



# Process evaluations in complex social and health interventions

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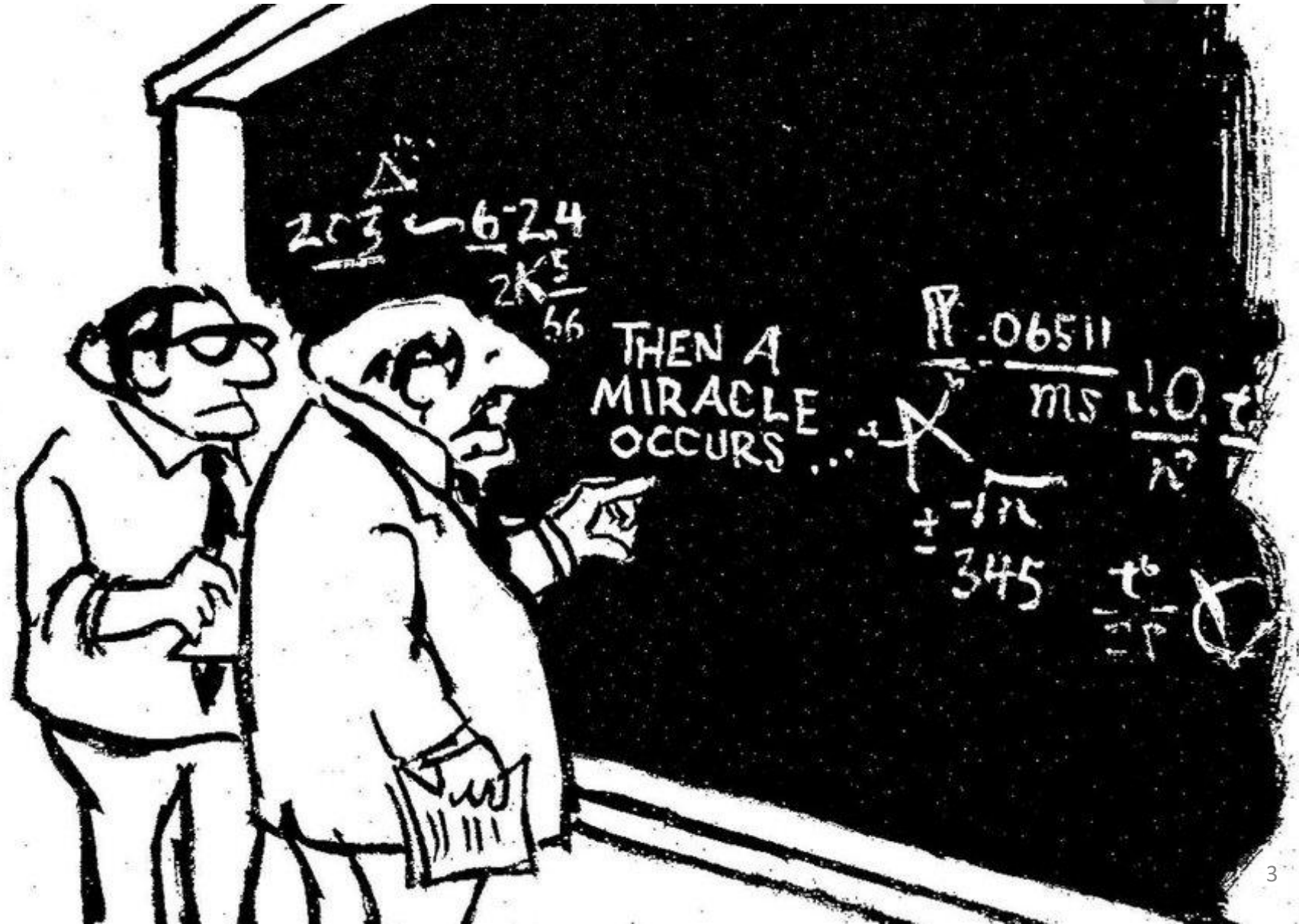
# Overview

- Defining process evaluation
- Uses of process evaluations
- Key methods used in process evaluation, their strengths & challenges

# Process evaluation –

study aiming to understand the functioning of an intervention.

How is the intervention implemented? How does it work in the context?





# “An apple a day keeps the doctor away”

*(example based on Funnell & Rogers, 2011)*

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## Mechanisms

- Increase in vitamin C? quercetin? fiber?
- Decreased consumption of unhealthy snacks?

## Context

- What are the social norms about eating fruit?
- How was the harvest and what are the prices?

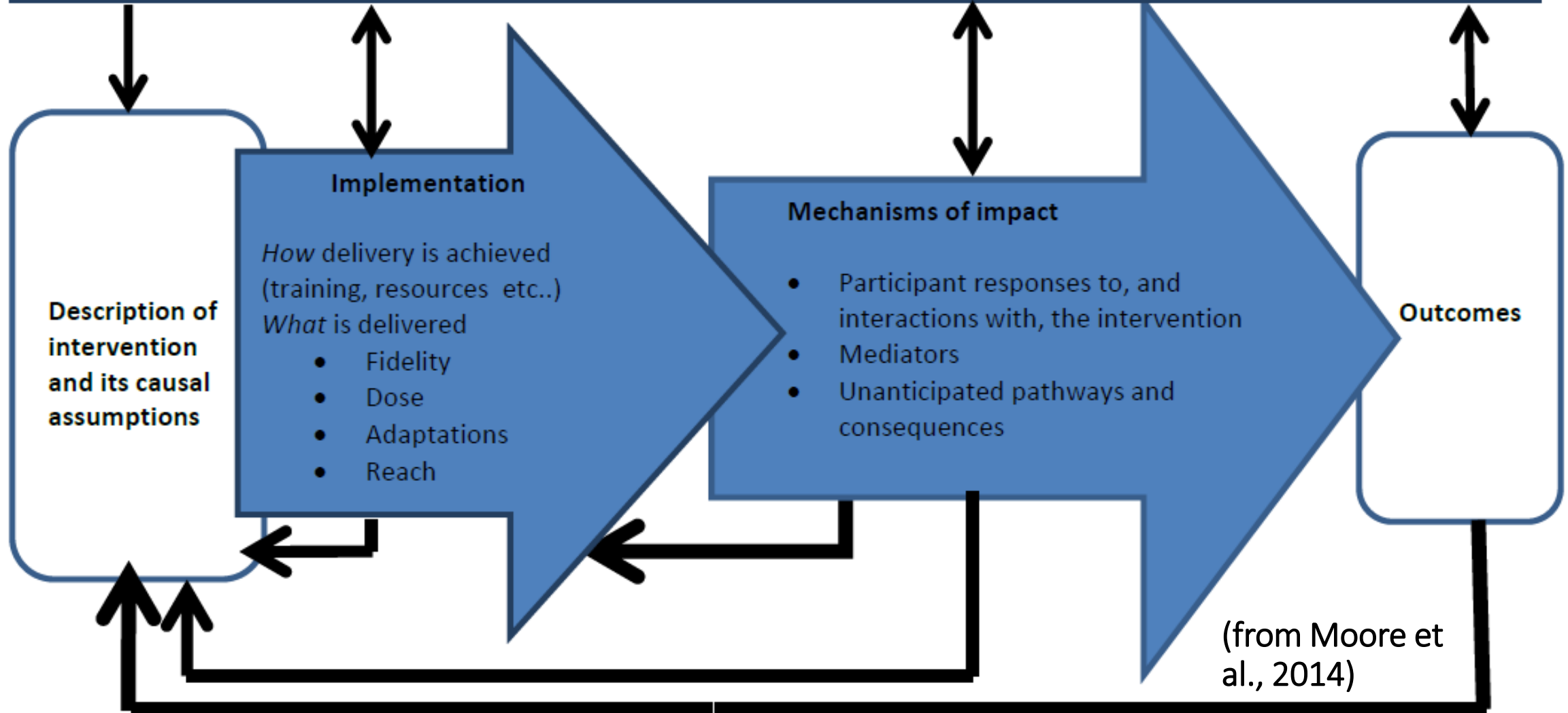
## Implementation

- Do the participants receive and consume the fruit?



## Context

- Contextual factors which shape theories of how the intervention works
- Contextual factors which affect (and may be affected by) implementation, intervention mechanisms and outcomes
- Causal mechanisms present within the context which act to sustain the status quo, or enhance effects





# Related concepts

- Program monitoring
- Theory-based evaluation (Weiss 1997)
- Theory-driven evaluation (Chen & Rossi 1983)
- Realist evaluation (Pawson and Tilley 1997)
- Realist trials (Bonell et al. 2012)
- Implementation assessment (JPAL)
- Implementation research (Peters, Tran & Adam 2013)
- Causal map (Montibeller & Belton 2006)
- Logic model (Rogers 2004)
- And many others!



## Example: Stop Smoking in Schools Trial

- Intervention: training influential students as peer supporters to encourage their peers not to smoke
- ASSIST trial, evaluation in the UK (Audrey et al., 2004), integrated findings from process and outcome evaluations
- Outcome evaluation found reductions in smoking amongst occasional and experimental smokers, but not regular smokers
- Process evaluation (observations, interviews, focus groups in 4/30 schools): peer supporters concentrated their attention on peers who they felt could be persuaded (protecting themselves from potential hostility)





# Stages of program development

Process evaluation has applications during:

- Feasibility and piloting
- Efficacy & effectiveness evaluation
- Implementation
- Pragmatic policy trials and natural experiments





# Example: National Exercise Referral Scheme

- Evaluation of a government-funded scheme in Wales, UK (Moore et al., 2012)
- Individuals referred for a group exercise programme and motivational interviewing if: over 16 years & have mental health or coronary heart disease risk factors
- Fidelity assessed by observations & review of session audio recordings
- The majority of staff were not delivering sessions in line with motivational interviewing principles and goal-setting
- Qualitative data suggested other influences on physical activity motivation (social support, realistic role models, less intimidation) (Moore et al., 2013)
- The intervention was effective for increasing physical activity (outcome evaluation)



# Relevant tools and methods

- Interviews
- Focus groups
- Other consultative designs
- Observations
- Surveys
- Review of program records and administrative documentation

# Trade-offs in collecting fidelity data

Method	Definition	Pros	Cons
Self-report	From provider	<ul style="list-style-type: none"> <li>- Time and cost efficient</li> <li>- Gives perspective of provider</li> </ul>	<ul style="list-style-type: none"> <li>- Uncertain validity</li> <li>- Social desirability bias</li> </ul>
Observation	Independent rater	<ul style="list-style-type: none"> <li>- Objective</li> <li>- Validity and reliability can be assessed</li> </ul>	Time and cost
In vivo	Live	Overall assessment (e.g. of context)	<ul style="list-style-type: none"> <li>- Feasibility</li> <li>- Reactivity effects</li> </ul>
Video	Recorded	Enables review and check on coding reliability	<ul style="list-style-type: none"> <li>- May miss things</li> <li>- Cost</li> <li>- Reactivity</li> </ul>
Audio	Recorded	<ul style="list-style-type: none"> <li>- Cheaper</li> <li>- Can still review and check coding reliability</li> <li>- Less reactivity</li> </ul>	<ul style="list-style-type: none"> <li>- Miss non-verbal aspects</li> <li>- Miss context</li> </ul>

- **Hawthorne (observer) effect:** individuals modify an aspect of their behaviour in response to their awareness of being observed.
- What if we find out something is going wrong?

# Example: Parenting for Lifelong Health evaluation in South Africa

- Evaluation of a 14-week parenting programme for families with adolescents, focusing on family relationships and skills (Cluver et al., 2018); developed by academics, WHO, UNICEF, other partners
- Observations of all programme sessions to normalize the presence of an observer (Shenderovich et al., 2019) & explaining the purpose of data collection – but we cannot be sure if that reduced bias & whether observation became a part of the intervention





# Upcoming evaluation in Moldova and N. Macedonia

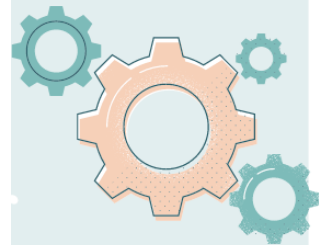
Family-Focused Adolescent & Lifelong Health Promotion (FLOURISH)

<https://www.flourish-study.org/about.html>



## Study 1 Delivery context Co-design of adaptations

Mapping of the delivery context and co-design of programme adaptations through consultations and qualitative data collection, and a feasibility pilot study



## Study 3 Randomized trial Testing intervention

Study 3 will test the intervention package selected in Study 2 with a hybrid implementation-effectiveness randomized trial

## Study 2 Factorial trial Intervention selection

Study 1 will inform design and refine conditions to test in Study 2 to optimize programme implementation and cost-effectiveness



## Study 4 Studying dissemination Looking at practitioners and policymakers

Study 4 will explore the dissemination of the intervention and study how the intervention has been positioned with practitioners and policymakers



PhD research and other collaboration opportunities



FLOURISH



FLOURISH

# FLOURISH Consortium

## Principal Investigators



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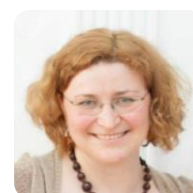
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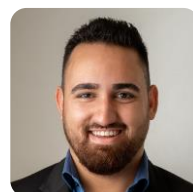
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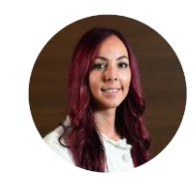
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Müller



Franziska  
Waller



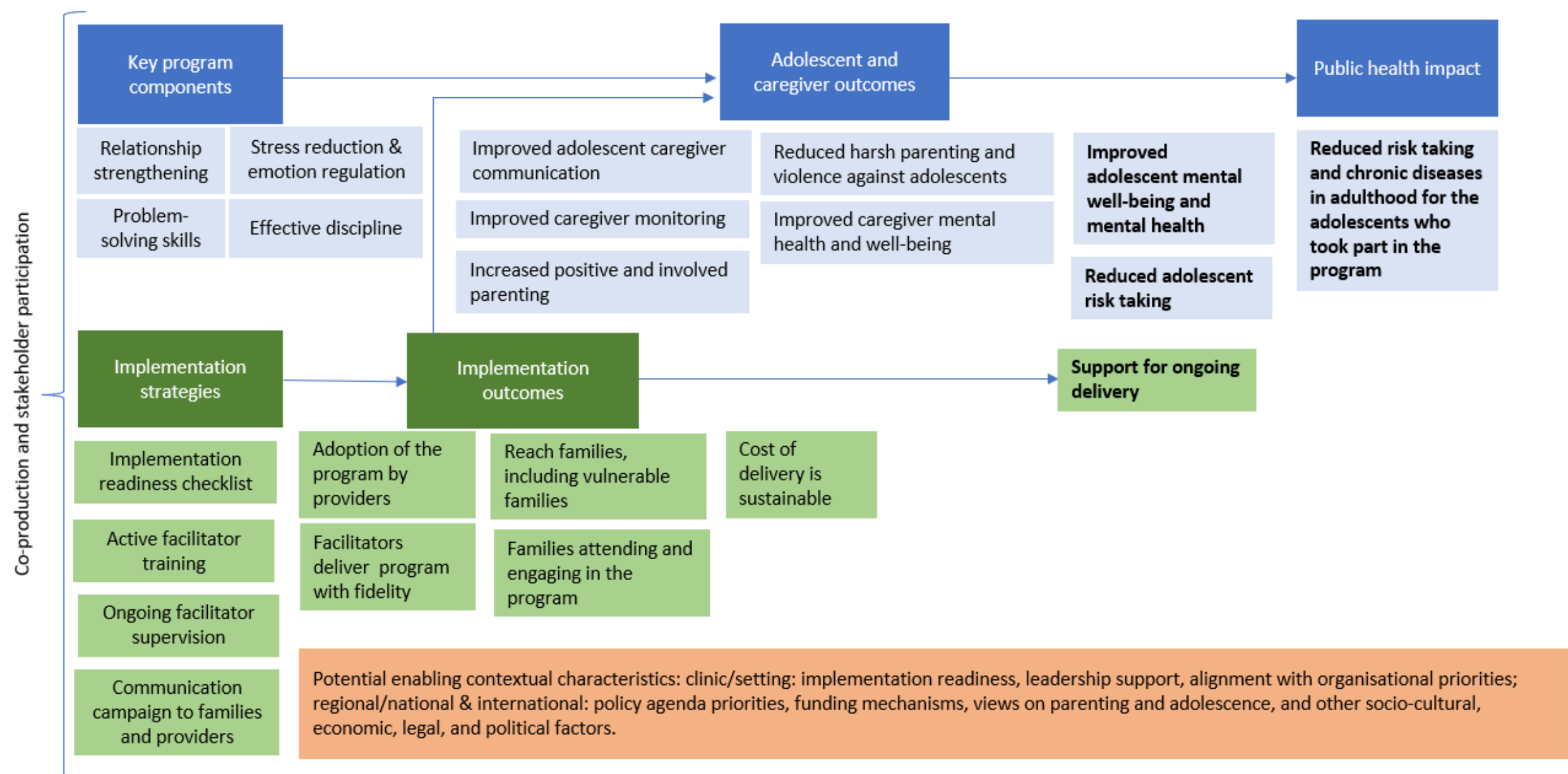
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*Theory of change for FLOURISH*





# Why is process evaluation necessary?

- Explaining success (*Will outcomes be similar in other contexts?*)
- Explaining failure (*Is it due to the intervention, poor implementation, context?*)
  - Type III error (Basch et al 1985; rejecting a promising intervention due to poor implementation)
- Equity (*Were all the relevant subgroups in the target population able to access the intervention and have beneficial outcomes?*)
- Considering implications for scaling up
- Looking across multiple studies - understanding the nature of intervention and implementation heterogeneity (TIDieR, CONSORT-SPI)





# Resources on process evaluation

- Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O’Cathain A, Tinati T, Wight D: Process evaluation of complex interventions: Medical Research Council guidance. *bmj* 2015, 350.
- Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, Boyd KA, Craig N, French DP, McIntosh E: A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *bmj* 2021, 374.
- <https://implementationscience-gacd.org/case-studies/> - GACD implementation science hub

# References

- Audrey, S., Cordall, K., Moore, L., Cohen, D. and Campbell, R. (2004) The development and implementation of a peer-led intervention to prevent smoking among secondary school students using their established social networks, *Health Education Journal*, 63, 266-284.
- Basch, Slipevich, Gold, Duncan, and Kolbe (1985) Type 3 error
- Breitenstein, S.M., Gross, D., Garvey, C.A., Hill, C., Fogg, L. & Resnick, B. (2010). Implementation Fidelity in Community-Based Interventions. *Research in Nursing and Health* 33: 164-173
- Cluver, L. D., Meinck, F., Steinert, J. I., Shenderovich, Y., Doubt, J., Romero, R. H., ... & Gardner, F. (2018). Parenting for lifelong health: a pragmatic cluster randomised controlled trial of a non-commercialised parenting programme for adolescents and their families in South Africa. *BMJ global health*, 3(1), e000539.
- Funnell, S. C. and P. J. Rogers (2011). Purposeful program theory: effective use of theories of change and logic models, John Wiley & Sons.
- Grant, A., et al. (2013). "Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting." *Trials* 14(1): 15.
- Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., ... & Michie, S. (2014). Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ: British Medical Journal*, 348.
- Humphreys, D. K., & Eisner, M. P. (2010). Evaluating a natural experiment in alcohol policy. *Criminology & Public Policy*, 9(1), 41-67.
- Linnan, L. and A. Steckler (2002). Process evaluation for Public Health Interventions and research: an overview. *Process evaluation for public health interventions*. L. Linnan and A. Steckler. San Francisco CA, Jossey Bass.
- Michie, S. & Prestwich, A. (2010). Are Interventions Theory-Based? Development of a Theory Coding Scheme. *Health Psychology* 29(1): 1-8.
- Mihalic, S. (2004). The importance of implementation fidelity. *Emotional and Behavioral Disorders in Youth* 4(4): 83-105.
- Montgomery, P., Grant, S., Hopewell, S., Macdonald, G., Moher, D., Michie, S., & Mayo-Wilson, E. (2013). Protocol for CONSORT-SPI: An Extension for Social and Psychological Interventions. *Implementation Science*, 8, 99. doi:10.1186/1748-5908-8-99
- Moore, G. F., Raisanen, L., Moore, L., Din, N. U. and Murphy, S. (2013) Mixed-method process evaluation of the Welsh National Exercise Referral Scheme, *Health Education*, 113, 6, 476-501.
- Moore, G., Audrey, S., Barker, M., Bond, L., Bonell, C, Hardeman, W., Moore, L., O’Cathain, A., Tinati, T., Wight, D., Baird, J. (2014). Process evaluation of complex interventions. UK Medical Research Council (MRC) guidance.
- Moore, J., Bumbarger, B.K. & Cooper, B.R. (2013). Examining Adaptations of Evidence-Based Programs in Natural Contexts. *The Journal of Primary Prevention* 34, 1, 147-61
- Mowbray, C. T., Holter, M. C., Teague, G. B., & Bybee, D. (2003). Fidelity criteria: Development, measurement, and validation. *American journal of evaluation*, 24(3), 315-340.
- Palinkas, L. A., G. A. Aarons, et al. (2010). "Mixed method designs in implementation research." *Adm Policy Ment Health* 38: 44-53
- Shenderovich, Y., Eisner, M., Cluver, L., Doubt, J., Berezin, M., Majokweni, S., & Murray, A. L. (2019). Delivering a parenting program in South Africa: the impact of implementation on outcomes. *Journal of Child and Family Studies*, 28, 1005-1017.
- Walker, R., Hoggart, L., & Hamilton, G. (2008). Observing the implementation of a social experiment. *Evidence & Policy: A Journal of Research, Debate and Practice*, 4(3), 183-203.
- White, H. (2009). "Theory-based impact evaluation: principles and practice." *Journal of development effectiveness* 1(3): 271-284.
- On process evaluations in education: <https://educationendowmentfoundation.org.uk/news/what-can-we-learn-from-implementation-and-process-evaluations>



**Thank you!**

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