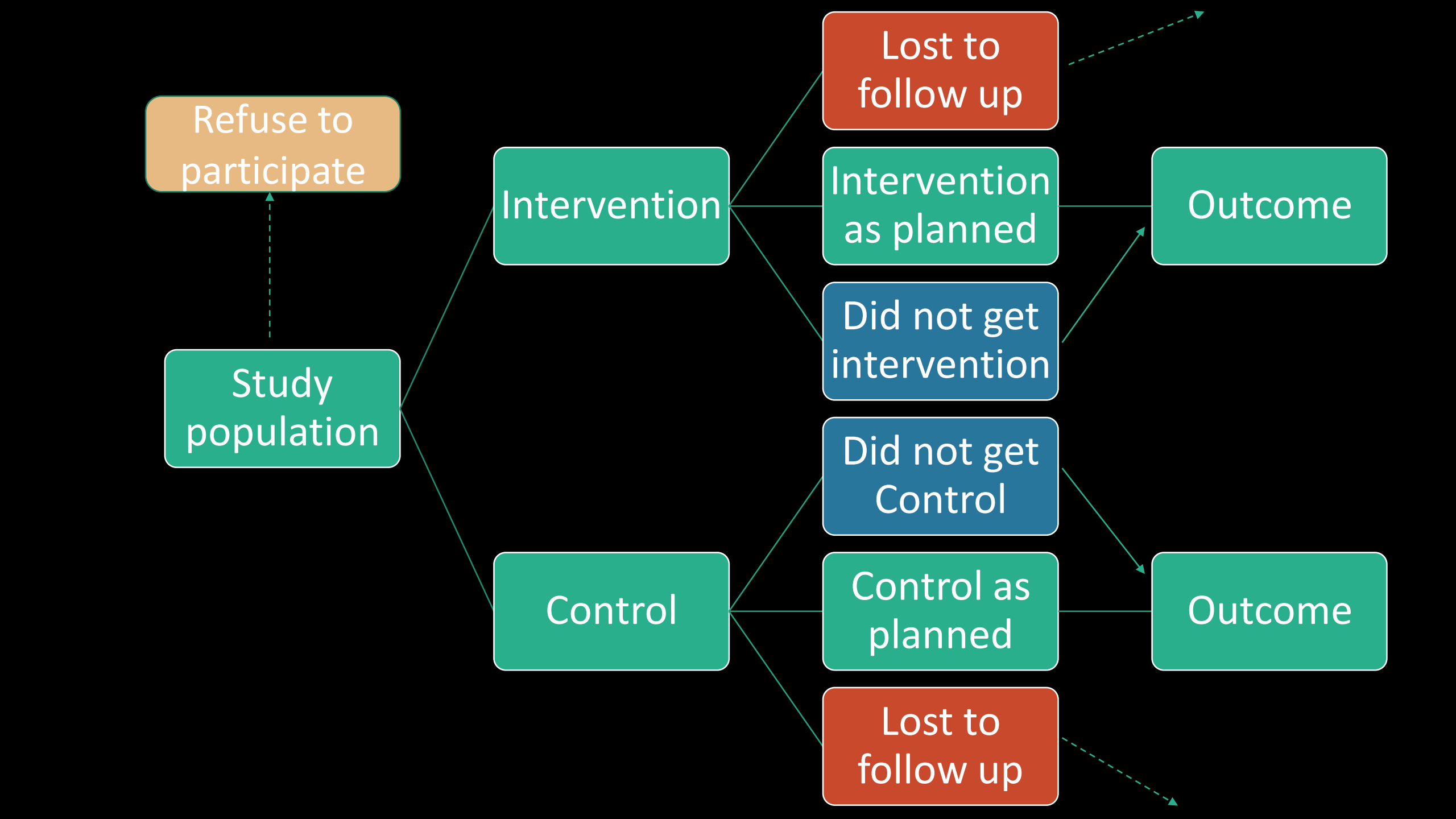
Misclassification

Differential

Outcome assessment

Minimise misclassification by:

- Objective outcome e.g. death
- Blinding participants/investigators measuring outcome
- Standardising assessment of outcome
- Measure agreement in assessing outcome (intra/inter-observer variablility)


Refuse to participate
Study population
Intervention
Control
Lost to follow up
Intervention as planned
Did not get intervention
Did not get Control
Control as planned
Lost to follow up
Outcome
Outcome

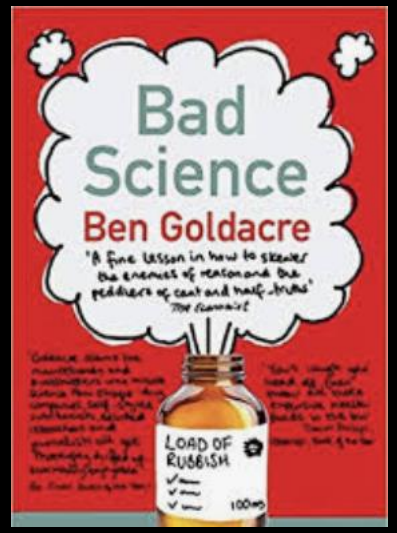
Analysis

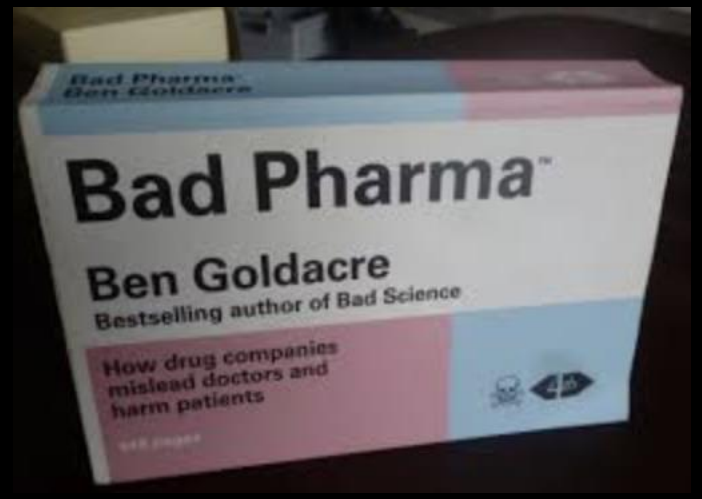
- MUST be pre-planned- especially outcome definitions
  - Should include interim analysis if long/large trial
- Intention to Treat
  - Full benefits of randomization maintained
  - Idea of ‘operational’ efficacy
  - Results may be not easily generalizable (e.g. health planners want to know if one/two vaccine doses given
- Per Protocol
  - Those not included may be selected group, e.g. SAEs, poorer- introducing bias.
  - *May* be acceptable if loss to follow up low and similar

Registration/protocol publication

- Why register?
  - Clinicaltrials.gov
- Protocol publication
  - Ensure transparency
  - Analysis
  - Publication bias
- Prevent duplication of effort
- Encourage collaboration

https://www.ted.com/talks/ben_goldacre_battling_bad_science/up-next





Policy Implications

Impact of introduction of rapid diagnostic tests for malaria on antibiotic prescribing: analysis of observational and randomised studies in public and private healthcare settings

BMJ 2017 ; 356 doi: https://doi.org/10.1136/bmj.j1054 (Published 29 March 2017)

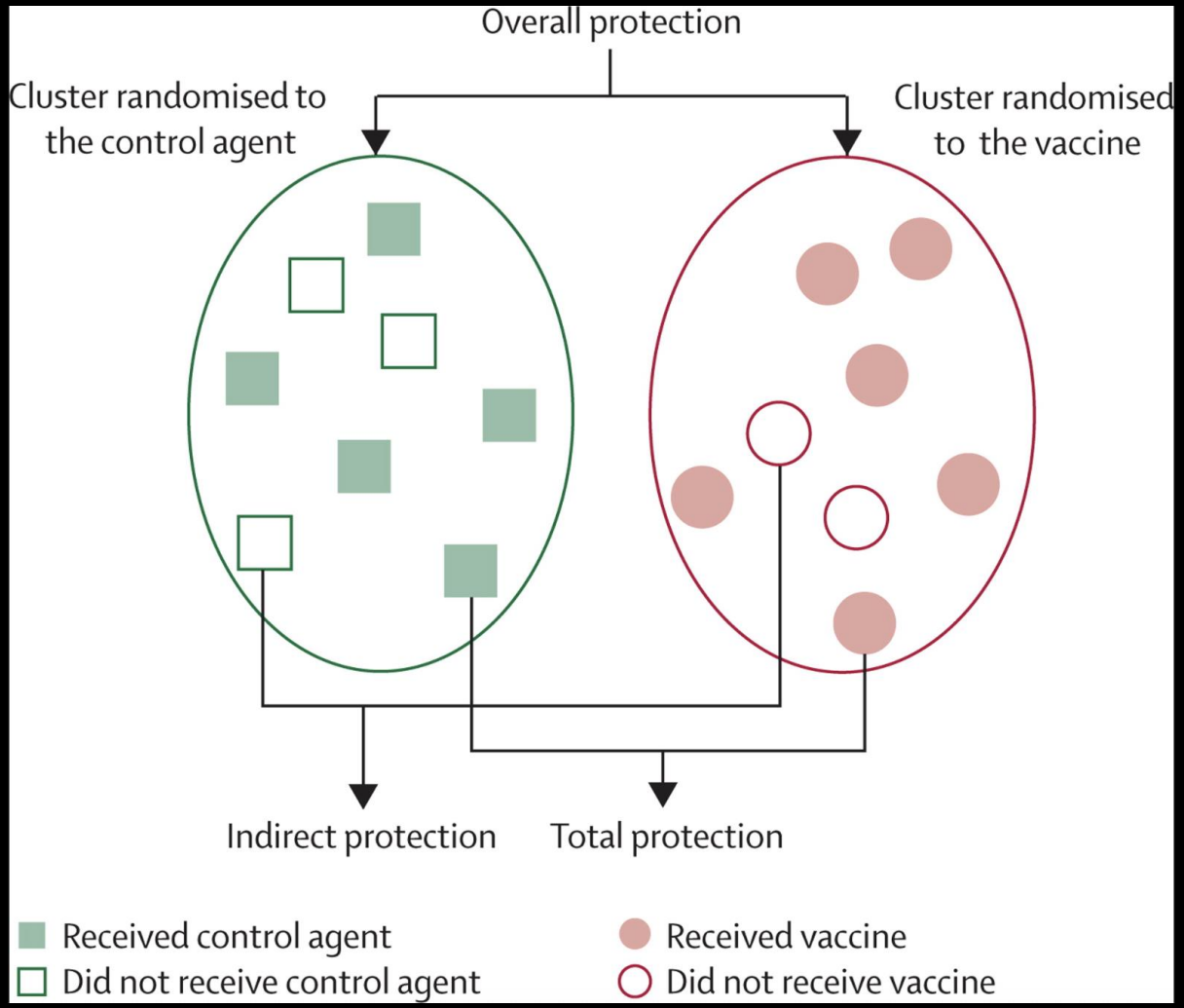
Beyond the double blind RCT…

Cluster randomization

- Intervention at cluster level
- Risk of ‘contamination’
- Similarity within clusters: design effect

Community randomization

- E.g. fluoridation

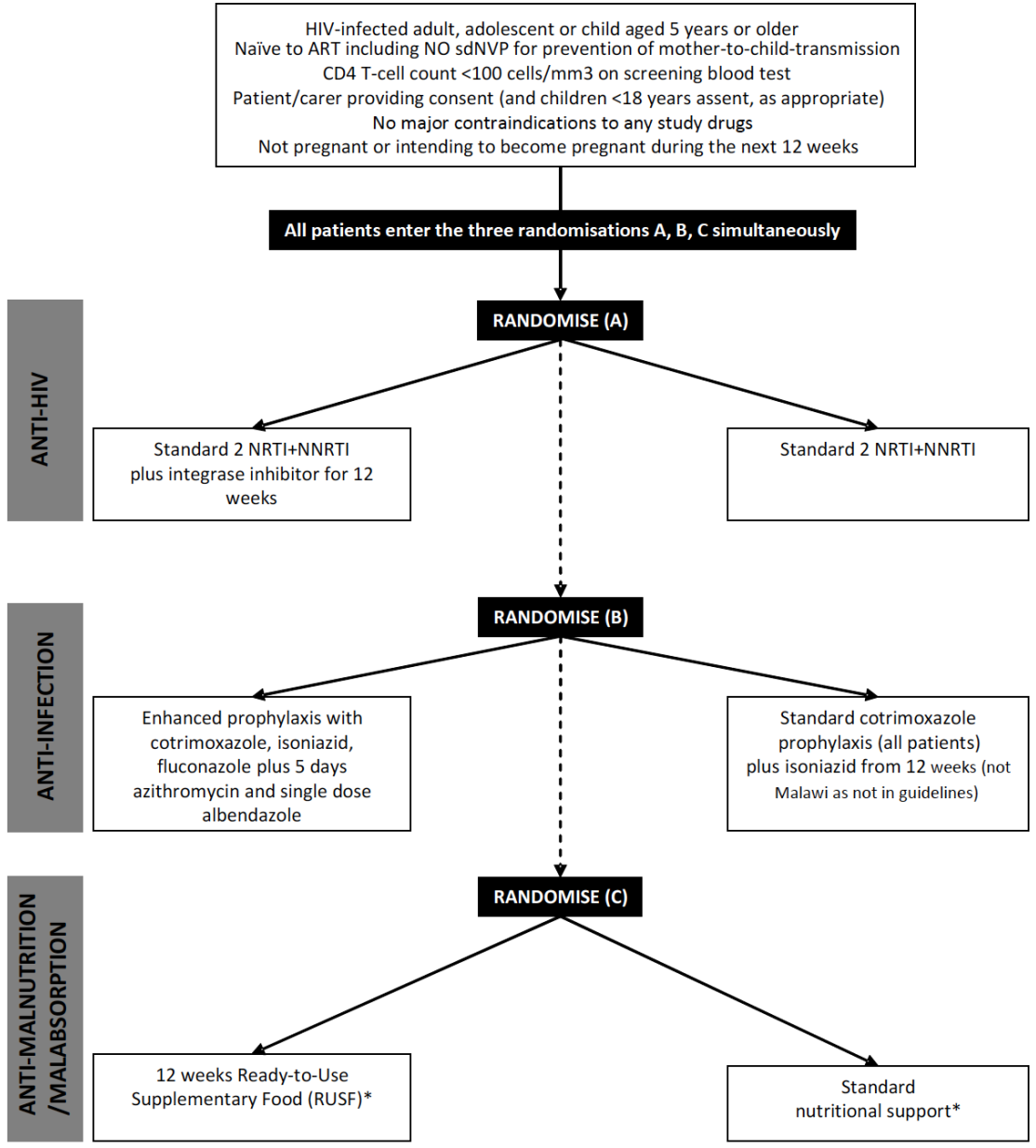


Clemens et al. Lancet ID, 2011

Factorial design (trials within trials)

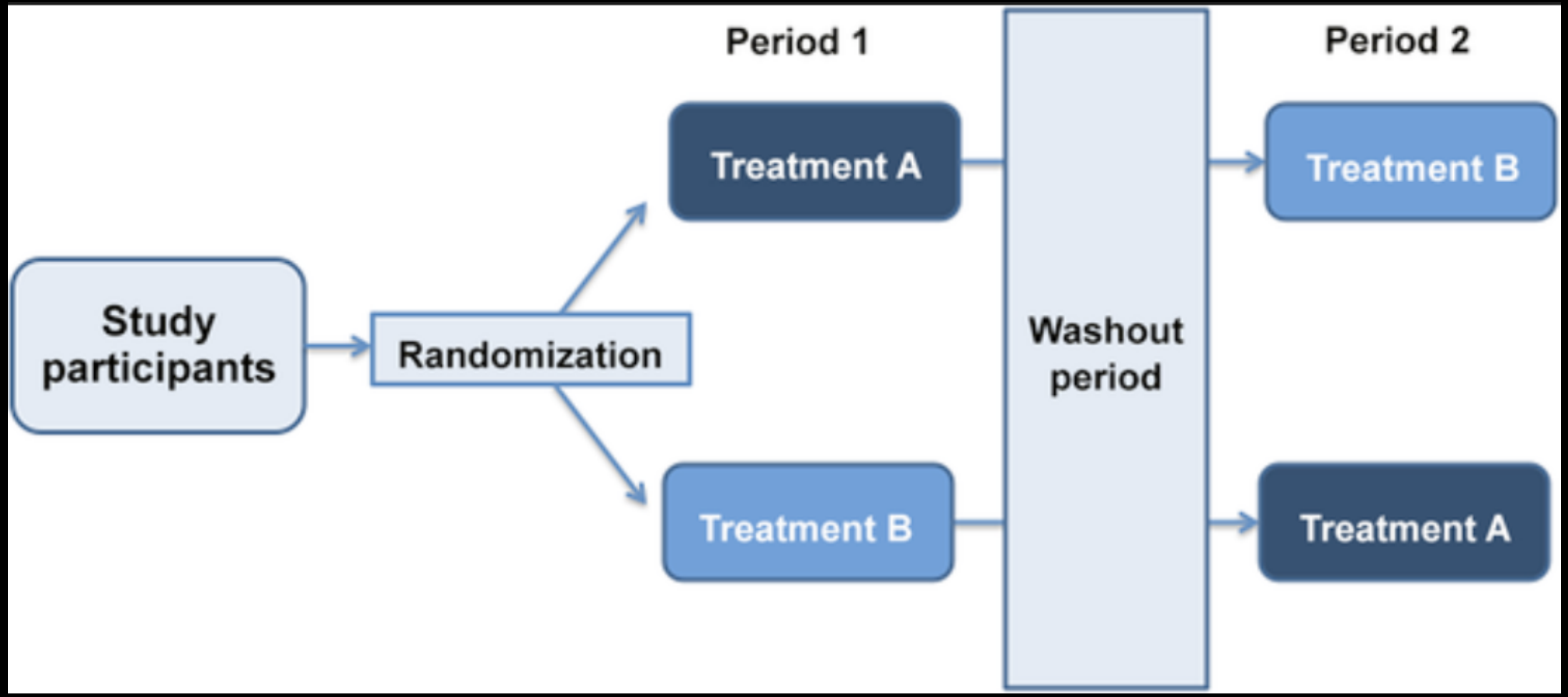
- Cost/time effective
- Assessment of package
- Complex to analyse

Figure 1. Trial Entry, Randomisation and Treatment



* all patients meeting criteria for Ready to Use Therapeutic Food will receive this, regardless of randomisation

Cross over trials



Unrandomised- is it an option?

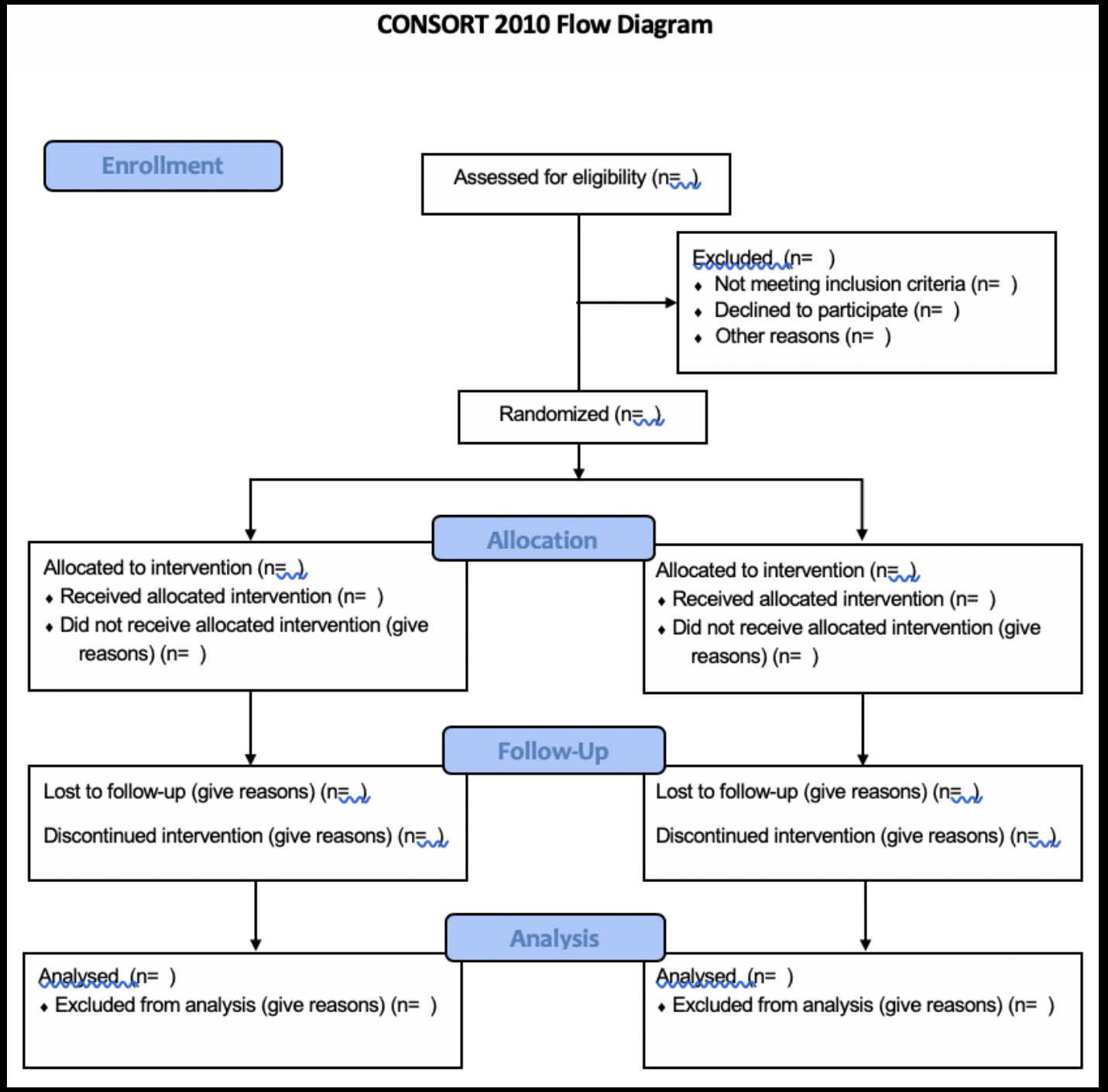
- Before/after studies
  - Affected by ‘secular trends’
  - Monitor other changes
  - Can be useful especially with health service evaluations
  - Monitor outcomes unlinked to intervention to see if they change
  - Monitor outcome in general as well as intervention population
- Non-randomized controlled trials
  - Vulnerable to bias/confounding
  - May suggest that intervention worth more rigorous assessments
  - Evaluation e.g. of mass media approaches
  - If stakeholders won’t allow interventions

CONSORT- Consolidated Standards of Reporting Trials

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	

CONSORT 2010 Flow Diagram



Summary

- RCTs high level primary evidence if well-designed- follow CONSORT
  - Representative of general population
  - Effectively randomized
  - Outcomes objective and/or robustly assessed
  - Analysis pre-planned (Intention to Treat if possible)
  - Registered and protocol published
- RCT types
  - Factorial, cluster, cross-over
- Non-randomized trials can also have merit if well designed