Intervention Development Science

Do we need it? What would it do?

Prof Cathy Zimmerman

Request for Proposals

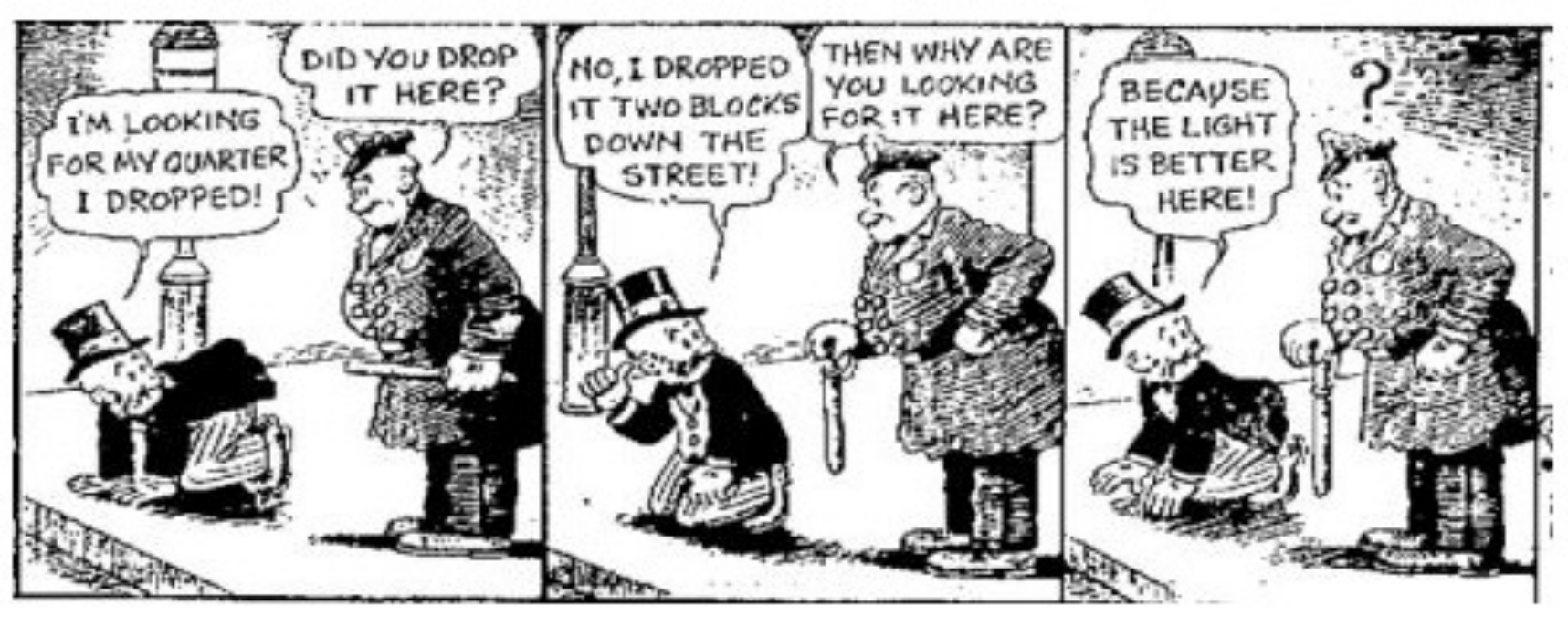
What intervention will you propose?

Hazardous child labour

Child domestic work

Forced marriage

Will we do what seems do-able or what is needed? The *streetlight conundrum*



"There is the risk that research questions and designs favoured by methods guidance and funders are those that have a **greater probability of a certain answer even though the question may be of less importance"**

(Skivington, et al 2021)

Measuring: Is it really ready for evaluation?

Evidence to *design* an intervention

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What do we need to know to know what to do?

What evidence do we need to develop a good prototype? And, how do we get it?

How do we determine who and what is most important?

Specific target group

Determinants of the problem

How do we know what to do?

Effective intervention content and mechanisms

How will we collect the evidence for a good prototype?

R&D

What are complex systems and complex social problems ?

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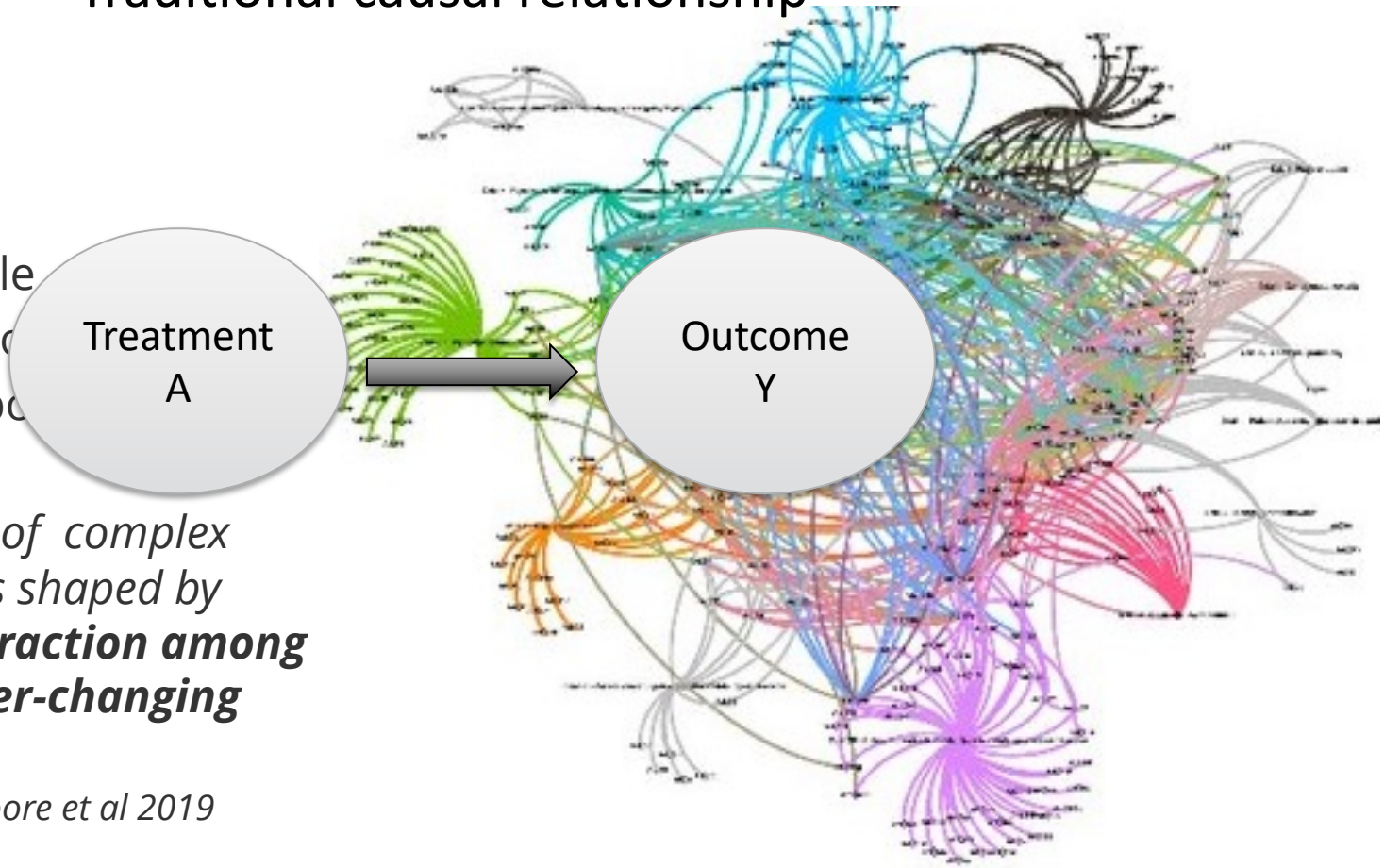
Traditional causal relationship

- Non-linear
- Dynamic
- Interactive
- Unpredictable
- Emergent pro
- Permeable bo



The functioning of complex social systems is shaped by patterns of ***interaction among diverse and ever-changing agents.***

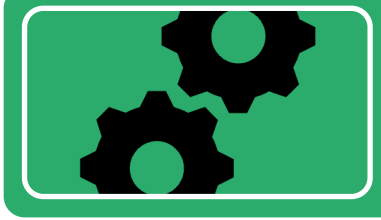
Moore et al 2019

Evaluation Stages

Intervention Development Science

Pilot Test

Intervention Trial



Implementation Science

Nascent area of methods development

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NIHR | National Institute for Health Research

Journals Library

Check for updates

Health Technology Assessment

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Framework for the development and evaluation of complex interventions: gap analysis, workshop and consultation-informed update

Kathryn Skivington, Lynsay Matthews, Sharon Anne Simpson, Peter Craig, Janis Baird, Jane M Blazeby, Kathleen Anne Boyd, Neil Craig, David P French, Emma McIntosh, Mark Petticrew, Jo Rycroft-Malone, Martin White and Laurence Moore

DOI 10.3310/hta25570


RESEARCH METHODS AND REPORTING

OPEN ACCESS

Check for updates

A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance

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The UK Medical Research Council's widely used guidance for developing and evaluating complex interventions has been replaced by a new framework, commissioned jointly by the Medical Research Council and the National Institute for Health Research, which takes account of recent developments in theory and methods and the need to maximise the efficiency, use, and impact of research.

Complex interventions are commonly used in the health and social care services, public health practice, and other areas of social and economic policy that have consequences for health. Such interventions are delivered and evaluated at different levels, from individual to societal levels. Examples include a new surgical procedure, the redesign of a healthcare programme, and a change in welfare policy. The UK Medical Research Council (MRC) published a framework for researchers and research funders on developing and evaluating complex interventions in 2000 and revised guidance in 2006.[1-3] Although these documents continue to be widely used and are now accompanied by a range of more detailed guidance on specific aspects of the research process,[4-8] several important conceptual, methodological and theoretical developments have taken place since 2006. These developments have been included in a new framework commissioned by the National Institute of Health Research (NIHR) and the MRC.[9] The framework aims to help researchers work with other stakeholders to identify the key questions about complex interventions, and to c
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BMJ: first published as 10.1136/bmj.n2061 on 30 September 2021. Downloaded from

O'Cathain et al. Pilot and Feasibility Studies (2019) 5:41
https://doi.org/10.1186/s40814-019-0425-6

Pilot and Feasibility

REVIEW

Taxonomy of approaches to developing interventions to improve health: a systematic methods overview

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Pat Hoddinott[2]

Abstract

Background: Interventions need to be developed prior to the feasibility and piloting phase of a study. Ther variety of published approaches to developing interventions, programmes or innovations to improve health. Identifying different types of approach, and synthesising the range of actions taken within this endeavour, c inform future intervention development.

Methods: This study is a systematic methods overview of approaches to intervention development. Approa were considered for inclusion if they described how to develop or adapt an intervention in a book, website journal article published after 2007, or were cited in a primary research study reporting the development of specific intervention published in 2015 or 2016. Approaches were read, a taxonomy of approaches was devi and the range of actions taken across different approaches were synthesised.

Results: Eight categories of approach to intervention development were identified. (1) Partnership, where p who will use the intervention participate equally with the research team in decision-making about the inter throughout the development process. (2) Target population-centred, where the intervention is based on the and actions of the people who will use it. (3) Evidence and theory-based, where the intervention is based o published research evidence and existing theories. (4) Implementation-based, where the intervention is devi with attention to ensuring it will be used in the real world. (5) Efficiency-based, where components of an intervention are tested using experimental designs to select components which will optimise efficiency. (6) or phased, where interventions are developed with an emphasis on following a systematic set of processes. (7) Intervention-specific, where an approach is constructed for a specific type of intervention. (8) Combination, where existing approaches to intervention development are formally combined. The actions from approaches in all eight categories were synthesised to identify 18 actions to consider when developing interventions.

Conclusions: This overview of approaches to intervention development can help researchers to understand the variety of existing approaches, and to understand the range of possible actions involved in intervention development, prior to assessing feasibility or piloting the intervention. Findings from this overview will contribute to future guidance on intervention development.

Trial registration: PROSPERO CRD42017080553.

Keywords: Intervention development, Review, Methodology, Guidance, Health

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BMC

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SUMMARY POINTS

Complex intervention research can take an efficacy, effectiveness, theory based, and/or systems perspective, the choice of which is based on what is known already and what further evidence would add most to knowledge

Complex intervention research goes beyond asking whether an intervention works in the sense of achieving its intended outcome—to asking a broader range of questions (eg, identifying what other impact it has, assessing its value relative to the resources required to deliver it, theorising how it works, taking account of how it interacts with the context in which it is implemented, how it contributes to system change, and how the evidence can be used to support real world decision making)

A trade-off exists between precise unbiased answers to narrow questions and more uncertain answers to broader, more complex questions; researchers should answer the questions that are most useful to decision makers rather than those that can be answered with greater certainty

Complex intervention research can be considered in terms of phases, although these phases are not necessarily sequential: development or identification of an intervention, assessment of feasibility of the intervention and evaluation design, evaluation of the intervention, and impactful implementation

At each phase, six core elements should be considered to answer the following questions:

- How does the intervention interact with its context?
- What is the underpinning programme theory?
- How can diverse stakeholder perspectives be included in the research?
- What are the key uncertainties?
- How can the intervention be refined?
- What are the comparative resource and outcome consequences of the intervention?

The answers to these questions should be used to decide whether the research should proceed to the next phase, return to a previous phase, repeat a phase, or stop


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Increasing value and reducing waste by optimizing the development of complex interventions: Enriching the development phase of the Medical Research Council (MRC) Framework

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information provides answers regarding the potential effectiveness of the intervention (Petticrew et al., 2013). The goal is to identify what works, what works in whom, which assessments are valid and reliable, and what determinants are modifiable within the causal pathway. Several systematic literature reviews regarding various questions may therefore be conducted to reduce the chance of exposure to non-effective interventions or use of invalid outcome measurements (Richards and Hallberg, 2015a). Van Meijel et al. recommend identifying existing literature on similar interventions and methods to evaluate them (van Meijel et al., 2004). Each aspect of evidence that contributes to the design of the proposed intervention should be reviewed (van Meijel et al., 2004). However, critical appraisal of the methodological quality of the systematic reviews remain important since poorly prepared and conducted systematic reviews might present biased results and therefore, add to research waste (Roberts and Ker, 2015). The results of the various literature reviews can provide information regarding the effectiveness of existing interventions, contextual variation, relevant outcome measures, acceptability, feasibility, and mechanisms of action (Richards and Hallberg, 2015a). An example from our experience is described in Box 3.

2.3.3. Identifying or developing theory

The identification and development of theory that underpins the underlying theory is often not clearly described. Multiple theories may explain the proposed mechanism and actions within the causal chain. If a theory is lacking, defining one using a grounded theory approach might be crucial step to undertake. By understanding the causal mechanism, the key components of the intervention can be defined based on the knowledge gained from other elements in the development phase such as the systematic reviews. The rationale for the intervention, its components, and the expected outcomes are reflected by the identified modifiable determinants and requires an in-depth understanding of the causal mechanisms. For example, one may examine the relationship between the symptoms of a disease and the intervention that can lead to a desired clinical outcome, including the identification of moderating variables (Richards and Hallberg, 2015b). A theoretical framework provides information on how the possible intervention influences the causal chain. Furthermore, a theoretical method needs to be translated to practical applications, for example the translations of behaviour change methods into practical intervention elements that fit the intervention context and target population characteristics. When theoretical parameters are not properly translated into practice, the effectiveness of a method can be undermined or counter intuitive. For example, the International Classification of Functioning (ICF) framework is widely used (WHO, 2001). When this framework shows gaps, new theoretical ideas can be gained by conducting quantitative (i.e., cross-sectional,

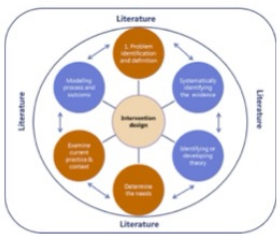

Fig. 1. Adapted MRC Development phase. Blue elements are from the original MRC Framework (Craig et al., 2008). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

Intervention Development science: The flipside of ‘implementation science?

Intervention development science is the scientific study to inform intervention designs for intended contexts and populations, which facilitates the development of evidence-based intervention prototypes to be piloted and evaluated for delivery, uptake and effectiveness.

Intervention Development Science

This ‘emerging’ field, of **intervention development science aims to improve what we know** (evidence to build the intervention) **to inform what we do** (the prototype) by generating the evidence needed to foster the design and delivery of a context-relevant intervention *before* we test how well it works (evaluation) and examine how it is implemented in reality (implementation science)

Co-production, co-creation, co-design

...the collaborative generation of knowledge by academics working alongside stakeholders from other sectors'.

The main purpose is to devolve control so that particularly service users, but also community members, can be more active in the design of the services they receive.

(Greenhalgh T, 2016, Halvorsrud, 2021)

IDS components

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The aim of IDS is to identify:

1. Intervention evidence
2. Target group characteristics, needs, preferences
3. Risk and protective factors of the target problem(s)
4. Modifiable determinants
5. Causal pathways and causal mechanisms
6. Contextual influences
7. Local resources
8. Measurable indicators
9. Costs
10. Simulation, modelling

1. Intervention evidence

1. Search the literature for evidence from intervention **evaluations** of the same or similar intervention types, particularly those conducted in relevant settings.

2. Use “realist” and IDS to extract data on ‘**mechanisms**’, ‘**outcomes**’, ‘**contexts**’”, plus: **modifiable determinants, causal pathways** and **measurable indicators**.

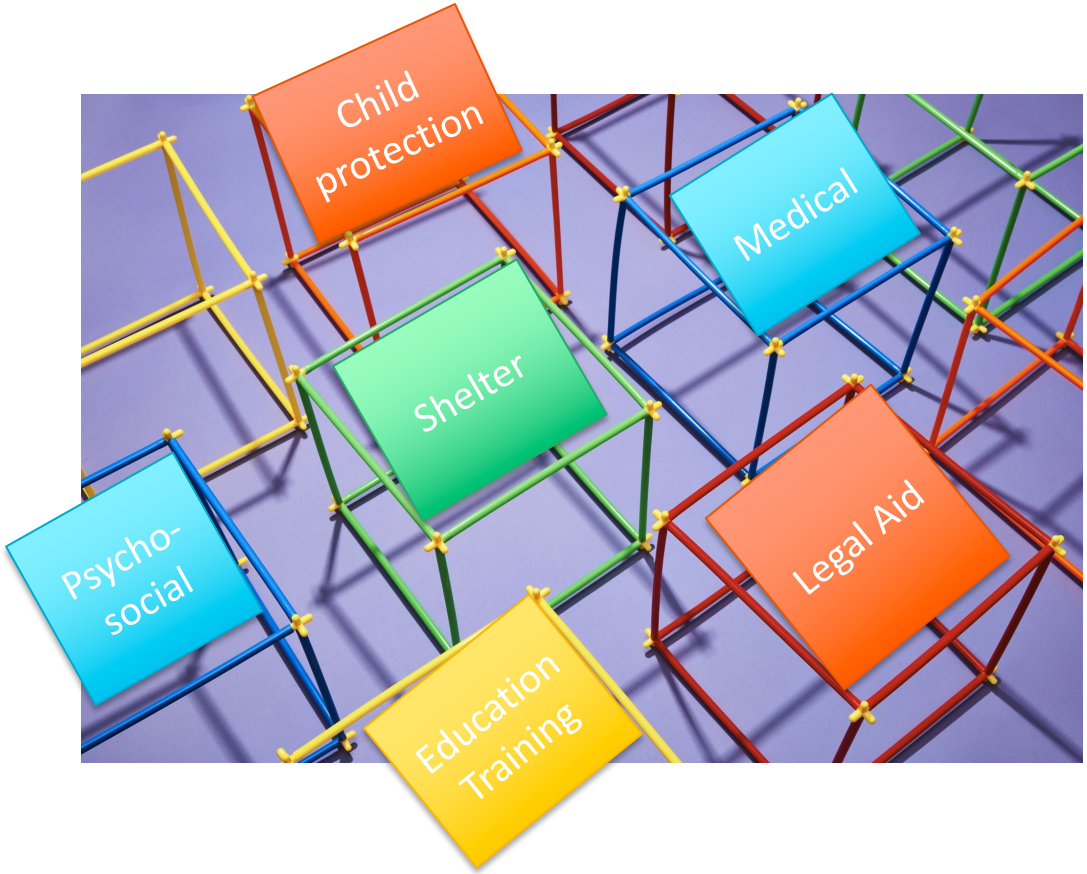
2. LOCAL RESOURCES AND IMPLEMENTATION

What resources might we want to address hazardous child labour?

1. What local actors, programs or policy-makers might **deliver, contribute to or affect** the intervention.

2. How might local groups or resources **mutually benefit** from participation in the intervention and/or the study?

3. Which partners can support the **safe and ethical conduct** of the research.



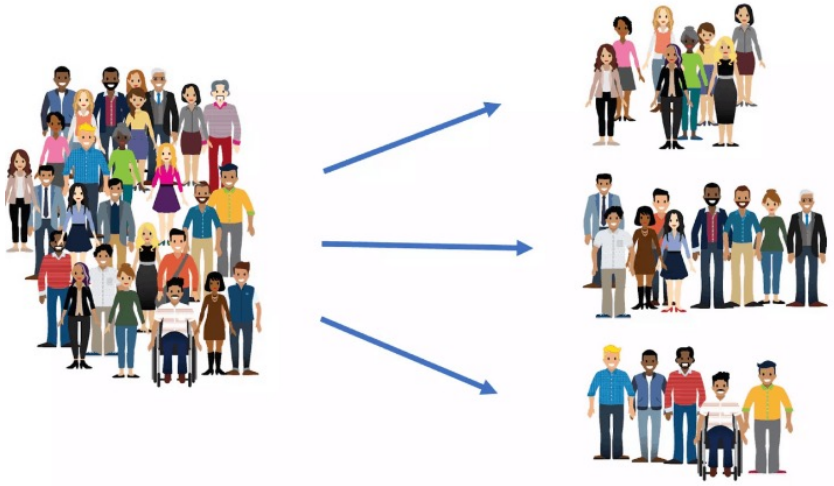
3. TARGET GROUP

1. Clarify **who will be included** in the intervention e.g., most in need, largest prevalence who suffer from the problem; most amenable to responding? **… and who might be excluded?**

2. Define **what are target group's relevant characteristics, needs, preferences**.

3. Determine options for **intervention delivery, access and engagement options** (e.g., mobile phone use, proximity, free time).

1. Assess potential **risks of engagement**.



4. RISK AND PROTECTIVE FACTORS

1. What are the '**determinants**' or '**causal factors**' that contribute to the presence, prevalence and severity of the problem among the specific target group(s).

2. What are the risk ***and protective*** factors.

3. What is the **interaction** between various factors and their different **effects**.

5. Modifiable determinants

1. Which factors are **important and amenable to change** by an intervention within the project *time and resources.*

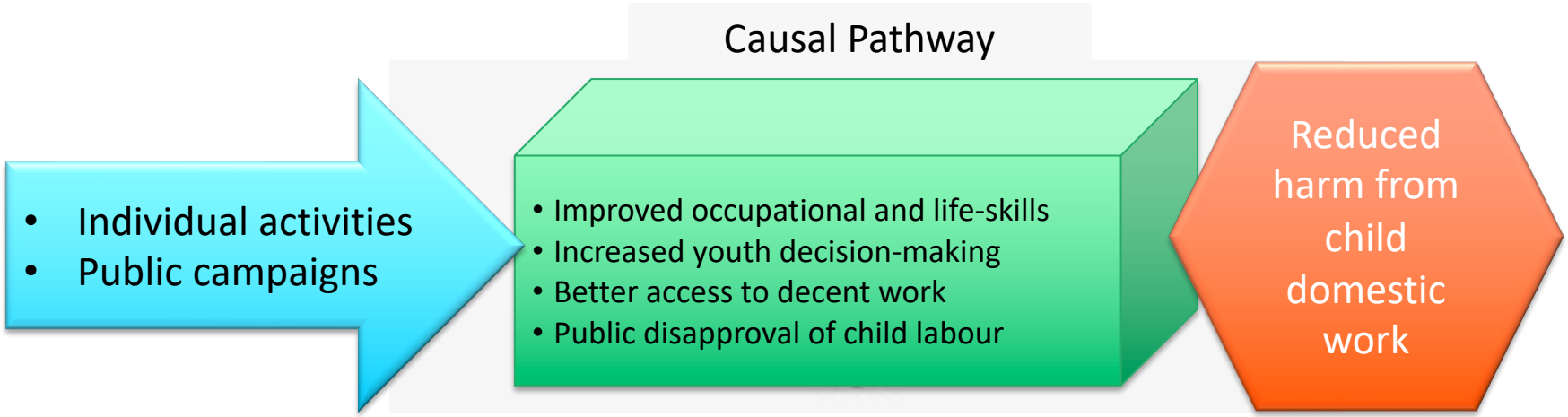
2. **How** might they be modified?

3. How might our modification(s) **act within the system to create exponential or diminished effects**?

4. What might be **adverse consequences** and for whom?

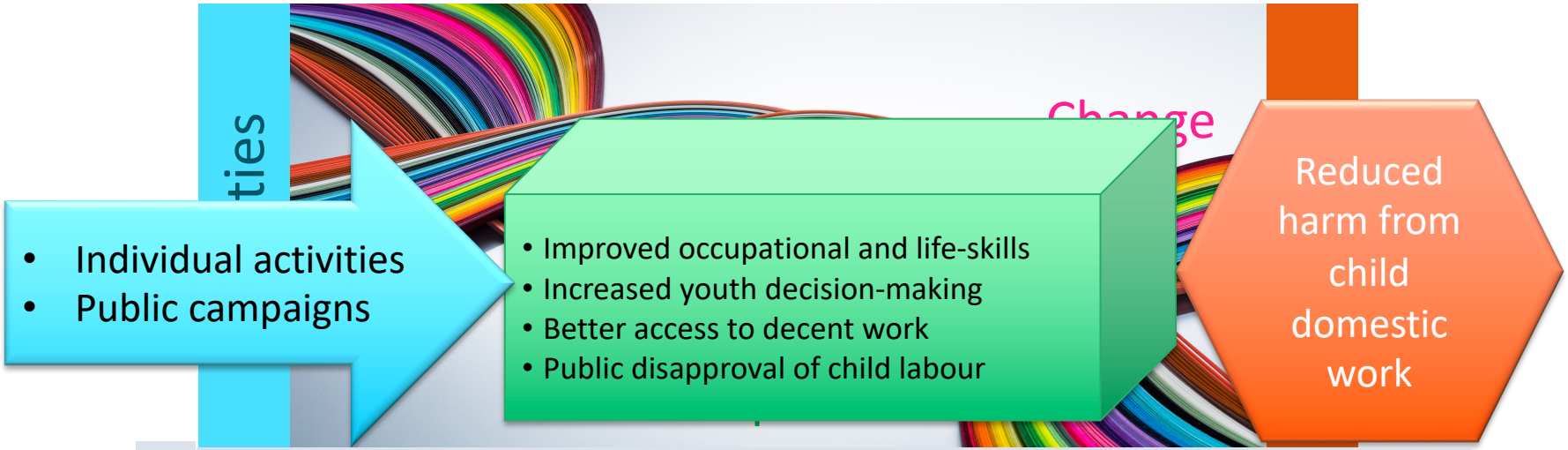
6. CAUSAL PATHWAYS AND CAUSAL MECHANISMS

1. What is in the **causal pathway between the intervention activity and proposed outcomes**, Theory of Change. i.e., how, why X might cause Y.



7. CONTEXTUAL INFLUENCES

1. Which contextual factors are most likely to affect:
   - **Delivery**, e.g., reaches the target group?
   - **Uptake,** e.g., target group benefits from the intervention?
   - **Change** e.g., behaviours?



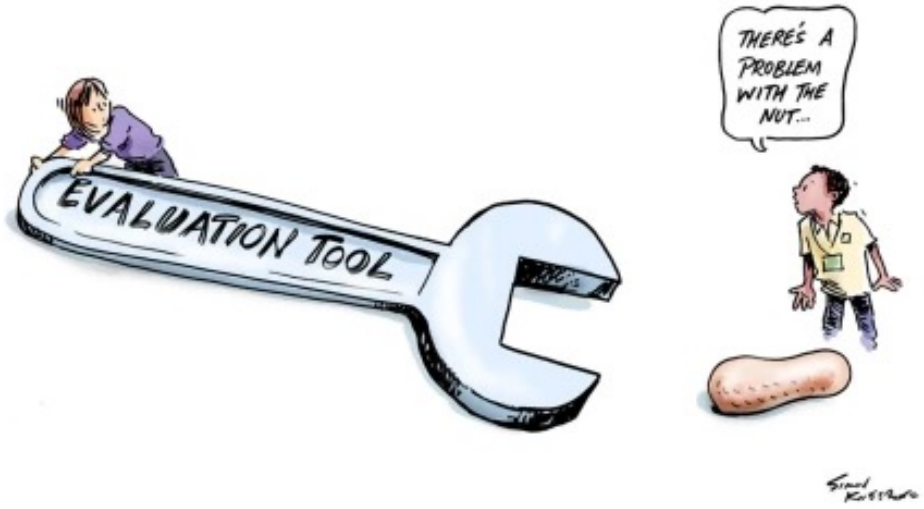
8. COSTS-BENEFITS

1. How much will the activities cost in the prototype?
2. What will be the value of likely benefits and to whom?
3. Are there more cost-effective ways to achieve similar outcomes?
4. What might be potential savings from scaling up?

9. MEASURABLE INDICATORS

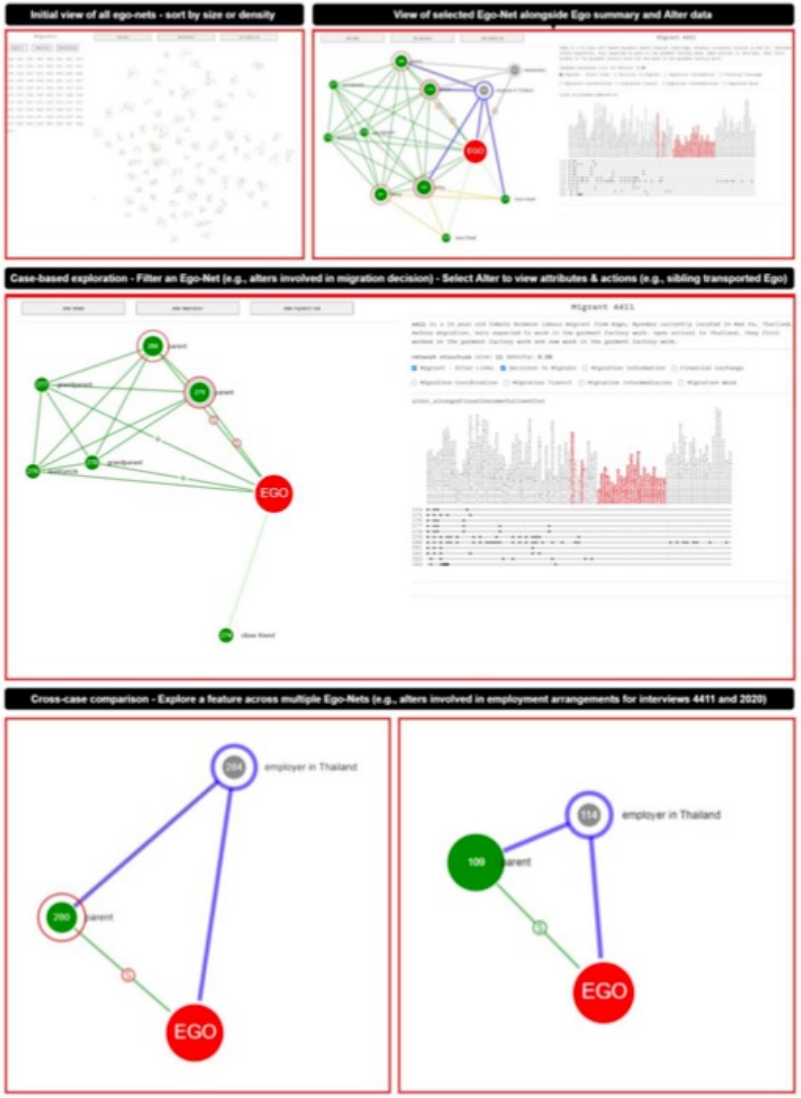
1. What are ‘measurable and credible indicators’ for the inputs, mechanisms, outputs and outcomes and contextual variables?

2. Are these indicators ‘measurable’? What tools or approaches are most feasible to measure them?



10. SIMULATION, MODELING

What results would we get if simulate the workings and logic of our proposed intervention in a real system by modelling different prototypes?



Alys McAlpine, 2021

What might an IDS study look like?

1. Review literature and analyse secondary data
2. Co-produce IDS study with local partner(s), include target group representatives
3. Conduct interviews with relevant participants
4. Small survey to explore patterns
5. Workshop theories of change
6. Cost intervention components
7. Simulate prototypes

Zimmerman Cathy, Mak Joelle, Pocock Nicola S. and Ligia Kiss (2021). ***Human Trafficking: Results of a 5-Year Theory-Based Evaluation of Interventions to Prevent Trafficking of Women From South Asia .*** Frontiers in Public Health. Vol 9.

https://www.frontiersin.org/article/10.3389/fpubh.2021.645059