

# Study designs for implementation research



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# Do you consider yourself to be...

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Mentimeter

8



...an epidemiologist?

6



...a clinician?

11



...a social scientist?

3



...a policymaker or  
advocate?

12



...an implementation  
scientist?

11



I would say something  
else!

37 / 47



GA

Menti

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Mentimeter

# How familiar or confident do you feel with the following study designs and methods:



Not familiar or confidence

Very familiar or confident

10 44 / 47



GA

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### Choose a slide to present





# Overview

1

Common study designs

2

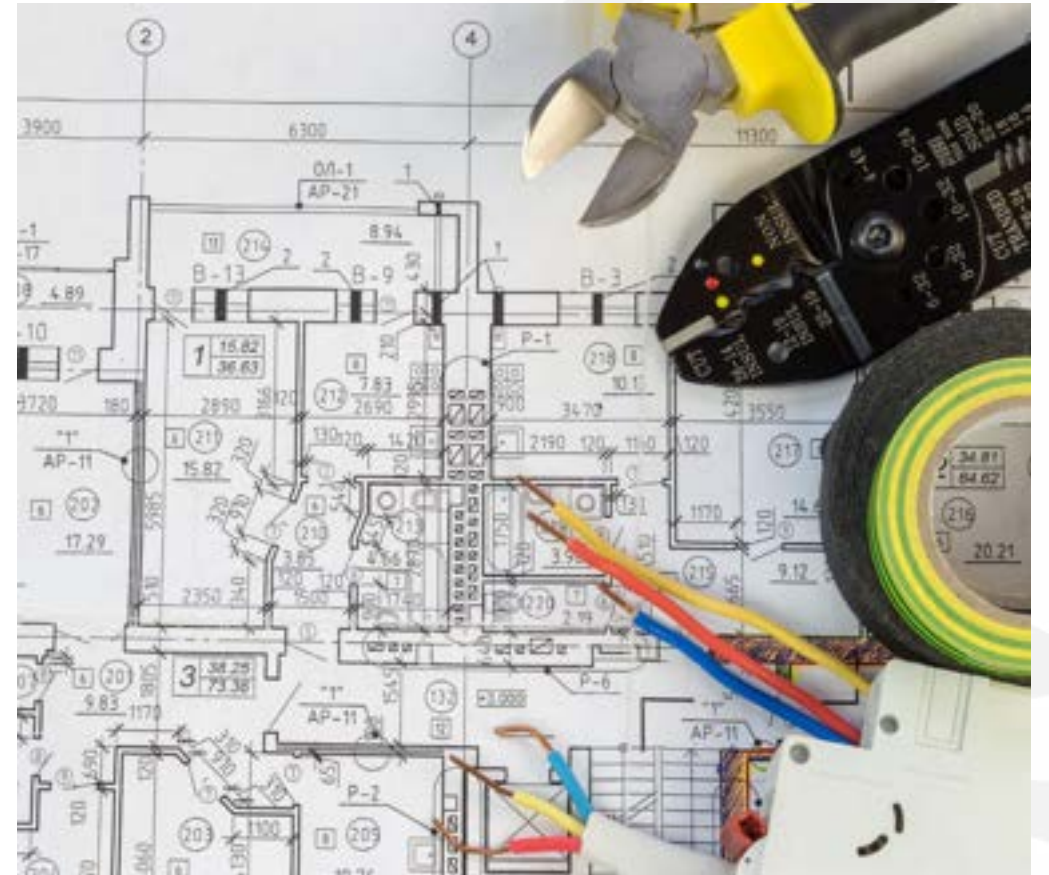
Decision-making crossroads

3

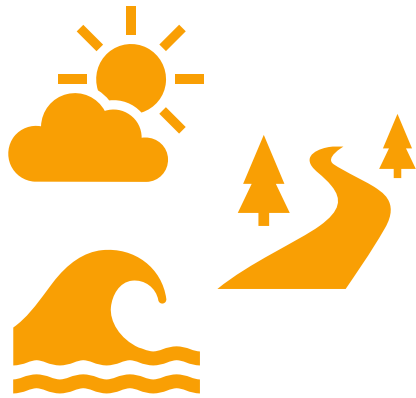
The impact of design choice

4

Key ideas

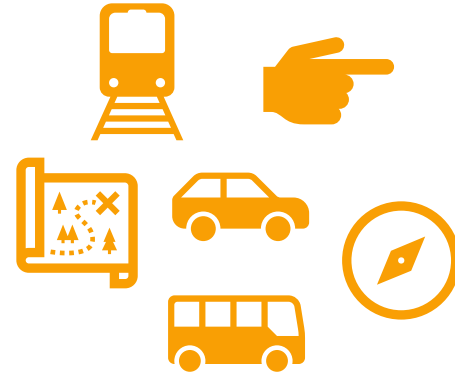


# What do we mean...?



## **STUDY DESIGN**

*The route to the destination*



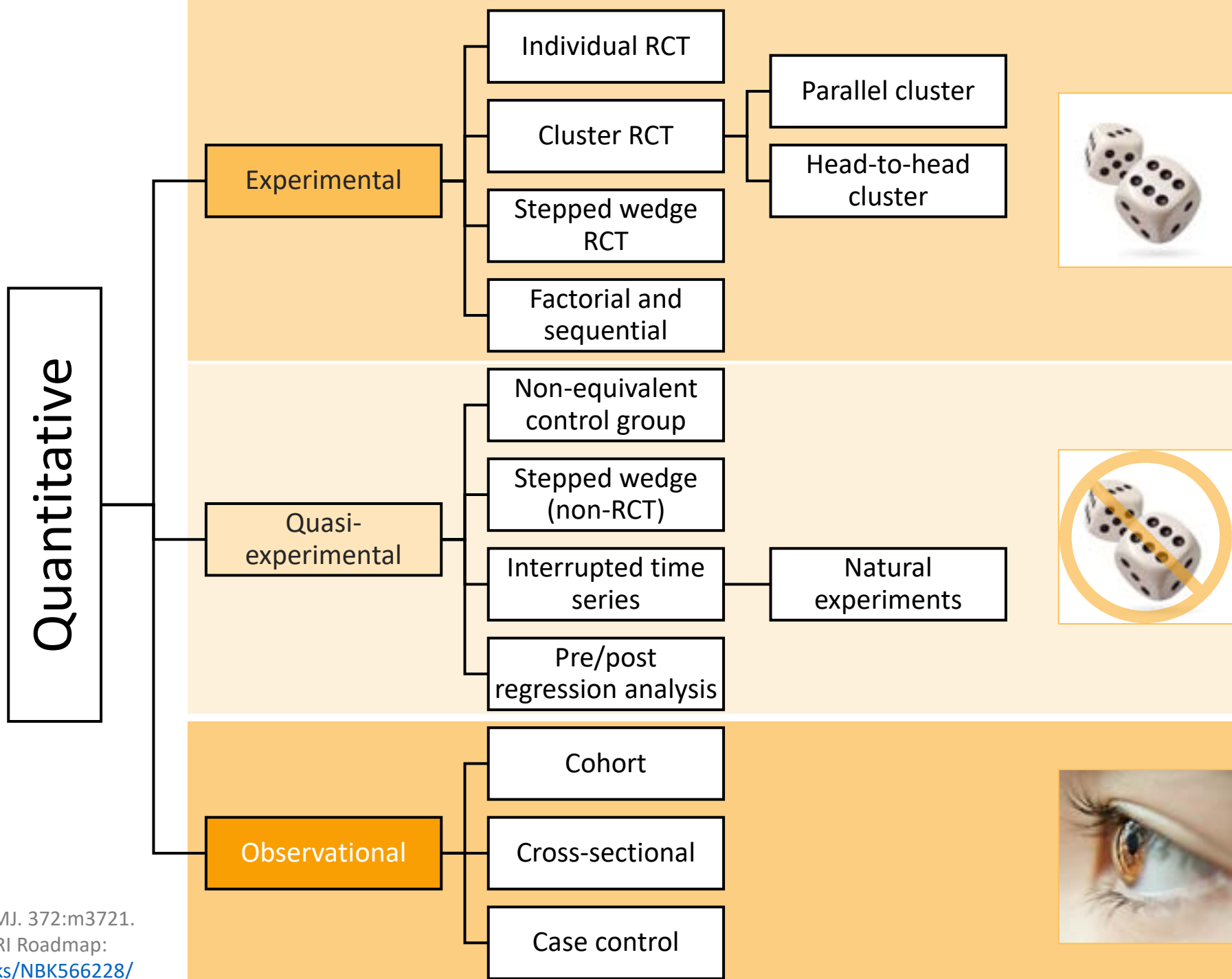
## **METHODS**

*Modes of transport and tools*

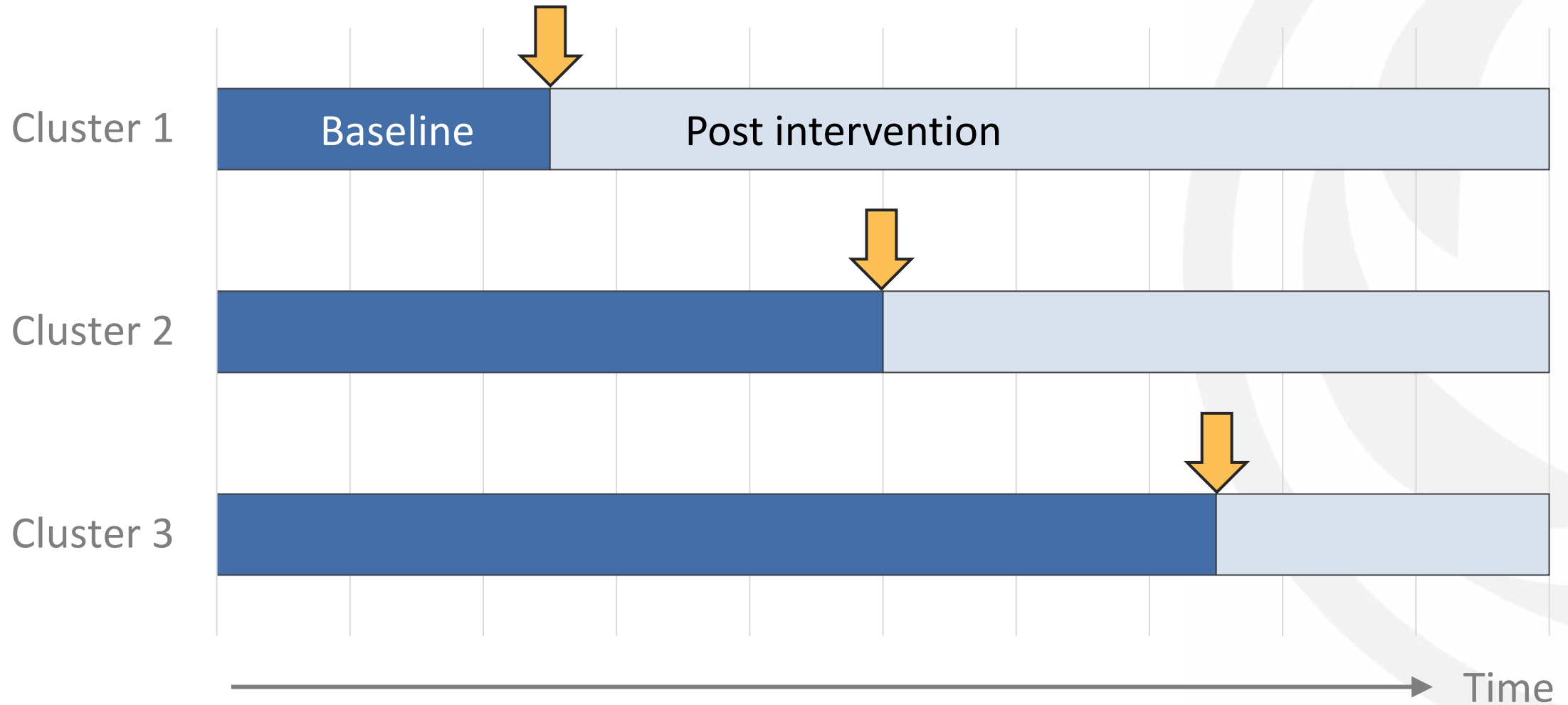


## **METHODOLOGY**

*The guiding philosophy*



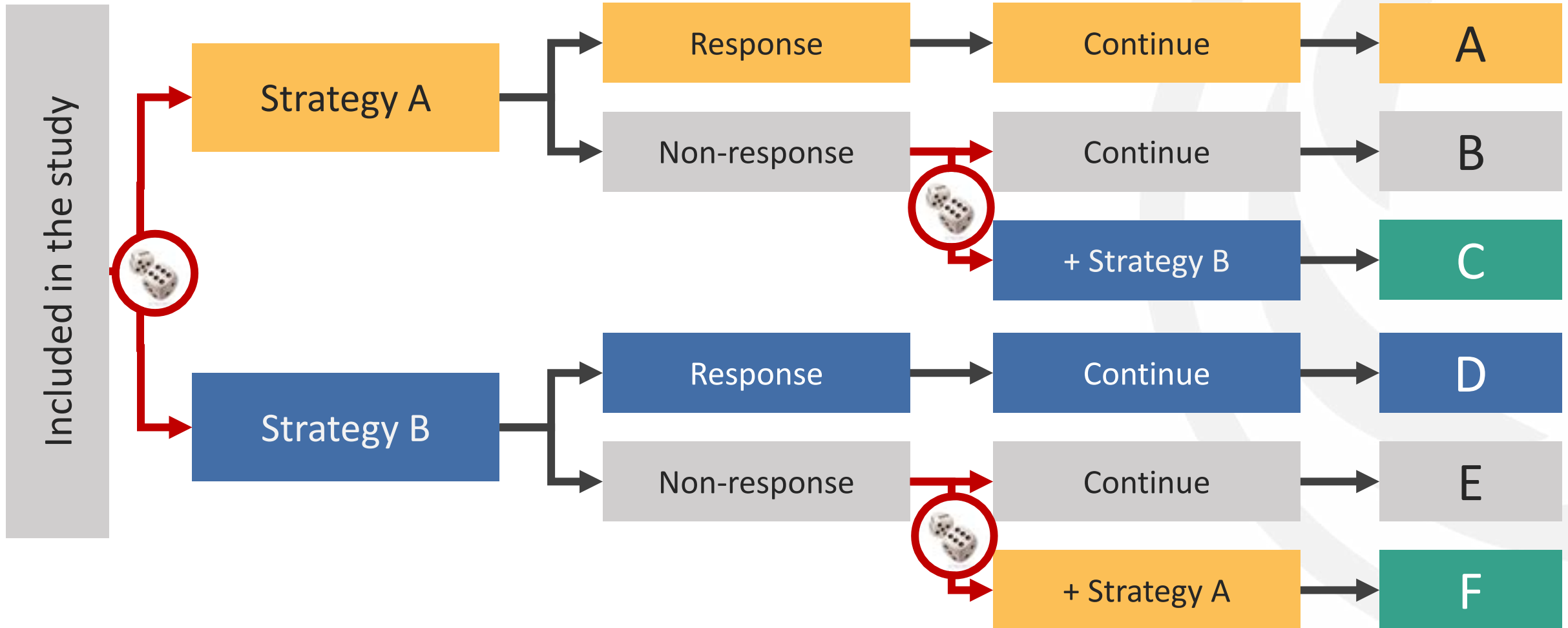
# Stepped wedge



# Factorial

		Implementation strategy A Example: SMS reminders	
		Low intensity Example: Monthly SMS	High intensity Example: Weekly SMS
		Yes	CONDITION 1  Monthly SMS + health worker training
Implementation strategy B  Example: Health worker training	No	CONDITION 3  Monthly SMS only	CONDITION 4  Weekly SMS only

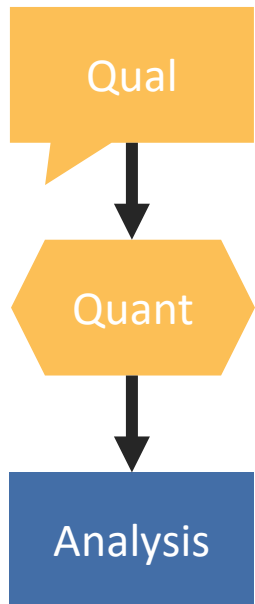
# SMART (Sequential multiple-assignment randomised trials)



# Mixed methods

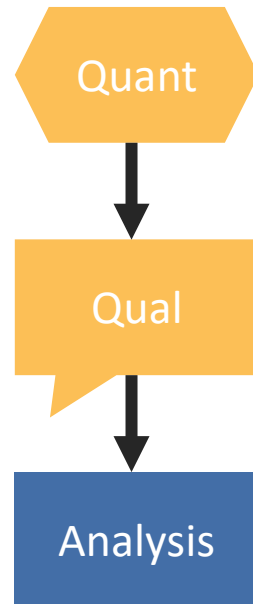
## Sequential explanatory

Qualitative data is collected first, followed by quantitative data to explain findings



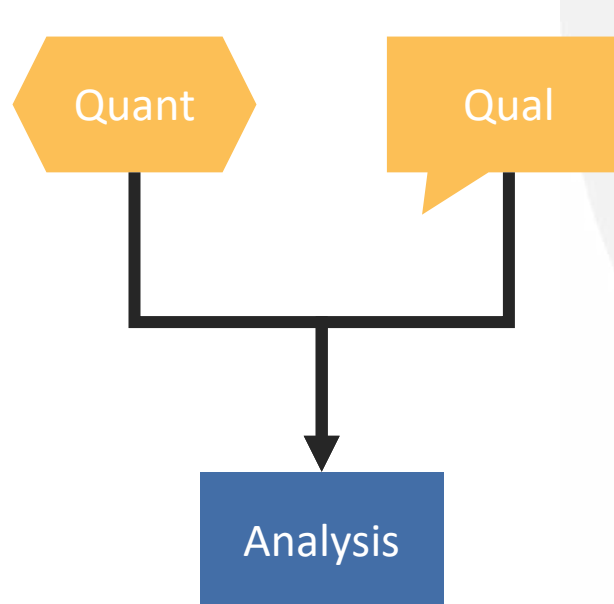
## Sequential exploratory

Quantitative data is collected first, followed by qualitative data to explore in more detail



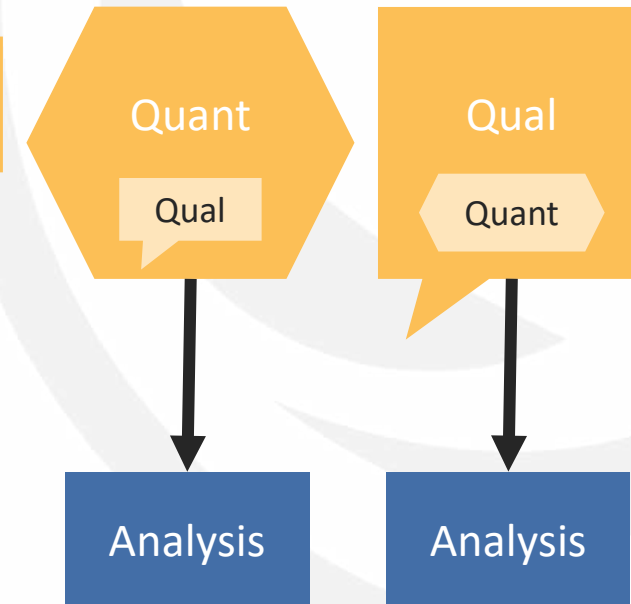
## Concurrent triangulation

Qualitative and quantitative data are collected simultaneously to verify findings



## Concurrent embedded

One data type is primary, while the other is secondary and used for support



Please edit this table according to the collective knowledge and experience at the table. What looks right to you? What edits would you add?

You can leave your edits anonymously, or you can write your name(s) here:

FIELD	FOCUS	EMPHASIS	CHARACTERISTICS	OTHER FEATURES? Please state:
...implementation science?	Understanding and addressing the barriers and facilitators to the adoption, implementation, and sustainability of evidence-based interventions, practices, and policies in real-world settings.	Pragmatic and applied research focused on how to effectively translate evidence into practice. Utilises mixed methods to study the process and outcomes. Considers the context, stakeholders, and system-level factors that influence implementation success.	Focuses on the 'how' of getting evidence into practice. Often conducted in real-world healthcare, community, or policy settings. Aims to improve the uptake and impact of interventions to benefit population health.	
...medicine?	Understanding the biological and physiological basis of health and disease, developing and evaluating diagnostic tools, treatments, and preventative measures for individual patients.	Rigorous, often reductionist, investigation into disease mechanisms at the molecular, cellular, and organismal levels. Strong emphasis on clinical trials to establish efficacy and safety of interventions.	Often involves studying human subjects and their biological samples. Adherence to ethical guidelines. Strong value placed on evidence-based practice.	
...public health?	Understanding and improving the health and wellbeing of populations and communities. Investigating the social, environmental, behavioural, and biological determinants of health. Developing and evaluating interventions and policies at the population level.	Epidemiological approaches to identify patterns of disease and risk factors in populations. Focus on prevention, health promotion, and reducing health disparities. Often interdisciplinary collaboration with social scientists, environmental scientists, and policymakers.	Studies large groups of people. Considers contextual factors and social determinants of health. Aims to translate research into health programmes and policies that benefit entire communities.	

FIELD	FOCUS	EMPHASIS	CHARACTERISTICS	OTHER FEATURES? Please state:
...social science?	Understanding behaviour, interactions, and societies. It examines individuals, groups, institutions, and systems, exploring how they operate, develop, and influence the world around them. This includes culture, economics, politics, history, geography, and psychological processes.	Systematic analysis and explanation of social phenomena. Emphasis on research-based enquiry using diverse methods (qualitative and quantitative) and critical thinking to understand human behaviour and societal structures. Aims to provide insights for policy and societal improvement.	Human-centred and often interdisciplinary, addressing complex issues. Findings are typically context-dependent and dynamic, reflecting the variability of human societies. Employs a wide range of methodologies and strives for objective analysis within complex social contexts.	
...psychology?	Understanding mental processes, behaviour, and experience at the individual and group levels. Investigating topics ranging from basic cognition and emotion to social interactions and <u>psycho-pathology</u> .	Application of the scientific method to study the mind and behaviour. Utilises both quantitative and qualitative methods. Strong focus on theoretical frameworks to explain psychological phenomena.	Examines individual differences and commonalities in mental processes and behaviour. Strives for objectivity, reliability, and validity in its findings. Considers the interplay of biological and social factors.	
...data science?	Extracting knowledge and insights from data using computational and statistical methods, identifying patterns, trends, and predictions from large and complex datasets.	Application of algorithms, machine learning techniques, and statistical modelling to analyse data. Focus on data collection, cleaning, processing, and visualisation. Often involves working with 'big data' from diverse sources.	Data-driven approach. Relies heavily on computational power and statistical expertise. Aims to discover hidden patterns and make predictions. Applicable across various domains, including health.	
Another field? Please state:				

# LC19 ISOBAR

Implementing Early Mental & Physical Health  
Detection & Support: Promoting a Whole-School  
Approach to Health and Well-being

Focus	Mental health
Country	Nigeria, India
Population	Youth aged 12 to 18
EBI*	Hub-and-spoke model of trained school counsellors to provide mental health literacy, physical and mental health screening and appropriate support



\*EBI, evidence-based intervention being implemented

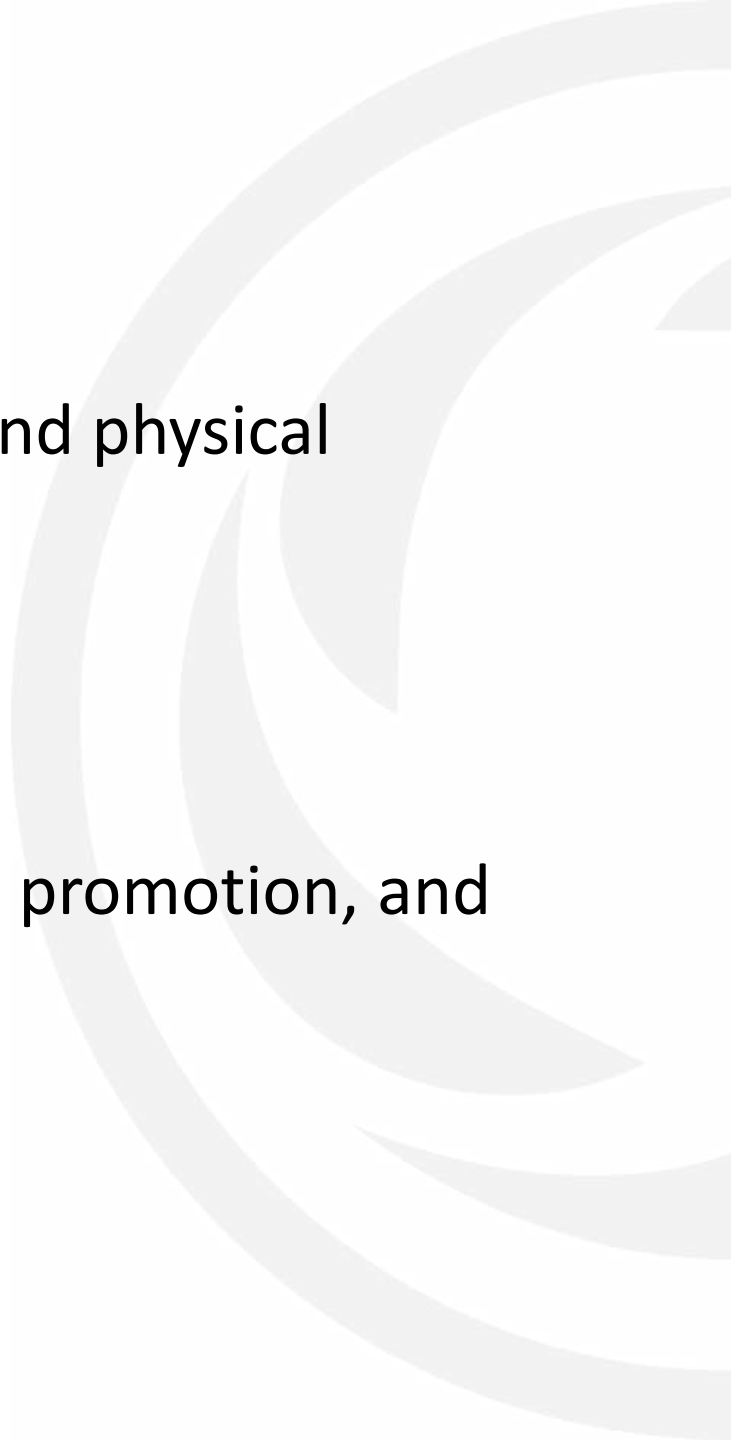
# Background

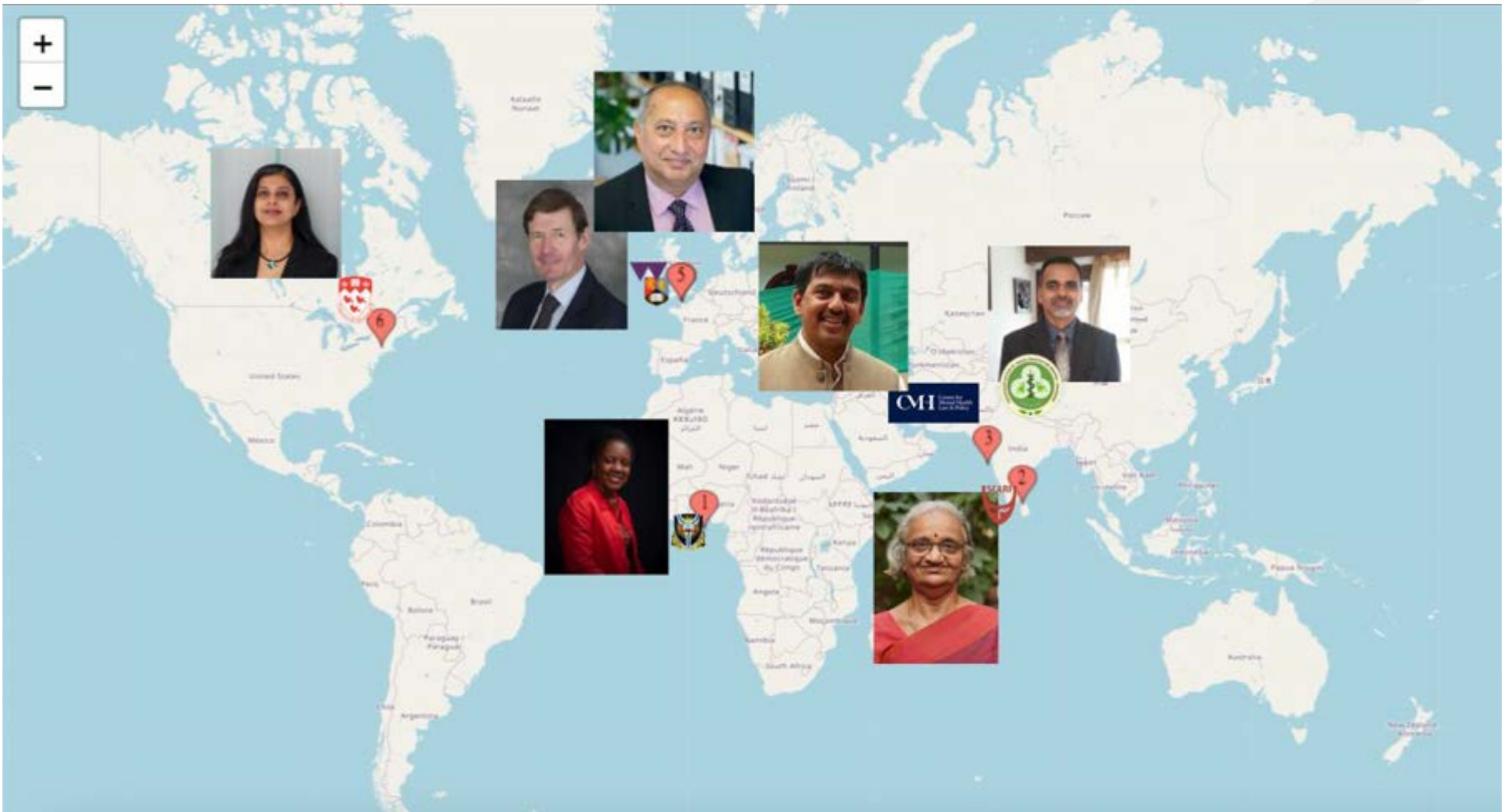
- Adolescence is a critical time for physical and mental health development<sup>1</sup>
- LMICs face a growing burden of NCDs and mental health conditions beginning in youth<sup>2</sup>
- Most adolescents in LMICs have limited access to preventive or early intervention services<sup>2</sup>
- Schools offer a unique platform for health promotion and early intervention

# Challenges with Current School-Based Interventions

- Fragmented approaches<sup>3,4</sup>
- Often ‘imported’ models from high-income countries
- Weak implementation
- Rarely scaled due to lack of pragmatic implementation evidence
- Implementation barriers can exist at individual<sup>5</sup>, organisational<sup>6</sup>, and community<sup>7</sup> levels

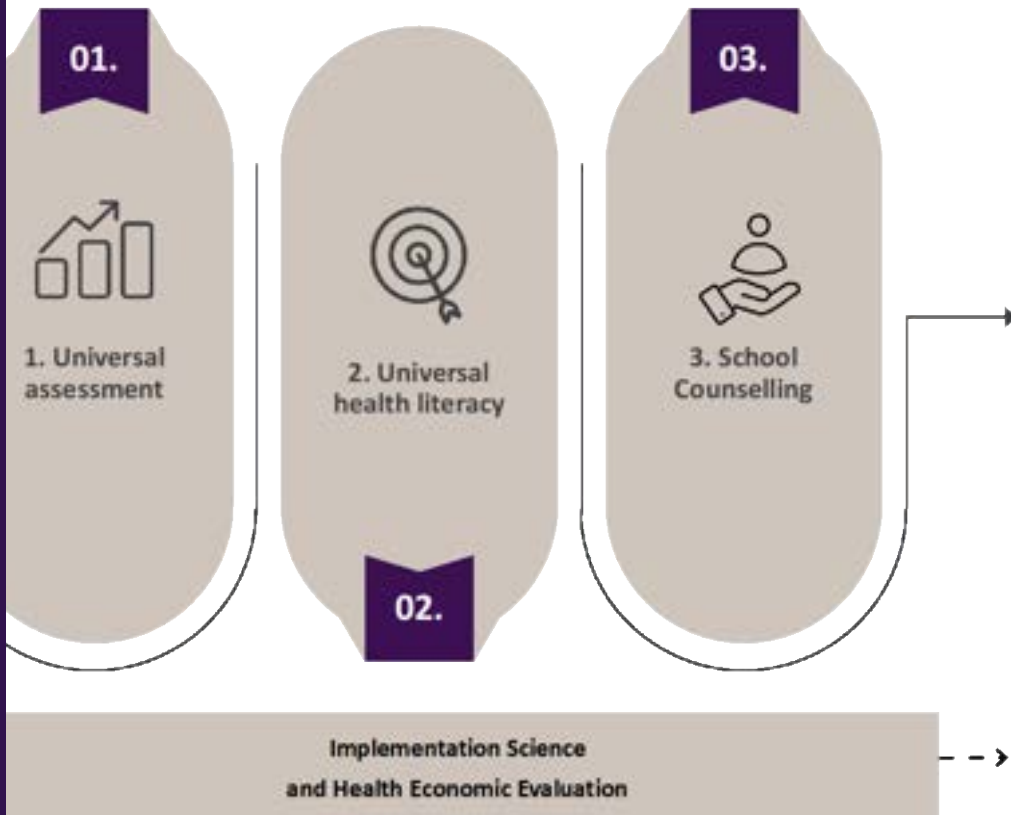
# About ISOBAR

- A school-based intervention for adolescent mental and physical health
  - Three sites:
    - India (South and North)
    - Nigeria (Ibadan)
  - Integrates universal assessments, health literacy and promotion, and targeted counselling
  - Grounded in implementation science principles
- 



# The Three Components of the School-based Intervention

-  Physical wellbeing
-  Nutrition
-  Physical activity
-  Mental wellbeing
-  Mental health/illness
-  Stress, relationships  
Coping mechanisms,  
treatment, recovery,  
help-seeking



## Implementation Science Measures

-  **Acceptability of Intervention Measure (AIM)**  
Assess the acceptability of the intervention
-  **Intervention Appropriateness Measure (IAM)**  
Assess the appropriateness of the intervention
-  **Normalisation Measure Development Questionnaire (NoMAD)**  
Assess integration of the intervention into routine practice
-  **Screening and process forms**  
Monitor implementation progress and fidelity
-  **Implementation logs**  
Document adaptations and challenges
-  **Focus groups**  
Explore implementation experiences
-  **Semi-structured interviews**  
Identify implementation barriers and facilitators
-  **Cost tracking forms**  
Track costs of intervention activities

# Our study design

- Type: Hybrid Type 2 Implementation-Effectiveness Study
- Design Elements:
  - Staggered roll-out
  - Universal + targeted + referral components
- Three phases:
  - Pre-intervention → Implementation → Post-evaluation
- Populations:
  - Three schools at each site
  - ~1,800 adolescents across nine schools



# Why a Hybrid Implementation-Effectiveness Design?

1. Logistically feasible across multi-country, multi-site settings
2. Ethical: no students/schools are denied the intervention
3. Allows both between-group and within-group comparisons
4. Supports real-time learning and adaptation
5. Common in pragmatic, implementation-focused programs in LMICs

# Some learnings

- "implementation science" views success differently than efficacy trials
  - uptake, feasibility, and system readiness matter
- Theory-driven design and guided by implementation assessment frameworks (CFIR, RE-AIM)
  - Think “meta-data”

# Thank you for listening & some acknowledgements

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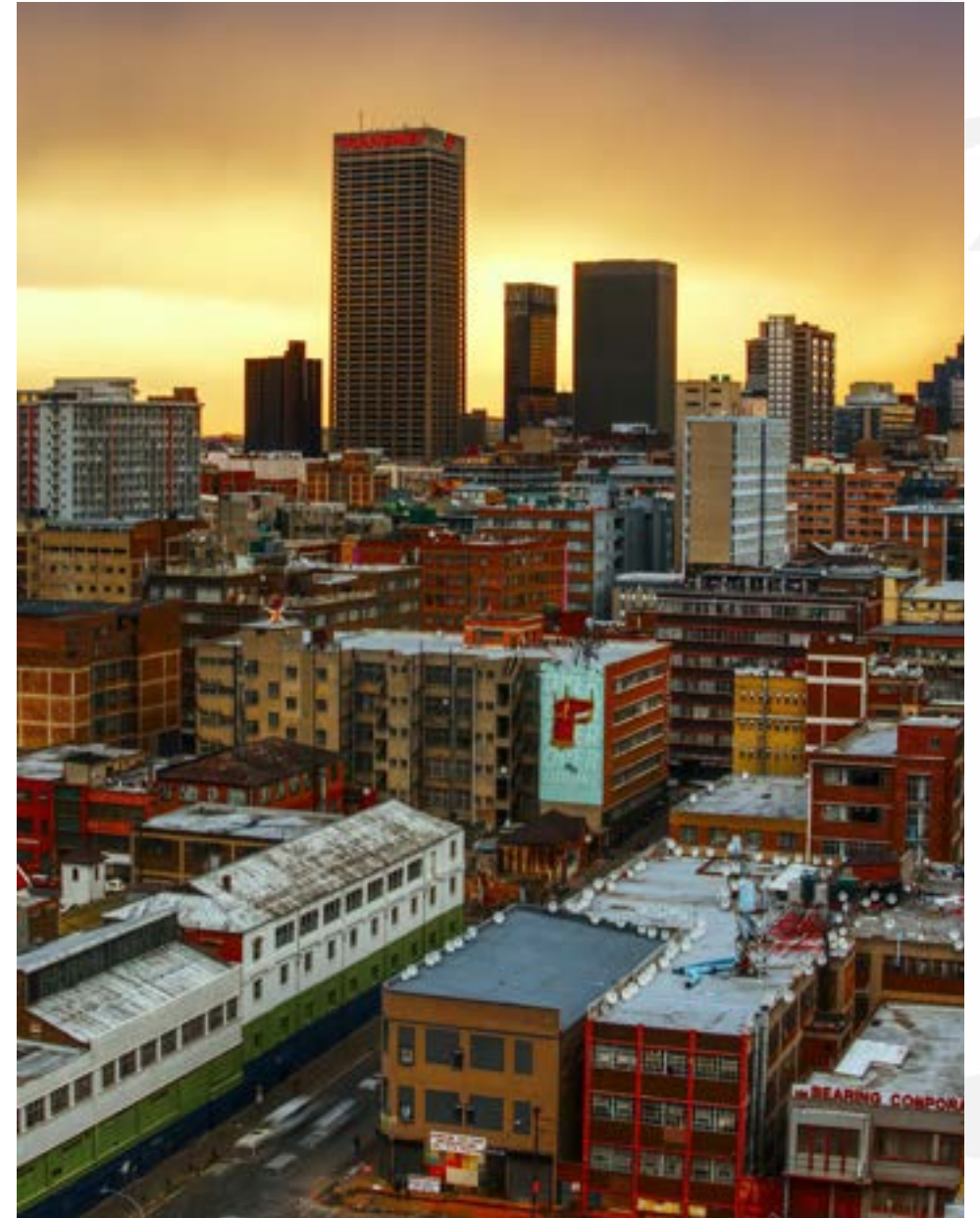
And all teachers, staff, participants,  
young people, parents!

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under the Global Alliance for Chronic  
Diseases (GACD) Life Course Research  
Programme

# HC08 Healthy Jozi

A Staged Approach to Better Workplace Food Choices and Chronic Disease Screening and Linkage to Care

Focus	hypertension, diabetes
Country	Johannesburg, South Africa
Population	Employees at risk of NCDs living/working in deprived inner-city areas
EBI*	Work-based screening and healthy food choice programme





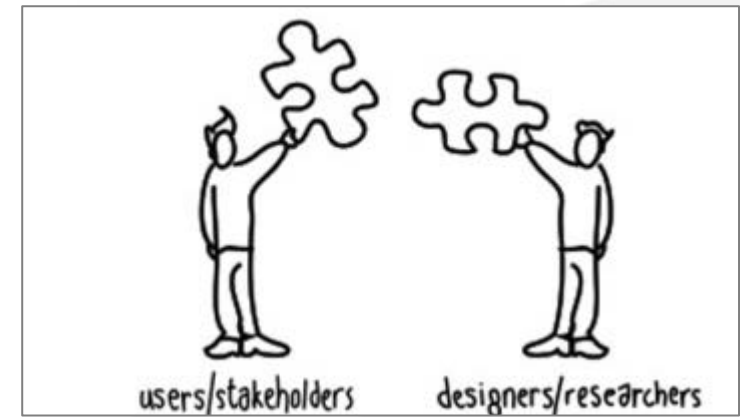
# WHAT IS HEALTHY JOZI?

## Aim

To co-design, implement, and rigorously evaluate workplace-based interventions in inner-city Johannesburg to:



- Improve screening and linkage-to-care for hypertension and diabetes
- Promote healthier food choices among employees



# PLANNED DESIGN

(multi phased, multi-component)

## Activities include:

- Contextual inquiry and discrete choice experiments (DCE) to understand behavioural barriers and preferences
- Human-centred design (HCD) workshops to co-design intervention components
- Prototyping and iterative refinement of interventions within the Behavioural Hub (B-Hub)
- Stakeholder engagement and feedback to finalize the intervention package

## Phase 1: Exploration and preparation

Mixed-methods research to identify barriers, facilitators, and preferences

Chronic disease screening, linkage to care, and healthy food choices in Johannesburg workplaces

Utilizes the EPIS and CFIR frameworks

## Phase 2: Implementation and evaluation

Cluster-randomised factorial trial across 52 facilities (26 intervention, 26 control)

Implementation of the co-designed “Healthy Jozi” approach, combining staged screening/linkage interventions with a healthy food choices programme

Control sites receive minimal screening and lifestyle information

## Evaluation focuses on:

- Number of employees screened for hypertension
- Percentage successfully linked to care
- Uptake and satisfaction with each intervention component, referral preference, reported changes in food choice
- Costing/ economic evaluation

# WHY THE SELECTED STUDY DESIGN/APPROACH

Design element	Rationale
Screening, linkage, and food choices	Targeting key gaps: The largest failures in NCD care are at the initial stages—screening and linkage to care. HIV programmes showed that closing these gaps yields the greatest impact. Knowledge of one’s condition can drive positive behaviour change
Workplace-based intervention	High reach, diversity, existing infrastructure, sustainability potential
Staged approach	Maximizes reach and efficiency, targets key programme gaps
Discrete choice experiment	Understand how people make decisions between alternatives that differ across multiple attributes (e.g. convenience, time, cost)

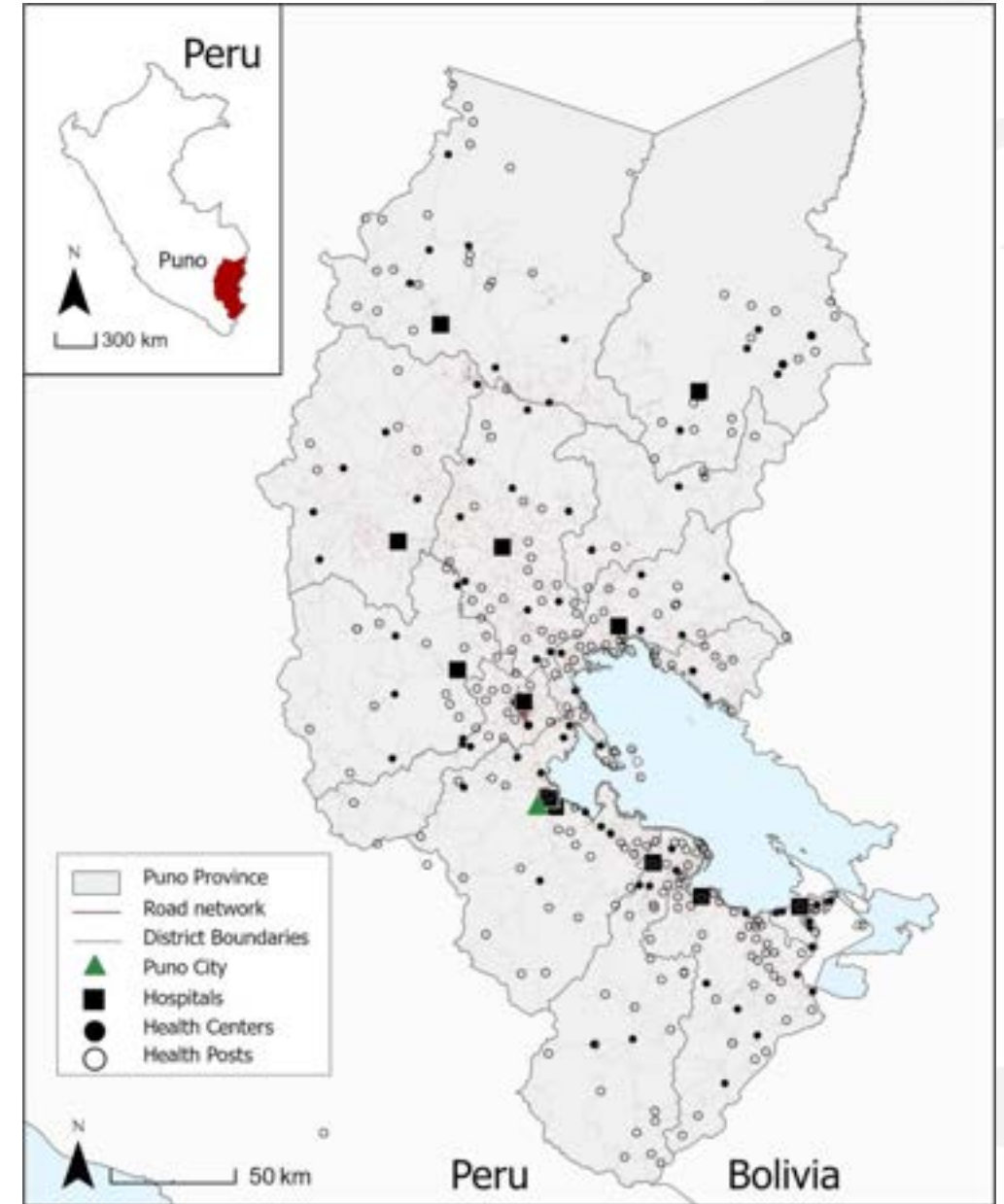
# WHY THE SELECTED STUDY DESIGN/APPROACH

Design element	Rationale
Human-centred design	Behavioural insights and discrete choice experiments ensure interventions are tailored to real-world barriers and motivators. Ensures interventions are acceptable, relevant, and user-driven
Cluster-randomised trial	Minimizes contamination, reflects real-world delivery
Factorial design	Assesses individual and combined effects of interventions, informing future scale-up and policy
Implementation science lens	Identifies barriers, supports adaptation and scale-up/sustainability planning

# SU27 ANDES Study

Addressing Hypertension and Diabetes through  
Community-Engaged Systems in Puno, Peru

Focus	Hypertension, diabetes
Country	Peru
Population	Adults aged 18+ living with hypertension
EBI*	Multicomponent intervention to reduce blood pressure in a high-risk population



\*EBI, evidence-based intervention being implemented

# WHY ANDES?

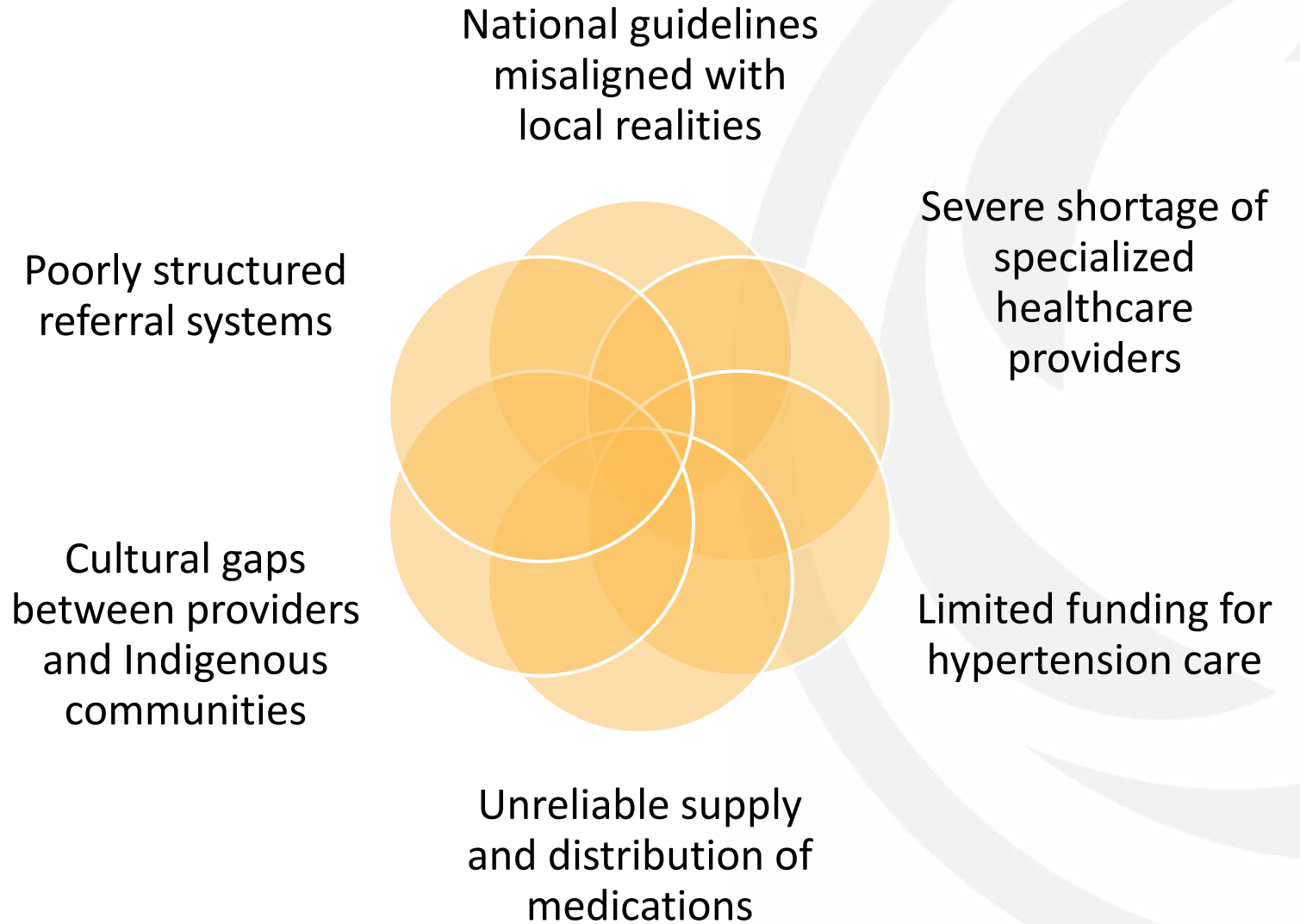
**1. Peru has a critically low HBP control:**



Proportion of patients  
with controlled hypertension.

# WHY ANDES?

## 2. Multiple health system and contextual barriers:



# WHY ANDES?



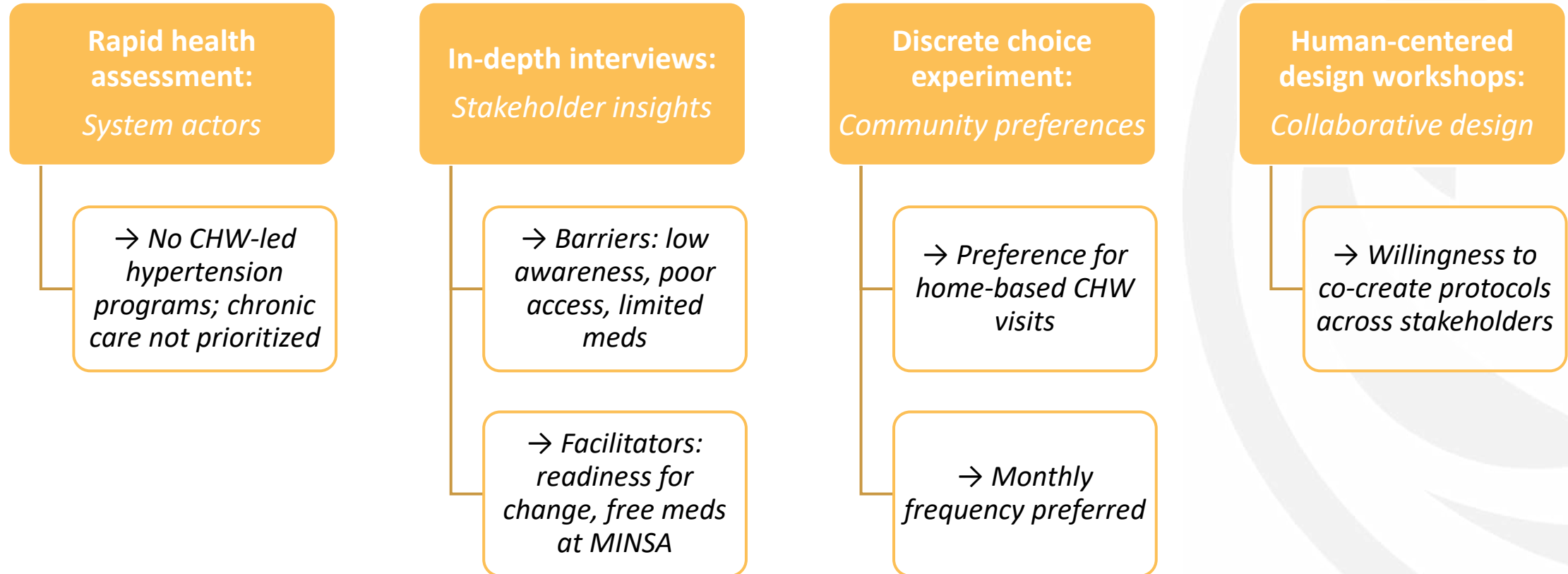
Technical package for cardiovascular disease management in primary health care



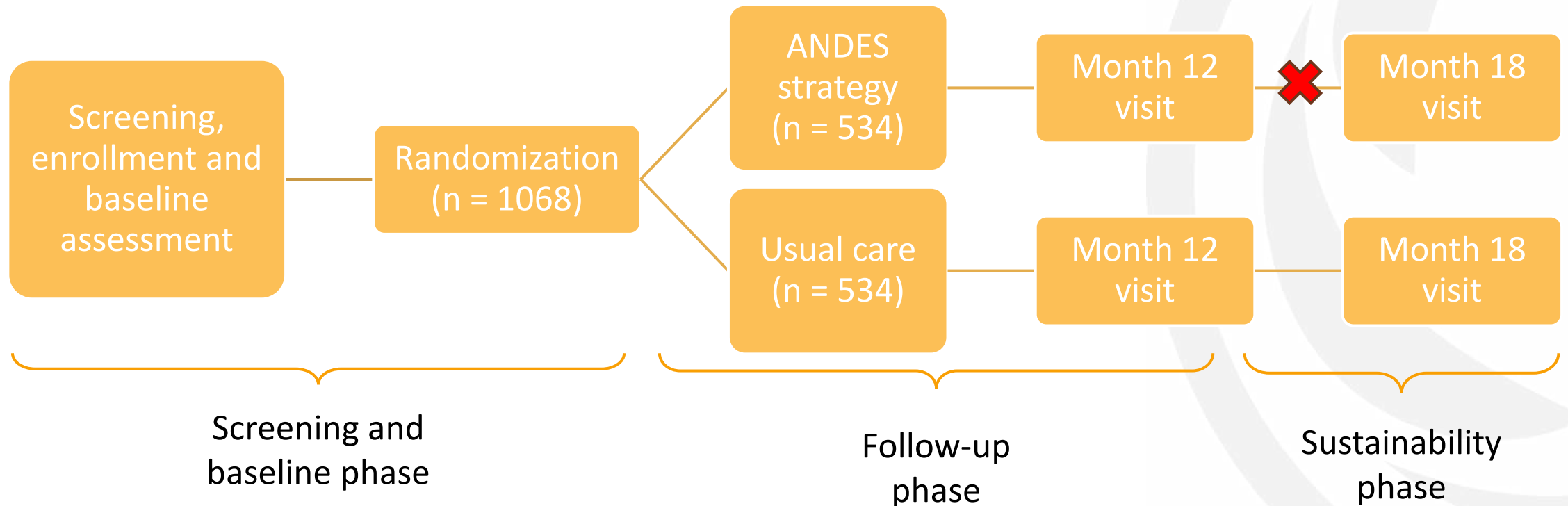
## 3. HEARTS initiative:

Healthy lifestyle counseling	→ Home visits with CHW-led personalized lifestyle counseling
Evidence-based treatment protocols	→ BP monitoring at home aligned with national/WHO guidelines
Access to essential medicines and technology	→ Personalized adherence support + access tools (pillboxes, calendars)
Team-based care	→ Health facility + CHW-led, team-based hypertension care
Systems for monitoring	→ Performance tracking via CHW + health facility reporting

# STUDY DESIGN: FORMATIVE RESEARCH



# STUDY DESIGN: HYBRID CLINICAL TRIAL



# DESIGN RATIONALE

- HEARTS has previously shown effectiveness in other populations.
- But contextual validation of **effectiveness** in rural, high-Andean settings was essential.
- We included **Implementation outcomes**: fidelity, acceptability, and sustainability.
- Goal: generate policy-relevant evidence to inform national scale-up.

# HYBRID CLINICAL TRIALS: WHAT ARE THEY?

Effectiveness



Implementation



**Hybrid clinical  
trials**

# HYBRID CLINICAL TRIALS: SUBTYPES

Characteristic	Type 1	Type 2	Type 3
Primary focus	Clinical effectiveness	Both (effectiveness + implementation)	Implementation outcomes
Also evaluates	Implementation outcomes	-	Clinical effectiveness
Example	Tula trial: Patient-level RCT focused on clinical effectiveness; also evaluated implementation strategies.	ANDES trial: Patient-level RCT focus on clinical effectiveness and implementation strategies equally	DIGITS trial: Clinic-level RCT where primary outcomes were implementation; clinical effectiveness was secondary.

# What influences decision making for your project's study design?



Research question



Resources



Data availability



Funding



Ethics



Team expertise



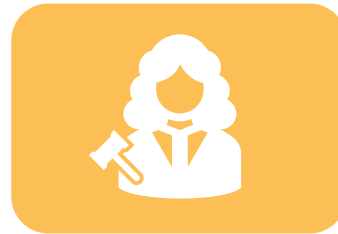
Sample size



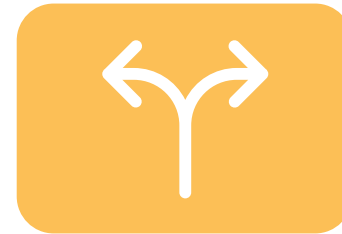
Equipose



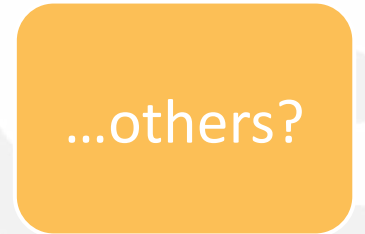
Time



Policy drivers



Internal vs external validity



...others?


# Question to discuss...

- What influences decision making in your project's study design?
- How does study design affect project practicalities?
- What could lead to a mismatch between design and practical feasibility?



What influences  
decision making in  
your project's study  
design?

**DISCUSSION 1**



How does study  
design affect project  
practicalities?

**DISCUSSION 2**

Researchers chose a **Hybrid Type 2** design to test a new evidence-based clinical intervention for managing chronic disease within primary care.

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## Impact on Practicalities



### **Balancing Dual Objectives**

Collected both clinical and implementation outcomes



### **Resource and Time Considerations**

Increased resources required for concurrent interventions



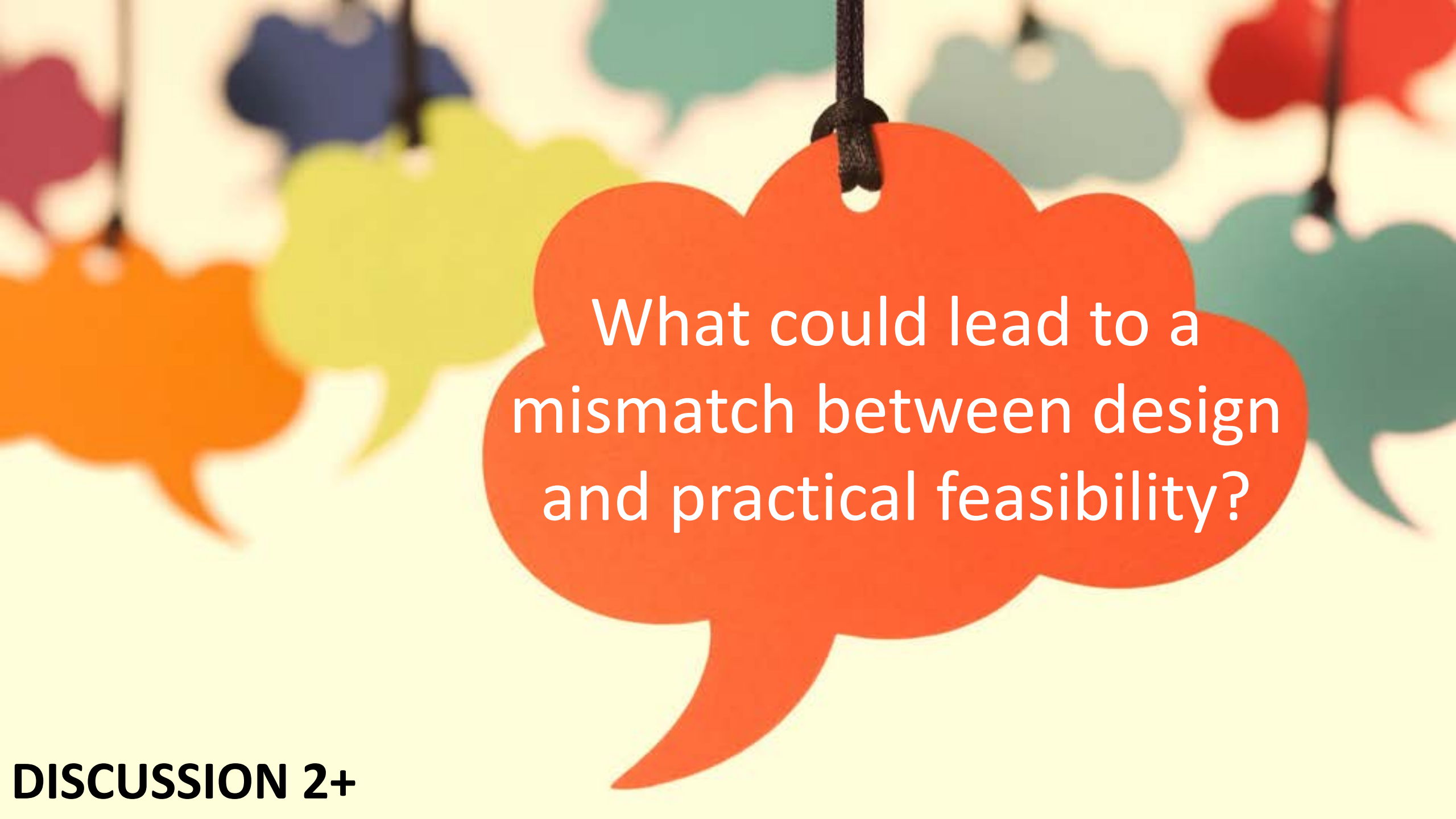
### **Contextual Adaptations**

Adapted implementation strategy based on feedback



### **Enhanced Relevance and Uptake**

Insights facilitated quicker



What could lead to a mismatch between design and practical feasibility?

**DISCUSSION 2+**



**Key ideas**