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Behavior change in practice: Hands-on guides for research and intervention development

Gjalt-Jorn Y. Peters Many health psychologists
co-editor are involved with

Marta M. Marques behaviour change, be it
co-editor through developing

interventions, studying ways to change behaviour or explaining why people engage in risk and health behaviors. Therefore, much of our communication is concerned with the primary research related to behaviour change. This issue of the *European Health Psychologist*, however, addresses a side of our work we rarely discuss in the literature: the practical side of developing or studying behaviour change interventions. Specifically, this issue will address the basic steps required in order to identify which beliefs and determinants to change, and which behaviour change methods can achieve these changes; how to utilize theory in the development of behaviour change methods/techniques; how to publish behaviour change interventions and how to assess and promote fidelity of intervention implementation; how to apply N-of-1 methodology and analyses to examine intervention effectiveness; and how one can go about working towards consensus regarding a specific behaviour change method. Each of these contributions offers practical guidelines that can be useful to students, Ph.D. candidates or other early-career researchers, and practitioners.

In addition, these contributions point out a number of avenues deserving of debate, such as the sometimes ambiguous terminology we use, the rigor of our research, and how to advance behaviour change science. For example, it becomes clear that while at first glance, different terminology may seem to refer to the same concepts, a closer look reveals useful differences in definition. *Methods of Behaviour Change*, a term original from *Intervention Mapping*

(IM; Bartholomew, Parcel, & Kok, 1998), may appear to be a synonym for Behavior Change Techniques (BCTs), a term coined by Abraham and Michie (2008) in their *Taxonomy of Behavior Change Methods*. Closer inspection, however, makes clear that while *Methods of Behaviour Change* are theory-based, and therefore in theory effective, Behavior Change Techniques are descriptions of potential ingredients of an intervention, explicitly detached from theory (Michie, Johnston, & Johnson, 2014). It is important to work towards an integration of these concepts, such that one coherent toolbox of behaviour change methods/techniques can be presented to intervention developers, along with guidelines as to when these methods/techniques are effective. This requires clear reporting of Behavior Change Interventions (BCIs), with a clear vocabulary that acknowledges the dynamics of behaviour change. We hope that the contributions in this issue can facilitate this process.

Content of the Special Issue

The first two contributions by Peters (2014, this issue) and Kok (2014, this issue) pave the way for developing effective theory and evidence based health behaviour change interventions, using the IM framework (Bartholomew, Parcel, Kok, Gottlieb, & Fernández, 2011). IM is a useful tool for planning health promotion interventions that considers a series of key steps. Peters (2014, this issue) presents the rationale to start planning an intervention by identifying target determinants/beliefs. Determinants/beliefs are essential for the development of effective behaviour change methods or techniques, as we need to know exactly what we

are aiming to change when we develop and apply these techniques. In this paper, the author provides a practical guide on how to identify which determinants/beliefs should be targeted, using both quantitative and qualitative methods, and concludes by drawing the reader's attention to the importance of setting clear behaviour change objectives for BCIs.

The article by Kok (2014, this issue) follows on this last point by describing how to link change objectives to theory-based behaviour change methods (or techniques). As illustrated by the author, this means choosing appropriate methods (e.g. modeling) to target selected determinants/beliefs (e.g. Self-efficacy), and correctly translate these to practical applications tailored to each identified situation (e.g. a role model story). In this paper, Kok emphasizes that to translate these methods to effective applications, planners need to respect a method's parameters for use, which are the theoretical constraints within which the method is effective (i.e. moderators of the effect size of a method).

Next, Silva, Marques, and Teixeira (2014, this issue), discuss how theory informs the development of behaviour change methods/techniques, illustrating with Self-Determination Theory (SDT; Deci & Ryan, 2000). The article describes the application of SDT in health behaviour change interventions, providing examples of behaviour change methods that target underlying key theoretical constructs (i.e. support for autonomy, competence, relatedness), which according to this theory lead to sustained behaviour change. The authors provide a summary of a systematic review testing the extent to which SDT-based interventions are theory-based, conducted using the Theory Coding Scheme tool (Michie & Prestwick, 2010). The authors also provide further insight into additional issues related to metatheoretical compatibility when using behavior change methods from different theoretical frameworks, and the need to consider the quality of participant-provider interactions (autonomy vs. controlled interpersonal climate) when delivering behaviour change techniques.

Marie Johnston (2014, this issue) compiles

valuable information on how to better report BCIs. Poor intervention reporting can lead to misinterpretations, which, in turn, will result in the development of BCIs that are not based on the best available research evidence. Based on the recently published Template for Intervention Description and Replication (TIDierR; Hoffman et al, 2014), the author provides a useful guide on what BCIs related procedures to follow and report, with an emphasis on the available tools for the identification, delivery and reporting of behaviour change techniques, such as the Behaviour Change Technique Taxonomy v1 (BCTTv1; Michie et al., 2013). Johnston also discusses the relevance of adequate training in delivering BCIs (i.e. what competence should providers have to be able to effectively deliver BCIs), illustrating this with the Health Behaviour Change Competency Framework (Dixon & Johnston, 2010).

Next, Knittle (2014, this issue) discusses the fidelity of delivery of planned BCIs, emphasizing that lack of fidelity assessment and reporting is an important flaw in behaviour change research. The author discusses the importance of assessing if, when and how behaviour change techniques are delivered in the context of BCIs, in order to increase rigour in behavior change research. Knittle also provides a useful guide on how to assess and promote fidelity, which starts by providing adequate training to intervention providers and by conducting rigorous fidelity assessments when delivering BCIs.

Felix Naughton and Derek Johnston (2014, this issue) present us with an introductory guide to N-of-1 methodology. N-of-1 trials, in which a single participant is the entire trial (within-subject experimental design), have clear advantages over other design methods in health behavior change research, but it is not yet widely used as many researchers (and students) do not know what it is and how to perform it. Naughton and Johnston (2014, this issue) use a case study (caffeine withdrawal for one individual) to illustrate how N-of-1 is applied. In this paper, the authors give an overview of the applications and benefits of using this methodology

in health psychology research, provide useful information on the available tools to conduct such studies, and share their dataset and analysis scripts to help readers to learn how to conduct N-of-1 analyses themselves.

This special issue ends with a contribution from Hagger and Luszczynska (2014, this issue) who report on this year EHPS Synergy Expert Meeting to illustrate how good practice in BCIs can be achieved through Consensus methodology. The purpose of this 2-day meeting was to develop a Consensus statement on Planning/Implementation Intentions interventions in health contexts, from an expert panel composed by researchers and practitioners with knowledge and experience in the field. Using as a starting point a recent review carried out by the facilitators of the meeting (Hagger & Luszczynska, 2014), the panel debated key issues in Planning in health care, such as identifying common features of interventions; salient gaps in the literature; priority topics for future research; and formulation of guidelines for best practice. In this paper, the authors provide an overview of the topic; the methodology used and planned activities; as well as a brief description of the outline of the Consensus statement that is currently under preparation.

In conclusion

This special issue combines a number of up-to-date practical guidelines for the development and research of behaviour change interventions. Because the European Health Psychologist is open access, these contributions can easily be integrated in teaching activities and trainings. This is further facilitated by the fact that many resources have been made publicly available by the authors. In addition to these practical uses, these pieces also offer opportunities for critical reflection on how our science progresses. For example, one question implicit in this issue is how we can deal with the different definitions (operationalisations) of determinants

between studies. And how can we merge the more extensive Intervention Mapping approach to methods of behaviour change with the reliably applicable BCT Taxonomy to work towards a vocabulary useful for both development and analysis of interventions? To what extent do we effectively develop theory- and evidence-based interventions? And how do we report these interventions and the decision process leading up to their development? How can we introduce fidelity registration and analysis in our projects? And should we still accept between-subject designs that examine associations that theory predicts exist within, but not necessarily between, participants? We hope the contributions in this issue can foster debate about the methodology of studying and applying behaviour change principles, and of course, the European Health Psychologist welcomes all responses!

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Gjalte-Jorn Y. Peters
Open University of The Netherlands,
The Netherlands
gjalte-jorn@behaviorchange.eu



Marta M. Marques
Faculty of Human Kinetics, University
of Lisbon, Portugal
martamarques@fmh.ulisboa.pt

A practical guide to effective behavior change: How to identify what to change in the first place

Gjalt-Jorn Y. Peters In 1947, mathematician John von Neuman remarked that mathematics is simple, supporting this claim with a comparison with something infinitely more complicated: "If people do not believe that mathematics is simple, it is only because they do not realize how complicated life is" (Alt, 1972). Behavior change scientists who study behavior change or who develop behavior change interventions operate in between these two extremes of overwhelming complexity and, well, at least *relative* simplicity. Effective behavior change methods (Peters, de Bruin, & Crutzen, 2014) employ theory-based¹ processes of change to influence psychological variables that are postulated to determine behavior. Because, bar physical coercion, no behavior change method operates directly on behavior, this means that identifying the relevant determinants and beliefs to influence is a crucial step in the development, or evaluation, of any behavior change method/technique. The current contribution intends to pave the way for more in-depth discussion of behavior change by outlining basic guidelines for establishing which determinants, and, maybe even more importantly, which beliefs, to influence. This document has been set up to be useful when explaining the basics of behavior change to, for example, students, early-career Ph.D. candidates, or practitioners. Therefore, it will start with outlining, assuming very little knowledge of psychology, why it is imperative to map beliefs and determinants before

even thinking about how to change a given behavior. In the second part, practical pointers will be given as to how to actually do this – map beliefs and determinants. In other words, first I'll explain *what* to change; and then, how to *identify* what to change.

Starting from scratch

Although the approach outlined in these guidelines is not based on any particular single theory, it does make a number of basic assumptions. To make sure that everybody is on the same page, and to make this text as widely accessible as possible, I will start with outlining these assumptions, so feel free to skip the next paragraphs if you already know all this (this bit is where the pretty pictures are though). The first assumption is that influences on human behavior exist either inside or outside a person. Influences outside a person are discussed below in the section on environmental conditions. The second assumption specifically concerns influences within a person. These influences are not directly observable (skin, bones, and muscle tissue unfortunately block the view), so psychologists resort to a variety of indirect methods and combine these with sets of assumptions to draw conclusions about a person's psyche. For example, some methods detect electrical signals or oxygen transport and assume that these are correlated to psychological activity. Other methods use questionnaires, assuming that the answer options that participants endorse provide data on their psyche; or computer tasks measuring reaction times, assuming that comparison of different types of reaction times provides information about associations within participants' psyches.

¹ After all, even basing method employment on exclusively empirical evidence in itself constitutes implicit postulation of a theory regarding the determinants/beliefs that method targets and under which conditions; this implicit theory will just be excessively simplistic in most cases.

One assumption, for which a lot of evidence has been collected, is the assumption that human sensation, emotion, and cognition (basically, everything determining behavior) consists of activation patterns of neurons ('brain cells'). At any given moment, each neuron has an activation level. If this activation level reaches a certain threshold, the neuron 'fires': this causes it to release molecules (called neurotransmitters) that either increase or decrease the activation levels of whichever neurons the firing neuron is connected to. Figure 1 shows an example of three neurons. If the activation level of neuron 1 reaches its threshold, it will activate (or potentially inhibit) neurons 2 and 3. If such activation ('excitation', technically) causes the activation levels of neuron 2 to reach the threshold as well, neuron 2 will also release neurotransmitters to contribute to the excitation or inhibition of neuron 3, which may then in turn excite or inhibit more neurons. Perception of external stimuli (a sunrise, the smell of bacon, or the touch of a friend) cause the activation of neurons; motor activity (basically, any observable behavior) is controlled by activation of neurons; and in between, a *lot* of neurons are excited and inhibited (around 86 billion; Azevedo et al., 2009). Thus, at the most fundamental level, it appears that the human psyche consists of, or functions through, neurons that activate and inhibit each other.

Interestingly, these spreading activation patterns as illustrated in Figure 1 have been shown to exist at higher conceptual levels, as well. An example I frequently use in presentations and trainings for practitioners is the DRM paradigm (Roediger & McDermott, 1995). This is a simple paradigm for creating a very basic 'false memory'. Participants are read a list of words and are instructed to remember these. Then, another word list is read aloud and participants have to indicate, for each word, whether it was present in the first list. The words on the first list are all strongly related to one core concept, such as 'sleep', which itself is not on the list. These relationships, however, all cause the core concept to

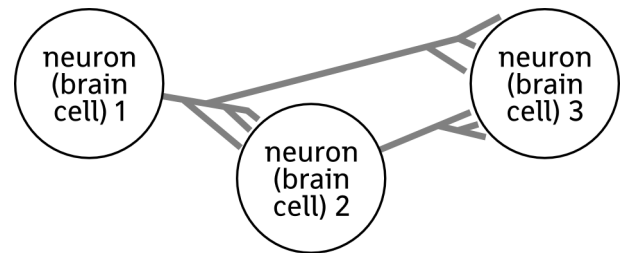


Figure 1: Three connected neurons.

become slightly more activated as more and more related words are presented, and when the core concept is finally listed in the second list, many participants erroneously indicate that they heard it in the first list (when asking a group to raise hands, around one-thirds indicate this, in my experience). Figure 2 shows a fragment of this paradigm; through their connections, 'bed' and 'rest' each contribute to the activation levels of 'sleep'. Of course, more everyday examples are available as well: one memory can trigger another; the first movement in the procedure of tying ones shoelaces automatically activates the next; and more relevantly, pairing cues and thoughts such as when using implementation intentions (see Hagger & Luszczynska, 2014, this issue) can cause perception of a mailbox to remind one of mailing a letter. Thus, it appears this concept of spreading activation is a useful metaphor when thinking about explaining and changing human behavior.

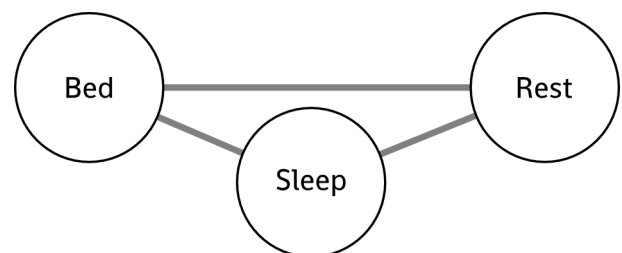


Figure 2: Three connected words or concepts.

What to change: determinants and beliefs

Now, back to determinants and beliefs. The guidelines outlined in the present contribution are

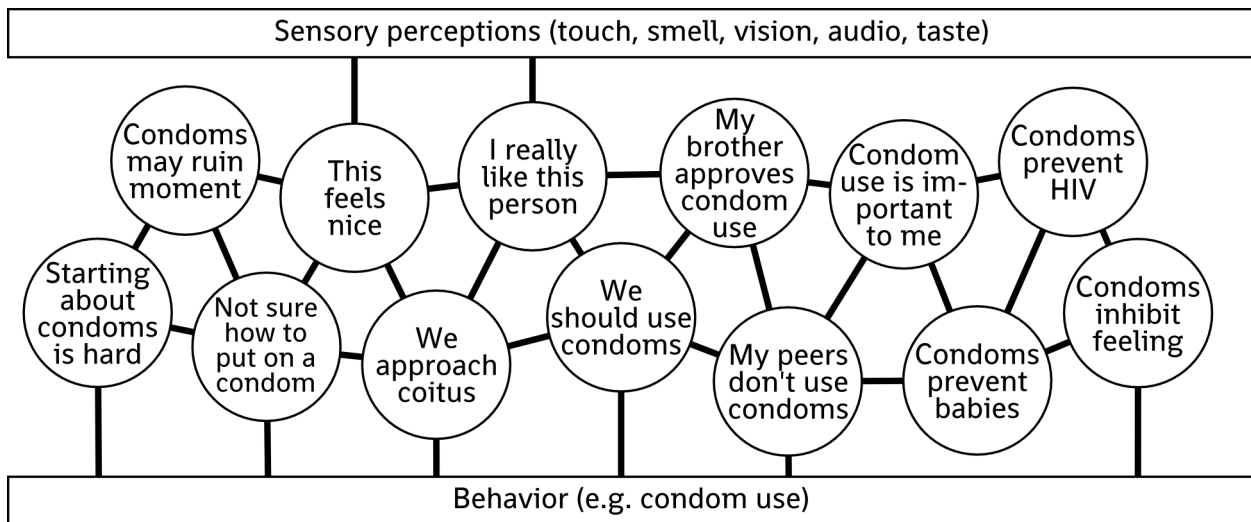


Figure 3: Connected beliefs that contribute to the decision to use condoms.

based on the assumption that behavior is a consequence of a set of processes operating on a set of variables. These variables can be visualised as a network of interconnected nodes, each node representing, for example, a perception, emotion, or cognition. An example showing a fragment of such a network involved in the decision to use condoms during sexual intercourse is shown in Figure 3. Each node corresponds to a belief. It is important to note two things. First, of course, such beliefs do not actually exist in our brains; this visualisation is just a useful metaphor that captures some of the properties of beliefs, which helps to think about beliefs and determinants. Second, although so-called 'implicit' cognitions (as opposed to the more easily verbalisable 'explicit' cognitions), as well as processes that operate on these variables, have been omitted from this illustration, this metaphor holds for those as well. The basic idea is: there is stuff in our minds; this stuff is connected; and when discussing this stuff, it is useful to distinguish entities we call 'beliefs', which correspond to single thoughts, emotional associations, perceptions, cognitions, elements of processes, concepts, associations between

² As I said, this redefinition of a belief as a specific, bounded psychological entity, be it a cognition, an affective association, or an element of a process, is much broader than the definition usually used in the literature.

concepts, etc. Note that this definition of a belief as a psychological entity is substantially broader than the definition generally used in the literature, for example in the Reasoned Action Approach (Fishbein & Ajzen, 2010). In this shiny new definition (i.e. as a psychological entity that is a component of a determinant), a 'belief' can also be an implicit association, or an element of a process, such as attention deployment. This is useful, because in this new definition, all human behavior within a given environment is (by definition) determined by beliefs². It follows that mapping all beliefs allows prediction of behavior.

However, the low-level, specific nature of these beliefs also means that they have a very narrow scope. The belief that condoms prevent HIV will likely contribute to some extent to the decision to use condoms during intercourse; its role in the decision to go jogging despite the rain is likely considerably less substantial (of course, the connections of the belief that condoms prevent HIV to beliefs related to jogging and rain are also very weak or non-existent). Fortunately, psychologists have identified categories of functionally similar or functionally related lower-level psychological entities (beliefs). Such categories are higher-level variables: compound constructs that aggregate these functionally similar or functionally

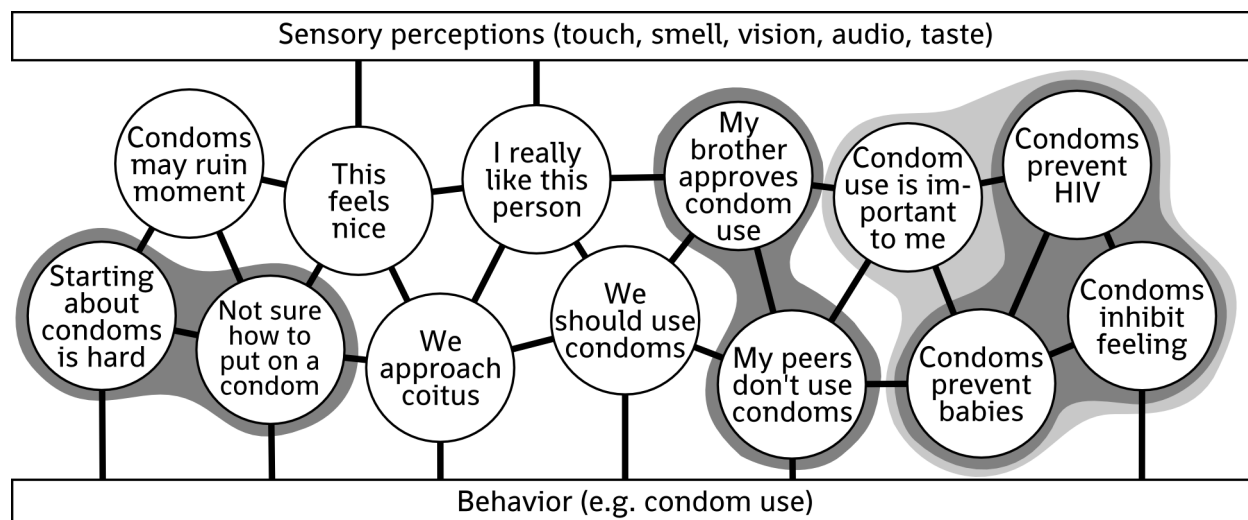


Figure 4: Connected beliefs that contribute to the decision to use condoms, with the determinants formed by the beliefs indicated by shading (from left to right, self-efficacy, subjective norm, traditional TPB attitude (dark gray) and revised RAA attitude including 'importance' (light gray)).

related lower-level beliefs. The definitions of these compound constructs are formulated in theories, which I here consider to be anything that combines variables (something which can have a value) and processes (something which changes values of variables) in a hopefully somewhat coherent description of how part of the human psyche operates. Well-known examples in health psychology are the Reasoned Action Approach (Fishbein & Ajzen, 2010), Social Cognitive Theory (Bandura, 1991), the Health Action Process Approach (Schwarzer, 2008), and the theory of Implementation Intentions (Gollwitzer, 1999; Sniehotta, Schwarzer, Scholz, & Schüz, 2005). Psychological theories postulate psychological variables that predict behavior (or other variables) and/or postulate processes that explain the dynamics of these variables, such as processes by which psychological variables can be changed. The Reasoned Action Approach, for example, mainly concerns itself with defining a number of determinants of behavior and how they relate to each other, rather than postulating methods to change these determinants³; Social Cognitive

³ Although the RAA explains that changing a determinant requires changing the underlying beliefs, it does not concern itself with methods to change those beliefs and thus the overarching determinants.

Theory, on the other hand, does postulate such methods, such as Modeling. Theories about behavior change are discussed more in depth in the contribution by Kok (2014, this issue); for now, we focus on theories that explain behavior.

When a theory postulates the existence of one or more psychological variables, it frequently also defines the (kind of) beliefs that together form the hypothesized variable(s). After all, if the theory limits itself to the description of one or more psychological variables as abstract entities, without considering operationalisation of those variables, the theory cannot be studied empirically. For all practical purposes a psychological variable *is* its operationalisation; any aspects of a variable that are not measured or manipulated unfortunately but necessarily fall without the scope of empirical investigation. If a theory does provide an operationalisation (i.e. a measurement instrument, manipulation, stimulus, etc) or guidelines detailing how to develop an operationalisation, this operationalisation, or the guidelines, will have to be somewhat specific and concrete: in other words, these operationalisations or guidelines address beliefs. For example, questionnaires measuring psychological variables necessarily use relatively concrete/specific items to make sure that all participants can complete

the questionnaire: the variation in capacity for abstract thought in most populations means that using items that employ complex, abstract, concepts severely undermines the validity of the relevant measure.

Sticking to the 'activation patterns' metaphor of beliefs and determinants, a theory, then, consists of definitions as to which beliefs together form which psychological variables. This is illustrated in Figure 4. The RAA, for example, holds that the impression that starting a conversation about condoms is hard and uncertainty about how to put on a condom would together (with many more beliefs) form⁴ the determinant 'perceived behavioral control'. Similarly, the RAA holds that the determinant called 'perceived norm' consists of beliefs such as the perceptions that one's brother approves of condom use, and that one's peers do not use condoms; and that the beliefs that condom use prevents HIV and pregnancy, and that condoms decrease the sensations during intercourse together form 'attitude'. Different theories can (and, of course, often do) contain contradictory definitions. For example, the Reasoned Action Approach holds that effects of distal behavioral predictors such as personality, past behavior, age and gender are mediated by the more proximal determinants attitude, subjective norm, and perceived behavioral control, which in turn predict the even more proximal determinant intention, which finally predicts behavior. However, over time, several potential fourth proximal determinants have been proposed, such as self-identity. One belief proposed to be a part of self-identity is "Condom use is important to me". In their 2010 revision of the TPB into the RAA, Fishbein and Ajzen argued that in fact, this aspect of self-identity can be subsumed in their attitude construct, when a number of adjectives assessing the importance of a

⁴ Note that in most situations, it is very hard to empirically distinguish whether two psychological variables *influence* a third variable, or whether the two variables are *a part of* the third variable. In both cases, the same pattern of correlations will be observed, and in both cases, changing one of the two 'minor' variables changes the 'major' variable. Neither case usually makes explicit predictions as to what happens with the 'minor' variables if the 'major' variable is changed.

behavior are added to the semantic differentials used to operationalise attitude (2010, p. 292). Of course, when trying to *explain* behavior, the most important thing is that all relevant beliefs are identified, and of which particular psychological variable one considers these beliefs to be a part is secondary. However, when trying to *change* behavior, determining to which determinant a belief 'belongs' becomes crucial, because methods for behavior change are usually matched to determinants, not to beliefs. After all, psychological researchers usually try to study behavior change methods that are applicable across a variety of behaviors and populations. Applying a behavior change method that has been shown to successfully enhance self-efficacy, such as Guided Practice, to change a belief that doesn't underlie self-efficacy but instead underlies subjective norm, such as "My parents disapprove of me drinking too much", will most likely fail. Therefore, it is important to have a clear idea of which beliefs 'belong' to which determinants (and therefore, often, which theories are employed).

What to change: environmental influences on behavior

In addition to influences within a person, there are also influences in a person's environment that influence his or her behavior. Free provision of condoms facilitates condom use; ubiquity of gyms facilitates exercise; and widespread availability of unhealthy foods complicates adherence to a healthy diet. These environmental conditions are usually changeable as well – they can usually be changed by the behavior of other people. Such other people, holding key positions in the environment of target population individuals, are usually referred to as environmental agents or actors (Kok, Gottlieb, Commers, & Smerecnik, 2008). Examples are parents, partners, nurses, teachers, directors of hospitals, school boards, or politicians. Each environmental

actor is located with a certain proximity to the target population, or perhaps more accurately, has a certain role in the environment of the target population. For example, some environmental agents directly socially interact with the target population; others control an infrastructure in which the target population is involved either directly (employers, schools, hospitals) or indirectly (politicians). Four such environmental levels are often distinguished, usually visualised as concentric circles around the target population individuals: interpersonal (e.g. parents, peers), organisational (e.g. director, school board), communal (e.g. community leaders, religious leaders), and societal (e.g. politicians). In theory, a fifth 'global' level exists (e.g. the World Health Organisation and the United Nations). These levels are useful, because research into behavior change methods to target environmental actors has identified, for example, methods that work for actors on the societal level, methods that work for actors on the organisational level, etc. The contribution by Kok (2014, this issue) will treat this more thoroughly: for now, it is important to remember that environmental influences on behavior can be traced to environmental agents, and that for each of these agents, it is important to identify on which environmental level(s) they reside.

What to change: behaviors and sub-behaviors

There is one more important term to agree on before starting with the practical guidelines. This relates to sub-behaviors. When we discuss behaviors we want to change, we often talk about very broadly defined behaviors, such as smoking, safe sex, physical activity, substance use, or diet. These behaviors usually comprise a set of preparatory and/or sub-behaviors, sometimes quite limited and clear (van Empelen & Kok, 2006), but sometimes compiling an exhaustive list can be practically impossible (e.g.

diet). In all cases, it is important to try to be aware of which preparatory and/of sub-behaviors are to be influenced, because the determinants and environmental conditions can differ between these behaviors. For example, adolescents may have different reasons to refrain from buying condoms than they have for carrying condoms; and different reasons again for bringing up the subject of condom use with a partner. Making these preparatory and/or sub-behaviors explicit makes it much easier to obtain an overview of the relevant determinants and environmental conditions. We could say that any behavior change intervention in fact has several behavioral objectives, each of which concerns performance of a preparatory or sub-behavior. Therefore, from here on we will refer to such preparatory and/or sub-behaviors as *performance objectives* of an intervention (Bartholomew, Parcel, Kok, Gottlieb, & Fernández, 2011). Achieving all performance objectives, then, means that the intervention is effective; if all performance objectives are performed, the overarching behavior is by definition also performed. If one or more performance objectives are not achieved, the likelihood that the overarching behavior is performed is much lower; for example, if an adolescent buys condoms, but does not carry condoms when needed, the likelihood of safe intercourse is very low. Thus, an intervention promoting condom use that addresses communication about condoms is more likely to be effective than an intervention that only addresses the benefits of condom use.

How to identify what to change in the first place

Combining these bits of information, we could say that most behaviors consist of sub-behaviors (called performance objectives in a behavior-change context), each of which is determined by personal determinants and environmental conditions. We have

psychological theories proposing ways in which these determinants are related to each other and to behavior, as well as theories about how to change these variables. Because determinants have similar dynamics over behaviors and populations, they are by definition generic and abstract: determinants are convenient categories of functionally similar or functionally related sub-entities which we call beliefs. These beliefs are specific to behaviors and populations, and therefore provide 'tangible', concrete objectives to target in an intervention. Now a vocabulary has been established, we can discuss the task of identifying these performance objectives, environmental conditions, determinants, and beliefs for a given target behavior. In applied research such as this, methodological promiscuity has considerably benefited. Ideally, an overview of the existing literature is supplemented with interviews with target population members and possibly key environmental actors, and the results of these two steps are quantitatively verified so that the relative importance of determinants and beliefs can be established. Each of these three steps will be explained below in more detail.

Systematic reviews

A useful start is to compile the available empirical evidence. It usually pays to do this sufficiently thorough and systematic, so that the findings can be published in the literature. That way, others can benefit from your efforts as well. There are a lot of workshops and resources available that deal with conducting systematic reviews (Khan, Kunz, Kleijnen, & Antes, 2003; Moher, Liberati, Tetzlaff, & Altman, 2009), but many of these focus on how to extract, analyse, and report data. Therefore, to give you an idea of all involved phases, Box 1 shows a rough overview in case you want to plan a systematic review.

Ideally, there is a lot of literature available reporting correlations between determinants and

behavior, or between more distal determinants of behavior, such as self-efficacy, and more proximal determinants of behavior, such as intention. In such situations a meta-analysis can be conducted to integrate the evidence. Sometimes, there is even enough evidence to examine which beliefs are important in the same way. Often, however, a lot of evidence, especially on the more specific level of beliefs, will be qualitative; and sometimes, bivariate associations are not reported, and only univariate results such as percentages of participants endorsing a belief are reported. Such evidence is by design excluded from a meta-analysis, and therefore, it is usually worthwhile to consider conducting a qualitative review as well. For an example of a meta-analysis and subsequent qualitative analysis on the same topic, see Peters, Abraham and Kok (2008) and Peters and Kok (2009).

A literature overview and integration yields an overview of what is already known about your target behavior, sometimes even for your target population. However, what is known might be very little; and even if it is a lot, it is very common that most studies examined populations that differ slightly, or a lot, from the target population at hand. Therefore, it is often necessary to verify these findings for the specific target population and context at hand.

Interviews

Whenever you develop an intervention, it pays to actually talk to your target population members and relevant stakeholders. In fact, it is wise to involve them in an early stage, for example in so-called Linkage Groups (Bartholomew et al., 2011). However, in addition to their active participation in the intervention development and preparation for that development, interviewing target population members in a qualitative study also has substantial benefits. Any behavior change intervention that does not exclusively work through environmental change will need to know which beliefs are important to the

Box 1: Basic steps for synthesizing the literature on determinants and beliefs

1. *On the basis of your research question and your knowledge of the literature, develop a first version of a coding sheet to extract methodological and statistical data from publications;*
2. *On the basis of your research question and the information required in your coding sheet, establish in- and exclusion criteria, and invert all inclusion criteria to exclusion criteria that can be used for screening;*
3. *On the basis of your research question, coding sheet, and in- and exclusion criteria, craft a query using the logical operators OR (to combine synonymous keywords) and AND (to combine sets of synonymous keywords);*
4. *Select bibliographic databases and interfaces to use (e.g. PubMed using its own interface; PsycINFO using Ebscohost or Ovid; etc), and translate your query to each database/interface combination;*
5. *Run the query in all interfaces, export the hits and merge these records into one file;*
6. *Establish exclusion criteria and let two or more independent screeners screen the records on basis of title/abstract;*
7. *Acquire full texts for all records that could not be excluded by both screeners, and let the screeners screen these again in the second screening round;*
8. *Apply secondary methods to identify relevant publications, such as the ascendancy approach (screen reference lists of included publications), descendancy approach (screen publications citing the included publications), and identifying grey literature (e.g. through mailing lists etc);*
9. *Use the coding sheets to extract methodological and statistical data;*
10. *Synthesize the data and report your results.*

NOTE: the appendix at <http://osf.io/fp8kv> has a list of free and cheap software packages that you can use for these tasks.

target population. After all, even if the important determinants have been identified, any intervention targeting these determinants will need to communicate one or several specific messages, and these messages need to address beliefs that are important to the targeted determinants. For some behaviors, risk perception beliefs will be an important part of attitude; for other behaviors, risk perception will be irrelevant; and even if risk perception beliefs are important, the risks that are perceived differ from behavior to behavior and from population to population. Therefore, conducting a qualitative study can considerably increase the likelihood that your intervention is effective. Like for systematic reviews, the basic steps in conducting a qualitative study are

summarized (see Box 2; and for an excellent practical textbook, see e.g. Ritchie, Lewis, McNaughton Nicholls, & Ormston, 2014).

At this point, you will have collected a wealth of information about why your target population behaves the way they do. You will know the reasons that people report for behaving as desired, and the reasons that people report when they exhibit the undesirable behavior (usually the unhealthy behavior). You will know what sub-behaviors people consider this behavior to consist of, and you will know which environmental conditions, beliefs, and determinants might play a role for each sub-behavior. Unfortunately, 'might' is the operative word here. After all, people are not always aware of the reasons

Box 2: Basic steps for qualitative exploration of determinants and beliefs

1. *On the basis of the literature review, theory, and consultation with experts regarding your target behavior and target population, establish a topic list of topics that you want to address in the interviews. Make sure that you also pay attention to what participants actually do: your definition of the behavior at hand might differ from theirs;*

2. *Determine whether you will only conduct individual interviews, or also focus groups. Focus groups allow observation of norms and group dynamics, but can inhibit openness of individual participants. For public behaviors, focus groups can be a useful addition, whereas for more private behaviors, they may have little added value (and be quite awkward);*

3. *Recruit target population members. This may be quite hard depending on your target population; when you study exercise behavior among students, it's considerably easier than when you are interested in needle sharing among hiv-positive migrant sex workers. Getting in touch with dedicated NGO's may be very helpful (in fact, having these in your Linkage Group can be helpful as well);*

4. *Secure a quiet, neutral venue, recording equipment, and possibly organise support for the interviewer and/or the participants (interviews can become quite intense). Also, acquire ethical approval and plan your data management (e.g. how will you make sure the original audio recordings are safely stored and that only one or a few people have access?);*

5. *Conduct the interviews, updating the topic list as your insights develop;*

6. *Transcribe the data (or get an organisation to transcribe; this may be considerably cheaper);*

7. *Code the data. Specifically, try to identify whether the beliefs you observe 'belong to' a known determinant. Our knowledge on methods for change is, after all, based on research into determinants.*

8. *Report your results.*

NOTE: the appendix at <http://osf.io/fp8kv> has a list of free and cheap software packages that you can use for these tasks.

for their behavior. In addition, reasons that are considered important to people do not necessarily have to be important predictors of behavior: after all, the correlation of a belief with behavior is rarely a factor people take into account when determining how important they consider the belief. Therefore, a quantitative verification of the combined outcome of the literature review and the qualitative study is often necessary.

Survey

As De Bruin, Viechtbauer, Hospers, Schaalma and Kok concisely stated, "the quality of an intervention can be defined as the degree to which effective behavior change techniques are adequately applied to important determinants of target behaviors" (2009), and this means that determining relative importance of behavioral determinants is necessary. By extension, given that any behavior change method will have to address specific beliefs, this means that determining relative importance of the beliefs underlying each determinant is also necessary. This requires

Box 3: Basic steps for quantitative verification of determinants and beliefs

1. Compile an overview of all determinants and beliefs that you identified up until this point;
2. Develop operationalizations for each determinant and belief. Some theories provide guidelines; Francis et al. have developed an excellent manual for the TPB (2004), and the RAA (Fishbein & Ajzen, 2010) also contains sections on measurement. In any case, try to avoid categorical or dichotomous operationalisations, as these considerably decrease your power and are usually less valid. Avoiding 'disagree-agree' answer options can also be useful, as 'disagree' can often be interpreted either as "neutral" or "the opposite";
3. Combine these operationalizations in one measurement instrument, and pilot-test this with your target population to make sure your items are understandably and unequivocally formulated;
4. Acquire ethical approval and plan your data and resource management (e.g. if your data is not collected anonymously, how will you anonymize it, and how will you restrict access to the raw, un-anonymized datafiles? If you do collect your data anonymously, then how will you obtain the measures of participants' behavior(s) after the chosen timeframe? How will you secure your resources for later inspection and publication?);
5. Once you have your data, visualise the univariate distributions of all variables, inspect scattermatrices to assess item and variable associations, and aggregate items into variables (see e.g. Peters, 2014).
6. Compute confidence intervals for correlation coefficients to estimate how strongly each determinant predicts your target behavior or performance objective (the 'userfriendlyscience' R package described in Peters (2014) contains the function *rMatrix*, which creates a correlation matrix with confidence intervals);
7. Compute confidence intervals for correlation coefficients to estimate how strongly each belief predicts the determinant it is a part of;
8. Conduct a regression analysis to obtain an R^2 measure to get an impression of the degree to which you understand your performance objective or target behavior and each respective determinant. Note that regression coefficients should not be interpreted as coefficients of importance; bivariate analyses lend themselves better to determine relative importance.
9. Report your results.

NOTE: the appendix at <http://osf.io/fp8kv> has a list of free and cheap software packages that you can use for these tasks.

quantitative data, which can be acquired using, for example, a survey⁵. Box 3 shows the steps typically involved in conducting such a survey.

⁵ Of course, if methods are available to change implicit associations, it can be useful to measure these as well; and similarly, measuring processes, such as for sample self-regulation, can be useful as well.

Towards selection of behavior change methods/techniques

After these three studies, you will have a pretty good idea of what you should target in your intervention. At this point, it is easy to get quite confused by the overwhelming plethora of performance objectives, determinants, and beliefs.

Fortunately, there exists a standardised method of combining and documenting all this information for a given behavior and population: the so-called matrix of change objectives (Bartholomew et al., 2011). Such a matrix provides a convenient method to organise almost everything you know about predicting a given behavior. The rows of the matrix are the performance objectives (the preparatory/sub-behaviors), and the columns are the determinants. In each cell, the

beliefs are listed for the corresponding determinant/performance objective combination. Of course, some cells will contain multiple beliefs and some will be empty. It can be convenient (and is somewhat customary) to phrase these beliefs as so-called 'change objectives', describing the desirable situation to be achieved. For example, the control belief related to one's ability to go to the gym in adverse weather conditions, which might be measured

Target population: EHPS member Target behavior: submit EHP contribution	Determinant 1: Attitude	Determinant 2: Injunctive norm	Determinant 3: Self-efficacy
PO1: Decide to contribute	CO1.1.1: explains how contributing can foster collaboration and networking CO1.1.2: explains how contributing can cause a warm fuzzy feeling	CO1.2.1: describes peers' approval of EHP contributions	
PO2: Select an interesting topic		CO2.2.1: describes peers as being interested in interesting topics	CO2.3.1: expresses confidence in determining what topics are 'hot' in the field CO2.3.2: expresses confidence in identifying an intersection of these 'hot' topics with one's own expertise
PO3: Approach co-authors	CO3.1.1: explains how writing papers alone can feel lonely		CO3.3.1: explains how to convince co-authors of the benefits of collaborating on an EHP contribution

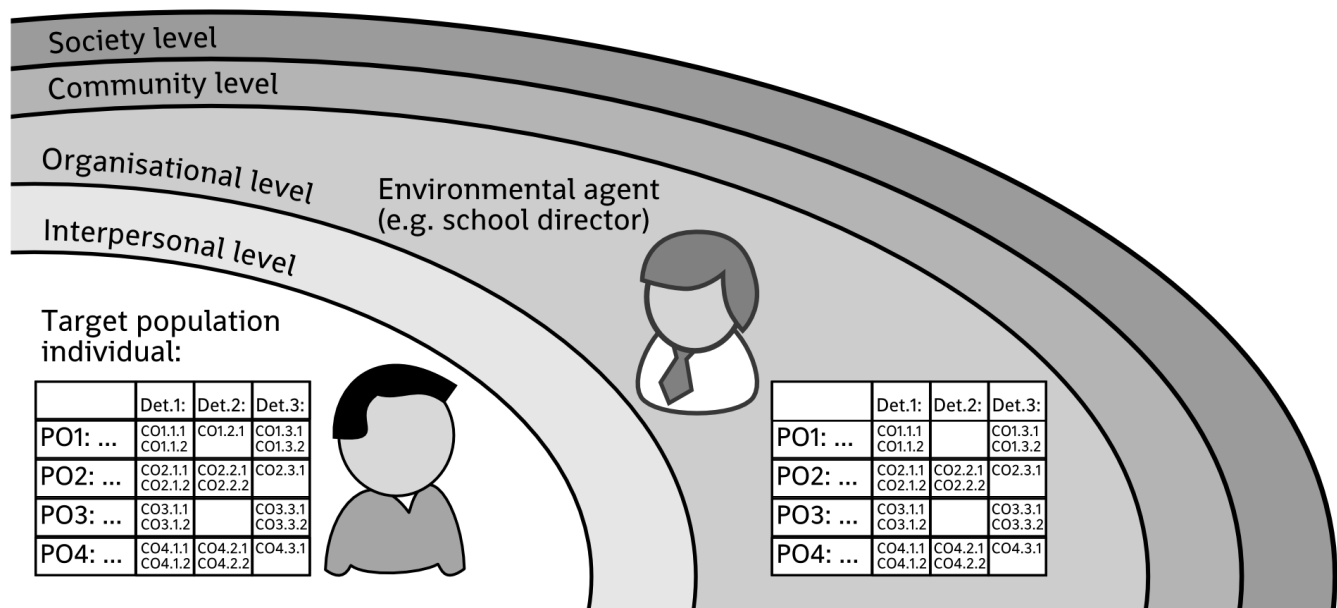


Figure 5: The matrix of change objectives for a target population individual, and at the organisation environmental level, an actor with his/her matrix of change objectives to change an environmental condition.

with the item “I know I can go to the gym, even if it rains” in a questionnaire, corresponds to the change objective “The target population individual expresses confidence regarding going to the gym despite rainy weather”. If this change objective has been achieved, the likelihood that the target population individual exercises regularly is increased. So, if all change objectives for a performance objective have been achieved, the performance objective has been achieved; and if all performance objectives have been achieved, the relevant individual changed his or her behavior, at least, to the degree that this behavior is independent from environmental conditions. To change these environmental conditions, it is necessary to identify which environmental agents have the ability to change these conditions, and then identify what they can do to effect these changes. Of course, these environmental agents’ behaviors consist of performance objectives, which again are predicted by personal determinants and environmental conditions. This is systematically shown in Figure 4. A fictitious example of a matrix of change objectives is shown in Table 1. For more inspiration, real world examples of matrices of change objectives are available in the literature (Dalum, Schaalma, & Kok, 2012; Mikolajczak, Kok, & Hospers, 2008).

With this information, you can consult overviews of behavior change methods/techniques, and match these to the relevant determinants. Documenting your choices and their justifications will allow you to clearly report the empirical and theoretical evidence for your intervention (Fuller, Pearson, & Peters, 2013; Peters, Abraham, & Crutzen, 2012; Schaalma & Kok, 2009). In addition, by carefully planning your evaluation, this will allow you to pin-point opportunities for improvement, by making it easier to see where you may have omitted important beliefs (Bartholomew et al., 2011). Hopefully, the basic guidelines provided in this paper, combined with the free/cheap software suggestions in the appendix at <http://osf.io/fp8kv>, can contribute to making the mapping of determinants, beliefs, and environmental conditions more accessible. Note that the figures in

this paper have been released into the public domain and are available at <http://osf.io/fp8kv>, so feel free to use these in training students or practitioners.

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Gjaltn-Jorn Y. Peters
Open University of The Netherlands,
The Netherlands
gjaltn-jorn@behaviorchange.eu

A practical guide to effective behavior change

How to apply theory- and evidence-based behavior change methods in an intervention

Gerjo Kok

Maastricht University

In planning behavior change, we encounter three major challenges: 1) the correct identification of the change objectives (and thereby the evaluation outcomes), 2) the selection and application of appropriate behavior change methods in an intervention, and 3) adequate implementation of the intervention. As a consequence, the most frequent intervention failures include: incorrect identification of change objectives, inappropriate choice of methods or applications, or inadequate implementation in terms of completeness and fidelity of the program being delivered. The current contribution provides a practical guide to effective behavior change, with a particular focus on the second challenge: choosing behavior change methods, translating methods into practical strategies, and combining strategies in order to develop an effective intervention. This paper therefore fits well between the paper written by Peters (2014, this issue) on "How to identify what to change in the first place?", and the paper by Knittle (2014, this issue) on "Fidelity in intervention delivery".

Intervention Mapping

Our approach to intervention development is based on Intervention Mapping (IM). IM is a protocol for systematic theory- and evidence-based planning for behavior change (Bartholomew, Parcel, Kok, Gottlieb, & Fernández, 2011). The IM protocol describes the iterative path from problem identification to problem solving or reduction. Each of the six steps of IM comprises several tasks, and each of these tasks

integrates theory and evidence. The completion of the tasks in each step creates an end product that can be used as a guide for the subsequent step. The completion of all of the steps serves as a blueprint for the design, implementation, and evaluation of an intervention that is based on a foundation of theoretical, empirical, and practical information. The six steps of the IM process are: (1) Conducting a needs assessment or problem analysis; (2) Creating matrices of change objectives by combining (sub)behaviors with behavioral determinants; (3) Selecting theory-based intervention methods and translating these into practical applications; (4) Integrating methods and applications into an organized program; (5) Planning for the adoption, implementation and sustainability of the program (from the start of the IM process); (6) Generating an evaluation plan (also from the start of the IM process). The key words in IM are planning, research and theory. IM provides a vocabulary for program planning, procedures for planning activities, and technical assistance with identifying theory-based determinants and matching them with appropriate methods for change. Of the three major planning challenges that were mentioned in the introduction, the first-- identifying the change objectives -- comprises IM steps 1 and 2, and part of step 6. The second challenge--selecting the appropriate behavior change methods and applying those in an intervention--comprises IM steps 3 and 4, and the third challenge--adequate implementation--comprises IM step 5. Figure 1 summarizes the IM steps and tasks described above.

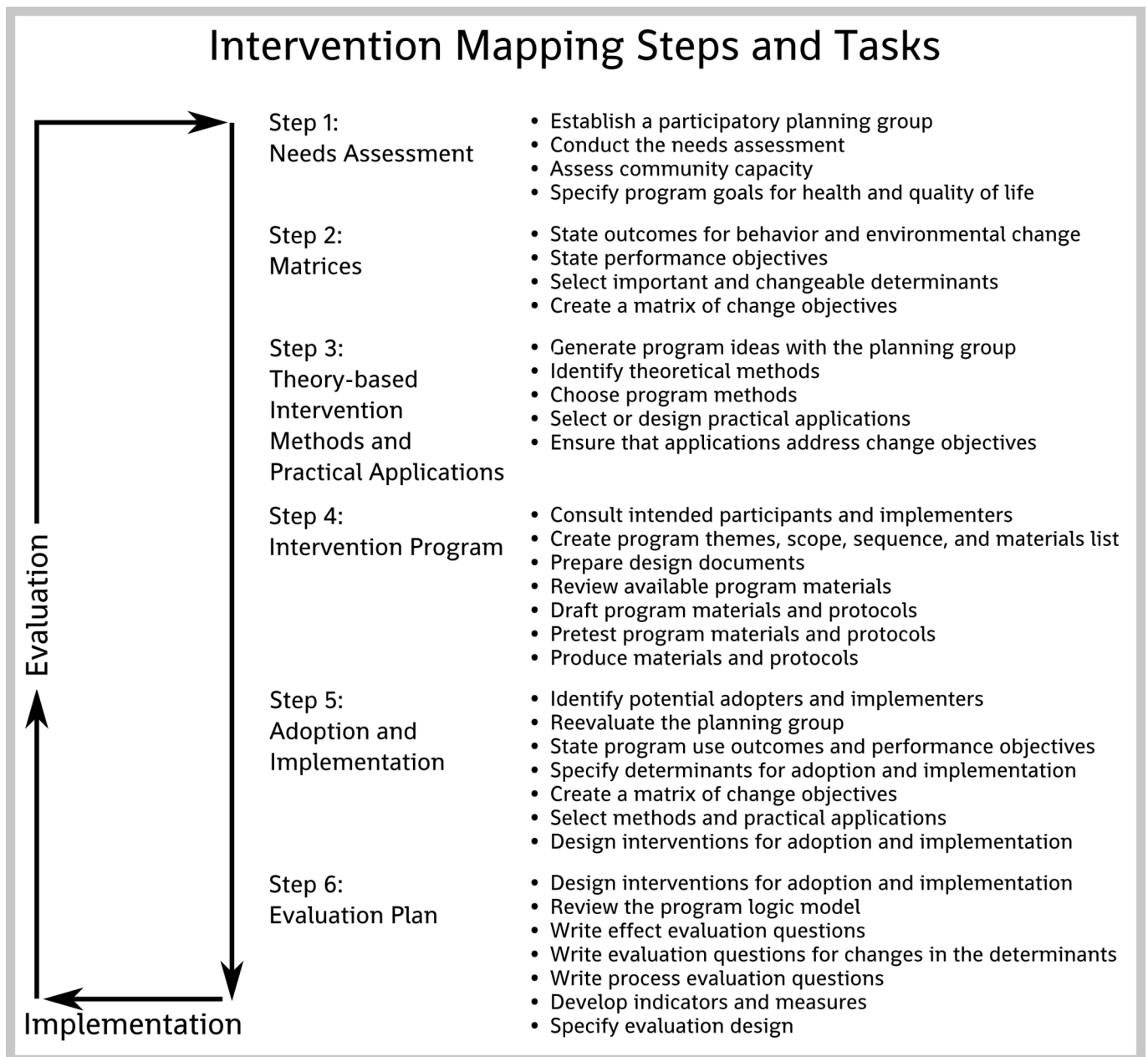


Figure 1: Intervention Mapping steps and tasks.

Perspectives on theory, systems and participation

IM is guided by three perspectives: a multi-theory approach, an ecological approach, and a participation perspective, each of which will be described in more detail below.

The multi-theory approach

IM encourages working with multiple theories. Theories can be seen as reductions of reality -- this is not a shortcoming, but rather the definition. One theory will therefore never explain all aspects of a real-life problem. As a consequence, we use various theories when planning behavior change, each of

which focuses on one aspect of the behavior or the behavior change (Bartholomew et al., 2011, Chapters 2 and 3). Some theories are especially relevant in terms of identifying the determinants of behavior (e.g., Reasoned Action Approach, Social Cognitive Theory, Dual Systems Theory and Ecological Approach); others are more useful with regard to choosing and applying behavior change methods (see Table 1). One theory will seldom be enough to inform all aspects of the process. However, at the same time, it must be noted that attempting to integrate various theories into one overarching framework is rarely helpful. A theory is more than a list of variables; the relationship among the variables often forms the core of the theory. The unique skill of the well-trained behavioral scientist is to link the relevant elements of a given problem to useful theories (Buunk & van Vugt, 2013). Ergo, behavioral scientists and their unique expertise are needed in an intervention planning team.

The ecological approach

As mentioned above, the second approach which informs IM processes is the ecological approach. IM acknowledges that humans and human behaviors are part of a complex system. Individuals live and work in many different kinds of multi-level environments, including interpersonal, organizational, community and societal environments (Bartholomew et al., 2011; Kok, Gottlieb, Commers, & Smerecnik, 2008). Changing people's health behaviors (e.g. the behavior of a group of employees) therefore also involves changing the relevant environmental conditions (e.g. the workplace). These environments are often not under the control of the individual, but rather under the control of some agent or decision maker (e.g. a manager). Thus, changing an environmental condition for health purposes also involves changing the behavior of the environmental agent. On the one hand, environmental agents are individuals and may be targeted with individual-level behavior change methods. On the other hand, they also function at an

environmental level, and may be targeted with behavior change methods that are effective at that level, e.g. organizational change methods or community development methods.

The participation perspective

The third approach that IM is guided by concerns the participation of all stakeholders (involved parties). IM sees planning health promotion interventions not as a solitary activity, but rather as team work. The participation of all stakeholders involved (including the target population) in the intervention planning team is not only a decent thing to do, but it is also essential for success. Earlier in this paper, we mentioned three possible major planning failures: incorrect identification of change objectives, inappropriate choice of methods or applications, and inadequate implementation. All three of these failures are often the result of insufficient participation of the target population (e.g. students), intended implementers (e.g. teachers), decision makers (e.g. school managers), and so forth. The only way to establish the relevant determinants of behavior, is by contacting the relevant target population, as well as the agents and stakeholders around them (see Box 1 and Box 2 in Peters, 2014, this issue). Similarly, the only way to find out how methods should be applied in the process is by contacting the target population, intended implementers and other relevant stakeholders.

From change objectives to theory-based methods

As mentioned earlier, Peters (2014, this issue) focuses on how to identify what needs to change (the first major challenge of the IM process), and ends his contribution with a matrix of change objectives for target individuals and environmental agents, the end product of IM step 2. As the next part of the process,

Box 1: Basic steps for linking change objectives to theory-based methods and practical applications

Before you start:

A. *Establish a participatory planning group and specify program goals. Ensure that there is a well-trained behavioral scientist in the planning team, as well as representatives of the target group and of the intended implementers.*

B. *Create a matrix of change objectives, see Peters (2014, this issue).*

Basic steps:

1. *Generate program ideas with the planning group. Most planning group members already have some ideas about the program. Planners must find a balance between preliminary ideas generated by team members on the one hand, and theory- and evidence-based decisions about methods, applications and programs on the other hand. What lay people think is effective may not be congruent with scientific evidence.*

2. *Identify theoretical methods. Order all change objectives by determinant, i.e. the columns in the matrix of change objectives, so that you end up with a list of change objectives (or, beliefs to influence) for each determinant. Then, determine which methods can change each determinant you have identified. Next, order the environmental change objectives according to their level (e.g. organizational, community, etc.). Determine which methods are appropriate for each level. Remember that individual level methods can also be applied to environmental level change objectives. Make sure you keep track of the parameters for effectiveness for each method, for example from the tables in Bartholomew, et al. (2011).*

3. *Choose program methods. On the basis of the lists of methods that you have compiled, select the methods you want to use. Ensure that all of the methods you select are theory-based. Again, keep in mind that all methods have parameters for effectiveness.*

4. *Select or design practical applications. Design creative program applications that fit the context and characteristics of the program participants while ensuring that the applications still address the parameters for the selected methods. When you are done, look through the lists of change objectives once again. Make sure that each change objective ended up in an application; that each application is the manifestation of one or several theoretical methods; and that all parameters of each method are satisfied.*

we now need to link those change objectives to theoretical methods and apply those methods correctly in an intervention, IM steps 3 and 4 (see also Box 1).

A theory-based behavior change method is a general technique or process designed to influence the determinants of behavior (for example, of members of an at-risk group, or of environmental decision makers) (Abraham & Michie, 2008;

Bartholomew et al., 2011). Theory-based methods are based on the literature regarding effective behavior change. This type of research almost never concerns methods for direct behavior change. Rather, in almost all cases, change methods are used to target determinants such as attitude or self-efficacy that are in turn thought to influence the behavior. In this way, theory-based methods are linked to change objectives via determinants. The generic nature of

Table 1: A selection of methods, parameters, and examples of applications

Methods, theory and definitions	Parameters for use	Examples
Examples of basic methods at the individual level		
Modeling		
<i>Providing an appropriate model being reinforced for the desired behavior.</i> (Social Cognitive Theory; Theories of Learning: McAlister et al., 2008; Kazdin, 2008)	Attention, remembrance, self-efficacy and skills, reinforcement of the model, identification with the model, use of a coping model instead of a mastery model.	The health promoter finds a role model from the at-risk group who will encourage identification and serve as a coping model: "I tried to quit smoking several times and was not successful, then I tried ... Now I have been off cigarettes for ..."
Facilitation		
<i>Creating an environment that makes the action easier or reduces barriers to action.</i> (Social Cognitive Theory: Bandura, 2004)	Requires real changes in the environment, identification of barriers and facilitators, power for making changes, and usually intervention at a higher environmental level to facilitate conditions on a lower level.	A program that targets improvement in drug users' self-efficacy for using clean needles must also facilitate accessibility of clean needles.
Examples of methods used to change awareness and risk perception		
Consciousness raising		
<i>Providing information, feedback, or confrontation about the causes, consequences of, and alternatives for, a problem or a problem behavior.</i> (Health Belief Model; Precaution-Adoption Process Model; Trans-Theoretical Model: Champion & Skinner, 2008; Weinstein et al., 2008; Prochaska, et al., 2008)	Can use feedback and confrontation. However, raising awareness must be quickly followed by an increase in problem-solving ability and (collective) self-efficacy.	An HIV counselor reminds a person of recent episodes of failure to use condoms when having sex, and the potential consequences of that behavior for significant others. Then the counselor encourages the planning of coping responses.
Scenario-based risk information		
<i>Providing information that may aid the construction of an image of the ways in which a future loss or accident might occur.</i> (Precaution-Adoption Process Model: Mevissen et al., 2009)	Plausible scenario with a cause and an outcome; imagery. Most effective when people generate their own scenario or when multiple scenarios are provided.	Peer models in an HIV-prevention program present a series of scenarios in which they describe how they found themselves in risky situations, for example, a sexual relationship over the summer holidays.

these determinants, and the methods used to change them, are consistent with the study of human behavior and psychology in general; yet at the same time, this means that such methods cannot immediately be applied in behavior change interventions. Rather, they require translation into practical applications (see next paragraph). With respect to environmental levels, methods are linked to each level: interpersonal, organizational,

community and policy levels.

In order to select appropriate methods for changing environmental conditions in a health intervention, the first step is to find out who may be in a position to make the expected change. The program planner has to identify the desired behaviors for the agent who will actually change the environmental conditions in order to address the health issue at hand. The health promoter can then

Table 1: A selection of methods, parameters, and examples of applications (continued)

Methods, theory and definitions	Parameters for use	Examples
Examples of methods used to change skills, capability, and self-efficacy, and to overcome barriers		
<p>Cue altering <i>Changing a stimulus, either consciously or unconsciously perceived, that elicits or signals a behavior.</i> (Theories of Goal Directed Behavior; Theories of Automatic, Impulsive and Habitual Behavior: Verplanken & Aarts, 1999; Wood & Neal, 2007)</p>	Existing positive intention.	Dieters change the route they take, walking to work in order to avoid easy access to snack shops.
<p>Planning coping responses <i>Prompting participants to list potential barriers and ways to overcome these.</i> (Attribution Theory and Relapse Prevention Theory; Theories of Goal Directed Behavior: Marlatt & Donovan, 2005; Hoffman et al., 2008)</p>	Identification of high-risk situations and practice of coping responses.	The HIV nurse and the patient define the causes of non-adherence. Then the HIV nurse and the patient formulate solutions to solve or avoid the causes for non-adherence.
Examples of basic methods at the environmental level		
<p>Participatory problem solving <i>Diagnosing the problem, generating potential solutions, developing priorities, making an action plan, and obtaining feedback after implementing the plan.</i> (Organizational Development Theories; Social Capital Theory; Models of Community Organization: Butterfoss et al. 2008; Cummings & Worley, 2015; Minkler et al. 2008)</p>	Requires willingness by the health promoter or convener to accept the participants as equals and as having a high level of influence; requires target group to possess the appropriate motivation and skills.	A health promotion consultant assists employees of a small company to identify the level and sources of stress and then develops a plan with management to address and monitor work stress.
<p>Technical assistance <i>Providing the technical means to achieve desired behavior.</i> (Organizational Development Theories, Diffusion of Innovations Theory, Social Capital Theory, Models of Community Organization: Flaspohler et al., 2008; Mitchell et al., 2002)</p>	Nature of technical assistance will vary according to environmental level but must fit needs, culture, and resources of recipient.	A health department liaison helps a community health center develop recruitment procedures, training, and supervisory guidelines as they establish a new lay health worker program.

apply methods to influence the determinants of the agent's behavior (using a variety of methods which are appropriate for changing determinants at different environmental levels). For example, a basic method used for changing determinants at all environmental levels is *advocacy*; a method used at the interpersonal level is *enhancing network linkages*, at the organizational level *sense-making*, at the community level *social action*, and at the policy level

agenda setting.

Most methods specifically target one type of determinant, e.g., *scenario-based risk information* is assumed to influence risk perception. It may also have a (weaker) effect on attitudes. Some methods are more generally applicable, e.g. *modeling* may be applied to influence self-efficacy, perceived norms, attitudes, or risk perception. *Organizational diagnosis and feedback* are most effective at the organizational

Table 1: A selection of methods, parameters, and examples of applications (continued)

Methods, theory and definitions	Parameters for use	Examples
Examples of methods used to change organizations		
Organizational diagnosis and feedback		
<i>Assessing organizational structures and employees' beliefs and attitudes, desired outcomes and readiness to take action, using surveys and other methods.</i> (Organizational Development Theory: Cummings & Worley, 2009)	Methods appropriate to organizational characteristics -- for example, size and information technology.	An organizational consultant conducts a survey of employees' health behaviors and determinants and holds focus groups consisting of employees to review the results and plan for health promotion programs.
Increasing stakeholder influence		
<i>Increase stakeholder power, legitimacy, and urgency, often by forming coalitions and using community development and social action to change an organization's policies.</i> (Stakeholder Theory) (Brown et al., 2003; Kok, et al., 2015; Mitchell et al., 1997)	The focal organization perceives that the external organization or group is one of its stakeholders.	A community group uses media advocacy to highlight the groundwater pollution by gas storage tanks located in the community, and to demand that the tanks be moved by the gas company that owns them.

level. *Participatory problem solving* can be used at any level. In Table 1, we present some examples of behavior change methods, basic methods and methods per determinant or environmental level, definitions, theory-base, parameters (see next paragraph) and practical applications; adapted from Bartholomew et al. (2011; chapter 6 provides an overview of many theory-based methods).

From theoretical methods to practical applications

Practical applications are specific translations of theory-based methods for practical use. They should be tailored to the intervention population and the context in which the intervention will be conducted, and take the parameters for use into account (Bartholomew et al., 2011; see also Box 1). For example, change objectives for an intervention might focus on influencing adolescents' self-efficacy beliefs about always using condoms when having sex. The accompanying belief could, for example, be: "I am not

very confident that I can always use condoms, when my partner does not want to". Successfully changing this belief would increase adolescents' self-efficacy (the generic determinant) to always use condoms: "I am confident that I can always use condoms, even when my partner does not want to". To achieve this change objective, theory-based methods might include *modeling*, *guided practice with feedback*, and *reinforcement*. One application of *modeling* in a school setting could be a videotaped step-by-step demonstration by similar adolescents of how to successfully convince an unwilling partner to use condoms, or how condom use can become more automatic. However, for a different population, such as intravenous drug-users, a booklet with carefully selected authentic modeling stories might be more appropriate (see Figure 2). Thus, the same method can be translated into a myriad of possible applications, depending on the specific population and context. Similarly, one application can be a manifestation of multiple methods (see Figure 3). Modeling applied in a school setting could improve self-efficacy and at the same time provide

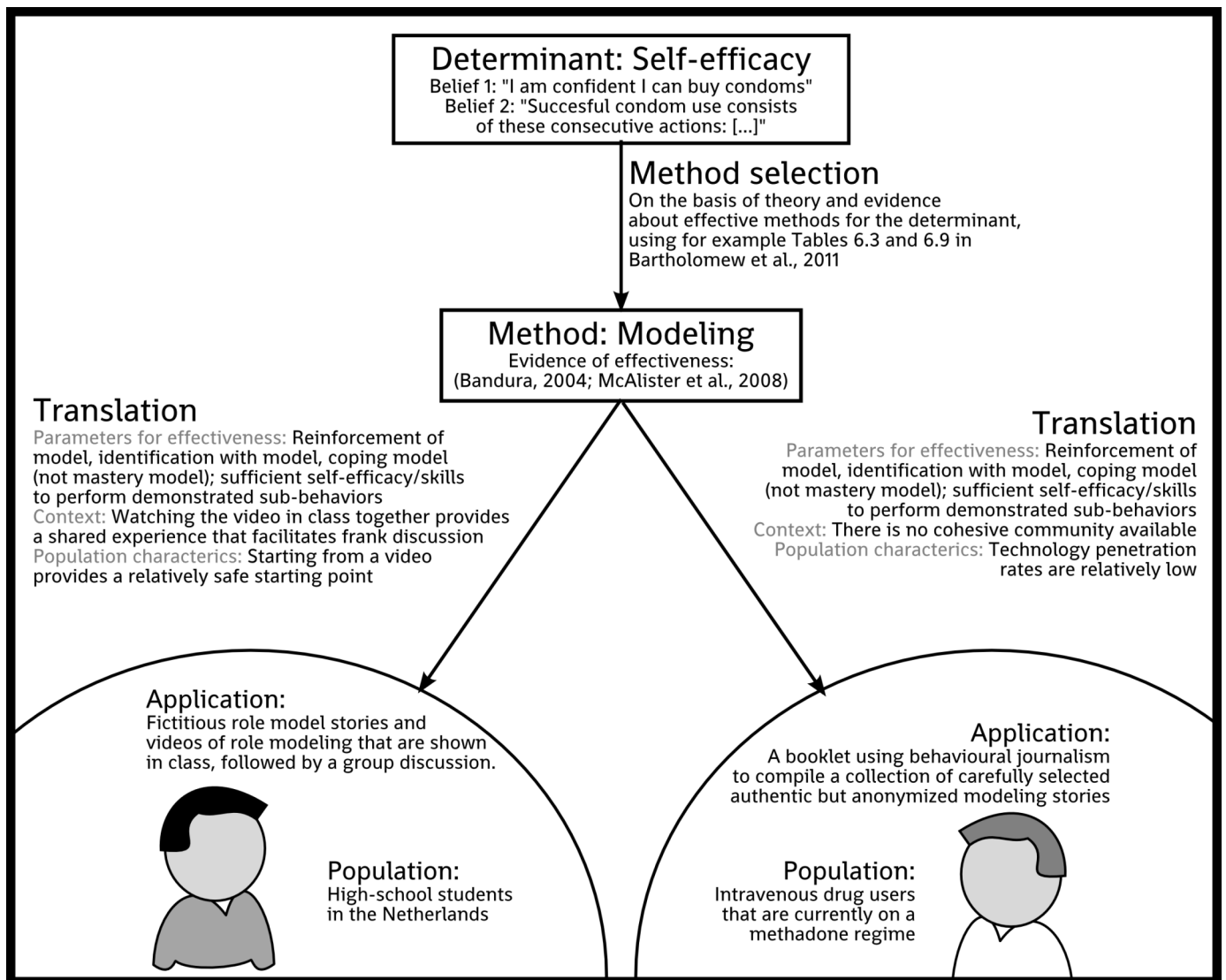


Figure 2: One method translated into different applications as a function of different populations and contexts.

information about the approval of others and change perceived norms.

The situation commonly encountered in the "real world" of intervention development (as compared to a tightly controlled research setting) is that theory-based methods tend to disappear in translation. In other words, even when there is a clear plan regarding which determinants to target, and which theory-based method to use, in the end, when translating these methods into actual materials and messages, some necessary methods are left out of the program. Some methods may be lost in translation

because logistical issues surrounding the development and production of program components and materials may become overwhelming, and so cuts are made to the plan. Other times, attempts are made to utilize theory-based change methods to influence each determinant, but the ways in which the practical applications are conceptualized and delivered do a poor job of translating the methods.

Translating methods into practical applications demands a sufficient understanding of the theory behind the method, especially the theoretical parameters which determine whether the theoretical

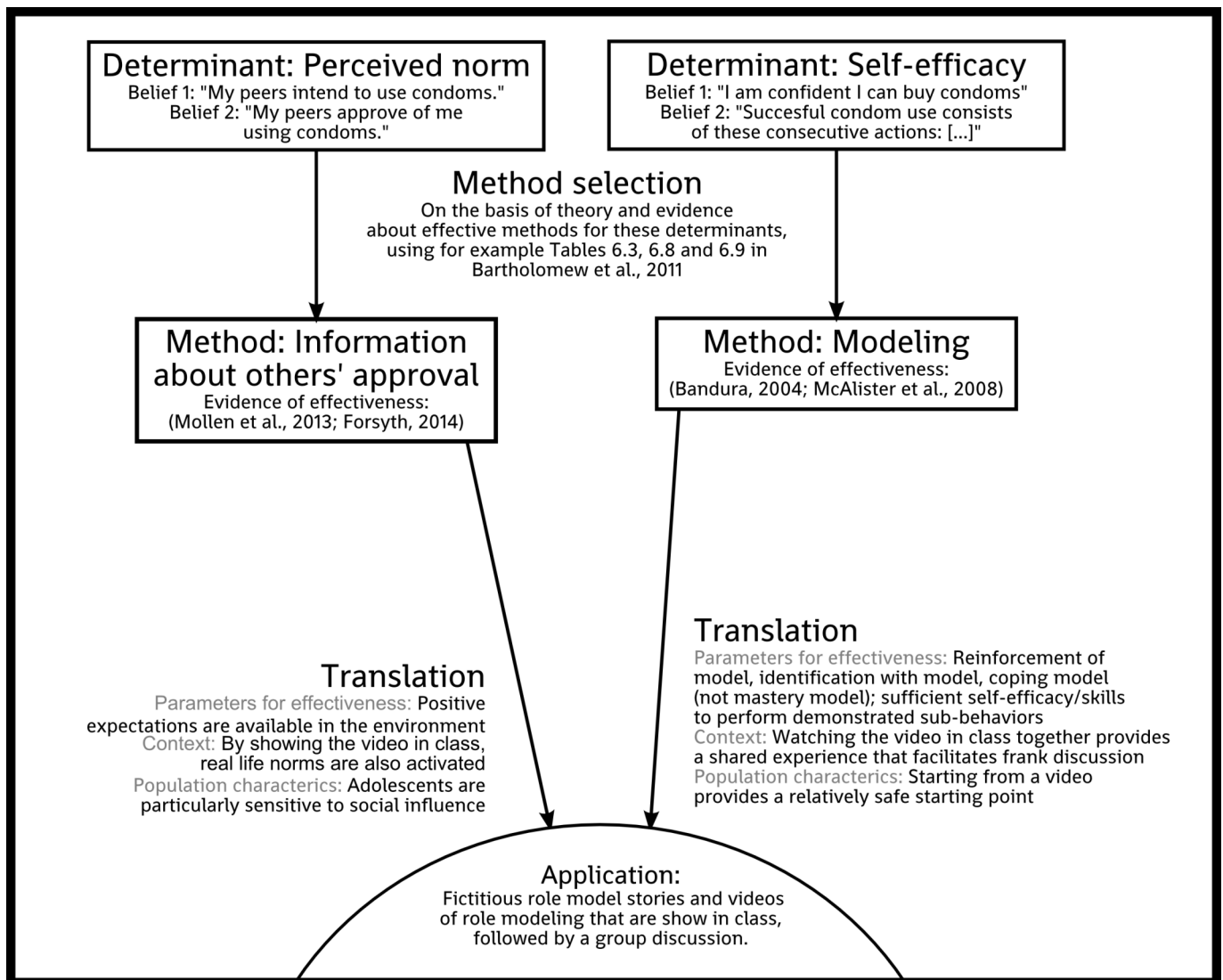


Figure 3: Two methods combined in one application.

process is effective or not (Kok, Gottlieb, Panne, & Smerecnik, 2012; Schaalma & Kok, 2009; Peters Ruiters, & Kok, 2014). No method is always effective! For example, *modeling* is a strong and popular method but is only effective when certain parameters are met, for instance reinforcement of the modeled behavior (McAllister, Perry, & Parcel, 2008). People or environmental decision makers do not imitate behavior simply because a model demonstrates that behavior; they behave in accordance with the model only when the model exhibits certain characteristics, such as being reinforced for that particular behavior

(and they expect to be reinforced in a similar way). Translating the method *modeling* into a practical application necessitates taking care that in the actual program, from the perspective of the program participants, the model is reinforced. To provide a second example: *goal setting* can be a very effective method, but only when the goal is challenging as well as acceptable for the actor. People often choose goals outside those parameters. Moreover, *fear appeals* are only effective when the at-risk population has high (self-) efficacy, and they may actually be counter-effective when efficacy is low (Peters, Ruiters, & Kok,

2013; Ruiter et al., 2014). Nevertheless, fear appeals are often inappropriately used (Peters et al., 2014; Ten Hoor et al., 2012). Behavior change is sometimes described as a two-step process involving 'motivation' and 'action' (Schwarzer, 2014). However, as a consequence of this, all theory-based methods that focus on 'action' presume that the target is already motivated, and yet this is not always the case. For example, implementation intentions are potentially very effective, but only when people have a positive intention in the first place; if not, implementation intentions will not be effective as a behavior change method. All theory-based methods have such parameters, which have to be taken into account when translating a method into a practical application. In Table 1, parameters are described for the examples of methods provided.

From practical applications to an intervention

So far, we have covered the various steps in the IM process. We have outlined perspectives on theory, systems, and participation, and described the journey from change objectives to theory-based methods, and how these methods are then translated into practical applications. How then, are these practical applications best integrated into an effective intervention?

"If you are not trained for something, don't do it" (Balderman, 1995). Essential in the collaboration with creative consultants is mutual respect: respect the creative professional, but also ensure that the creative professional respects the behavioral scientist's competence. Creative consultants are seldom aware of the parameters for effectiveness that apply to methods, and it is the responsibility of the behavioral scientist to make sure that those parameters will stay intact. Always return to the matrices of change objectives and the lists of methods, parameters and applications (see Box 2).

A program theme is a general overarching construct for a program, sometimes organized into sub-themes. Examples of themes include: the *Active Plus* exercise program for the over-fifties (van Stralen et al., 2008), the *Gay Cruise* safe sex program for internet dating MSM (Kok et al., 2006), or *Cultivando la Salud*, a lay health worker intervention to increase breast and cervical cancer screening among low-income Hispanic women (Fernandez et al., 2009). A theme should be attractive to the target population and might also already affect relevant determinants, e.g.: *Watch, Discover, Think and Act* (Bartholomew et al., 2000). The scope refers to the breadth and size of the program, describing what is and what is not in the program: for example, how much do we focus on topics such as abortion or sexual diversity in a school-based sex education program? The sequence refers to the order in which the elements of a program are delivered across time. Communication channels can be interpersonal or mediated; vehicles refer more specifically to how messages are packaged and delivered; each option has advantages and disadvantages. Peer education can be a powerful source of persuasion, is often inexpensive, and involves the community. However, peer educators can be difficult to train and to keep motivated. Entertainment-education via television has the benefit of a wide distribution and has norm changing capabilities. However, the influence of TV-producers with different objectives can be extremely difficult to counter (Bartholomew et al., 2011, Chapter 7).

Sometimes, existing materials may be useful. Still, new or existing materials need to be matched with the previously developed matrices of change objectives and the lists of methods, parameters and applications (especially the parameters for use, the appropriateness for the target group, and the context). The planning group needs to ensure that communication will go back-and-forth with the production group regarding all materials and products. All materials and products need to be pilot tested. Creative consultants, as well as managers or funders, have a tendency to suggest immediate

Box 2: Basic steps for integrating applications into an intervention

Before you start:

- A. *Establish a participatory planning group and specify program goals. Ensure that there is a well-trained behavioral scientist in the planning team, as well as representatives of the target group and of the intended implementers.*
- B. *Create a matrix of change objectives, see Peters (2014, this issue).*
- C. *Select or design practical applications, see Box 1.*

Basic steps:

1. *Consult intended participants and implementers. Avoid simplistic thinking by staying focused on the end products of the previous planning steps: program goals, change objectives, applications. Allow creativity to flourish. Respect the input from the target group, and respect any cultural differences. When ideas for the intervention setting take form, invite intended implementers into the planning team.*
2. *Create program themes, scope, sequence, and materials list. Specify program scope and sequence, describe each population group and program interface, and include a list of program materials and staff required for that interface. Describe the program budget for materials production.*
3. *Prepare design documents. Hire creative consultants and make sure that mutual respect is guaranteed. Talk about and agree what the creative people will return in various forms. Keep the matrix of change objectives available as well as the lists of methods, parameters and applications.*
4. *Review available program materials. Match existing materials against matrices of change objectives and lists of methods, parameters and applications. Determine suitability, availability and appropriateness of reading level.*
5. *Draft program materials and protocols. Ensure a back-and-forth interaction between the planning team and the production team. Observe budget limits and respect cultural differences.*
6. *Pretest and revise program materials. Resist all proposals to skip pretesting, check for parameters, and use experimental designs, if possible.*
7. *Produce materials and protocols. Oversee the final production.*

implementation, with the argument that the program has been developed carefully. However, there are enough examples of well-developed programs that turn out to be unintentionally counterproductive to insist on pretesting. If possible, apply experimental designs in pretests (Whittingham et al., 2009).

From the intervention to the implementation

Once the intervention has been created, a solid diffusion and implementation process is vital to ensure program success. Without implementation, the intervention will not have any impact on determinants, behaviors, or health. So, in IM Step 5, a plan is developed for the systematic implementation of the program. The first thing to do, actually right at the start of intervention development, is to develop a

linkage system, linking program developers with program users in the planning team. Next, an intervention is developed to promote adoption and implementation of the program by the intended program users. Intervention planners develop strategies to facilitate the implementation of the health promotion intervention with high fidelity and completeness. They develop theory-based strategies to facilitate program adoption by key stakeholders, to support appropriate implementation by program users, and to encourage program institutionalization by considering opportunities for incorporating the program into organizational routines. Thus, interventions are not only required to change individual behavior, but also to facilitate program implementation. Indeed, the same steps involved in intervention development are repeated to anticipate program diffusion and to target program implementers. Sustainable implementation almost always involves organizational change, for example in a school setting (Hendriks et al., 2013). See also the contribution of Knittle (2014, this issue).

Conclusion

Behavior change is extremely difficult to plan. If behavior change was easy, it would have already happened; professional health promotion planners become engaged when all simpler interventions to change behavior have failed and the desired behavior changes are extremely difficult to accomplish. An optimal approach has a higher chance of success, but success is never guaranteed. The highest chance for success can be expected from a theory- and evidence-based process. In this paper, we described IM as one such protocol. Essential to the IM process is the correct identification of the change objectives, followed by the selection of the appropriate behavior change methods, and the application of those in an intervention. Lastly, care must be taken that the intervention is adequately implemented. In this paper, we described the second challenge in detail:

applying theory- and evidence-based behavior change methods in an intervention promoting healthy behaviors and environments. Much of what we wrote is about logically and professionally applying the methods of behavioral science. To sum up with the most important message: methods are only effective when applied within their theory- and evidence-based parameters. In order to do this, well-trained behavioral scientists need to be involved in the planning process: everything should be as simple as possible, but no simpler (Peters, et al., 2013).

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Gerjo Kok

Maastricht University, The
Netherlands

g.kok@maastrichtuniversity.nl

Testing theory in practice: The example of self-determination theory-based interventions

Marlene N. Silva

University of Lisbon
ULHT

Marta M. Marques

University of Lisbon

Pedro J. Teixeira

University of Lisbon

Leonardo da Vinci once said that, *“He who loves practice without theory is like the sailor who boards ship without a rudder and compass and never knows where he may cast”*.

Similarly, advancing behavioral science requires a good understanding of how interventions are informed by theory, how they can better test theory, and which behavior change techniques should be selected as a function of theory (or theories). However, simply claiming that an intervention is theory-based does not necessarily make it so. Critical evaluation of applied theory is needed for a more integrated understanding of behavior change interventions, their usefulness, and their effectiveness.

The *Theory Coding Scheme* (TCS; Michie & Prestwich, 2010) was recently developed with the aim of providing a reliable research tool to describe and evaluate the theoretical basis of interventions. It includes a list of items assessing whether relevant constructs of a certain theory are targeted, how well they are measured, which behavior change techniques are used to impact those constructs, and whether study design allows for theory itself to be tested and refined. The TCS encourages a careful consideration of what constitutes a theory-based intervention (i.e. provides means for a more rigorous and systematic examination of the use of theory within intervention research), and how these interventions can be most usefully developed and evaluated serving as a structure to inform the design of theory-based interventions.

A recent meta-analysis (Prestwich et al., 2014)

tested the application of the TCS, investigating i) the extent and type of theory use in health behavior change interventions to increase physical activity and healthy eating, and ii) the associations between theory use and intervention effectiveness. The authors found poor reporting on the application of theory in intervention design and evaluation. For example, few interventions targeted and measured changes in all theoretical constructs defined by the theory or linked all the behavior change techniques to those constructs. Since this meta-analysis tested the TCS framework with only two theories (Social Cognitive Theory [SCT] and the Transtheoretical Model), more research is needed to test the fidelity to theory in health behavior change interventions based on other frameworks and its differential impact on interventions effectiveness. One such framework is Self-Determination Theory (SDT; Deci & Ryan, 2000), which is increasingly being used in the area of behavioral nutrition and physical activity (Teixeira et al., personal communication, May 22, 2014).

In this paper we will focus on the development, implementation, and evaluation of theory-based interventions, using SDT as the example. This paper follows on the first two articles of this issue by Peters (2014) and Kok (2014), which highlight the importance of identifying and selecting theory-based constructs and appropriated methods to develop effective complex behavior change interventions.

Self-Determination Theory-based interventions in health

SDT has emerged as a popular theoretical framework to explain the motivational dynamics

behind the regulation of health behaviors, focusing on the psychological antecedents, mechanisms, and basis for interventions in health contexts. Evidence regarding its rationale and utility in facilitating and explaining health behavior change and maintenance is rapidly increasing (Fortier, Duda, Guerin, & Teixeira, 2012; Ng et al., 2012; Ryan, Patrick, Deci, & Williams, 2008; Teixeira, Carraça, Markland, Silva, & Ryan, 2012). Readers are encouraged to consult Deci and Ryan (2000) and Vansteenkiste, Niemec and Soenens (2010) for a summary of the fundamental theoretical premises of SDT.

Briefly, SDT postulates that human beings have three essential psychological needs - autonomy (feeling of being the origin of one's own behaviors), competence (feeling effective), and relatedness (feeling understood and cared for by others). These needs represent "psychological nutrients" that are essential for ongoing psychological growth, integrity, and well-being (Deci & Ryan, 2000). Support and subsequent satisfaction of these needs provides the basis for the psychological energy that is predicted to, and has been empirically confirmed to, motivate the initiation and long-term maintenance of health behaviors (Ryan et al., 2008; Silva et al., 2011).

The issue of the *quality* of motivation is central to SDT, which is less concerned with "how much" motivation people have, and more about "which type" (or types) of motivation prevails in goal pursuit. Unlike some perspectives that only posit the intrinsic vs. extrinsic distinction, viewing extrinsically motivated behavior as invariably non-autonomous, SDT proposes that extrinsic motivation can vary greatly in the degree of internalization (i.e. self-congruence). In short, the fundamental distinction is between *autonomous* and *controlled* forms of motivation and behavioral regulation. Autonomous motivation is based on deeply reflected endorsement of one's behavior. When feeling autonomous, people perceive that their behavior emanates from the self and is self-authored, and they act because they find interest in or are challenged by the experience of behavior, or because they find personal meaning in

what results from it. The predominant feeling is what is sometimes referred to as "willingness" ('I truly chose and want to...'). By contrast, in controlled motivation, the predominant feeling is pressure, which is often associated with ambivalence. The pressure (or "controls") that regulates the behavior can either stem from external (rewards or demands) or internal (guilt, shame, pride) pressures (Deci & Ryan, 2000). Expressions such as 'must' and 'should' are typically associated with this form of motivation.

Importantly, different types of motivation have been associated with different outcomes and a growing body of research has demonstrated the importance of autonomous motivation for a range of health behaviors. To put it simply, the more autonomously motivated individuals are, the more adaptive their behavioral and health outcomes have shown to be (e.g. Ng et al., 2012; Teixeira, Carraça, et al., 2012).

SDT mechanisms of action and intervention component techniques

Social-environmental factors decisively influence cognitive, behavioral, and affective patterns exhibited in health behavior change processes. According to the SDT process model (Ryan et al., 2008), the effect of the environment on motivation and behavioral regulation is not direct, but occurs as a result of the support for, and consequent satisfaction of the three universal psychological needs. Thus, the most important social environmental factor within an SDT-based motivational climate concerns the degree of *need-supportiveness* or the extent to which others and the environment more broadly support vs. thwart these needs, objectively and as perceived by the individual. Indeed, one of the strengths of SDT is that it proposes processes of behavior change that can be targeted in different health behavior interventions. In these interventions, techniques are developed and implemented to satisfy

the three basic psychological needs, thus fostering the process of internalization (i.e. the active transformation of controlled regulation into more autonomous forms of [self-] regulation), in turn leading to increased *integration* of this regulation into a person's personality, and positive behavior change (Fortier et al., 2012; Ryan et al., 2008; Su & Reeve, 2011).

Key component techniques of need-support have been described in several papers and chapters and some operational definitions for each interpersonal condition have been advanced (see for example, Haerens et al., 2013; Reeve, 2009; Su & Reeve, 2011). These are briefly summarized next:

i) **Autonomy support:** Relevance, by providing a clear and meaningful rationale for activities, facilitating self-endorsement; Respect, by acknowledging the importance of clients' perspective, feelings, and agenda; Choice, by encouraging clients to follow their own interests and providing options whenever possible; Avoidance of control, by not using coercive, authoritarian, or guilt-inducing language or methods.

ii) **Structure (support for competence):** Clarity of expectations, by collaboratively setting realistic goals and discussing what to expect and not expect from the behavior-linked outcomes; Optimal challenge, by tailoring strategies and goals to individuals' skills; feedback, offering clear and relevant informational feedback (e.g. on goal progress), in a non-judgmental manner; Provision of instrumental and practical skills-training, guidance, and support.

iii) **Involvement (support for relatedness):** Empathy, by attempting to see the situation through the client's perspective; Affection, by displaying genuine appreciation and concern for the person; Attunement, through paying careful attention to and gathering knowledge about the person; Dedication of resources, through volunteering time and energy; Dependability, through availability in case of need.

A recent meta-analysis (Ng et al., 2012)

quantitatively synthesized the relatively large volume of empirical studies ($k = 184$) in health care and health promotion contexts addressing SDT-related constructs, and analyzed the relations among support for patients' psychological need satisfaction, autonomous regulation, and physical and mental health. Results from this meta-analysis showed that the relations of personal and contextual SDT constructs with each other, and with relevant positive health/exercise outcomes, were in the directions hypothesized by the theory. These findings were in accordance with those from a systematic review in the context of exercise behaviors (Teixeira, Carraça, et al., 2012), and are generally consistent across different study designs, health behaviors, and treatment settings.

Are SDT interventions theory-based? Preliminary results of a systematic review

Since SDT is increasingly advocated as a highly applicable and practically useful framework for designing physical activity, weight management, and dietary behavior change interventions, especially those aiming at long-term adherence (Fortier et al., 2012; Su & Reeve, 2011), it is important to analyze how adequately SDT has been applied in these domains.

This section summarizes the preliminary results of an ongoing systematic review, presented at the 2014 Annual Meeting of the International Society of Behavioral Nutrition and Physical Activity (Teixeira et al., personal communication, May 22, 2014), which assessed the extent of theory use in SDT-based interventions using the aforementioned TCS (Michie & Prestwich, 2010).

We first conducted a comprehensive search of studies published in peer-review journals in electronic databases (e.g. Pubmed) and key scientific journals (e.g. International Journal of Behavioral Medicine).

Studies were included if they reported on SDT-based interventions conducted with adults, measuring at least one of the outcomes of interest (physical activity/exercise, eating-related outcomes, weight change), assessed at post-treatment and/or follow-up. There were no restrictions with respect to the study design (randomized controlled trials – RCT; non-controlled trials), type of comparison condition (e.g. waiting list, active treatment), format and length of intervention and assessment points, and targeted population (e.g. healthy adults, chronic disease patients). Twenty-eight published studies reporting on 18 unique (controlled or non-controlled) trials were included (List of references of studies included available at: <https://osf.io/hufpj/>).

For the purpose of this review, the most relevant items of the TCS were combined, based on similarity of content, into the following categories: Theory-relevant constructs (items 2, 5), Link of behavior change techniques to theoretical constructs (7-11), Assessment of theory-relevant constructs (12, 13), Changes in theory-relevant constructs (15), Mediation of theory-relevant constructs (16), and Link between results and theory (17).

With respect to the first category (*Theory-relevant constructs*), all interventions targeted relevant SDT-related constructs. In most of the trials intervention techniques derived from theoretical constructs. Nonetheless there was great variability between studies on how thoroughly these constructs were described.

In *Link of intervention techniques to theoretical constructs*, less than half of the studies explicitly linked all behavior change techniques to SDT-relevant construct(s), and in the majority of the remaining studies either one technique or a group of techniques were linked to these construct(s). Three of the reviewed studies (Fortier et al., 2011; Hasse, Taylore, Fox, Thorp, & Lewis, 2010; and Hsu, Buckworth, Focht, & O'Connell, 2013), are good examples of studies that present the behavior change techniques used in the intervention in good detail, and describe link to theoretical constructs, namely need

satisfaction. Several trials reported the combined use of i) motivational interviewing (MI) techniques (e.g. personal values clarification used to support autonomy), ii) self-regulation skills training (such as goal-setting, self-monitoring, strategies for overcoming barriers, and problem solving) used to promote competence need satisfaction; or the 5 A's framework to promote need support at different levels.

In most studies, *SDT-relevant constructs were assessed* at pre and post-treatment, using measures with adequate validity and/or reliability. However, in a substantial number of trials a limited set of SDT-related constructs were measured, and often this was restricted to motivational regulations (e.g. autonomous and controlled motivation). Aspects such as need-support, needs satisfaction, or intrinsic/extrinsic goals were rarely reported.

In about two thirds of the studies (excluding ongoing trials: $k = 4$), *the intervention led to a significant favorable change in at least one SDT-relevant construct*. In addition, in all studies conducting mediation analysis of SDT-relevant constructs ($k = 5$), significant mediation effects were observed. However, we found a limited use of formal mediation analysis, with the PESO (Silva et al., 2011) and PAC (Fortier et al., 2011) trials as the only two studies reporting formal tests of mediation. Thus, more research is needed on whether changes in SDT-related constructs explain interventions' effect on behavior. Finally, in almost all studies, results of trials were *discussed in relation to the SDT premises*.

Overall, despite the limited pool of available studies and variability in the format and delivery of interventions, usefulness of SDT for behavior change is supported and the present scenario is encouraging of further testing and refinement. The preliminary results of the review indicate a moderately good use of SDT-based intervention studies in exercise, diet, and weight management. Furthermore, good descriptions of the behavior change techniques used in SDT-based interventions are increasingly available, most of which presenting clear links to theory

constructs. However, only half of the studies were completely clear in reporting specific intervention techniques and their theoretical underpinnings. An improvement in this criterion would not only strengthen researchers' ability to make statements regarding an intervention's theoretical grounding, but also allow other researchers to rely on the strategies employed in previous interventions.

Additional considerations

Because of its unique characteristics, the application of SDT to health behavior change interventions often raises additional questions. We will briefly address three of these questions, related to interventions' appropriate choice of outcomes, to the broader application of the SDT qualitative "criterion" (autonomous vs. controlled), and to meta-theoretical considerations in theory-based intervention research.

SDT is a broad theory of human motivation and, as such, its usefulness to explain the processes underlying behavioral regulation (choice, persistent, engagement, etc.) is straightforward. However, the organismic nature of SDT, deeply rooted in philosophical and psychological humanistic traditions, determines that SDT is ultimately concerned with human harmonic development and (eudaimonic) well-being (Deci & Ryan, 2000). Although "health behavior" should naturally relate to health and well-being – and in the biological sense, it usually does (e.g., a healthful diet tends to improve metabolic risk factors) – behavior change alone is not necessarily indicative of improved *psychological* outcomes. For example, one can think of rigid eating patterns aiming at obsessive weight loss as one case when success at dieting and weight loss is accompanied by psychological ill-being (Verstjuij, Patrick, Vansteenkiste, & Teixeira, 2012). A unique feature of SDT is that the key processes postulated to lead to adaptive motivation and behavior change – basic needs satisfaction – are also, and

simultaneously, theoretically linked to improved psychological health (Ng et al., 2012). Moreover, one of these processes, perceived autonomy, is considered a positive and irrevocable outcome in its own right, particularly in health care bioethics (Beauchamp & Childress, 2008). In brief, the application of SDT to health care may create a crossroad between choosing behavior change as the primary outcome and the satisfaction of "higher-order" human psychological needs, seen as essential conditions for wellness. This has several implications, one of which is that autonomous non-compliance – when a client or patient, upon informed reflection, decides he/she does not want to change – can, and in most cases, should be seen as a *positive* outcome despite the absence of behavior change. Another, more practical implication is that interventions based on SDT should first target the satisfaction of psychological needs (see above) and focus on behavior change as one possible consequence of that path. As we have indicated, the two are not necessarily linked.

We have addressed the SDT perspective on adequate choice of outcomes in health behavior interventions (for weight management) in more detail elsewhere (Teixeira, Silva, et al., 2012). Indeed, we went a step further, proposing that if autonomy, competence, and relatedness are accepted as basic psychological nutrients (i.e., essential needs), then health professionals should contemplate the possibility that, by promoting the satisfaction of those needs, they are creating the conditions for personal change at a level *beyond* what is currently designated as "behavior change". Research linking autonomous/intrinsic motivation with higher levels of behavioral engagement (Cesaroli, Nicklin, & Ford, 2014), more vitality and less ego depletion (Muraven, Gagné, Rosman, & 2008), and transfer of self-regulation across behaviors (Mata et al., 2009) are some examples. Anecdotally, we have frequently witnessed participants in our obesity treatment studies implementing broader changes in their lives as a whole, apparently "inspired" by what and how they were changing in the weight management

program. The participant that did not enjoy walking and later became a near-professional organizer of walking trips in nature; and the women who divorced her husband during the program (who did not support her losing weight and being away from the kitchen so often), exceptional as they may be, became symbolic of this phenomenon.

A second related issue raised by the application of SDT in health contexts is that it provides an alternative “criterion” by which to evaluate many of the processes that take place during behavior change interventions. In fact, the autonomous vs. controlled dichotomy can also be used to characterize and qualify many of the *constructs* defined by other theories as mediators of behavior change, as well as the *techniques* used to target them. Two examples of the former are attitudes and goals, common constructs in many health behavior change theories. It should be apparent that people can express positive attitudes about a given behavior rooted in deeply reflected personal beliefs about the value of the behavior or its consequences (the “autonomous route”) or, alternatively, based on more or less coercive persuasion or effective “convincing” by others (the “controlling route”). Notably, while the latter may be never fully self-endorsed, clients will still report that the behavior is important for them or a “good thing” (i.e. report positive attitudes). Similarly, goal selection (e.g., losing weight) and related expectations can be linked to aspects viewed by SDT as reflective of “intrinsic” motives such as improved functional health or being a positive role model for the children; or to motives not leading to need satisfaction and personal growth, such as impressing others or protecting one’s self-esteem. Thus, a SDT analysis of these determinants provides a nuanced understanding of their psychological functional significance and potentially of their impact in actual behavior change and well-being (Ng et al., 2012).

A similar exercise can be applied to *behavior change techniques* or practical strategies currently applied in behavior change interventions (e.g. Michie

et al., 2013). As pointed out in other contributions in this issue (Knittle, 2014; Kok, 2014) when selecting and evaluating behavior change techniques it is important to consider the theoretical parameters for its effectiveness and to look at *how* techniques are delivered as this can have a differential impact on results. According to SDT, these techniques can be employed within a need-supportive “motivational climate” or, by contrast, a controlling climate. As an example, one of us (PJT) was recently involved in a debate (Teixeira & Volpp, personal communication, April 24, 2014) where the use of financial incentives (a behavior change method) was discussed as to its potential to control individuals into behavior change versus contribute to their self-determination (c.f. Kullgren, Williams, & An, 2013). Briefly, the degree to which a particular technique is autonomy-promoting versus controlling is thought to result from aspects of its *content* (e.g., in the case of financial incentives, was the incentive or the incentive schedule chosen by the individual or imposed?) or its *delivery*. From an SDT view, emphasis falls on the prevailing *interpersonal style* involved in the communication between professionals and clients/patients. For instance, different use of language (e.g. avoiding “shoulds” and “musts”) and other interpersonal features such as warmth vs. coldness are expected to meet the need for personal relatedness quite differently. As another example, prompting self-monitoring, one of the most evidence-based BCT, can be achieved with a more or less authoritarian stance; according to SDT, variability in interpersonal style would yield different psychological and behavioral outcomes from its use. As we have indicated before, less “shoulding” and more “wanting” is expected to bring about the best outcomes, especially when evaluated in the long run. This issue was recently addressed in more detail elsewhere (Hagger & Hardcastle, 2014) using SDT and MI as examples.

We recognize that the development of a “taxonomy of intervention styles” may represent a challenging endeavor, with several perils. Interpersonal style encompasses “ways of being”

which may resist being reduced to a group of techniques. For instance, results from a meta-analysis in the field of Motivational Interviewing revealed that excessive coding and manualization of interventions actually detracted from outcomes (Lundhal, Brownell, Tollefson, & Burke, 2010). Although manualization should encourage fidelity to the MI approach, fidelity showed no significant correlations with MI outcome. The authors pointed out that in humanistic, client-centered approaches manualization may interfere with truly centering on the client by causing pressure on practitioners to focus on specified items or indicators. This notwithstanding, a process leading to the clarification of what best describes a need-supportive, need-thwarting, and a controlling style is needed and is underway (e.g. Su & Reeve, 2011). This should contribute to better describe what takes place between interventionists and clients/patients, how (theory/SDT-based) interventions can be tested scientifically, and how can those methods be taught when training health professionals. Ultimately, success in using SDT-based health behavior change interventions requires prior success at all three of these processes.

As a final note, and going back to our title – “from theory to practice” –, health behavior researchers and practitioners involved in interpersonal interventions should be reminded that theories have within them particular meta-theoretical (ontological) premises about human beings and how they function in the world. Given its humanistic origins, this is perhaps more evident in SDT than in other frameworks (a topic we will not expand on here). Regardless, if understood and endorsed by researchers and practitioners, these views can permeate the entire behavior change process, from the first contact (note: we are reminded of the famous movie line “you had me at ‘hello’!”), to implementation of behavior change techniques. Importantly, some of these fundamental premises may not be fully compatible with “competing” positions from other theories, a contrast which could impinge on the internal coherence and possibly the effectiveness of an

intervention. Just as an example, in SCT, autonomy is equated with independence and dismissed as a largely irrelevant process in motivated behaviors (Bandura, 1989). This represents a fundamental difference that could be hard to harmonize when intervening from *both* SCT and SDT perspectives. Another example concerns goal selection. From an SDT perspective, not all goals “are created equal” in the sense that some are more likely than others to satisfy basic psychological needs. By being “agnostic” on the nature of the goals, a health professional may find him/herself at odds with the prospect that promoting the psychological well-being of the client may not be served if SDT-extrinsic goals are being pursued and (especially) if they are met. Although there is surely overlap among health behavior change theories, and very few of them have been designed as truly integrative models to explain all aspects of behavioral regulation (Davis, Campbell, Hildon, Hobbs, & Michie, 2014), we believe that reflecting on deeper-level assumptions embedded within each theory is a step forward in designing future theory-based interventions. Whether interventionists would be more effective by learning not only how to select and employ behavior change techniques *but also* learning the key tenets of the theories underlying those techniques – and made aware of potential inconsistencies – is largely an empirical question.

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Marlene N. Silva
Faculty of Human Kinetics, University
of Lisbon, Portugal
Universidade Lusofona de
Humanidades e Tecnologia, Portugal
mnsilva@fmh.ulisboa.pt



Marta M. Marques
Faculty of Human Kinetics, University
of Lisbon, Portugal
martamarques@fmh.ulisboa.pt



Pedro J. Teixeira
Faculty of Human Kinetics, University
of Lisbon, Portugal
pteixeira@fmh.ulisboa.pt

Improving the reporting of behaviour change interventions

Marie Johnston Introduction

University of Aberdeen

The publication of the results of a behaviour change trial should have an impact on both science and practice, but this can only be done successfully if adequate information is available about the behaviour change intervention (BCI). Incomplete or confusing reporting may result in implementation of an intervention which omits essential elements included in the trialled intervention, while asserting that it is 'evidence-based'. If the intervention is misinterpreted by systematic reviewers, it may not be included or it may be wrongly categorised with potential negative impact on evidence synthesis and theory development.

There is ample evidence that interventions are inadequately reported. Hoffmann, Eructi and Glasziou (2013) found that essential information, such as the provider and the materials used, was missing from published reports of surgical, pharmacological, rehabilitation, psychotherapy and behavioural ('non-pharmacological') interventions and was not available even after contacting the authors (Figure 1). Pharmacological interventions may also be poorly reported: 16% of authors of cancer chemotherapy trials failed to mention the route by which the drug was administered (Duff, Leather, Walden, LaPlant, & George, 2010).

There is some evidence that reporting of BCIs is worse than for other non-pharmacological interventions (e.g. surgery, rehabilitation): McCleary, Duncan, Stewart, and Francis (2013) found that the titles and abstracts of BCIs frequently failed to mention the active ingredients of the intervention (Figure 2). Thus systematic reviewers might easily

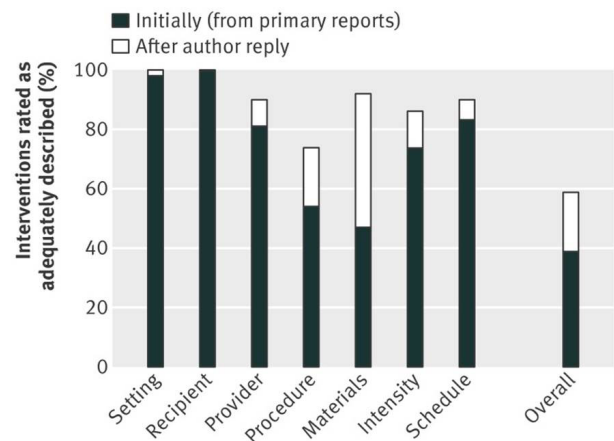


Figure 1: Adequacy of reporting on non-pharmacological interventions (Hoffmann et al., 2013)

overlook these papers when applying inclusion criteria.

Is this the fault of 'naughty' or 'secretive' triallists? A more likely explanation is that there has been no agreement about what needs to be reported, and for BCIs, no shared language for reporting active content. We need more precise reporting to make interventions recognisable and replicable. Recent developments have resulted in the beginnings of international, interdisciplinary consensus on what and how BCIs should be reported.

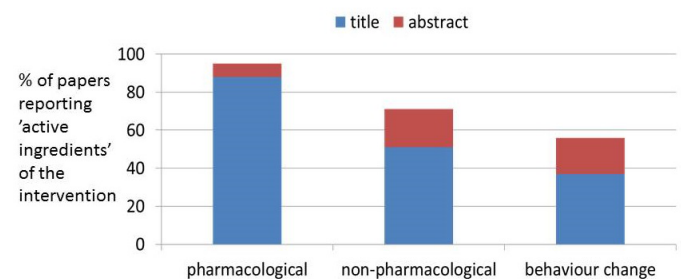


Figure 2: Reporting active ingredients of interventions in title or abstract (McCleary et al., 2013)

What to report: Template for Intervention Description and Replication (TIDieR)

Hoffmann and colleagues recently published the TIDieR checklist as an extension to the CONSORT 2010 (<http://consort-statement.org>) and SPIRIT (<http://spirit-statement.org>) guidelines as to what should be included in describing *any* healthcare intervention - including surgical, pharmacological, rehabilitation, psychotherapy and behavioural interventions (Hoffmann et al., 2014). The checklist was developed using EQUATOR network (www.equator-network.org/) recommended consensus procedures. A steering committee developed a list of 34 potential items based on existing checklists and literature reviews. This list was evaluated in a 2-round Delphi procedure by 90 international participants from many disciplines and including primary researchers, systematic reviewers and journal editors. The results were then discussed in a two day face-to-face meeting which agreed the items for inclusion in an essential, minimal data set, as well as how they should be labelled and defined. These labels and definitions with examples spanning different disciplines were piloted before publication, with video (<http://bmj.com/multimedia/video/2014/03/17/tidier-better-reporting-interventions>).

The resulting TIDieR checklist is shown in Table 1 and since publication has been widely downloaded and cited. The complete checklist which is recommended for use by reviewers and authors is available on the EQUATOR Network website (<http://equator-network.org/reporting-guidelines/tidier>). While most of the items are self-explanatory, the examples add further information. Ten items report the planned intervention, two items report any changes made during a trial and the fidelity of delivery of the planned intervention (see also Knittle, 2014, this issue). Of particular interest, and perhaps most challenging to behavioural and social scientists are items 2 'why', 4 'what procedures'

and 5 'who provided'. Importantly, the 'why' item seeks information on the theoretical or other rationale for the intervention (see also Kok, 2014 and Peters, 2014; both in this issue) and behavioural scientists might additionally wish to note how theory was used in developing the intervention (Michie & Prestwich, 2010; Prestwich et al., 2014). 'What procedures' and 'Who provides' a BCI are important issues which are discussed below.

'What procedures': Communicating the active ingredients of BCIs

BCIs are typically complex and we need clarity in interpreting what the intervention involves. The TIDieR item 'What procedures' involves both the activities that support the delivery of the active ingredients and the actual active ingredients of the BCI i.e. the behaviour change techniques (BCTs) which are somewhat similar to the methods of behaviour change discussed by Kok (2014) except that the latter are theory-based. A BCT is defined in the Encyclopedia of Behavioral Medicine as: 'a systematic procedure included as an active component of an intervention designed to change behavior, which is observable and irreducible. It is the smallest component compatible with retaining the postulated active ingredients, that is, the proposed mechanisms of change, and can be used alone or in combination with other BCTs' (Michie & Johnston, 2013). Recent developments in specifying BCTs have resulted in improved methods of reporting BCTs, culminating in the publication of the Behaviour Change Technique Taxonomy v1 (BCTTv1) with 93 hierarchically organised BCTs with labels, definitions and examples (Michie et al., 2013).

The first BCT list was published in 2008 by Abraham and Michie (2008). This paper has been widely cited and has been followed by publication of several other lists of BCTs appropriate for different applications. Michie and colleagues gathered all of

Table 1: *Template for Intervention Description and Replication: the TIDieR checklist*
 (*These items are not relevant to protocol reporting and cannot be described until study is complete.
 #Use this column to indicate where the item can be found.)

Item number and label	Definition	Location of information #
1. Brief name	Provide the name or a phrase that describes the intervention	
2. Why	Describe any rationale, theory, or goal of the elements essential to the intervention	
3. What Materials	Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL)	
4. What Procedures	Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities	
5. Who provided	For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given	
6 How	Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group	
7. Where	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features	
8. When and How Much	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose	
9. Tailoring	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how	
10. *Modifications	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)	
11. How well Planned	If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them	
12. * How well Actual	If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned	

the available lists of BCTs together and, over a 3 year project funded by the UK Medical Research Council and guided by an international, interdisciplinary advisory board, developed BCTTv1. The intensive development process involved Delphi and other consensus methods combined with repeated testing of the extent to which the labels and definitions resulted in agreement between coders using the developing list. In the final stages, the long list of BCTs was organised into a hierarchical structure grouping the BCTs by similarity of mode of action (Cane, Richardson, Johnston, Ladha, & Michie, 2014).

Table 2 illustrates labels, definitions and examples of BCTs from different groupings. The published BCTTv1 also provides additional guidance in the definitions about BCTs that might also be considered when selecting a BCT. A BCTTv1 App is also available in both the iTunes and Google Play stores; an example screenshot is shown in Figure 3.

The first step in using BCTTv1 is to be clear about the behaviour that is targeted. Reports of BCIs may apply different BCTs to different behaviours within the same programme e.g. BCTs directed at dietary behaviours vs activity behaviours in a weight loss

Table 2: Illustrative examples of BCTs from BCTTv1.

(* full definitions in BCTTv1 include notes on alternative or additional BCTs that should be considered in selecting the BCT)

BCT code	Grouping	Label	Definition (abbreviated*)	Example
1.1	Goals and Planning	Goal setting (behaviour)	Set or agree on a goal defined in terms of the behaviour to be achieved	Agree on a daily walking goal (e.g. 3 miles) with the person and reach agreement about the goal.
2.3	Feedback and monitoring	Self-monitoring of behaviour	Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy	Ask the person to record daily, in a diary, whether they have brushed their teeth for at least two minutes before going to bed.
5.1	Natural consequences	Information about health consequences	Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour	Explain that not finishing a course of antibiotics can increase susceptibility to future infection
7.1	Associations	Prompts/cues	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance.	Put a sticker on the bathroom mirror to remind people to brush their teeth
8.3	Repetition and substitution	Habit formation	Prompt rehearsal and repetition of the behaviour in the same context repeatedly so that the context elicits the behaviour	Prompt patients to take their statin tablet before brushing their teeth every evening

programme, or BCTs to enhance attendance at a class vs BCTs delivered within the class to reduce smoking. Some programmes involve the behaviour of more than one person e.g. parents may be targeted as well as their children in programmes to reduce children's sedentary behaviour. Short sections of text may contain several BCTs, sometimes in overlapping text; for example, consider the text in Box1 and try to identify text describing distinct BCTs. Table 3 indicates 9 BCTs that can be identified.

A central aim of BCT development is to ensure that a BCI is interpreted in the same way by different readers and so a key element has been the assessment of inter-coder agreement on the identification of BCTs. Evidence to date suggests that agreement between trained coders is satisfactory for most of the commonly occurring BCTs (Michie et al., 2013). Note that without a methodology for specifying BCTs it would not even have been possible to assess the degree of agreement as there would be no shared language for comparison of coding. The shared language of BCTTv1 can be applied to reports of BCIs in other languages provided the coders can

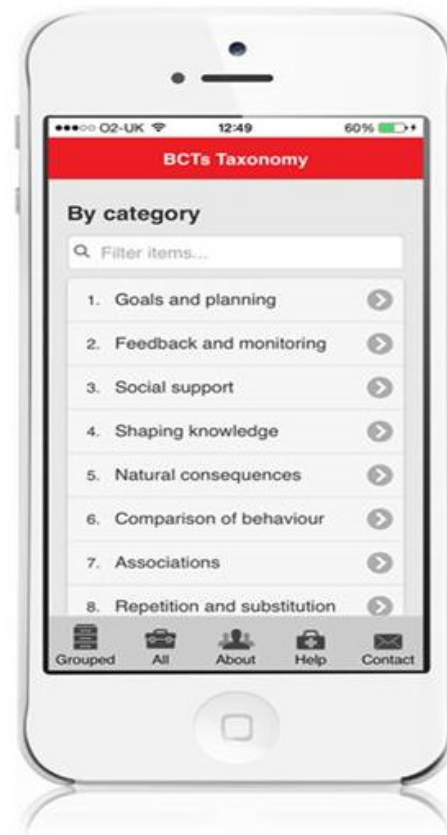


Figure 3: BCTTv1 App screenshot

Box 1: Short report of a BCI with several BCTs

Target Behaviour: hand washing

'After instruction on how to find and assess a patient's pulse, students practiced taking each other's pulse. They then read a booklet on hospital infection control procedures and, after a brief discussion, watched a video of a consultant washing his hands correctly and advocating the importance of this to all staff. Students were prompted to write down their handwashing aims, in particular, to ensure that they would try to always have bacteria-free hands at work and to ensure that they would wash their hands correctly after touching each patient. Students were observed washing their hands and the instructor discussed their technique. Finally, students were asked to identify a colleague on the ward who would remind them of their handwashing goal.'

use the English labels and definitions in addition to reading in the language of the BCI report.

Given that a main aim of BCTTv1 is to improve reliability in communicating about BCIs, it is recommended that researchers use BCTTv1 as a basis for reporting the active ingredients of BCIs. However BCT coding is a skilled activity and training is required to ensure that due attention is paid to the full definitions and that coders do not infer the presence of BCTs from ambiguous text. Two personal

methods of training, workshops and distance tutorials have been evaluated (Wood et al., in press) and these form the basis for on-line training. On-line training in the use of BCTTv1 is available at <http://bct-taxonomy.com/> with an introduction at <http://youtu.be/qR3lNe7ht2o>. It is anticipated that users will need to adapt, add to and suggest improvements which should result in an updated BCTTv2 within a few years. Other users may wish to tailor the list of BCTs with reference to a specific

Table 3: BCTs identified in the text in Box 1 reporting a BCI

Text in the report in Box 1	BCT (with BCTTv1 code)
watched a video of a consultant washing his hands correctly	Demonstration of the Behaviour (6.1)
watched a video of a consultant washing his hands correctly and advocating the importance of this	Credible source (9.1)
Students were prompted to write down their handwashing aims, in particular, to ensure that they would try to always have bacteria-free hands at work	Goal setting (outcome)(1.3)
Students were prompted ... to ensure that they would wash their hands correctly	Goal setting (behaviour) (1.1)
Students were prompted ... to ensure that they would wash their hands correctly after touching each patient.	Action Planning (1.4)
Students were observed washing their hands	Behavioural practice/rehearsal (8.1)
the instructor discussed their technique.	Feedback on behaviour (2.2)
asked to identify a colleague on the ward who would remind them of their handwashing goal	Prompts and cues (7.1)
asked to identify a colleague on the ward who would remind them of their handwashing goal	Social support (practical) (3.2)

theory and such tailoring is likely to result in the identification of additional BCTs: for example, Silva, Marques, and Teixeira (2014, this issue) discuss BCTs related to self-determination theory.

'Who provides' the BCI: competences for delivering BCIs

The TIDieR framework requires reporting of who provides the intervention, including any relevant training. Such information is essential for implementation of a BCI as a proven successful BCI may be less effective if delivered by a provider with less behaviour change competence than those delivering the intervention in the published trial.

BCIs are delivered by a wide range of practitioners including specialists in behaviour change, but also other professionals with a broader range of activities such as doctors, nurses, public health specialists, teachers etc. whose main training and experience are not in behaviour change. Others may have been trained for practice in a specific behavioural domain such as counsellors in smoking cessation, alcohol brief intervention or sexual health services. For example, Michie, Churchill, and West (2011) identified BCT competences and supporting activities which had evidence of effectiveness in smoking cessation programmes. Competent delivery of BCIs involves a range of knowledge and skills and there are several situations in which it is important to be able to describe and assess these competencies. Clearly successful implementation of an effective BCI requires practitioners of comparable competence to those involved in the evaluation of the BCI. Additionally, one may wish to consider the competencies that are transferable from one domain to another e.g. does a specialist in sexual behaviour change have the competencies to deliver a smoking cessation programme? What additional competencies would they require? Competencies are also important in employing staff to deliver behaviour change

programmes or in assessing training needs for oneself or for others.

Because of the increasing importance of behaviour change, we were commissioned by Scottish Government to develop a framework for describing the competencies required to deliver behaviour change programmes (Dixon & Johnston, 2010). We took as our starting point the items of the competency framework for cognitive behavioural therapy interventions (Roth & Pilling, 2007) as a recently developed framework with relevance to changing behaviour. Items were selected with good inter-coder agreement, re-formulated to be relevant to health behaviour change and organised to be readily accessible. In addition each competency was reliably coded into three levels of intensity of skill required: low (scripted protocol); medium (manual-based but with some flexibility); and high (flexible to match assessed client needs).

The HBCC framework has three domains, one concerning competency to deliver BCTs and two dealing with competences required to support the delivery of BCTs:

- Foundation competences: communication skills required to develop an effective intervention alliance professional and ethical guidelines required for effective practice with different clients and client groups (12 topics, divided into 56 competencies).
- Behaviour change competences: knowledge of the relationship between behaviour and health status; knowledge of models and theories of behaviour and how these have been used to develop behaviour change interventions; general assessment and core intervention skills required to implement theory based interventions for behaviour change in practice (12 topics, divided into 54 competencies).
- Behaviour Change Techniques: full breadth of behaviour change techniques relevant to health behaviour organised into three routes to behaviour and behaviour change (Motivation development; Action on motivation; and Prompted or cued behaviour).

The Foundation and Behaviour Change competence

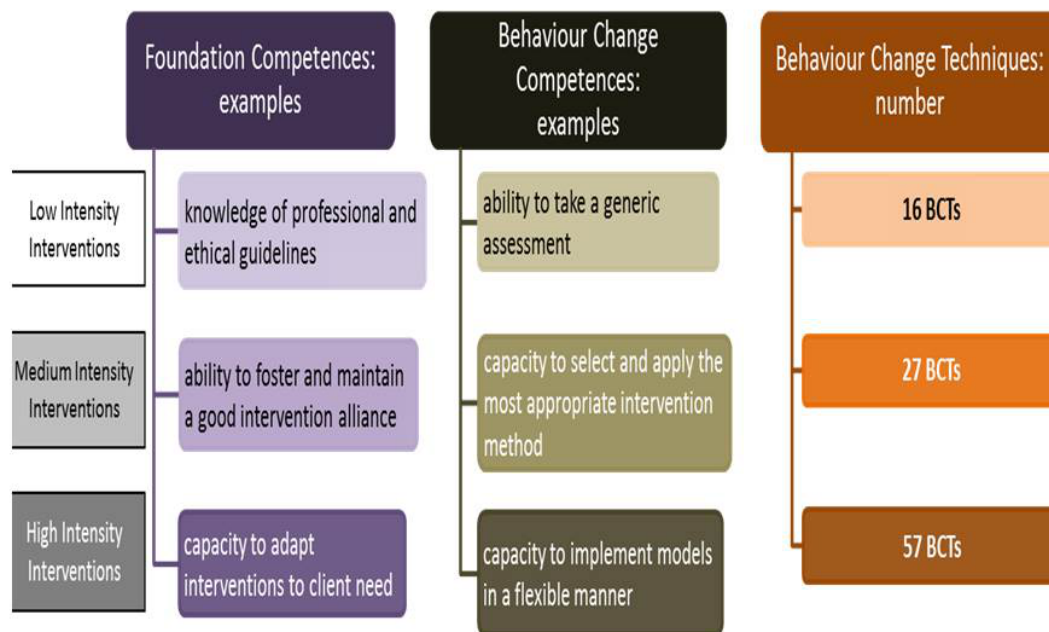


Figure 4: The Health Behaviour Change Competency Framework: Three domains and three levels of intensity

topics are listed in Table 4 with an indication of the number of competences included within each topic. So for example, Foundation Competence topic 6 (Ability to work with groups of clients) consist of 11 competences including:

- Ability to apply professional and ethical standards when working with groups
- Ability to engage the group
- Ability to encourage group discussions/didactic presentations
- Ability to communicate rules governing the group
- Ability to establish a closed group
- Ability to communicate group member identities

Behaviour Change topic 12 (ability to plan for maintenance of behaviour change after the end of the intervention) has 2 competences:

- Ability to help clients identify and elaborate their concerns about termination (e.g. worry that that they need support to manage on their own, or that they will relapse).

- Ability to help clients identify other resources that might help them maintain their behaviour change (e.g. weightwatchers, websites, gym membership).

The HBCC Framework has been used to specify the competence required for specific BCIs and to inform training programmes developed by Scottish Government. In addition, an online self-assessment has been developed and found to discriminate between health psychologists at different levels of qualification (Bull, Dixon, & Johnston, 2012).

Conclusions

Good reporting of interventions is essential both in implementation in practice and in creating a cumulative science. Historically BCIs have not been reported with sufficient completeness, precision and transparency to achieve these aims, largely due to lack of a methodology for reporting. However current and continuing progress in developing methods for

Table 4: *Foundation and Behaviour Change Competence topics (numbers indicate the number of competences within each topic)*

Foundation Competences	Behaviour Change Competences
1. Professional and ethical guidelines: 7	1. Knowledge of health behaviour and health behaviour problems: 9
2. Supervision: 4	2. Ability to undertake a generic assessment: 7
3. Knowledge of and ability to work with difference: 3	3. Knowledge of a model of behaviour change and the ability to understand and employ the model in practice: 4
4. Ability to communicate and work with individuals, groups and communities: 1	4. Ability to agree goals for the intervention: 2
5. Ability to engage client: 8	5. Capacity to implement behaviour change models in a flexible but coherent manner: 2
6. Ability to work with groups of clients: 11	6. Capacity to select and skilfully to apply the most appropriate behaviour change intervention method: 1
7. Ability to foster and maintain a good intervention alliance and to grasp the client's perspective: 8	7. Capacity to implement behaviour change in a manner consonant with its underlying philosophy: 6
8. Capacity to adapt interventions in response to client feedback: 3	8. Ability to structure consultations: 5
9. Ability to manage expectations of the intervention: 3	9. Ability to use measures and self-monitoring to guide behaviour change intervention and to monitor outcome: 6
10. Ability to deliver information: 4	10. Ability to carry out health behaviour problem solving: 9
11. Capacity to structure consultations and maintain appropriate pacing: 3	11. Capacity to manage obstacles to carrying out behaviour change: 1
12. Ability to recognise barriers to and facilitators of implementing interventions: 1	12. Ability to end the intervention in a planned manner and to plan for long-term maintenance of gains after intervention ends: 2

specifying what needs to be reported, how active ingredients of BCIs can be interpreted from reports and what competence is required to deliver an intervention should make this task easier in future.

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Marie Johnston
University of Aberdeen, Aberdeen,
UK
m.johnston@abdn.ac.uk

Fidelity in intervention delivery

A rough field guide

Keegan Knittle

University of Helsinki

In this special issue, Marie Johnston (2014) describes the increasing number of tools that behaviour change researchers have at their disposal to specify the contents, proposed mechanisms and modes of delivery of the behaviour change interventions (BCIs) they develop – including the v1 taxonomy of behaviour change techniques (BCTs) (Michie et al., 2013), the CONSORT and SPIRIT statements (Boutron et al., 2008; Chan et al., 2013) and the TIDieR checklist (Hoffman et al., 2014). When used universally, these tools will improve the precision of BCI reporting, and allow for greater replicability of BCIs in research and implementation. Despite this, incomplete reporting of adherence to protocols and the fidelity of BCI delivery still limit the advance of behaviour change science.

Treatment fidelity refers to a number of aspects of *actual* BCI delivery, as opposed to the *ideal* way BCIs are set forth in protocols. This includes factors such as the length of time spent delivering a BCI to each individual, the specific components (BCTs) of a BCI that were *actually* delivered, the order and quality of the delivery of these BCTs, and the way in which the BCTs were received and acted upon by the recipients of the BCI. While the importance of each of these factors has been described previously (Bellg et al., 2004; Moncher & Prinz, 1991; Nelson, Cordray, Hulleman, Darrow, & Sommer, 2012), precious little headway has been made in terms of requiring fidelity reporting in randomized controlled trials (RCTs) of BCIs. This article will discuss some specific examples of why promoting, documenting and reporting fidelity are important, provide an outline of common methods for doing so, and finally, recognizing that fully

detailed reporting of BCI fidelity may not always be possible, provide some key points for how to assess and account for fidelity when resources are limited.

What's all the fuss about?

According to the UK Medical Research Council framework for developing and evaluating complex interventions to improve health (Craig et al., 2008), achieving high fidelity of delivery should be achieved in a pilot phase before carrying out a full-fledged RCT. In real-life however, limited resources mean that a full piloting phase to improve fidelity is not always undertaken, and in the context of RCTs, variations in delivery (i.e. infidelity) can and do occur. In an ideal world, a BCI that contained BCTs A, B & C would be delivered uniformly to all recipients: Techniques A, B & C would be utilised in the same way and delivered in the same order as pre-specified in a protocol. Consider however these cases: Some participants did not receive C because the time for the session had run out; others received A, B & C, but in a different order (e.g. CAB or BCA); and others still received A, B & C, but also techniques D, E & F which were not mentioned in the protocol at all. Each of these scenarios is realistic when delivering a BCI, and such variations in delivery can affect outcomes and treatment effectiveness. When not properly accounted for and reported, as is often the case at present, infidelity effectively removes the 'control' from RCTs of BCIs and limits the advance of behaviour change science.

Apart from the questions of *whether* and *when* a BCT was actually delivered, the question of *how* it was delivered is also significant. Take for example

behavioural goal setting (BCT 1.1 from Michie et al., 2013), which is included in a majority of BCIs. Numerous factors of goal content can influence behavioural performance, including specificity, difficulty level, and ownership (Latham & Locke, 1991; Maes & Karoly, 2005). Although the setting of SMART behavioural goals (Bovend'Eerdt, Botell, & Wade, 2009) is mentioned in many protocols, actual goal content in BCIs is rarely reported, and infidelity in this domain (non-SMART goal setting) may covertly reduce behavioural performance. Variance in information provision (BCTs 4.1, 5.1, 5.3, 5.6, 6.3) might also affect behavioural performance. Consider the differences between clinician 1 who provides information by giving participants a leaflet, clinician 2 who supplements the leaflet with further information given verbally, and clinician 3 who uses the elicit-provide-elicit structure from motivational interviewing – first asking the participant what he or she already knows about the topic and supplementing this (if necessary) with verbal information and finally a leaflet (Rollnick, Miller, & Butler, 2008). Clearly, these differences in how BCTs are delivered have the potential to affect outcomes and intermediate predictors of outcomes, and should in some way be taken into account when reporting the results of an RCT.

Finally, some BCTs require that participants carry out particular actions on their own in order for behaviour change to occur (Hankonen et al., 2014). Self-monitoring of behaviour (BCT 2.3) is one clear example of this. When coupled with other techniques from control theory (Carver & Scheier, 1982), self-monitoring has been linked to greater improvements in physical activity and dietary outcomes than other interventions (Michie et al., 2009). Unfortunately however, self-monitoring is not always completed by the recipients of BCIs. In fact, within weight loss interventions, rates of self-monitoring for diet, exercise and self-weighting are only around 50% (Burke, Wang, & Sevick, 2011). The effectiveness of BCIs which include self-monitoring may therefore suffer, as incomplete or absent self-monitoring would

have knock-on effects on the efficacy of other techniques derived from control theory. Without self-monitoring records to draw from, feedback on behaviour cannot be given, and any behavioural goals that are subsequently set have the potential to be either too difficult or too easy, thus detracting from behavioural performance (Maes & Karoly, 2005). It is therefore not surprising that rates of self-monitoring completion have been shown to significantly predict intervention effectiveness (Burke et al., 2011).

How can fidelity best be promoted and assessed?

Infidelity in intervention delivery, when unaccounted for, has the potential to produce misleading results in RCTs. Researchers must therefore work to promote fidelity (and account for infidelity) at all stages: during BCI development, during piloting and full-scale testing, and during reporting and analyses. This section outlines some of the steps that can be taken at each phase to promote, assess and report fidelity of BCI delivery, many of which have been previously described elsewhere (Bellg et al., 2004; Moncher & Prinz, 1991; Nelson et al., 2012).

Promoting fidelity should begin well before the first participant is recruited. Creating detailed protocols, treatment manuals and sequential intervention materials (e.g. workbooks) provides a blueprint for the intended providers of the BCI. Reviewing these materials within a small group of potential providers can help to refine the materials and improve their clarity and detail. Small group settings also help to identify perceived skill deficits on the part of the providers so that methods to train providers can be optimised. When training providers to deliver a BCI, a building block approach is warranted, with each component BCT discussed individually and in the context of other frequently co-occurring BCTs. Providing training in a group format allows for role plays and rehearsal of key

skills, and provides ample opportunities for peer feedback. Video recording can be used to provide for self-observation and feedback if deemed appropriate. Upon completion of training, ensure that all providers achieve a pre-specified standard of competence by assessing knowledge and/or actual fidelity of delivery in role plays or with mock participants, and develop or identify existing tools to examine this (e.g. quizzes, checklists, self-report questionnaires).

After achieving the pre-specified standard of fidelity in training, a piloting phase allows for observation and assessment of BCI delivery *in vivo*. Where consented to by intervention recipients, record intervention sessions to identify whether the BCI is being delivered as specified in the protocol, and provide feedback to providers on areas which are delivered well and on those that could be improved. Allow providers the opportunity to view or listen to their own recordings in order to analyse their performance, identify barriers to fidelity, and develop coping plans on how to overcome similar barriers in the future. Note down commonly occurring deviations from the protocol and adjust or supplement existing training mechanisms to improve these aspects when training subsequent providers. Conduct exit interviews or administer questionnaires to participants to assess their thoughts about the importance and utility of the various BCTs, as well as ways they might be improved or expanded upon.

Once full-scale testing of the BCI begins, the task of researchers should shift toward monitoring fidelity, so that this can be recorded and reported with the results of the trial, and so that appropriate measures can be undertaken to maintain fidelity of delivery throughout the trial. Ask providers and recipients to complete a checklist after each session to assess whether or not they thought each BCT had been delivered (Presseau et al., 2014). This allows for the examination of differences in perception between providers and recipients, and can act as a reminder for providers about exactly what their tasks in delivering the intervention are. Observe and note the quality of participant-provider interactions (e.g.

provider warmth, directive versus collaborative approach, time spent talking) (Silva, Marques & Teixeira, 2014, this Issue). Use objective measures of fidelity where possible, and just as during the piloting phase, use the results to periodically provide feedback to providers.

Assessing fidelity of BCTs such as self-monitoring which require effort on the part of patients is particularly important during this phase. Ask participants to return completed self-monitoring diaries, make photocopies of these and note down when they are not returned. Monitor how incomplete and absent self-monitoring diaries affect the progress of a session, and whether there are differences between providers in how this is handled. If a BCI is delivered via the internet or on a mobile device, ensure that the website or mobile app has the capability to track the extent to which users engage with intervention components and self-monitoring tools. When a BCI includes goal setting, record the content of goals that participants set, and assess whether characteristics of these goals (e.g. SMARTness) are linked to behavioural outcomes. Use interviews or questionnaires to examine the extent to which participants make use of BCTs outside the formal intervention setting.

Once completed, report the results of the RCT and measures of fidelity as comprehensively as possible. At a minimum, provide a table which identifies the percentages of participants who received each BCT at each time point, including BCTs that were delivered but not included in the protocol (for an example, see Knittle, 2014). Provide data on the extent to which participants engaged with BCTs, such as self-monitoring completion rates, and attempt to link this to outcomes (Hankonen et al., 2014). Provide data on the length of sessions and the quality of participant-provider interactions. When possible, publish data on fidelity and outcomes as supplementary files *on a per-participant basis* (i.e. in a manner you would expect to find in a study using *n-of-1* methodology), so that fine grain detail of the BCI is available for further analysis and inclusion in meta-analyses. With all of

this data collected, it then becomes easy to analyse the extents to which fidelity of BCT delivery, participant engagement with BCTs, intervention duration and order of BCT delivery contribute to the efficacy of the BCI as a whole.

Gee, that seems like a lot...

Indeed, fully accounting for fidelity in BCIs is a big job, and requires additional resources beyond those needed to simply deliver an intervention. Researchers should therefore account for this when budgeting for grants and planning to develop or test BCIs. While the extension of the CONSORT statement for non-pharmacological treatments includes reporting the 'details of how adherence of care providers with the protocol was assessed or enhanced' (Point 4C; Boutron et al., 2008), it does not provide any further specifics about the required content of these reports. In a perfect world, all research teams would undertake all of the aforementioned activities (and more) to promote, assess and report on fidelity, but this is not always possible. Luckily, hope remains for those with limited resources and who have not budgeted for this in advance. The end of this article provides a list of key points that can be used as a guide for tackling fidelity if you're in a pinch or don't have the resources to assess fidelity for all participants.

An alternative view of the importance of fidelity

While fidelity of BCI delivery is clearly important and can affect outcomes, infidelity almost invariably occurs, and RCTs of BCIs therefore provide very little in the way of actual control. Does this mean that behaviour change science is at an impasse until BCIs can ensure 100% fidelity? No. On the contrary, when properly recorded, this individual variation in delivery (e.g. duration, *actual* BCT delivery, and order

and quality of BCT delivery) provides the opportunity for natural experiments within the context of each RCT. Which components of a BCI actually drive its effectiveness? Is there a critical mass of BCTs which needs to be delivered to ensure behaviour change? Which characteristics of participant-provider interactions make the most difference? While it would be impossible to answer all of these questions within one individual RCT, a decade worth of well-reported 'natural experiments' in BCIs, reported in a comprehensive way, would empower subsequent meta-analyses to properly investigate these fine inner-workings. An accumulation of open-access data with a high level of detail on fidelity and outcomes at the *per-participant* (n-of-1) level is therefore paramount to advancing behaviour change science to the next level.

Key Points for promoting and assessing fidelity (on a budget)

- Provide a checklist of BCTs for providers to use during sessions.
- Assess delivery of BCTs via a questionnaire to patients and/or providers after the session.
- Assess a subset of intervention sessions from each provider (as opposed to all participants).
- Focus on the fidelity of BCTs hypothesized to have the greatest effects on outcomes (e.g. self-monitoring, goal setting, action planning, problem solving).
- Use questionnaires to assess participants' use and enactment of BCTs outside of the intervention sessions.
- Provide detailed fidelity and outcome data at the per-participant level.

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Keegan Knittle
University of Helsinki, Finland
keegan.knittle@helsinki.fi

A starter kit for undertaking n-of-1 trials

Felix Naughton

University of Cambridge

Derek Johnston

University of Aberdeen

Preface

The aim of this article is to provide readers who have not yet undertaken n-of-1 or within-subject experimental studies with a general overview of the methodology from a health psychology perspective and to provide some tools to give readers the opportunity to give it a go themselves.

Introduction

The population based randomised controlled trial (RCT) has dominated intervention evaluation for many decades. However, one important downside of this general design is that it provides only an estimate of the *average* effect of an intervention for a given population. Although subgroup analyses within RCT samples are potentially informative, they fall short at being able to explain whether an intervention works for individual participants or small discrete groups of participants. There are also limitations with using group or population experiments to test psychological theory. Identifying relationships between theoretical constructs across individuals does not inform us on whether these relationships hold within individuals (Johnston & Johnston, 2013), which is arguably a valuable, perhaps essential, feature of any theory of behaviour. N-of-1 studies can generate evidence for the impact of an intervention or relationship between theory-derived constructs for specific individuals and identify inter-individual differences in these observations. Why is this valuable? For several

reasons.

N-of-1 studies, because they use regular and numerous measurements within individuals, can provide good evidence for directions of causality. For example, whether exposure to an intervention precedes and explains changes in self-efficacy, which in turn precedes and explains changes in behaviour (potentially via intention or goal). N-of-1 RCTs also provide an opportunity to test discrete components of interventions, such as Behaviour Change Techniques (BCTs) (Michie et al., 2013), on behavioural determinants and behaviour between and within individuals (Craig et al., 2008) without the large samples required in population studies. This includes factorial n-of-1 randomised controlled trials which vary treatments on multiple occasions within individuals to identify their impact on short-term changes in behaviour (Sniehotta, Presseau, Hobbs, & Araujo-Soares, 2012). Importantly, with the smartphone becoming ubiquitous, data collection for these studies can be undertaken relatively easily and efficiently. This includes Ecological Momentary Assessment, an approach for collecting within-individual data in a person's naturalistic environment in real time (Shiffman, Stone, & Hufford, 2008).

What is an n-of-1 RCT?

An n-of-1 RCT is a crossover experiment conducted with a single participant who acts as their own control. Multiple n-of-1 RCTs can be aggregated statistically in order to explore between-participant as well as within-participant effects (see discussion section). N-of-1 RCTs usually provide repeated and randomly allocated periods of treatment to participants with sufficient frequency to minimise any chance of confounding influences on the

outcome. Furthermore, n-of-1 RCTs are often undertaken 'double-blind' where both the participant and researcher collecting data are blinded from treatment allocation, although this is frequently not possible in psychology studies.

According to the American Medical Association's Evidence Based Medicine Working Group, n-of-1 trials are regarded as the gold standard for generating evidence for individual treatment decisions, over and above systematic reviews of randomised controlled trials, and can provide definitive evidence of treatment effectiveness in individuals (Guyatt et al., 2000). However, only certain types of intervention and behavioural or health outcomes of interest in health psychology and related fields are appropriate for n-of-1 RCTs.

What types of interventions or outcomes are n-of-1 RCTs suitable for?

For interventions, a key issue in assessing whether n-of-1 RCTs are suitable is whether the intervention is likely to generate substantial carryover effects. If an intervention aims to change an individual's beliefs to bring about some change in their behaviour, through using persuasion say, any belief changes could last well beyond a crossover to a different intervention. In this scenario it can be difficult to determine whether any changes in behaviour after the persuasion intervention had ended was due to any subsequent intervention or due to the carryover effects of the original persuasion intervention. Therefore, interventions expected to produce only short-lasting effects on the outcome of interest, such as planning, goal setting, contingent reinforcement or rewards, self-monitoring and feedback interventions, as Sniehotta et al. (2012) suggest, are most suitable for n-of-1 RCTs as their carryover effects can be minimised. Similarly, investigating the impact of drug interventions including treatment efficacy, withdrawal or side-effects is particularly suitable. The blinding of participants and researchers is usually straightforward with drug related trials and carryover effects can be managed, providing appropriate 'wash-

out' periods are factored in. When interventions have very substantial and/or enduring effects, other n-of-1 designs can be used, including multiple baseline designs where different behaviours are targeted sequentially or stepped wedge designs in which different participants have pre-intervention periods of different durations.

In terms of outcomes, those easily measured over short periods of time which are good predictors of longer term behaviour or clinical outcomes, are most suitable for n-of-1 RCTs e.g. abstinence from smoking. When investigating outcomes relating to specific health conditions, the stability of that condition can affect the ease to which changes in outcomes can be attributed to specific interventions. So stable conditions are most suitable for n-of-1 RCTs.

N-of-1 RCT case study

This next section of the article will describe a case study of an n-of-1 RCT undertaken to test a specific hypothesis about the experience of caffeine withdrawal for one individual. After the case study section, a description will be provided of how the analysis was undertaken and output interpreted with links to the actual data collected and analysis syntax to enable readers to undertake their own analyses for training purposes.

Hypothesis

PD [pseudonym] will experience caffeine withdrawal when her once-daily cup of caffeinated coffee is replaced with decaffeinated coffee.

Design

A single participant (n-of-1) double-blind randomised controlled trial of caffeinated versus decaffeinated coffee. Treatments were randomly allocated to twelve randomly selected treatment period blocks of 3 or 4 days (see allocation sequence in figure 1). Simple urn randomisation without

Treatment period	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6	Period 7	Period 8	Period 9	Period 10	Period 11	Period 12
Allocation	A	B	B	A	B	B	B	A	A	B	A	A
Day	1 2 3 4	5 6 7	8 9 10	11 12 13 14	15 16 17	18 19 20	21 22 23	24 25 26	27 28 29 30	31 32 33	34 35 36	37 38 39 40

Figure 1: Allocation sequence for the caffeine case study

replacement was used to generate the allocation sequence using WinBUGS software (Lunn, Thomas, Best, & Spiegelhalter, 2000), undertaken by the statistician (DL). The researcher (FN) and the participant (PD) were blinded to allocation but only the participant was blinded to the treatment blocks.

Procedure

A single-blind manipulation check prior to the study demonstrated that the participant was unable to distinguish between caffeinated and decaffeinated coffee with added milk. During the 40-day study period PD was provided with the allocated treatment (caffeinated or decaffeinated coffee with milk) once a day in the mid-morning as per usual consumption and was discouraged from consuming other food or drink which contained caffeine. Nominated colleagues and friends, who were blinded from allocation, made the coffee at work and home respectively for the participant. The coffee was stored in identical tins labelled A and B. Nominated colleagues/friends were informed every morning by SMS text message about PD's treatment allocation (A or B) for that day using a free automated text message programme for Android (SMS Scheduler). The participant completed a study questionnaire at approximately 4pm every day during the study period either on their mobile phone or a pc.

Measures

The primary outcome measure was the mean score on the Caffeine Withdrawal Symptom Scale (CWSQ) (Juliano, Huntley, Harrell, & Westerman, 2012). Secondary outcomes were three subscales of the CWSQ, mood disturbance, decreased sociability and headache, selected as symptoms the participant felt she had experienced prior to the study shortly after

abstinence from caffeine.

The participant was also asked to indicate on the daily questionnaire whether she believed she had consumed a caffeinated or decaffeinated coffee earlier that day, using a 5-point rating scale (from 'sure it was caffeinated' [1] to 'sure it was decaffeinated' [5]), whether they experienced any treatment violations (i.e. didn't drink a study coffee that day) and whether they had consumed any other food or drink containing caffeine that day. The participant could also add comments about their day which were considered relevant to the study using a free text field. Additional measures included perceived stress, sleep quality, alcohol consumption and minutes of vigorous physical activity.

Statistical analyses

Firstly, the CWSQ scale and subscale scores across the 40-day study period were plotted using SPSS. Secondly, we investigated whether these outcomes exhibited autocorrelation in SPSS. We then investigated whether allocation predicted scores on the CWSQ scale and subscales, when taking into account autocorrelation, using McKnight et al.'s double bootstrap method (McKnight, McKean, & Huitema, 2000). Finally, logistic regression was undertaken to assess whether the participant predicted, above chance, which treatment she was allocated to each day and linear regression was undertaken to assess whether allocation continued to predict CWSQ scores when the participant's assessment of which treatment she was receiving was taken into account.

Results

An essential first step in an n-of-1 study is to plot the data [*to create plot see A1 in the next section*].

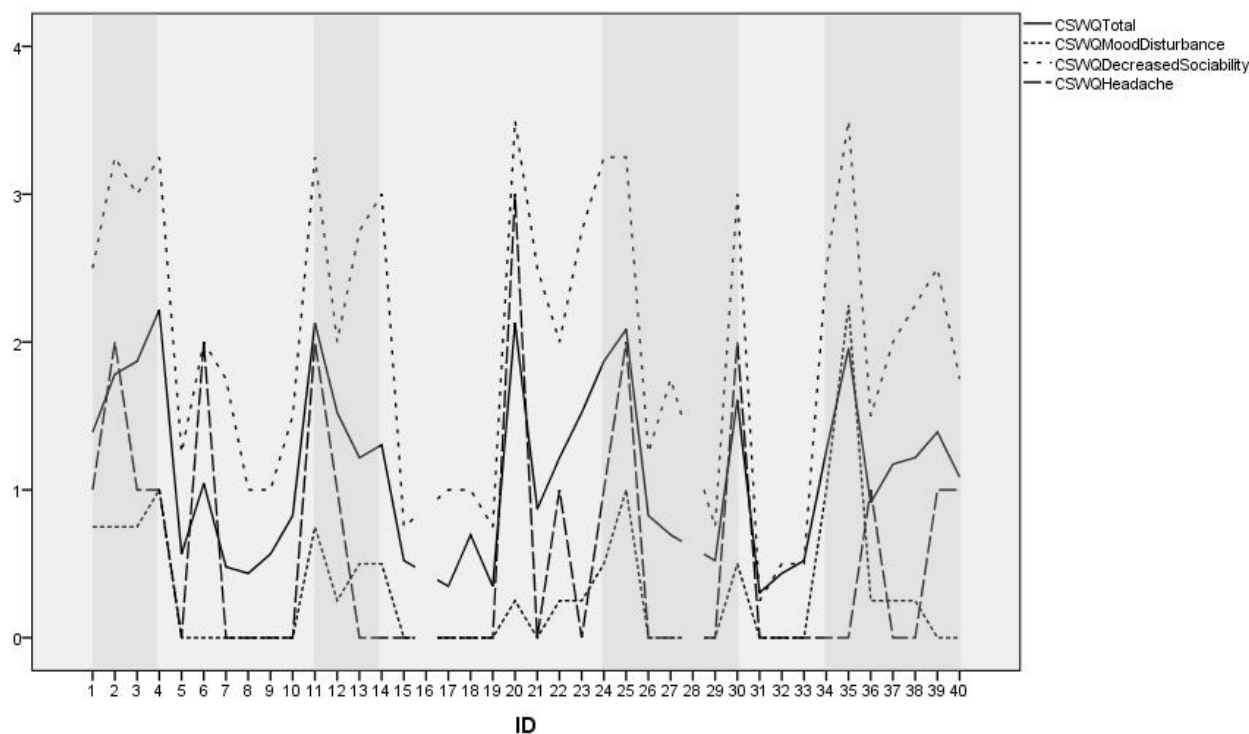


Figure 2: Plot showing the daily scores on the CWSQ and selected subscales over the 40-day study period (with missing data). Dark grey sections represent treatment periods where the participant received decaffeinated coffee

Figure 2 contains a plot showing the daily scores on the CWSQ and selected subscales over the 40-day study period. Overlaid in grey are the decaffeinated coffee treatment blocks when withdrawal symptoms, as measured by the CWSQ, are hypothesised to be higher. There were three treatment violations (days 14, 20 and 35), where the participant did not have a study coffee, and two days with missing data (days 16 and 28). The average value for the treatment block was substituted for the missing data. It is very likely that successive readings in an n-of-1 study will be correlated (autocorrelated, see glossary) a feature that can lead to inaccurate estimates of statistical significance. The CWSQ and subscales did not demonstrate significant autocorrelation [A2], although the mood disturbance subscale autocorrelation approached significance (figure 3). However the intervention could mask an underlying autocorrelation. This is allowed for in the analysis we used.

In a form of regression analyses designed for n-of-

1 studies which we describe below [A3], treatment allocation predicted scores on the CWSQ (unstandardised beta estimate -0.74 , $p < 0.001$), and the mood and decreased sociability subscales. As indicated in figure 2, there were two days (6 and 20) where scores on the CWSQ scale and subscales spiked, demonstrating increased withdrawal symptoms, despite being during a caffeine treatment period. When examining the additional information collected on the study questionnaire, the participant had indicated that these two days followed excessive alcohol consumption episodes the day before (“hangover”) and on day 20 the study treatment was missed out, which was meant to be a caffeinated coffee. These appear to explain these unexpected spikes in withdrawal symptoms, taking into account the general similarity between symptoms of alcohol hangovers and caffeine withdrawal (Finnigan, Hammersley, & Cooper, 1998). The participant performed better than chance at predicting which treatment she had been allocated to that day (beta

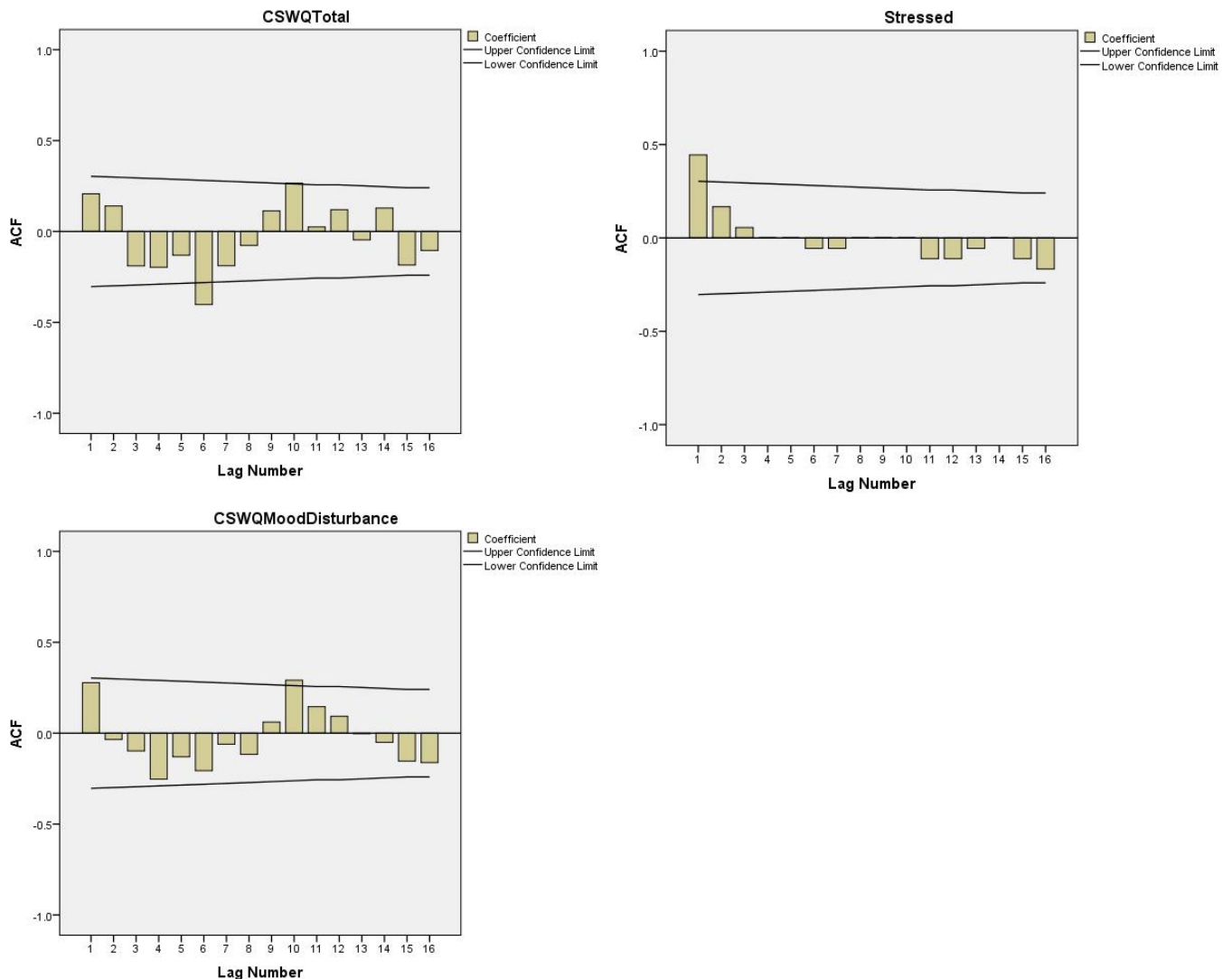


Figure 3: Autocorrelation charts for CWSQ total, mood disturbance CWSQ subscale and perceived stress

-1.26, $p = 0.002$), although allocation remained a significant predictor of scores on the CWSQ when her prediction was taken into account. The participant described guessing which treatment she had received based on how she felt later on in the day after consuming the treatment coffee in the morning rather than basing it on the taste, smell or appearance of the coffee.

Conclusion

The trial generated evidence that PD experiences caffeine withdrawal when caffeinated coffee, drunk

on a one-a-day basis, is replaced with decaffeinated coffee.

Undertaking the analysis and interpreting the output

With the participant's permission, we have made the data we collected for this study freely available to enable others to use it and replicate our analyses for training purposes (and potentially do further exploratory analyses). We have provided SPSS syntax

for creating the scale and subscale variables from the raw data and to carry out the SPSS-related analyses described in the case study. We have also formatted the data into ASCII so it can be used with McKnight et al.'s double bootstrapping web-tool.

Files made available at <https://osf.io/zp93r/files/> for use as part of this starter kit paper include raw data in CSV format (file 1), raw data in Excel format (file 2), transformed and coded data in SPSS v.21 format (file 3), SPSS syntax (file 4), CWSQ scale summary score data formatted for the McKnight software (file 5) and a guide on time series analysis of n-of-1 data using the prewhitening approach in SPSS (file 6).

Main analyses undertaken in caffeine case study

A1 - To plot the data in SPSS (as in figure 2), go to Analyse -> Forecasting -> Sequence charts and select your variable of interest and enter the time/date variable into the time axis label field.

A2 - To assess autocorrelations in SPSS, (including a graph as in figure 3), go to Analyse -> Forecasting -> Autocorrelations and select your variable of interest (you can leave the default options as they are).

A3 - To undertake McKnight's double bootstrap method go to the website (<http://www.stat.wmich.edu/slab/Software/Timeseries.html>)¹. The data is entered as an ASCII file (.txt) with the data for each measurement period being on a separate row and the final data point in each row being the dependent (outcome) variable, all the other variables being assumed to be independent (predictor variables). See the above link for the caffeine study data in the required format (file 5). We find it best to

¹ At the time of publishing 7 November 2014 the server holding this software was not available. We understand that a new operating system is being installed, when completed the software will be available again. We also understand that an R version of the software is near completion. Despite these current uncertainties we have chosen to present our analyses using this software since it appears the best available option for dealing with small n-of-1 data sets. If large data sets are available then the ARIMA modelling procedures available in most statistical packages can be used.

cut and paste the dataset into the space provided in the web tool. Unlike SPSS and other major packages the constant (intercept) has to be specified. This done by entering 1 and it is conventional to make it the first variable. The other variables specify the experimental conditions and any other covariates that you may wish to use. We find that many people initially find it helpful and reassuring to first specify and run the regression model (with no allowance for autocorrelation) in whatever statistical package they normally use². The software requires one to specify the degree of autocorrelation one wishes to allow for. First order (see autocorrelation in glossary) is the default and is a good starting point. The output from the double bootstrapping software provides estimates of the unstandardised beta weights, associated standard errors and tests of significance. The output also contains information on variances and covariances that can be ignored at least initially and estimates of the autocorrelation that was established and allowed for in the analyses. See figure 4 for an edited example of output from the web-tool.

Discussion

The remainder of the article provides some general rules of thumb about designing and analysing n-of-1 RCTs.

Aggregating n-of-1 trials

There are several ways to aggregate data from multiple n-of-1 trials, including meta-analysis and multi-level modelling (MLM). We favour MLM. Aggregating n-of-1 RCTs using these approaches enables the assessment of the overall or average effect of an intervention for a group of participants.

² It is possible to make some allowance for autocorrelation by prewhitening the outcome variable and using the prewhitened variable as the outcome in a regression analysis. Instructions for doing this in SPSS (produced by Karen Schroder and Diane Dixon) can be found in additional material file 6 and syntax to analyse the caffeine study data using this approach is in the SPSS syntax file 4.

Time Series Results

Parameter Estimates and Test that parameter is zero

Parameter	Estimate	t-ratio	p-value
Beta 1 (constant)	1738	6.92	<0.00001
Beta 2 (time)	-157	-1.72	0.0938
Beta 3 (intervention)	-742	-3.79	0.0006

Authors' comments

Constant significant (minor importance)

Slight effect of time

Significant effect of the intervention

Variance Covariance Matrix of Parameter Estimates

Beta 1	Beta 2	Beta 3
0.6295	<i>-0.0190</i>	<i>-0.2883</i>
	0.0008	<i>0.0046</i>
		0.3843

Diagonal indicates variance of beta

Covariances in *italics*

Bootstrap Estimates and CI's of AR Parameters

Bootstrap Residual MSE = .262397		
Parameter	Estimate	95% CI
AR 1	.102	-.312, .517

No significant first order autocorrelation

Variance Covariance Matrix of AR Estimates

0.41833

Figure 4: Edited and annotated output from McKnight et al.'s double bootstrap method

With sufficient n-of-1 RCTs, it is possible to compare the effect of interventions on individuals with different characteristics. The use of MLM in n-of-1 studies is well described by Shadish, Kyse, and Rindskopf (2013).

Determining the number of data points, and number and length of treatment blocks

A key question asked with n-of-1 RCTs is how many data points are required. Ideally this should be based on what would provide sufficient power to detect the predicted or clinically significant difference between conditions. This would be dependent upon the nature of the outcome and intervention (Lillie et al., 2011). Sniehotta et al. (2012) applied Cohen's rule of thumb of having at least 30 participants per condition to provide 80% power. So for their n-of-1 RCTs this was translated into 30 data points per study condition. Ultimately, the more conditions/treatment periods there are, the greater the reduction of any potential confounding effects of other factors or behaviours on the outcome

of interest. In terms of the length of treatment blocks, this very much depends on the length of time which one would expect an intervention to affect the outcome and cease affecting the outcome after it is removed. For the case study above, caffeine withdrawal is expected to start after 12 to 24 hours after caffeine abstinence and peak after 1-2 days. Withdrawal ceases rapidly once caffeine consumption resumes. Therefore treatment blocks of 3 or 4 days were deemed sufficient to capture caffeine withdrawal symptoms. However, interventions with long 'wash-out' periods or which take a significant amount of time to influence the outcome will require longer treatment periods and in some cases would not be suitable for n-of-1 RCTs. Practical considerations will often determine the number of observations possible in each replication of a treatment as well as the number of replications.

Testing for carryover effects

N-of-1 RCTs are most suitable for interventions with minimal carryover effects. But how do you know

if an intervention has a carryover effect? The first question to ask is whether an intervention is aiming or expected to produce anything more than a short-term effect on the individual. One rule of thumb suggested by Sniehotta et al. (2012) for assessing carryover effects after undertaking an n-of-1 RCT(s) is to see if there is an overall time trend i.e. does the outcome increase or decrease from the beginning of the study to the end. They also suggest that, for studies with very short treatment blocks e.g. one day, the existence of autocorrelation of the outcome could also be a weak indicator of carryover effects. Examination of the plot of the data is very helpful in detecting carryover effects.

Randomisation

In general, it is advisable to randomise the sequence of treatment blocks (Lillie et al., 2011). However, one downside of using simple randomisation is the risk that all treatment blocks end up clustered together. Therefore, where possible, some form of block randomisation is advisable to address this issue unless there are a large number of replications. In the above caffeine study example, we used a slightly different approach - simple urn randomisation without replacement. This is where exactly six treatment periods for each treatment were placed into a virtual urn and then selected at random in turn. Each time a treatment is 'pulled out' of the urn and selected for allocation to a treatment block, the probability of selecting the alternative treatment rises. This approach is considered to increase the unpredictability of allocation compared to permuted-block designs (Schulz & Grimes, 2002), although it does not entirely eliminate the risk of all treatment blocks of the same treatment ending up together in a row.

Conclusion

While N-of-1 RCTs have in the past predominantly been used to inform individual patient treatment,

they offer utility for intervention development and evaluation in health psychology. There is evidence that their use to evaluate health interventions is increasing, partly driven by the increased practicality for both researchers and participants of collecting data via mobile digital devices. There still remains much debate as to how best to design n-of-1 studies. However, this can be overcome with greater use and exploration of this methodology. With the increased focus in health psychology on the specific 'active' components of interventions, n-of-1 trials may have an important role to play in this exciting new chapter of behavioural science.

Useful resources

Kravitz, R. L., Duan N. (Eds), & the DEcIDE Methods Center N-of-1 Guidance Panel (Duan, N., Eslick I., Gabler, N.B., Kaplan, H. C., Kravitz, R. L., Larson, E. B., Pace, W. D., Schmid, C. H., Sim, I., Vohra, S.) (2014). Design and Implementation of N-of-1 Trials: A User's Guide. AHRQ Publication No. 13(14)-EHC122-EF. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from <http://www.effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=1844>

The European Health Psychology Society (EHPS) n-of-1 Special Interest Group (open to any researchers who want to engage with others interested in and using n-of-1 designs): currently located at <http://ehps.net/synergy/?q=node/135>

Glossary

Autocorrelation: The association between sequential data points within the same variable. If data is collected daily (as with the above caffeine withdrawal study), the autocorrelation will examine the correlation between a variable at T0 and T-24hrs (lag 1) and then between T0 and T-48hrs (lag 2) and so on always going back in time. For a 1st order autocorrelative (or autoregressive) relationship, there will be an association at lag 1 but very little else at

further lags after that first association is taken into account.

Crossover period: The transition where one intervention is stopped and another intervention or non-intervention phase starts.

Crossover effect: When the effect of an intervention lasts beyond the point at which that intervention is withdrawn.

Washout period: A period to allow any crossover effects to cease before a separate intervention is provided.

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Felix Naughton
University of Cambridge, UK
fmen2@medschl.cam.ac.uk



Derek Johnston
University of Aberdeen, UK
d.johnston@abdn.ac.uk

Planning interventions for behaviour change: A protocol for establishing best practice through consensus

Martin S. Hagger Background and

Curtin University

Key Issues

Aleks Luszczynska

Hazards Center, University of Colorado

University of Social Sciences and Humanities, Wrocław

There has been a rapid increase in the use of planning techniques in interventions to promote health-related behaviour (Abraham, Kok, Schaalma, & Luszczynska, 2011). The proliferation of interventions using planning has largely been a direct response to the considerable literature which has recognised the limitations of intentions as a predictor of behaviour (Dekker, 2008; Sheeran, 2002; Webb & Sheeran, 2006), the so-called intention-behaviour 'gap'. Recent theoretical models incorporating both *motivational* and *volitional* phases have sought to resolve this issue by examining the role that furnishing intentions with planning exercises plays in improving the link between intentions and behaviour (Gollwitzer & Sheeran, 2006; Schwarzer, 2001; Sheeran, Milne, Webb, & Gollwitzer, 2005). Prominent among these planning interventions are *implementation intention* and *action planning* techniques. These techniques aim to bolster or augment intentions with means to promote recall and enactment of the intended behaviour.

These planning techniques are two of the most recognised and frequently-applied components in health behaviour interventions (Adriaanse, Vinkers, De Ridder, Hox, & De Wit, 2011; Bélanger-Gravel, Godin, & Amireault, 2013; Webb, Sniehotta, & Michie, 2010). There are numerous reasons why these techniques have attracted so much attention: they are steeped in established social psychological theory (Gollwitzer, 1999; Heckhausen & Gollwitzer, 1987), have been embedded in popular and well-cited

theories of social cognition applied in health contexts (e.g., Theory of Planned Behaviour, Orbell, Hodgkins, & Sheeran, 1997), and address a commonly-known limitation of these theories (i.e., the intention-behaviour 'gap', Webb & Sheeran, 2006); they have intuitive appeal in their parsimony; they have low response burden making their dissemination through multiple modes of delivery comparatively easy; and they are low-cost. Above all, there is growing support for their effectiveness in engendering behaviour change health-related contexts as stand-alone intervention strategies or as part of more elaborate interventions involving multiple behaviour-change techniques. Implementation intention and action planning interventions have been shown to be effective in changing diverse behaviours such as physical activity participation (Arbour & Martin Ginis, 2009; Barg et al., 2012; Conner, Sandberg, & Norman, 2010; Gellert, Ziegelmann, Lippke, & Schwarzer, 2012; Luszczynska, 2006; Milne, Orbell, & Sheeran, 2002; Prestwich et al., 2012; Prestwich, Lawton, & Conner, 2003), healthy and unhealthy eating (Adriaanse, de Ridder, & de Wit, 2009; Adriaanse et al., 2010; Armitage, 2007; Chapman, Armitage, & Norman, 2009; Prestwich, Ayres, & Lawton, 2008; Sullivan & Rothman, 2008), quitting smoking (Armitage, 2008; Armitage & Arden, 2008), alcohol consumption (Armitage, 2009; Hagger et al., 2012), breast self-examination (Orbell et al., 1997; Prestwich et al., 2005), rehabilitation from injury (Scholz, Sniehotta, Schuz, & Oeberst, 2007), vitamin consumption (Sheeran & Orbell, 1999), cancer screening behaviours (Browne & Chan, 2012; Rutter, Steadman, & Quine, 2006; Sheeran & Orbell, 2000), workplace health and safety (Sheeran & Silverman, 2003), vaccine uptake (Milkman, Beshears, Choi, Laibson, & Madrian, 2011;

Payaprom, Bennett, Alabaster, & Tantipong, 2011), contraception use (de Vet et al., 2011; Martin, Sheeran, Slade, Wright, & Dibble, 2009; Teng & Mak, 2011), and dental health behaviours (Orbell & Verplanken, 2010; Schüz, Wiedemann, Mallach, & Scholz, 2009). In addition, systematic reviews have confirmed the effect of implementation intentions on behaviour in multiple behavioural domains (Gollwitzer & Sheeran, 2006) and in specific health-related behavioural domains such as physical activity (Bélanger-Gravel et al., 2013) and healthy eating (Adriaanse et al., 2011).

However, while there is growing support for these planning interventions in the health-behaviour literature, a number of limitations in the research have been noted. For example, the meta-analytic findings indicate substantial heterogeneity in the effect size for implementation across studies (Adriaanse et al., 2011; Bélanger-Gravel et al., 2013; Gollwitzer & Sheeran, 2006). In other words, there is a lot of variation in the strength of the effects of planning interventions, implying that their effectiveness varies across studies. The presence of heterogeneity should lead to a search for possible moderators of the effect (i.e. the parameters for effectiveness explained in Kok, 2014, this issue). Examples of 'classic' moderators that may account for the heterogeneity in effects across studies include variations in study design and execution, sample characteristics and contexts, and individual difference variables (Hagger, 2006). For example, studies may differ in their definition and operationalisation of planning procedures and their proposed mechanisms for the effect (e.g., mediation analyses). In addition to the heterogeneity, there also appears to be considerable variation in the definitions of the constructs and techniques that comprise planning techniques. This makes it difficult for experienced researchers to establish a consistent pattern of effects for planning interventions and also makes it difficult for practitioners, particularly those unfamiliar with the theory or terminology, to make sense of the findings and establish the best means to implement

planning interventions. The heterogeneity in the effect sizes and lack of consensus in the definitions and operationalisation of planning interventions in health contexts present considerable challenges for researchers and practitioners attempting to develop interventions to change health behaviour adopting planning techniques. There is therefore a need to conduct a close examination of the current literature to establish whether there is sufficient evidence that may assist in accounting for the variation which may identify important considerations to take into account when designing interventions adopting planning interventions to change behaviour. This will assist researchers to identify what is 'best practice' when it comes to developing planning interventions and the limitations and gaps in the research that to be addresses in future studies. It also will assist interventionists interested in developing planning interventions based on the 'best available' evidence.

Establishing Consensus on Planning Interventions: Aims

A possible approach that may contribute to identifying the current state of the literature on a particular research topic, to help resolve outstanding gaps in the literature, and to arrive at a set of guidelines or recommendations for 'best practice' is to use a panel of experts and arrive at a consensus based on a thorough review and discussion of current research and pool expertise. In August 2014, the EHPS hosted a *Synergy* expert meeting on the topic of planning interventions to stimulate discussion and debate of the evidence on planning interventions in health behaviour. The meeting drew together leading theorists, intensive researchers and practitioners to form an expert 'panel' with considerable experience in the development, implementation, and evaluation of planning interventions in health behaviour. The goal was to develop a consensus on the most effective means to implement and evaluate planning

interventions, resolve some of the theoretical, operational and methodological 'gaps' in the literature through consensus on the current state of the research, and identify future priority areas for research to move knowledge in the field forward.

Key Topics and Issues: Starting Points for the Consensus Statement

Specifically, the consensus meeting focused on the following key topics identified in a recent review of planning interventions in health contexts (Hagger & Luszczynska, 2014): evaluating the research evidence on interventions adopting planning components; identifying the common features and differences of planning interventions in terms of operationalisation, design, measurement, mechanisms, and evaluation of planning components; identifying the salient gaps in the literature; formulating possible guidelines for good practice; and identifying priority areas for future research that will improve understanding of planning interventions in the field of health behaviour. This list was not considered definitive by the expert panel, but rather as a starting point to generate discussion and identify key topic areas. The ultimate aim was to produce a consensus statement on guidelines for 'best practice' for research and practice with planning interventions.

What will the 'statement' look like? The planned consensus statement is being prepared in the form of a 'research article' and will be submitted for publication under the authorship of the Synergy expert panel with all participants as co-authors. The 'consensus' statement is a rare, underused format for the dissemination of academic discussion and debate, but those that have been published are often considered highly influential as they represent the 'state-of-the-art' of pooled knowledge and expertise on a given topic or issue. Consensus statements provide practitioners with a set of recommendations for most effective practice based on current evidence. They

also have the potential to move the knowledge of the topic issue forward and develop new knowledge by outlining the key areas of research in need of future investigation and maximising researchers' effectiveness to contribute to the field by directing them to topics that are of the highest priority. The statement will outline 'best practice' guidelines under key headings including operationalisation – (e.g., What should a planning intervention 'look like'? What are the defining features?), mechanisms (what are the 'knowns' and the 'unknowns' in terms of the evidence for planning interventions?), measurement and design issues (e.g., What are the best form or format for planning interventions? How should they be best presented?), key constructs and measures (e.g., what measures should be included to evaluate the effectiveness of a planning intervention?), key moderating variables (e.g., what conditions will magnify or diminish the effects of planning interventions on behaviour?), and recommendations for researchers and practitioners (e.g., what is the best protocol to use when developing an planning intervention?).

Methods and Planned Activities

The meeting aimed to draw consensus on key issues relating to planning interventions using a 'nominal group' approach. The approach is defined by Delbecq and van den Ven (1971) as a structured meeting that attempts to provide an orderly procedure for obtaining qualitative information from a target group who is most closely associated with a problem area. The approach requires the assembly of the 'expert' panel and to follow a three stage process. In the first step, members are asked formulate their own list of ideas on the topic with only a brief introduction and no discussion. At the completion of the step, each member feeds his/her key ideas back to the group and they are recorded on a chart. This process is repeated until the lists are exhausted. In the second step, group members engage in a

structured discussion on the listed ideas. This stage should lead to a clarification of the key ideas and their evaluation. The third step involves each member privately rating the worthiness of the ideas. All issues/solutions are rated on a five-point scale and only issues receiving a mean rating of 3.0 or greater across group participants are accepted. The ideas can then be discussed by the group and support for each evaluated by a consensus vote. Based on general guidelines for consensus, any particular topic should be supported by no less than two-thirds of participants with any topic opposed by at least 25% of participants dropped outright (Fink, Kosecoff, Chassin, & Brook, 1991).

We asked researchers to bring their own experiences of intervention research, with a specific focus on including implementation intentions and action planning techniques, to the expert meeting, particularly the scripts and methods they have used in their interventions themselves, and the source material for their interventions. The idea was for these to be a basis for discussion of variations and consistencies in the current literature and practice of planning interventions. We also asked participants to report on the success of their manipulations, any failed replications, and feedback and reports from participants on the use of the techniques. This enabled the identification of where the strengths of current descriptions of these techniques in the literature and the limitations, omissions, lack of clarity, and needs for future research. The meeting included a number of themes (outlined below) that were introduced by the facilitators, initial exercises in which participants worked in small groups on a particular aspect of the theme, and then a collaborative session where each group reported to the main group on their findings. The feedback session was followed by a general discussion of the main issues, with all participants encouraged to contribute. Ideas and points were recorded on a spreadsheet. The feedback session was followed by a summary discussion to finalise the points and ask for additions. The points from the session and the

spreadsheet were typed up and formed a set of summary notes. At the end of the expert meeting, a final summing-up session using the notes as a stimulus aimed to arrive at a consensus in terms of the definition, contents, appropriate study design (e.g., intervention components, measures, and analyses), and key issues in need of research with respect to planning interventions.

Program and themes:

(1) Defining and conceptualising of planning interventions (e.g., distinguishing between types of planning intervention and their role in social-cognitive models), how should they be operationalised, and what are the conceptual differences between types of planning e.g. implementation intentions and action planning.

(2) Format and measurement of planning techniques (e.g., mode of delivery, measurement effects, format, use of examples, self- vs. other-defined plans).

(3) Mechanisms and processes underpinning planning techniques (e.g., the role of habit, moderators of planning intervention effects, forming multiple plans, planning interventions for low intenders).

(4) Design issues around planning techniques and interventions based on them (e.g., sustainability of behaviour change, intervention fidelity).

(5) The way forward: what would a 'gold' standard design for a planning intervention study look like?

Practical Contribution

An increasing number of studies across multiple health-behaviour contexts are adopting planning interventions, and many researchers, whether or not they are affiliated to the European Health Psychology Society, are affiliated to labs and research groups currently incorporating at least one form of planning as part of their health behaviour interventions. There were also researchers with links to policymakers and practitioners interested in how planning

interventions can be most effectively employed on a practical level in the field to maximize health behavior maintenance. The topic is, therefore, a pertinent one for many members of the society and beyond and this was an opportunity for an in-depth discussion of the issues surrounding planning interventions and their implementation that did not only benefit the participants, but will also provide consensus recommendations for non-attending members and researchers unaffiliated with the society interested in using planning interventions in their research. It is anticipated that the consensus statement will also provide guidelines for best practice in the content, design, implementation, and evaluation of planning interventions as a means to change health behaviour.

The Expert Panel

The lead facilitators of the expert meeting were Martin Hagger (Curtin University, Australia) and Aleks Luszczynska (University of Colorado, Colorado Springs), both of whom have considerable experience with the use of implementation intentions and action planning interventions in health behaviour. The lead facilitators were supported by a team of international world-leaders in planning interventions including John De Wit (University of New South Wales, Australia), Peter Gollwitzer (New York University, USA and University of Konstanz, Germany), Gabriele Oettingen (New York University, USA and University of Hamburg, Hamburg, Germany), and Paschal Sheeran (University of North Carolina, USA) who have a wealth of expertise on planning interventions including the inception of implementation intention theory and techniques and the theoretical and application of interventions in numerous health-behaviour context. The panel of experts for the meeting were selected from self-nominated applicants with demonstrable experience (e.g., through publication, grant award etc.) on the design of intervention using planning and other behaviour-

change techniques to offer varying and complementary perspectives.

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Martin S. Hagger
Curtin University, Perth Australia
Martin.Hagger@curtin.edu.au



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University of Colorado, USA and
University of Social Sciences and
Humanities, Poland
aluszczyn@uccs.edu

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