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Article

ARTICLE

Bridging Theory and Intervention: The Need for Proof-of-Principle RCTs to Advance Health Psychology Interventions

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Abstract

A big part of intervention development is testing before implementation. Bridging the gap between observational findings gained from interviews, focus groups, and correlational studies, theoretical science-focused evidence from experiments, and the gold-standard in intervention testing in large-scale randomized controlled trials (RCTs) remains a challenge in behaviour change intervention development.

This article introduces Proof-of-Principle RCTs (PoP-RCTs) as an intermediate step in bridging this gap. PoP-RCT are designed to test whether the intervention changes specific targeted mechanisms of action (MoAs), thus having the potential to change the behaviours targeted, before instigating larger trials. By focusing on the MoAs, PoP-RCTs offer a critical step that ensures theoretical assumptions are validated using experimental methodology, improving the overall rigor of intervention development.

Practical case studies are included to illustrate real-world application of PoP-RCTs in health psychology. Highlighting their role in refining interventions before full-scale RCT testing, in work on recovery of activity after stroke. Following interview studies, evidence was obtained that greater perceived control predicted better and faster recovery. These studies were followed by experimental testing of interventions to enhance perceived control, in studies we now term PoP-RCTs. Having demonstrated that the interventions could change perceived control, a full trial found that they were effective in increasing activity. Taken together, we think PoP-RCTs are already an implicit part of intervention development. Proposing this as an explicitly labelled step between experiments and RCTs, could improve effectiveness/efficacy and increase intervention success.

Key words: Proof-of-Principle RCTs (PoP-RCTs), Interventions, Mechanisms of action (MoAs), Methodology

Introduction

Behaviour change interventions are used to address many health-related outcomes, but trials of effectiveness yield inconsistent and small effects, resulting in costly, inefficient use of resources (Nielsen et al., 2018). Many authors suggest that interventions should target theory-based mechanisms of action (MoAs), which are processes that are causally active in the relationship between an intervention and outcome behaviour (Human Behavior Change Project, 2023). Using MoAs will achieve greater, more reliable behaviour change, but identifying a valid MoA is challenging (Rothman and Sheeran, 2020). As they point out, many interventions target constructs, selected because of correlational evidence.

There are downsides to the use of correlational studies to select MoAs to target in interventions. Even if these correlational studies find concurrent or predictive associations between the proposed MoA and the behaviour the MoA might still not be suited for use in interventions. For one, the observed relationship maybe reverse, i.e. the behaviour leads to the proposed MoA, or the correlation may be due to a third variable. In addition, the correlations only indicate that people higher on the proposed MoA are more likely to perform the behaviour, not that increasing the level of MoA for an individual makes the behaviour more likely. For all three situations correlational evidence would lead to the selection of the MoA for an intervention, but in increasing the MoA would not change the behaviour. Paradoxically, even if there is no relationship between the predictor and behaviour, the predictor may still be causal and therefore an appropriate target for intervention e.g. if the measure of the predictor has a ceiling effect (Johnston, 2015).

Other interventions are based on an intuitive understanding of the relationship between the MoA and the behaviour in question, or by insights from observational studies or interviews. These are often analysed using the Theoretical Domains Framework, to propose an MOA to target in an intervention (e.g., Atkins et al., 2017; Little et al., 2015). They have similar problems to the correlational studies – they do not demonstrate that changing the proposed MoA would affect the behaviour.

Recognising the limitations of these methods, other authors, including the NIH Science of Behaviour Change (SOBC) programme, recommend an experimental medicine approach with four steps: (1) Identify the MoA (2) Measure the MoA (3). Test the effect of the intervention on the MoA, and (4) Test the effect of changing the MoA on changes in the behaviour (Riddle and Science of Behavior Change Working Group, 2015; Rothman et al., 2020; Rothman and Sheeran, 2020; Sumner et al., 2019). However, step 3 the causal effect of the MoA is rarely investigated or reported (Edmondson et al., 2018). The omission of causal analyses may result in costly RCTs of interventions based on weak or insufficient evidence (Eccles et al., 2007b). We propose that

prior to expensive full RCTs examining effects of the intervention on behaviour, Proof-of-Principle RCTs (PoP-RCTs) are used to test the effects of the intervention on the MoA (Johnston and Den Daas, 2024) . PoP-RCTs are defined as randomized controlled trials conducted under controlled conditions to test whether a theoretically informed intervention can influence a hypothesised MoA, and whether change in that MoA leads to a change in behaviour or its proxy. Previously we have recommended the use of Intervention Modelling Experiments (IMEs) that serve to model as much of the intervention and evaluation as possible by manipulating elements of the intervention and evaluating interim endpoints (Eccles et al., 2007b). PoP-RCTS focus IMEs on understanding intervention effects on postulated MoAs.

Table 1
Overview of the study designs used in behaviour change intervention development, and some of their distinguishing their features

	Observational Studies	Experiments	Proof-of-Principe RCTs	Randomized Controlled Trials
Purpose	Examine relationships or describe phenomena without controlling the conditions.	Test causal relationships predicted by theory without necessarily planning an intervention.	Test the ability of interventions to influence the theorised MoA and behaviour under controlled conditions.	Test the efficacy or effectiveness of interventions in the real-life context where the intervention will be implemented.
Design	Observational, no manipulation of variables.	Manipulation of proposed theoretical causal variables and control of extraneous variables.	Intervention: Manipulation of proposed causal intervention variables and control of extraneous variables, with random allocation to groups.	Intervention: Manipulation of proposed causal variables with random allocation to groups.
Result	Relation between two or more variables or levels of variables.	Evidence of causal relation between constructs in a theory.	Evidence of effectiveness of intervention in changing MoA and that changing MoA changes behaviour or a proxy of behaviour.	Evidence of efficacy or effectiveness of on intervention on socially valued outcome.
Randomization	Not applicable; participants are selected based on pre-existing conditions or characteristics.	May or may not involve random assignment of participants to experimental groups.	Participants are randomized into intervention and comparator groups.	Participants are randomized into intervention and comparator groups.
Causation	Cannot establish causal relationships; can identify associations.	Can confirm or reject causation as proposed by theory.	Can confirm or reject causation of the intervention on the MoA or of the MoA on the behaviour.	Provides robust evidence of causation due to randomization and control.
Population	Convenience sample.	Population allowing control of extraneous variables but may or may not plan to develop an intervention for this population.	Specific target population for the intervention.	Specific target population for the intervention.

Proof-of-Principle Randomised Controlled Trials (PoP-RCTs)

PoP-RCTs are an intermediate step in bridging the gap between observational studies, science-focused experiments, and the golden-standard RCTs. Table 1 contrasts features of PoP-RCTs with the features of observational studies, experiments, and RCTs. RCTs give evidence of effectiveness but usually do not provide information about possible MoAs. RCTs are costly, in money and time, and often result in the conclusion that the intervention does not work (Nielsen et al., 2018), but RCTs do not provide information about why it did not work. PoP-RCTs are designed to test whether the intervention changes the specific MoAs it targets and thus have the potential to change the behaviours targeted, before instigating larger trials. PoP-RCTs address experimental medicine's third step by assessing the effect of the intervention on the MoA.

Based on prior evidence from observational, correlational or other studies, the PoP-RCT researcher should identify which MoA or MoAs will be targeted through the intervention. Ideally, interventions should be purposefully designed to target specific MoAs. Once developed, participants are randomly assigned to either the intervention group or a control group. The first objective is to assess whether the intervention changes the targeted MoAs in the expected direction, compared to the control and then, to evaluate whether these changes in the MoAs explain, or mediate, the intervention's effect on the target behaviour, a simulated behaviour, or a behavioural proxy. For example, we conducted a PoP-RCT testing a messaging intervention targeting physical distancing to prevent Covid-19 through the MoA self-efficacy (den Daas et al., 2022). We found that the message increased self-efficacy: participants who received the message reported higher levels of self-efficacy than those in the control group, who received no message (see Table 2 which shows three examples of PoP-RCTs). Furthermore, the increase in intention to maintain physical distance was mediated by this rise in self-efficacy. However, as can be seen in Table 2, using very similar messaging to affect self-efficacy in Covid-19 PCR-testing did not successfully increase the MoA self-efficacy, and hence nor did it affect intentions for testing. One message does not fit all behaviours even if underlying MoA might be correctly selected. Furthermore, in the other example in the Table, on bowel cancer screening, the PoP-RCT showed that the intervention affected the MoA under certain conditions only. By focusing on the MoA, PoP-RCTs play a crucial role in testing theoretical assumptions using experimental methods, thereby enhancing the rigour of intervention development.

Table 2
Description of the components of three PoP-RCTs.

Condition	Bowel Cancer (manuscript in preparation)	Covid-19 (den Daas et al., 2022)	Covid-19 (manuscript in preparation)
Behaviour	Using the bowel cancer screening kit immediately when it arrives.	Physical distancing, keeping 2 meters away from people not in your household. Physical distancing, keeping 2 meters away from people not in your household	PCR testing for Covid-19 when experiencing Covid-19 symptoms.
Population	People over 50, who received the bowel cancer screening kit.	General population, of people leaving their house during the Covid-19 pandemic.	General population, who experience Covid-19 symptoms.
Targeted MoA	Beliefs about capabilities, Intentions, Memory, attention, and decision process.	Beliefs about capabilities.	Beliefs about capabilities.
Source of MoA	Observational studies.	Social Cognitive Theory (Bandura, 1986), Observational studies (Dixon et al., 2021)	Social Cognitive Theory (Bandura, 1986), Observational studies (den Daas et al., 2022; Dixon et al., 2021)
Intervention	'Half a million people in Scotland have done it (6.3 Information about others' approval), so can you (15.1 Verbal persuasion), use the bowel cancer screening kit (1.1 Goal setting (behaviour)), as soon as it arrives (1.4 Action planning and 7.1. Prompts/cues).'	'About 8 out of 10 of people in Scotland who have taken part in the study before, say they are managing to keep 2m distance from other people most or all of the time [vicarious experience], which shows that people like you can do this [verbal persuasion]. By keeping to the 2m distancing, you can help reduce the spread of the virus and keep people safe [emotional arousal]'	i) Vicarious experience: 'In a typical week over two hundred thousand people in Scotland are doing a PCR-test to check if they have COVID-19'. ii) Verbal persuasion: 'People like you can do a PCR-test' iii) Both: 'In a typical week over two hundred thousand people in Scotland are doing a PCR-test to check if they have COVID-19, which shows that people like you can do this'
	No message control	No message control	iv) No message control

Condition	Bowel Cancer (manuscript in preparation)	Covid-19 (den Daas et al., 2022)	Covid-19 (manuscript in preparation)
Result	Some messages worked under some conditions to increase self-efficacy and intentions. However, not in all messages, and one message even had detrimental effects.	Increasing self-efficacy for physical distancing with a short message successfully increased intention to physical distance via (mediated by) increased self-efficacy.	Messages did not affect self-efficacy for PCR-testing, and even negatively affected intentions.

Practical Examples of PoP-RCTs as part of intervention development and (non-)implementation

Two examples of behaviour change intervention development and evaluation using Pop-RCTs are presented: one which led to a successful RCT and intervention to reduce disability in stroke and a second in which an intervention to reduce GPs' prescribing of antibiotics was deemed too weak to be trialled.

Case study 1: Disability following stroke

Clinically we observed that patients with apparently similar levels of physical impairment differed in their observed activity limitations. We aimed to understand the processes and, if possible, develop an intervention to enable patients to reduce activity limitations in a sequence of studies. The steps below illustrate the entire research process preceding the intervention being implemented through a workbook by the Scottish Government in 2012.

1. **Identifying MoAs:** In an unstructured interview study, a common theme was 'lack of control over activity limitations' (Partridge, 1985).
2. **Measuring the MoA and testing association with the behaviour.** We measured perceived control through self-report, and activity limitations in relation to stroke through observed performance rather than self-report as observation and self-report were not reliably related (Powell et al., 2007). In a series of correlational studies, perceived control predicted activity limitations concurrently, over one month, and over 3 years controlling for earlier activity limitations (Johnston et al., 1999, 2004; Partridge and Johnston, 1989). Perceived control also predicted which activity would be regained over one month (Bonetti and Johnston, 2008). We concluded that perceived control replicably predicted activity limitations and might be targeted as a MoA in an intervention.
3. **PoP-RCTs to test effects of intervention on MoA and behaviour.** In a PoP-RCT we increased perceived control through a persuasive communication in letters send to a random half of patients before their appointment, while the others just received a routine appointment letter (Johnston et al., 1992), the PoP-RCT did not assess the effect on behaviour. In a second PoP-RCT, patients were randomly allocated to receive a verbal persuasive communication, which resulted in increased perceived control and reduced activity limitations (Fisher and Johnstion, 1996). This confirmed that perceived control was a valid target for intervention.
4. **RCT comparing the workbook with usual care** in stroke patients over 6 months (Johnston et al., 2007). Patients receiving the workbook made more recovery and had less activity limitations 6 months after discharge from hospital than those receiving usual care. However, mediation analyses indicated that perceived control (measured as in previous studies) did not change and therefore was not the MoA that caused the behaviour change and so the workbook was implemented without full understanding of the MoA. It is possible that an unmeasured MoA affected the behaviour instead, possibly the intervention sustained patient 'confidence in recovery' while this declined in the comparator group.

Case study 2: Prescribing of antibiotics by general practitioners

Evidence from several sources indicated that GPs were over prescribing antibiotics for upper respiratory tract infections (Smith et al., 2006). Following work on measuring the behaviour of overprescribing, we conducted correlational and PoP-RCT studies.

1. **Identifying MoAs, measuring MoAs, and developing interventions.** The constructs of several theories of behaviour were used to predict the behaviour in correlational studies. Self-efficacy, anticipatedconsequences, and risk perception, all predicted intentions as proxies to behaviour, and behaviour in a simulated behavioural task (Eccles et al., 2007a). Based on these findings two interventions were developed to target self-efficacy and anticipated consequences respectively (Hrisos et al., 2008a,b).
2. **PoP-RCTs to test effects of intervention on MoA and behaviour.** Each intervention significantly enhanced the target MoA (Hrisos et al., 2008b). However, only the persuasive communication intervention targeting self-efficacy was effective in changing intention and simulated behaviour. Moreover, these effects were mediated by the target MoA. Nevertheless, the effects were considered too small to be worth investing in an RCT.

Concluding remarks

While the concept of Proof-of-Principle RCTs is not new, similar studies have been conducted for years as part of intervention development. However, they have often been referred to using a variety of terms (i.e., experiments, RCTs, or pilot RCTs) making them difficult to clearly identify in the literature. Also, it often remains unclear whether these methodologies are used interchangeably, or whether they indicate meaningful differences as also illustrated for some in Table 1. In addition, the aim of these studies is not always just focused on establishing the appropriateness of the targeted MoA, sometimes both the MoA and the behaviour or health status are measured as outcomes. A key aim of proposing PoP-RCTs is to clarify and define this approach more explicitly, highlighting its unique role in the process of developing behaviour change interventions.

One of the benefits of PoP-RCTs is that the language used matches the language in other fields (RCTs). This is important as

even foundational terms like experiment may be interpreted differently across different disciplines. Terms might even be completely unknown, anecdotally, one of the researchers on a medical panel once had to explain to people in the medical field what an experiment is. This could explain why Intervention Modelling Experiments as terminology might not have received the traction it deserves (a Google Scholar search resulted in 86 results since 2005). Most researchers in most fields will understand what an RCT is and what it does. Moreover, using a bespoke term defines the purpose of PoP-RCTs as precursors to interventions while distinguishing their purpose, i.e., proofing the principle of an interventionPoP-RCTs have a different purpose from full RCTs, a design more closely related to experimental studies, but with conclusions about interventions and practice. Pop-RCTs can be done in a much more cost- effective manner than RCTs.

In addition to clarifying and specific language for this type of work, designing PoP-RCTs forces researchers to be specific about which MoAs are targeted in their intervention. Ideally PoP-RCT are done before the intervention is implemented and in response to interventions that have been developed with specific MoAs in mind. However, even after implementation of an intervention PoP-RCTs may be useful in strengthening the effects or even explaining disappointing results. In the latter case, PoP-RCT can show researchers where they can improve the intervention. For existing interventions, PoP-RCTs can be employed with one extra step involved. This would entail identifying the MoA the developers were aiming to change. This can be done by linking intervention content to MoAs using available tools (Connell et al., 2018; Johnston et al., 2020). PoP-RCTs may also be used to determine whether different MoAs are effective for different sections of the population, allowing tailoring of interventions or leading to targeted interventions.

However, interventions typically target more than one MoA, and so multiple PoP-RCTs would be required, increasing the burden on respondents. Ideally PoP-RCTs test the ability of the intervention to influence *all* the theorised MoAs and behaviour. Also, what if the intervention is successful in influencing some MoA but not others as required by theory (e.g. attitudes are enhanced but perceived control is not while using the Theory of Planned Behaviour)? Then the underlying theoretical principles applied in the intervention have not been proven. Some behaviour change techniques are linked to multiple MoAs (Connell et al., 2018; Johnston et al., 2020), what if the intervention works through a different MoA then the one theorised, but still works? Moreover, some of the MoA are easier to measure than others, for example it is more difficult to assess automatic MoA, such as implicit attitudes (Cunningham et al., 2001). Work is needed to find ways to assess the effect of intervention on these more automatic MoAs, so they can be incorporated in PoP-RCTs.

PoP-RCTs are already an implicit part of intervention development. By making them an explicit part of intervention development and implementation we think the methodology may be developed, improved, and formalised. By explicitly encouraging research to be specific about the MoAs, interventions become more testable, more standardised, and therefore contribute to an accumulating evidence-base, ultimately, leaving a more secure basis for developing strong effective interventions, and better health behaviours.

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