



**A Guide to Development and
Evaluation of Digital
Behaviour Change
Interventions in Healthcare**

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A UCL Centre for Behaviour Change Monograph

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A Guide to Development and Evaluation of Digital Behaviour Interventions in Healthcare

First Edition

Robert West and Susan Michie

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1. Summary

<i>What are the aims of the guide?</i>	This report aims to provide guidance on development and evaluation of digital behaviour change interventions (DBCIs) in healthcare, taking into account the current state of the evidence, behaviour change theory, and principles of intervention development and evaluation as applied to this area. New versions will be produced as new information become available.
<i>Who is the guide for?</i>	The guide has been written for researchers and practitioners wishing to develop or update DBCIs as well as those wishing to commission, use or evaluate such interventions.
<i>What does the guide draw on?</i>	The guide draws on the research literature on behaviour change, digital intervention development, and other guides with a broadly similar scope and purpose.
<i>What is behaviour?</i>	Behaviour is what we do. We can measure how many of us do something, how often we do it, and the features of how we do it.
<i>What behaviours are relevant to this guide?</i>	Behaviours that may harm health such as smoking, those that may protect health such as being physically active, engagement with healthcare services, adherence to treatment regimens, and self-management, as well as healthcare worker behaviours such as those involved in implementing evidence-based practice and in policy formation.
<i>What is 'behaviour change'?</i>	Behaviour change involves acting differently from how one would have acted, as a result of an intervention. It may involve not doing something one would have done, doing something one would not have done, or doing something differently. The change may or may not be deliberate.
<i>Why is behaviour change important for population health?</i>	The major causes of premature death and disability globally arise from the way we behave. This includes tobacco use, excessive alcohol consumption, poor diet, and being physically inactive. Changing these behaviour patterns is an urgent priority to maintain and improve the wellbeing of the global population.
<i>When does behaviour change?</i>	Behaviour changes when our <i>capability</i> or <i>opportunity</i> to engage in the behaviour changes, or our <i>motivation</i> to engage in the behaviour changes relative to potentially competing behaviours.

<i>How is behaviour change achieved?</i>	Behaviour can be changed in many different ways: by helping people to understand why they should make the change or how to change, getting them to feel attracted to the idea of the change, removing psychological, physical and social barriers to the change, creating social and physical environments conducive to the change, providing resources that facilitate change, providing examples for them to follow or training them to think, feel or act in new ways.
<i>What is the 'big question' for behaviour change interventions?</i>	The 'big question' for behaviour change interventions is: What interventions (defined in terms of features of content and delivery), with what usage (defined in terms of uptake and level and type of engagement in those using it), in what context (defined in terms of features of the target population and the setting) has what effect on what behaviours, through what mechanisms of action?
<i>What is a 'digital behaviour change intervention' (DBCI)?</i>	A DBCI is a product or service that uses computer technology to promote behaviour change. It includes computer programs, websites, mobile applications (apps), wearable devices, body and environmental sensors and telecommunications. These can be for use by members of the public, patients, healthcare workers, managers or policy makers.
<i>Where do DBCIs fit into a behaviour change strategy?</i>	There are many ways of changing behaviour such as punishing it, incentivising it, restructuring the environment, providing advice and counselling and running persuasive mass media campaigns. Digital interventions are not a substitute for these but focus on amplifying or adding to them by increasing users' abilities to put decisions to change behaviour into effect, and to sustain the new behaviour.
<i>What have DBCIs achieved so far in health?</i>	Research into the effectiveness of DBCIs in healthcare is at an early stage. However, there is good evidence that websites and text messaging programmes can help with smoking cessation, reducing alcohol consumption, improved diet, increasing physical activity, self-management of chronic conditions, and improving adherence to treatment regimens. Mobile applications have been found to improve diet, and increase physical activity. Uptake and engagement with DBCIs of proven effectiveness are mostly low. Little is known about why some DBCIs are effective and others are not.
<i>How can DBCIs reach a large global user base?</i>	While access to the necessary technology is growing worldwide, in low and middle income countries consideration needs to be given to issues of literacy and

	<p>access involving devices that are affordable. Challenges also remain with regard to achieving a sustainable infrastructure for, and effective promotion of, DBCIs.</p>
<p><i>What principles should underlie DBCIs?</i></p>	<p>DBCIs need to be <i>usable, used</i> and <i>effective</i>. They will be usable to the extent that they are easy to navigate and comprehensible. They will be used to the extent that they are accessible, promoted, and rewarding. They will be effective to the extent that they effectively deliver behaviour change techniques (BCTs) that make required changes to capability, opportunity and/or motivation.</p>
<p><i>How should DBCIs be developed and evaluated?</i></p>	<p>Given the pace of change in technology and the digital environment, development and evaluation of new interventions needs to involve a process that is flexible, ongoing and workable ('FLOW'). Initial development should be driven by direct and indirect evidence and behaviour change theory, coupled with extensive and repeated user testing. Experimental tests should be used to optimise the intervention in the early stages. Both effectiveness and engagement should be assessed. Once a workable intervention has been developed this should be evaluated in a comparative study either with another active intervention or with a 'minimum credible intervention'. Depending on the results, the intervention may be abandoned, revised, or rolled out. If it is rolled out, its engagement and effectiveness should be routinely monitored and an ongoing process of optimisation put in place.</p>
<p><i>How should effective DBCIs be promoted?</i></p>	<p>Many DBCIs operate within a very crowded marketplace and a population of users who are not in a position without help to make an informed judgement about effectiveness. Promoting DBCIs is a behaviour change task like any other. Users have to believe that using it would be worthwhile, feel more attracted to using it than to a competing DBCI and find it easy to access. They need to be prompted to make first contact. Like any product, resources need to be allocated to achieving these goals.</p>

2. Background, aims and readership

Digital behaviour change interventions (DBCI) and their areas of application

The term 'digital behaviour change intervention' (DBCI) is used in this report to describe computer services, devices and programs that aim to promote behaviour change (1). 'Behaviour change' usually refers to a change in a pattern of behaviour such as smoking, drinking or level of physical activity (2). However, it can also refer to one-off behaviours such as making a blood donation, and to forestalling a change in a behaviour pattern such as preventing uptake of smoking. Thus in principle a 'behaviour change intervention' is an activity, product or service that may be used by an individual, organisation or social grouping to change the behaviour of a person, group, organisation or population from what would have occurred otherwise.

DBCI are behaviour change interventions that involve, not necessarily exclusively, computer technology or digital encoding of information. They include SMS text messaging programmes, email, websites, smartphone applications, body and environmental sensors and whole computer systems. They can also include DVDs and computer-generation of materials that are delivered via another route such as printed materials. Many DBCI involve more than one of these components.

DBCI for healthcare are a subset of digital healthcare interventions otherwise known as 'E-health' (3). Other types of digital healthcare interventions include systems for improving data management and systems for automating diagnostic tests (4).

DBCI have potential for low unit-cost, high reach, effective and acceptable ways to benefit individuals and society. However, they may also involve a waste of resources, an opportunity cost or even possibly cause unintended harm (for example, by undermining use of more effective interventions).

The field of healthcare has been identified as one where DBCI could make a substantial contribution. The reason for this is that a substantial proportion of premature mortality and morbidity arises from the way people behave, whether it be smoking, consuming excessive alcohol, unprotected sex, traffic accidents, physical inactivity, a poor diet or any of a wide range of other activities (5). In addition, behaviour change can play a very important role in self-management of chronic and acute conditions, reducing healthcare costs and improving outcomes. Moreover, DBCI can support healthcare professionals in their roles, promoting adherence to evidence-based practice and improving their efficiency and effectiveness. Table 1 shows the ways in which DBCI may improve health.

There are many features of DBCI that make them potentially effective and cost-effective. They can:

- be highly personalised and interactive

- deliver information in a way that is engaging and rewarding
- elicit, record and use responses, and
- can adapt to users' needs.

Compared with human-delivered interventions they will usually deliver the intervention content with a high degree of fidelity (that is, as planned). And once they have been developed, the unit cost of delivery to large numbers of users can be very low.

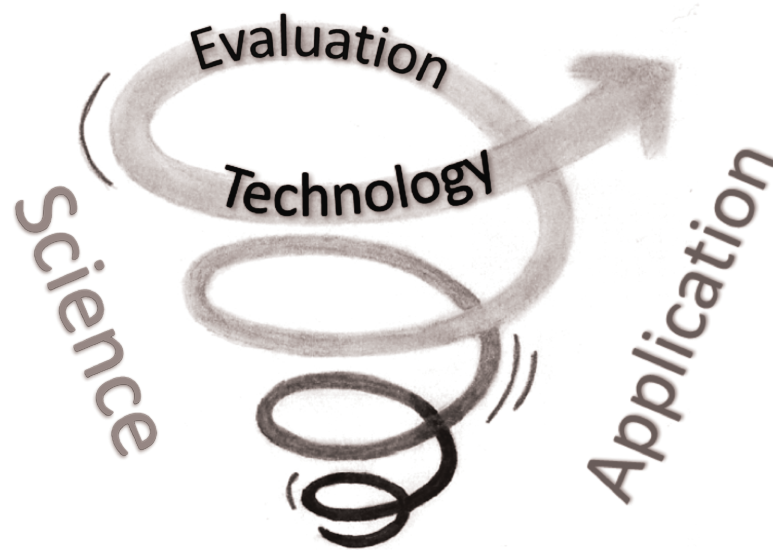
On the other hand, the development costs can be very high, and in a rapidly changing digital environment they may need rapid updating just to stand still. Also, they may not be able fully to capture all the benefits of a human-to-human interaction. Therefore, it cannot be taken for granted that a DBCI is the best approach in any given case. The value of using a DBCI has to be demonstrated (6).

Table 1: Ways in which digital behaviour change interventions may improve health

Area of application	Examples
Reducing unhealthy or potentially harmful behaviours in the population or high risk groups	Helping smokers to stop, helping people reduce their alcohol consumption, helping people avoid engaging in unprotected sex
Increasing healthy behaviours in the population or high risk groups	Increasing physical activity, promoting attendance at screening programmes, promoting self-screening
Self-management of chronic or acute conditions	Stress management, combating insomnia, improving control of blood sugar in people with diabetes
Improving health professional adherence to evidence-based guidelines	Promoting hand hygiene practices, promoting effective delivery of healthcare advice
Enhancing health professional effectiveness or efficiency	Improving diagnostic accuracy, improving treatment selection

The development and evaluation of DBCIs should form part of a 'virtuous spiral' in which science is used to create an ever-improving technology that is applied to improve human welfare, and evaluation of this application provides crucial information needed to advance the science (Figure 1).

Figure 1: The virtuous spiral of science and its application



Given the many challenges involved in achieving this virtuous spiral, there is a need for a document that sets out details of how to approach the task, a kind of 'manifesto' for the development and evaluation of DBCIs. This manifesto needs to be updated regularly as experience is gained with the process and as the context and available technology change.

Importance of behaviour change for population health

There is a broad consensus that behaviour change is crucial for improving the health and wellbeing of individuals and societies, and may be crucial in preventing a catastrophic explosion in the need for healthcare resources.

The Global Burden of Disease project has estimated the disability-adjusted life years lost due to a wide range of factors: behaviour is central to all of the leading ones, including tobacco use, poor diet, physical inactivity, and excessive alcohol consumption (5). Other major causes of ill-health and death such as air pollution and high blood pressure are also modifiable by changes in behaviour.

As life expectancy increases we are seeing increasing numbers of older people who require healthcare. Behaviour change will be essential to maximise the quality of life for these people and minimise their need for healthcare resources.

The broad principles of behaviour change are well understood (see below). If these can be developed into a more detailed and specific understanding and applied to generate effective DBCIs, the scope for improving human welfare will be considerable.

Aims and readership

This report aims to provide guidance on the development and evaluation of DBCIs in healthcare, taking account of the current state of the evidence, behaviour change theory, and evolving principles of intervention development and evaluation.

The guide has been written for researchers and practitioners seeking to develop and/or evaluate DBCIs, as well as potential commissioners, funders and users.

3. Approach and sources

The approach to writing this guide was to review the literature for synoptic articles on 1) methods for developing and evaluating DBCIs, and 2) reviews relevant to the likely effectiveness of DBCIs relating to health.

The guide also benefitted from a series of workshops and symposia in which leading academics and developers in the field discussed these issues and related topics: 1) a European Health Psychology Society Synergy expert meeting on 31 August to 1 September 2015 on developing and evaluating digital healthcare interventions, 2) a workshop organised by US National Science Foundation held in London on 8-9 September 2015 on dynamic modelling of behaviour, and 3) a Medical Research Council and Robert Johnson Wood Foundation-funded workshop organised by the UCL Centre for Behaviour Change in London on 10-11 September 2015 on how to develop, evaluate and implement effective digital healthcare interventions.

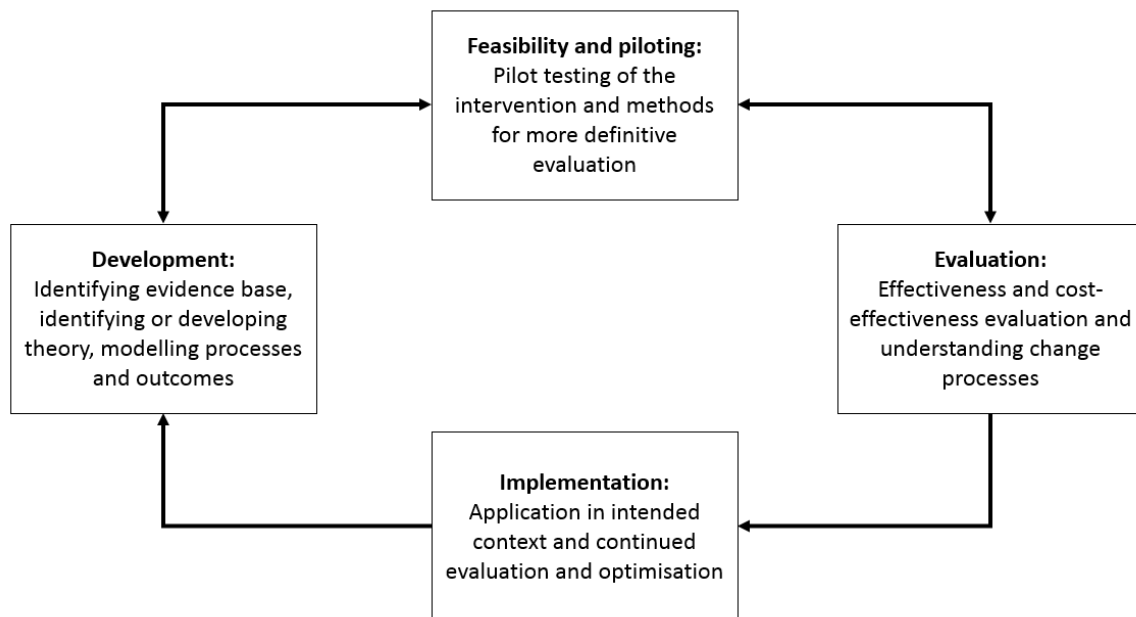
These meetings and the literature search informed discussion between the authors of the current guidance with a view to arriving at key propositions that could be the basis for guidance. The meetings themselves will result in other publications addressing topics in more detail than can be covered by this guidance.

The major reviews relating to behaviour change frameworks and theories, development and evaluation methods, and effectiveness of DBCIs were discussed by the authors and a draft report prepared. The guide will be updated as new information becomes available.

Literature on methods for developing and evaluating DBCIs

DBCIs are complex, comprising many interacting behaviour change techniques offered in a variety of modes. There are a number of guidance documents relevant to the development and evaluating of DBCIs. One of these is the UK's Medical Research Council guidance on the development and evaluation of complex interventions (7). This proposes a cycle of development involving establishing a theoretical underpinning, undertaking appropriate development and piloting and at some point undertaking a full scale evaluation, often, but not necessarily, using a randomised controlled trial. The need for early modelling and development work and for taking implementation issues into account from the beginning is illustrated in Figure 2.

Figure 2: Adaptation of Medical Research Council Guidance for developing and evaluating complex interventions



A methodology that is proving useful for both the development and piloting stage of this process is Multiphase Optimisation Strategy (MOST) (8). This approach stresses the importance of evaluating components that make up a complex intervention before moving to a full-scale evaluation of effectiveness.

A key stage in this is the use of a factorial or fractionated factorial experiment. In this kind of experiment two or more components are included as present or absent, or high versus low intensity, in a crossed design so that there is no confounding between them. Further details are given later in this document. Such experiments provide the possibility to simultaneously test several components in a single study; they can also test for possible interactions.

There is also a literature on the use of adaptive designs for intervention development and evaluation, known as SMART designs (8). This involves a formal process for adding or removing intervention components over time and evaluating the effects in different sub-groups formed as a result of differential responsiveness to the intervention.

A further source for this guide was Michie et al's review and analysis of methods that have been used for specifying, and evaluating the effectiveness of, behaviour change techniques (BCTs) (9, 10) (11). This review identified a set of experimental and observational methods that have been used, and their strengths and limitations.

There are a large number of frameworks for characterising and classifying behaviour change interventions. Most of the main ones have been reviewed by

Michie et al (12) and a more comprehensive and coherent version has been developed: the Behaviour Change Wheel (BCW). This has been expanded and elaborated in a book-length guide (2). The BCW Guide also includes Michie et al's taxonomy of 93 BCTs, BCTTv1 (9, 11) which provides a way of characterising the content of behaviour change interventions at a finer grain level than in the BCW.

Reviews relevant to understanding DBCI effectiveness

The current review used several primary sources for drawing conclusions about behaviour change theory and practice, and the potential value of DBCIs. With regard to theoretical perspectives on behaviour change it drew on a review of behaviour change theories which identified 83 (13, 14). It also drew on the report from the UK's House of Lords Report into behaviour change and a summary of the contribution made to that report by Michie and others (15). It drew on National Institute for Health and Care Excellence guidance documents on behaviour change published in 2007 and 2014 (16, 17). West and Brown's review of motivation theories (18) were also used to cover that aspect of behaviour.

A search for evidence relating to the potential effectiveness of DBCIs involved a Pubmed search with the following keywords in the title:

(((((((((((((internet[Title]) OR digital[Title]) OR email[Title]) OR mobile[Title]) OR smartphone[Title]) OR text messaging[Title]) OR sms[Title]) OR computer[Title]) OR online[Title]) OR web-based[Title]) OR e-health[Title]) AND (review[Title] OR meta-analysis[Title])))

This was combined with the following keywords: smoking or tobacco, alcohol, diet, physical activity, sexual, HIV, adherence, sleep, hygiene, communication, diagnosis.

We also identified all Cochrane reviews addressing the topic. These have the advantage that they are typically undertaken to a high standard and follow strict rules regarding selection and evaluation of studies and synthesis of findings. A limitation is that in a fast-moving area they are not always the most up-to-date reviews available.

If no review was found for a given behavioural target we omitted the 'review' and 'meta-analysis' keywords in order to see if there were any relevant individual studies.

The purpose was not to undertake a full systematic review of all these areas, a project that would take several person-years, but to gain a broad impression of what kinds of DBCIs had been developed and evaluated for these areas and whether there was any evidence that they had been effective or showed promise.

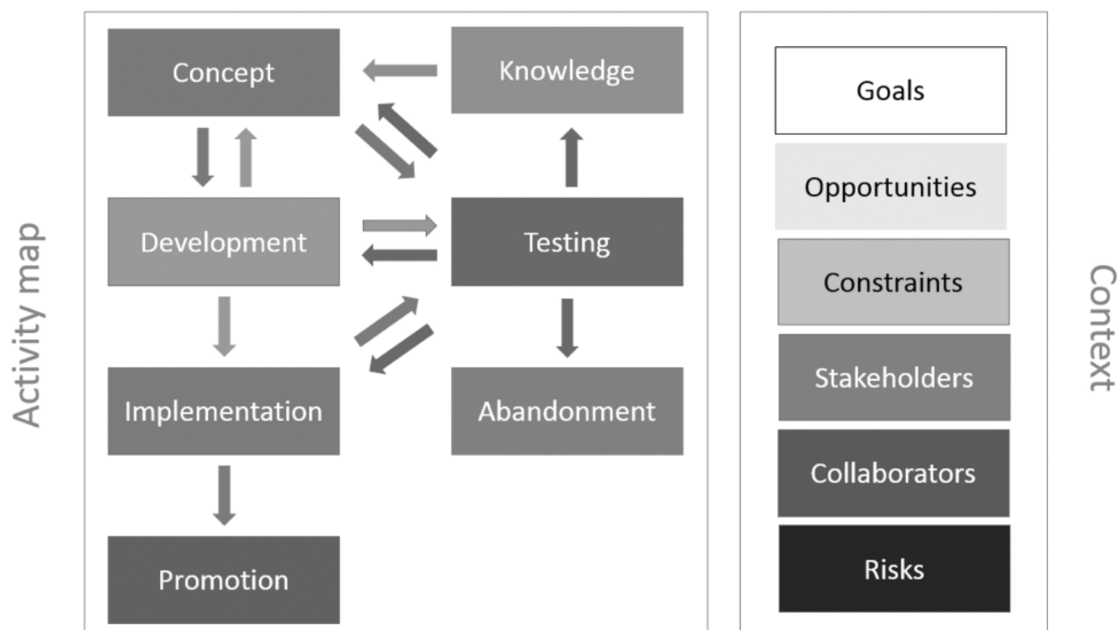
4. The process of development and evaluation

Analysis of the literature relating to the development of complex behaviour change interventions indicates that development and evaluation consist of a set of activities that follow a sequence, but that the sequence cannot be defined in advance because it depends on what happens and on the data collected.

The MRC Guidance on development and evaluation of complex interventions provides a valuable broad framework for the process of developing and evaluating DBCIs, but can be usefully elaborated to address the specific issues that arise with DBCIs. With DBCIs it is clear that a highly iterative process is required with continual testing at every stage. This involves much more than effectiveness evaluation; testing acceptability to people who would be the ultimate users plays at least as substantial a role. Moreover, the development cycle often needs to move to implementation without full pivotal trials that can estimate effect size. The reason is that the context and technology change so rapidly that the typical lead time in healthcare interventions is too long to be useful. In addition, the concept of effect size estimation may not be meaningful because of the difficulties establishing an appropriate control condition. These issues are considered further in Section 9.

Thus the process of development and evaluation of DBCIs can be more accurately characterised in terms of a set of activities that are linked in terms of their influences on other activities. These activities need to be considered within a given context. The activities, the way they are related and the features of the context are shown in Figure 3.

Figure 3: The development and evaluation process for complex behaviour change interventions



The activity map shows the types of activity involved and their potential linkage with other activities. A period in which an activity occurs may be thought of as a *phase*. Activities may be undertaken in parallel or in sequence as required but the project as a whole typically begins with the state of knowledge that would inform a concept. Some key points can be noted:-

- The *concept* is proposed, tested and revised until a point where it is considered suitable to enter the development phase.
- The *development* typically involves multiple cycles of revision and *testing* until a point was reached where it is considered that the intervention can be *implemented*. These sometimes need to take place over a very short time period. It may happen that the testing would lead to reformulation of the concept.
- Following implementation there would be further testing for the purposes of *optimisation* and to check that the intervention was achieving its goals in a potentially changing context.
- At any stage the testing of the intervention might result in *abandonment*.
- The testing should also be designed so that it feeds back into increased knowledge.
- Implementation would also typically lead to some form of *promotion* to help ensure that the intervention was used by those who could benefit from it.

The Context

The context of developing, testing and evaluating DBCIs consists of six factors. First there are the goals of the intervention. These are the basis for any testing, and establish the criteria for determining whether the intervention will be further developed, implemented or abandoned. The goals relate to more than just effectiveness of the intervention (2). Michie et al propose a set of criteria under the acronym APEASE for the range of criteria against which an intervention should be evaluated. Table 2 shows these criteria.

Table 2: The APEASE criteria for evaluating behaviour change interventions (2)

Criterion	Definition
Acceptability	To what extent is the intervention likely to be acceptable to key stakeholders, including users, funders, and those charged with implementing it?
Practicability	To what extent can the intervention be implemented as designed to the intended users at scale?
Effectiveness	To what extent is the intervention likely to achieve or exceed a desired level of effectiveness for a given target behaviour and how cost-effective is it likely to be in relation to a desired outcome?

Affordability	Can the intervention be implemented at the desired scale to the intended users within a realistic budget?
Safety	To what extent is the intervention likely to have unwanted side-effects?
Equity	To what extent is the intervention likely to increase or decrease economic, social or health inequalities?

Secondly, there are the opportunities afforded for development, implementation and evaluation of the intervention. Thus a project sometimes arises out of the fact that an intervention has already been developed and is being widely used and there is an opportunity to evaluate and possibly improve it. Sometimes opportunities arise from financial resources being made available through grants or gifts. Opportunities also involve access to potential samples of users with whom one can test the intervention or who one can involve in the concept and development phases. There are many other factors that could contribute to a project being started or, having started, taking a particular direction.

Thirdly, a project will always be subject to constraints. These typically involve: financial resources, timescale, access to potential users, availability of skilled developers and availability of skilled researchers. There will often also be structural constraints in terms of organisations and ethical constraints. Any project plan needs to consider these and how they are to be addressed.

The fourth aspect of the context of a project consists of the stakeholders. These are all those individuals and organisations who are affected by, or have an interest in, the intervention. This includes funders, potential users, those who would be engaged in delivery, and bodies with a responsibility for ensuring safety and effectiveness. The interests of these groups may conflict and in that case it will be necessary to have a process for addressing this. It is often useful to establish a steering committee involving the more important of these stakeholders.

The fifth aspect is collaborators. Developing a DBCI will typically involve scientific and technical input. The scientific input may come from behavioural scientists, social scientists and computer scientists. The technical input may come from software developers and marketers. Establishing a multidisciplinary team and appropriate relationships between them is essential for the success of a project. A particular issue arises in terms of the core relationship between the scientists and the developers. In some cases it will be the scientists who are driving the project and call on developers to assist, while at other times it will be the converse. Each model has its own opportunities and pitfalls.

The sixth feature of the context is the risks. These may relate to failure of the project, or untoward effects of the project. Risks can arise from uncertain funding streams, loss of key personnel, changes in the external environment, unexpected hurdles or many other factors. It may not be possible to engage in a full review of all of these but it would generally be advisable to have an explicit process of assessing these and managing them.

Having set out the key activities in the project, the remainder of this guide will consider the choices that need to be made in carrying out the activities and how these can be informed.

5. Knowledge

In this guide 'knowledge' encapsulates:

1. understanding of the need for a DBCI in the context of other interventions that are already in existence or that might be developed, including other DBCIs
2. the science of behaviour change, and engagement and use of digital interventions
3. computer science underpinning intervention development
4. understanding the specific behavioural domain and what other interventions are effective.

Clearly all of these are substantial areas of study and it is only possible in this guide to provide a very broad overview. It will focus primarily on the science of behaviour change and evidence thus far on effectiveness of DBCIs in changing selected target behaviours.

Understanding the need

A DBCI may be needed if there is an important health-related problem to address and there is reason to believe that a DBCI can address this need in a way that meets the APEASE criteria better than possible alternatives. This requires a sufficiently thorough review of the effectiveness and reach of other interventions, including other DBCIs, to be confident that it is worth making the investment to fill an important gap.

For example, in the case of smoking cessation, there is strong evidence for effectiveness of a range of interventions from price increases, and mass media campaigns to face-to-face behavioural support and pharmacotherapy (19). This raises the question as to what role a DBCI might play. In this case the rationale would be that it could supplement existing aids to smoking cessation or be used by people who are not willing to use one of the other methods and cannot be persuaded to do so. It might also be relevant in areas where specialist face-to-face support is not available.

In the case of alcohol reduction, brief advice from a health professional has been found to lead a proportion of people who drink excessively to report that they have reduced their consumption for at least a few months (20). However, this advice is rarely given (21) and it is not clear how far the reported reduction lasts or reflects a genuine decrease. Wider societal policies such as price increases, reductions in alcohol availability and control of alcohol advertising can have a large effect on excessive alcohol consumption but few governments in the world appear willing to use these policies (22). It is therefore possible that DBCIs for alcohol reduction provide a widely used, acceptable means of helping people reduce their drinking. It has been found that brief advice that proposes goal-setting and self-monitoring can be effective in reducing alcohol consumption (23) and these BCTs may lend

themselves well to implementation using DBCIs. However, it is not clear whether such products could help people with severe alcohol dependence.

For increasing physical activity, a number of interventions have been found to be effective, at least in the short to medium term, including promotion in primary care settings (24-26). DBCIs, and particularly use of mobile devices, may be well suited to providing support for this given the capacity for automated monitoring of activity levels, which has been found to be an effective technique. For diet and weight loss there are population-level and individual approaches that can be effective if implemented (27). There are also effective interventions available to support a range of self-management approaches to chronic and acute conditions such as diabetes and asthma (28, 29). So, as with other behavioural targets, it is essential to consider what role a DBCI can play.

In general the key issues to research when considering a DBCI in order to establish a need are:

1. What interventions are already in existence?
2. How effective are these and what is their reach?
3. How can a DBCI add to what is available in terms of improved effectiveness, reach or efficiency?

The science of behaviour and behaviour change

Behaviour is observable activity that can be assessed for prevalence (the proportion of people who engage in it at a given time), incidence (the rate at which it occurs in a population over a given time period) and characteristics such as frequency, intensity and duration. A *behaviour pattern* refers to a behaviour that is repeated at a given frequency or intensity over a period of time. Smoking is an example of a behaviour pattern.

Behaviour change involves intervening so that, other things being equal, either: 1) the incidence of one or more activities in an individual, group or population is different from what it would have been without that intervention, or 2) activities are undertaken differently from how they would otherwise have been performed. The change may occur as a result of an intention to change or without any such intention. The change may be sustained for a period of time or the behaviour may revert to the original pattern

Behavioural science is advancing rapidly, and knowledge of this area can inform decisions about what to target in a DBCI and how to do it. This guide uses the COM-B model of behaviour and the Behaviour Change Wheel as an integrative framework for understanding behaviour and behaviour change (2, 12).

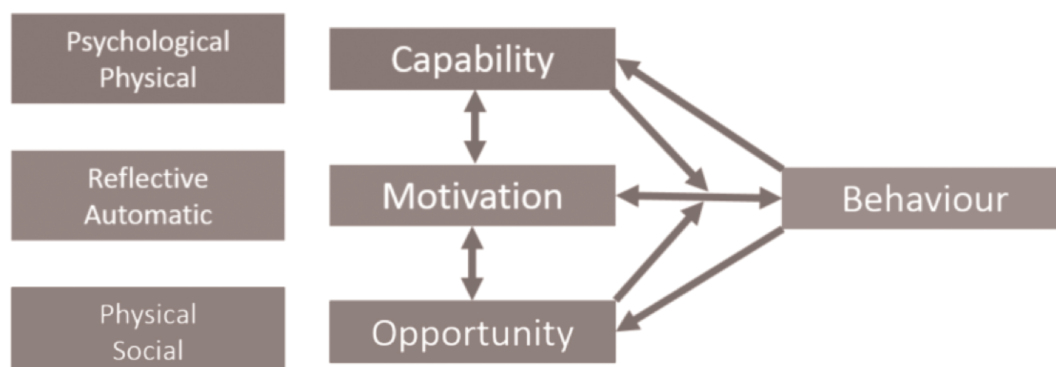
Causes of behaviour

The COM-B model of behaviour recognises that for any behaviour to occur the person concerned must have the capability and opportunity to engage in the behaviour, and the motivation to engage in the behaviour must be greater than to engage in any potentially competing behaviour (Figure 4).

The COM-B model reflects the interactions that exist between the different parts of the behaviour system.

- Motivation drives behaviour but behaviour also influences motivation (e.g., we eat because we are hungry and eating makes us less hungry).
- Capability moderates the influence of motivation on behaviour (e.g., if we do not have the self-control to stop ourselves eating the motivation to eat will dominate our behaviour).
- Opportunity also moderates the motivation-behaviour link (e.g., no matter how hungry we may be we cannot eat if there is nothing to eat).
- Behaviour influences capability (e.g., by exercising self-control we can train ourselves to improve our capability). It also influences opportunity (e.g., once we have eaten the available food, there will be none left unless we go and get some more).
- Capability directly influences motivation (e.g., we are often motivated to do something because we are good at it).
- Opportunity also influences motivation (e.g., having tasty food immediately available can increase feelings of hunger).
- Motivation can also influence capability (e.g., becoming overexcited at the prospect of achieving a goal can interfere with performance).
- Motivation can also influence opportunity (e.g., we attend more to cues that are relevant to our current motivational state).

Figure 4: The COM-B model of behaviour



Each of the three causal influences on behaviour can be broken down further.

- Capability includes both physical and psychological capability. Physical capability consists of the strength, stamina and physique needed to enact a behaviour. Psychological capability refers to knowledge and cognitive skills as well as our intellectual capabilities of perception, memory, reasoning, analysis and self-regulation.
- Motivation involves all those mental processes that energise and direct behaviour. This includes reflective process such as planning and thinking, and automatic processes involving our feelings, habits and instincts.
- Opportunity consists of the immediate environmental factors that promote or enable a behaviour. These may be physical in terms of time, financial resources, equipment etc. or they may be social as in the case of social cues and normative influences.

The COM-B model of behaviour encapsulates, and is compatible with, the top-level features of most of the behaviour change models and theories currently used (13). Some theories emphasise societal factors, which can be construed in terms of 'opportunity' and its direct influence on behaviour and its influence on motivation. Many theories focus on beliefs and attitudes which are encapsulated in the concept of motivation.

Theories of habit, self-control, norms, and intentions are accommodated within this framework. An advantage of doing so is that it provides a way of examining how these concepts relate to each other and which theoretical approach may be most likely to bear fruit for a particular application.

Motivation plays a crucial role in behaviour and behaviour change. There are numerous theories of motivation, each focusing on particular aspects such as habits, choice, intention, self-control, and drives. These theories have been brought together into an overarching theory called PRIME Theory (18). As with COM-B, this is not a substitute for specific theories of motivation but a framework in which these theories can be understood and compared in order determine what may be appropriate targets for a behaviour change intervention.

An important part of PRIME Theory is specification of the structure of the human motivation system (Figure 5). The theory registers the fact that all behaviour occurs 'in the moment' and that at every moment, what we do is the result of potentially competing impulses and inhibitions.

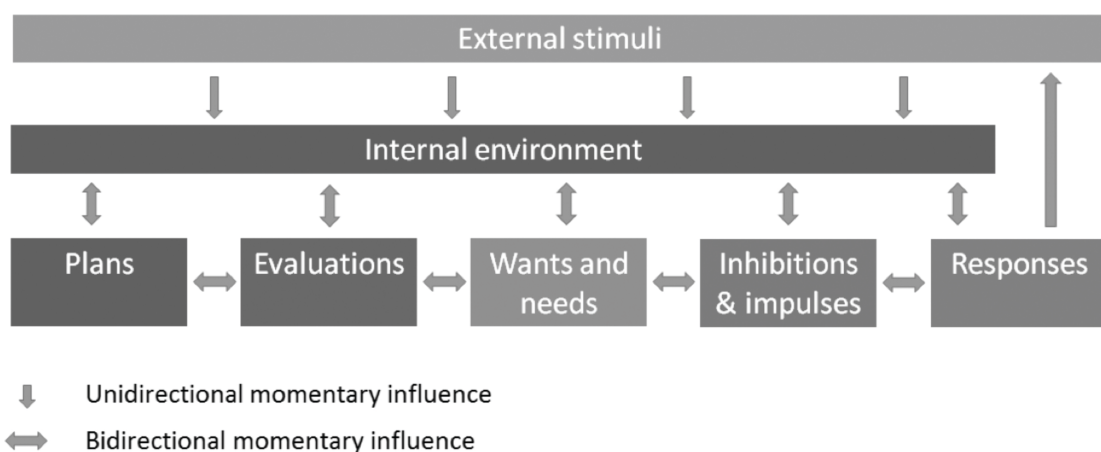
These are influenced by stimuli acting on innate or learned associations (instincts and habits), and also by feelings of want or need. Wants involve imagining a state of the world and feeling anticipated pleasure or satisfaction associated with that. Needs involve feelings of anticipated relief from actual or expected physical or mental discomfort, distress or pain.

These wants and needs can be triggered directly by stimuli but they can also be influenced by our evaluations of what is good or bad, harmful or beneficial and right or wrong.

The evaluations can lead us to form plans and themselves be influenced by our plans. Plans are self-conscious intentions to perform an act at some point in the future – it could be the near future or the distant future.

For plans to have an influence at a given moment they need to be recalled to mind; the action still has to seem like a good thing to do; this evaluation has to generate the want or need to engage in the act and this has to generate the necessary impulses or inhibitions. All this time the motivational force of the plan is competing with evaluations, wants and needs and impulses or inhibitions coming from other sources.

Figure 5: The structure of the human motivational system



Details of PRIME Theory can be found in several sources, including a book that is available free to download (30), and the website www.primetheory.com.

It should be apparent that for a DBCI to help an individual change his or her motivation to engage in a new behaviour, it is going to have to address the momentary wants, needs, impulses and inhibitions that govern behaviour in the moment.

One way of thinking about this is that the intervention needs to ensure that at the critical moments, the user either engages in the desired activity without thinking, or wants or needs to engage in the desired behaviour more than any other competing behaviour.

The intervention may do this in many ways, from helping the user to develop more effective plans, to providing distraction to suppress the desire to engage in an

unwanted behaviour. However it does it, the ultimate task of the intervention is clear. For behaviour patterns (i.e. behaviours that are regular rather than one-off or occasional), the goal is to ensure that the user engages in the desired activity habitually and to help the user to routinise more plans and other supportive behaviours.

Conditions needed for behaviour change

For behaviour change to occur there must be a change in at least one of capability, opportunity or motivation. For the change to be sustained the COM-B system must become reconfigured into a new equilibrium.

A potentially useful first step in designing a DBCI is to undertake a 'behavioural diagnosis'. This is an analysis of what needs to change for the behaviour to change. Often we make presumptions that turn out to be incorrect. For example, it would be easy to presume that one could help a smoker to stop by reinforcing their reflective motivation and that could be done by strengthening their belief that smoking is harmful. In fact, the evidence tells us, once a smoker has decided that he or she wishes to stop, a more effective strategy is to target the automatic motivation by reducing exposure to smoking cues and using medicines to reduce the drive to smoke.

More details about the process of behavioural diagnosis are given in Michie et al (2)

Intervening to promote behaviour change

Having undertaken a behavioural diagnosis, one can consider what intervention strategy is likely to be most effective in targeting the relevant mechanisms of change. It involves using the BCW to select one or more 'intervention functions' (education, persuasion, incentivisation, coercion, training, environmental restructuring, modelling and enablement) and then from among 93 behaviour change techniques (BCTs) that can deliver these functions. Readers are referred to the Behaviour Change Wheel guide for further details (2). Table 3 gives the labels of the BCTs and Appendix 1 gives their definitions. A searchable free smartphone app is available (search 'BCTs') and an online free BCT training course can be found at www.bct-taxonomy.com.

Different combinations of BCTs will be relevant for different 'mechanisms of action' (things that when changed lead to a change in the target behaviour). Currently, we lack a formal scientific basis for making links between BCTs and mechanisms of action but certain types of BCTs have been found to be effective in at least some cases. Of particular relevance to DBCIs, goal-setting and self-monitoring appear to have achieved results across quite a broad range of conditions and behaviours (31). For research articles with interventions coded by BCTs, updates of current work and other BCT resources, see <http://www.ucl.ac.uk/behaviour-change-techniques>.

Table 3: 93 Behaviour Change Techniques

Grouping and BCTs	Grouping and BCTs	Grouping and BCTs
1. Goals and planning	6. Comparison of behaviour	12. Antecedents
1.1. Goal setting (behaviour)	6.1. Demonstration of the behaviour	12.1. Restructuring the physical environment
1.2. Problem solving	6.2. Social comparison	12.2. Restructuring the social environment
1.3. Goal setting (outcome)	6.3. Information about others' approval	12.3. Avoidance/reducing exposure to cues for the behaviour
1.4. Action planning	7. Associations	12.4. Distraction
1.5. Review behaviour goal(s)	7.1. Prompts/cues	12.5. Adding objects to the environment
1.6. Discrepancy between current behaviour and goal	7.2. Cue signalling reward	12.6. Body changes
1.7. Review outcome goal(s)	7.3. Reduce prompts/cues	13. Identity
1.8. Behavioural contract	7.4. Remove access to the reward	13.1. Identification of self as role model
1.9. Commitment	7.5. Remove aversive stimulus	13.2. Framing/reframing
2. Feedback and monitoring	7.6. Satiation	13.3. Incompatible beliefs
2.1. Monitoring of behaviour by others without feedback	7.7. Exposure	13.4. Valued self-identify
2.2. Feedback on behaviour	7.8. Associative learning	13.5. Identity associated with changed behaviour
2.3. Self-monitoring of behaviour	8. Repetition and substitution	14. Scheduled consequences
2.4. Self-monitoring of outcome(s) of behaviour	8.1. Behavioural practice/rehearsal	14.1. Behaviour cost
2.5. Monitoring of outcome(s) of behaviour without feedback	8.2. Behaviour substitution	14.2. Punishment
2.6. Biofeedback	8.3. Habit formation	14.3. Remove reward
2.7. Feedback on outcome(s) of behaviour	8.4. Habit reversal	14.4. Reward approximation
3. Social support	8.5. Overcorrection	14.5. Rewarding completion
3.1. Social support (unspecified)	8.6. Generalisation of target behaviour	14.6. Situation-specific reward
3.2. Social support (practical)	8.7. Graded tasks	14.7. Reward incompatible behaviour
3.3. Social support (emotional)	9. Comparison of outcomes	14.8. Reward alternative behaviour
4. Shaping knowledge	9.1. Credible source	14.9. Reduce reward frequency
4.1. Instruction on how to perform the behaviour	9.2. Pros and cons	14.10. Remove punishment
4.2. Information about Antecedents	9.3. Comparative imagining of future outcomes	15. Self-belief
4.3. Re-attribution	10. Reward and threat	15.1. Verbal persuasion about capability
4.4. Behavioural experiments	10.1. Material incentive (behaviour)	15.2. Mental rehearsal of successful performance
5. Natural consequences	10.2. Material reward (behaviour)	15.3. Focus on past success
5.1. Information about health consequences	10.3. Non-specific reward	15.4. Self-talk
5.2. Salience of consequences	10.4. Social reward	16. Covert learning
5.3. Information about social and environmental consequences	10.5. Social incentive	16.1. Imaginary punishment
5.4. Monitoring of emotional consequences	10.6. Non-specific incentive	16.2. Imaginary reward
5.5. Anticipated regret	10.7. Self-incentive	16.3. Vicarious consequences
5.6. Information about emotional consequences	10.8. Incentive (outcome)	
	10.9. Self-reward	
	10.10. Reward (outcome)	
	10.11. Future punishment	
	11. Regulation	
	11.1. Pharmacological support	
	11.2. Reduce negative emotions	
	11.3. Conserving mental resources	
	11.4. Paradoxical instructions	

Computer science

DBCIs can be built using existing knowledge and hardware. However, the science underpinning the design of software and improved computers and devices continues apace and DBCI development may contribute to this. It is beyond the scope of this guide to consider these issues in detail. The following are areas that

DBCI developers may wish to consider in terms of a) what aspects of computer science will be used and b) what contribution the DBCI may make to further development in this area.

1. Sensing technology: ability to measure important physiological, biochemical, psychological and physical parameters (e.g. location, limb movement)
2. Human computer interaction: understanding how humans interact with devices in ways that are enjoyable, satisfying and useful
3. Machine learning: methods of using data to build relevant ontologies and personalise DBCI functioning incrementally as data are gathered over time
4. Decision support: developing intelligent decision support tools that can be implemented by DBCIs.

Evidence of effectiveness of DBCIs

Apart from working from a theoretical understanding of behaviour change, one should also use research that is directly relevant to the DBCI that is being proposed. This section provides a brief summary of evidence as of 2015 (see Section 5 for methods).

Many DBCIs have the potential to change health-related behaviour. However, many have not proved effective, and it is unclear why one intervention should have had an effect in one context for a given target behaviour and another did not. The methodology for evaluating effectiveness of DBCIs is still at an early stage and so in many cases studies do not provide a clear indication as to whether the intervention being evaluated was effective.

Table 4: Overview of achievements of digital behaviour change interventions, 2015
(numbers in cells are citations to references at the end of this report)

	Modality				
	SMS	Email	Website/ computer	Mobile app	Systems ¹
Smoking cessation	+ (32-35)	? (36)	+ (37, 38)		
Alcohol reduction	+ (32-34)	? (36)	+ (37, 39)		
Diet improvement	+ (33)	? (36)	+ (37, 40)	+ (41)	
Activity increase	+ (33)	? (36)	+ (37)	+ (42)	
Weight management	+ (33)	? (36)	+ (37)	+ (43)	
Risky sex reduction			+ (44, 45)		
Adherence improvement	+ (33, 46-48)		+ (39)	? (49, 50)	
Self-management of acute and long-term conditions	+ (33, 48, 51, 52)		+ (37, 53)		
Sleep improvement			+ (54)*		
Professional support		? (55-57)			+ (58)
Hand hygiene				? (59)	
Multiple risks factors			? (60)		

¹Modalities may subsume ones to the left. A + indicates that reviews have concluded that there is some evidence for effectiveness, though it may be limited. ? indicates that there are reviews but they are unable to draw useful conclusions about effectiveness. A gap indicates that the search strategy did not find any reviews. *indicates that no review was found but there were single articles.

Table 4 summarises the results of the review for a number of behavioural targets. The table indicates whether examples could be found of interventions that appear to have been effective within the target user group.

Adherence was construed broadly in terms of taking medicines as prescribed, following recommendations regarding attendance at screening or other appointments, or following instructions around management of a condition. Self-management of acute and chronic conditions typically included behaviours relating to management of chronic conditions such as diabetes and asthma. Professional support covered topics such as communication between health professionals, and adherence to evidence-based practice guidelines.

No reviews were found relating to DBCIs for improving sleep. However, we did find one randomised controlled trial with positive results. One review found that use of the internet for leisure was associated with poor sleep (39) so it is worth bearing in mind that DBCIs that become highly engaging might have this unwanted side effect.

It is important to consider the relative effectiveness of DBCIs and other types of intervention, for example face-to-face behavioural support. It is generally not clear whether DBCIs are as effective as, or possibly more effective than, face-to-face interventions. Neither is it clear to what extent DBCIs may enhance effectiveness when added to these other types of intervention. One recent review did find evidence that face-to-face interventions appeared to be more effective than computer-delivered ones in reducing alcohol consumption in university and college populations (61).

With regard to cost-effectiveness, a recent systematic review found 16 relevant articles. It concluded that guided internet interventions (ones that involved some health professional involvement) for smoking cessation and alcohol consumption could be cost-effective. Unguided internet interventions for suicide prevention and smoking cessation were also considered to be cost-effective (62).

Cutting across the different modalities for delivery of DBCIs, there are questions about fully automated versus guided or partially automated interventions, and use of online facilities such as social networks. At present there is very little research to inform decisions on this. For example a recent review of social networks for behaviour change was unable to draw firm conclusions (63). The review noted that engagement was low. 'Gamification' is a term that has become widely used in the field: the application of psychological principles promoting engagement with computer games to applications with a more serious purpose. There is little good evidence to guide this at present. One review of gamification in alcohol education mobile apps was not able to draw firm conclusions (64).

Even where there is evidence for DBCI effectiveness, major challenges remain around how to get users to engage with the interventions (65). Uptake is typically low and disengagement rates are very high. It is also important to consider how far users may engage in activities that are promoted by a DBCI. For example a review of adherence to activities proposed by insomnia applications showed this to be around 50% (66).

Another major issue with regard to use of DBCIs is equity. A recent review of tobacco control interventions concluded that many interventions used in European countries may be associated with increased inequalities (67). There has been relatively little research directly addressing the potential equity impact of DBCIs. A recent systematic review of mobile health applications concluded that DBCIs could improve healthcare delivery for low and middle income countries. However, it identified several limitations that would apply to DBCIs, notably interoperability (generalisation from evaluation contexts which are likely to be quite different), lack of evaluation standards, and lack of a technology infrastructure (68).

An attempt has been made to assess how far DBCI effectiveness can be linked to use of particular theoretical approaches and BCTs (69). This provides a useful starting point for the development of the kind of ontology (organising structure to represent DBCIs) needed to inform the development of new DBCIs (see Figure 6 below).

Quality of DBCIs in the marketplace

Several studies have evaluated the quality of smartphone applications that are available on the major platforms and found these generally not to provide evidence-based advice. For example a review of physical activity coaching apps found most of the ones for iPhones to be of low quality (70). Similarly, reviews of smoking cessation and weight loss apps have found that these generally do not adhere well to evidence-based behaviour change principles (71). Only a minority of alcohol-related apps promoted health while the majority implicitly or explicitly promoted the use of alcohol. Alcohol-related apps that promoted health contained few BCTs and none referred to theory (72).

6. The concept

The concept for a DBCI arises from knowledge of a given area of interest and an idea for an intervention that will address a particular need. The concept needs to be sufficiently well elaborated and justified to enable an informed decision to be made about whether and how to proceed.

The concept for a DBCI needs to address some key questions.

1. What is the need for the DBCI?
2. How will it address the 'big question' in behaviour change? (see below)
3. What kind of DBCI will it be?
4. What data will be collected and how will they be used?

Need for the proposed DBCI

The concept should use existing knowledge to establish what role the DBCI will play by establishing the need in the context of other available interventions. From the discussion earlier this should take into account:

1. What are the potential health gains from a successful DBCI in this particular area, in terms of improved outcomes, reach, or efficiency?
2. Where does the DBCI fit into the wider context of available interventions?

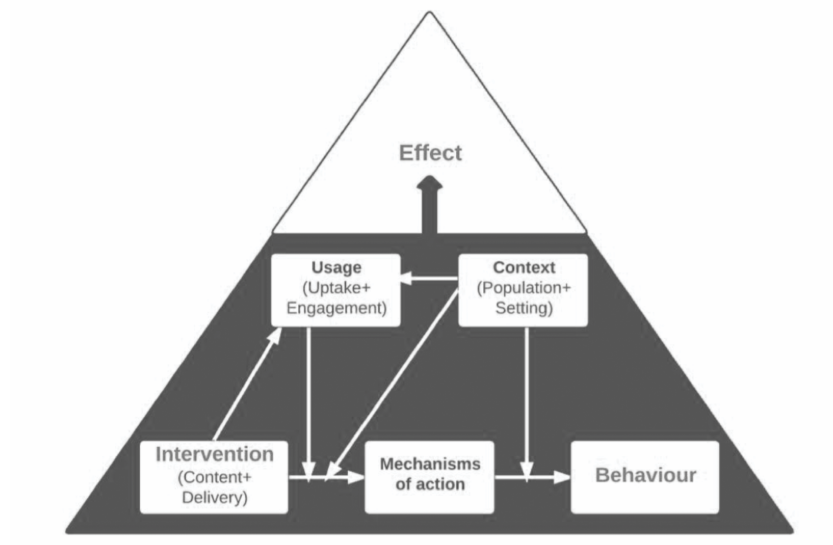
The 'big question' for behaviour change interventions

The DBCI concept needs to address what may be termed the 'big question'. The 'big question' for behaviour change interventions is: What interventions (defined in terms of features of content and delivery), with what usage (defined in terms of uptake and level and type of engagement in those using it), in what context (defined in terms of features of the target population and the setting) has what effect on what behaviours, through what mechanisms of action? For many interventions, such as DBCIs, a key part of this is: What benefits can be achieved by what degree and type of personalisation? (73).

Figure 6 illustrates this in the form of a proposed ontology structure¹, reflecting the fact that many of the variables in this question can interact with each other.

¹ An ontology is a set of constructs, their definitions, and specification of relationships between them.

Figure 6: Proposed structure of an ontology of behaviour change interventions



The figure illustrates how different aspects of a behaviour change intervention (relative to a comparator) and its usage and context, combine to generate a given effect on a designated behavioural outcome. Thus, for example, a mobile app aimed at helping users to reduce their alcohol consumption (intervention) may include a prompt to substitute a non-alcoholic drink at key moments (BCT 8.2 in the Michie BCTTv1). This may reduce the weekly amount of alcohol consumed (behaviour) by repeatedly reducing momentary motivation to consume an alcoholic drink (mechanism of action). The effect of this intervention will be influenced by how often it is used on relevant occasions (usage), which will be influenced by the way the intervention is designed, the type of person using it and the settings encountered (context). The user characteristics and settings may also influence how far reducing motivation to consume alcohol translates into a reduction in actual alcohol consumption.

In this ontology structure, 'effect' is a feature of the intervention-usage-mechanism of action-context-behaviour complex. It is defined in terms of a specific behavioural outcome measure and the difference in the values on that measure for an intervention versus a comparator. It is important to appreciate that without specification of a comparator, the concept of 'effect' has no meaning.

This ontology structure can be used to characterise intervention evaluations and their findings. The report of the evaluation can specify key features of an intervention and comparator, usage patterns, study sample and setting, and primary outcome measure. This can then be linked with an effect size estimate together with appropriate confidence intervals. Intervention evaluations described in this way can then be combined using statistical aggregation tools (e.g. meta-regression), or ones involving reasoning algorithms, to arrive at generalisations linking components of the ontology in order to build answers to the 'big question'. Table 5 defines each of the constructs in this ontology structure (73).

Table 5: Key constructs in the behaviour change intervention ontology structure

1. Intervention	A product, service, activity or structural change, intended to achieve behaviour change. It can be specified in terms of content of the intervention and the way this is delivered.
1.1 Content	What is delivered by the intervention in terms of behaviour change techniques (BCTs) and intervention functions (from the BCW). BCTs are potentially active ingredients that may be specified in terms of an appropriate taxonomy which may be mapped on to the Michie BCTTv1 taxonomy.
1.2 Delivery	Includes mode of delivery including face-to-face, telephone, SMS text, mobile app, website, mass media etc. It also involves style of delivery such as engagement features of an app, or communication style of a counsellor. It also includes duration, amount, and fidelity to designed content.
2. Usage	Uptake of the intervention and engagement.
2.1 Uptake	Prevalence of at least some level of engagement with or exposure to the intervention in a given target population or subgroup.
2.2 Engagement	The amount and manner of use of, or interaction with, an intervention among people who use it at least to some degree.
3. Context	Target population and setting.
3.1 Target population	Characteristics of the individuals, groups, sub-populations or populations whose behaviour one is seeking to change, including their other behaviours, mental health status etc.
3.2 Setting	Includes the social and physical environment. The social environment includes culture including prevailing norms, commercial environment, social cues and reference and membership groups. The physical environment includes financial resources, material resources, time pressures, physical cues, location.
4. Mechanism of action	What mediates the effect of the intervention on the behavioural outcome. These can be specified in terms of changes to capability, opportunity, motivation or other behaviours.

5. Behaviour	Specification of the behavioural outcome in terms of the target behaviour and precisely how and when it is assessed.
6. Effect	This consists of the estimated effect size for the combination of intervention, usage, context, mechanism or action and behaviour, always specified in relation to a comparator. Each effect size will have a confidence interval associated with it.

The concept underpinning the DBCI should indicate how it is expected to operate in terms of all aspects of this ontology. It should also indicate how it will improve understanding of behaviour change by helping to flesh out and develop this ontology.

What kind of DBCI?

DBCIs come in many different forms. The primary goal is that they should be *usable*, *used* and *effective*. Decisions need to be made early on in the process as to what form the proposed DBCI will take and why. Thus key decisions have to be made (amongst others) about whether it will:

1. Be targeted to a specific population or subgroup
2. Involve a registration process
3. Be fully automated or involve operator or health professional input
4. Be personalised by information collected within the app and if so in what way, including dynamic adaptation
5. Involve other users in social networking, peer support or 'crowd agents'
6. Involve 'future-self communication' (messages to one's future self)
7. Involve a mentoring, peer or servant role
8. Involve a 'persona' or 'avatar'
9. Involve Just-in-Time adaptive interventions
10. Involve delivery of behavioural intervention 'packages' such as motivational interviewing
11. Involve a limited number of platforms (e.g. iOS)
12. Involve scheduled sessions
13. Aim to create self-sufficiency and autonomy
14. Use video materials, animation, and/or audio
15. Use 'gamification'
16. Require additional devices to be obtained (e.g. wearable devices)
17. Involve getting users to undertake activities outside of interaction with the device
18. Link with other applications
19. Involve self-report measures and if so how many, when and what
20. Involve automated data collection through sensors

21. Involve reporting exceptional cases to another authority

All of these decisions and others will need to be informed by understanding the problem in hand and what has and has not worked in the past. It will also be influenced by the scientific agenda and what new knowledge can be created by studying the intervention.

It is worth considering in a little more detail three of the choices to be made above: personalisation, use of Just In Time Adaptive Interventions (JITAs) (74) and use of behaviour change 'packages'. Determining whether and how to design these feature into the intervention will influence many of the other decisions about the intervention.

Personalisation

Personalisation, that is tailoring content and delivery to the individual, has been found to improve effectiveness in at least some cases (75). There are many ways in which it can be achieved. One is to use information about the user when they start to use the application that has been gathered from other sources, for example using Facebook or Twitter APIs. Alternatively the user could be asked to provide the information when they start to use the application, or soon afterwards.

It is also possible, and will become increasingly so using machine learning, to personalise the intervention on the basis of information gathered as the person uses it (76). For example, the application can automatically monitor their usage patterns in relation to physiological and external sensors in the social and physical environment and adapt accordingly. This information can be supplemented by asking users about their emotional state, thinking and/or behaviour and to report their reactions to particular aspects of the application.

Just-in-time adaptive interventions

A key issue for just-in-time adaptive interventions is how to determine when to intervene and how proactive to be. Thus it may be that by the time a DBCI has learned about an opportune moment it is too late to do anything about it. This is a major area of study and one that DBCI developers need to engage with (77, 78).

Delivery of behaviour change packages

There already exist a number of what may be termed behaviour change 'packages'. These are collections of BCTs that are based on a body of theory or a common set of assumptions. Examples are Cognitive Behavioural Therapy (CBT), Acceptance and Commitment Therapy (ACT), Motivational Interviewing (MI), and Implementation Intentions (II).

DBCI developers may wish to focus on one of these packages in order to give the application a particular theme and conceptual structure, or because their analysis suggests that the package concerned has a strong chance of success. However, it may be that there are BCTs that could be included in the intervention that could supplement the package and consideration needs to be given to these. Ultimately, the choice of BCTs should be based on the behavioural diagnosis and the intervention functions likely to be effective (see Section 6).

Data collection

It will be essential for the DBCI to gather information to support its functioning, to assist with evaluation and optimisation, and to contribute to wider scientific knowledge (79). Deciding how much and what data to collect will usually involve a compromise between the need for detailed information and the burden placed on the user. In addition, the more information is collected the more challenging the data management and analysis task can become.

It is recommended that users develop a data analysis plan in some detail during the concept development phase of the process. In particular it can be helpful to set up a dummy database or spreadsheet with labels and definitions of the key variables that are desired, how each one will be measured or derived, and what it will be used for.

7. The development process

The process of development of DBCIs is usually highly iterative, with material being developed first of all using media that are cheap and flexible and then moving to versions that are closer to the final product. The fundamental concept behind the development is that the process should be flexible, ongoing and workable (FLOW).

This guide separates out development and testing but in practice they usually go hand-in-hand, in a cycle (see the MRC framework, Section 5).

DBCIs, like other computer-based products, require many different tools and methods in their development. The concept will need to be turned into a 'logic model' (80) that sets out more precisely how the concept will be implemented. This will need to be discussed and tested, either formally or informally. This then typically leads to 'white-boarding' (presenting a schematic of the intervention content) and then development of 'wire-frames' (a more detailed representation of the intervention in terms of the screens that will be viewed and how they will be interacted with). These can lead to development of screenshots and on to behaviour change modules (a BCT or combinations of BCTs that serve a single purpose).

It is likely that developers will wish to name a completed version as an alpha version and test that, following which they will create a beta version which will undergo further testing before full implementation.

There is growing interest in the use of modular designs and open source platforms for DBCIs to improve the efficiency of the process (e.g. www.openmhealth.com). There are repositories for open source modules that can be shared by developers, and it is likely that these will grow in popularity and coverage.

This section provides a brief consideration of some of the development options.

The 'person-based' approach

The person-based approach places emphasis on user involvement from the initial formulation of the concept, right the way through to implementation. Yardley et al (81) have summarised this as follows: 'There are two key elements to the person-based approach. The first is a developmental process involving qualitative research with a wide range of people from the target user populations, carried out at every stage of intervention development, from planning to feasibility testing and implementation. This process goes beyond assessing acceptability, usability, and satisfaction, allowing the intervention designers to build a deep understanding of the psychosocial context of users and their views of the behavioural elements of the intervention. Insights from this process can be used to anticipate and interpret intervention usage and outcomes, and most importantly to modify the intervention

to make it more persuasive, feasible, and relevant to users. The second element of the person-based approach is to identify "guiding principles" that can inspire and inform the intervention development by highlighting the distinctive ways that the intervention will address key context-specific behavioural issues.'

Use of modules

Development of DBCIs can be made much more efficient by adopting a modular approach. Considerable further efficiency can be achieved if the modules are written in such a way that they can be shared across interventions and made open source, for example using the Open Science Framework (www.osf.com). There are a number of source code sharing initiatives available and DBCIs may consider joining one or more of these.

Agile

'Agile' is probably the dominant method for software development currently (82). According to www.agilenutshell.com, 'Agile is a time boxed, iterative approach to software delivery that builds software incrementally from the start of the project, instead of trying to deliver it all at once near the end. It works by breaking projects down into little bits of user functionality called user stories, prioritizing them, and then continuously delivering them in short two week cycles called iterations.'

It will be important for everyone involved in creating DBCIs to be familiar with this way of working. It is not a panacea for efficient development but experience has shown that it has considerable advantages over previous methods.

8. Testing and evaluating DBCIs

Testing² of DBCIs takes place from the moment the concept is first mooted. The basic idea must be tested for conceptual clarity and sound assumptions and analysis. It should also be tested with potential stakeholders, including users.

As the idea is fleshed out into a detailed 'concept', each of the choices made and their rationales should be tested. This may involve gathering empirical data and/or conducting literature reviews.

Once the components of the project begin to be developed these need to be tested and refined in an iterative manner. The resources devoted to testing and use of formal testing methods will typically increase as the development continues, subject to constraints as set out earlier in this guide.

At some point it is likely that evidence will need to be gathered as to whether the intervention is creating the kind of effect that it was designed to, and to assess its usability and any side-effects. This is likely in the first instance to be in a pilot study (83) but eventually may well be in a full scale efficacy or effectiveness study. The traditional method for doing this is the randomised controlled trial. Although the desirability of other methods for complex interventions has been emphasised (7), a review of the available literature shows that this remains the most widely used of establishing effectiveness and can be adapted e.g. sequential multiphase assignment randomised trial (SMART) designs (84). However, there are major limitations to this approach and it is likely that in the future effect size estimation will need to involve other research methods. This is particularly the case where interventions are dynamically personalised for ongoing use and each individual receives essentially a different intervention (75).

It is important to recognise that evaluation involves much more than effect size estimation. It involves assessing how far the intervention is reaching the intended users, how far they are engaging with it in the way believed to maximise effectiveness and what is mediating observed effects. It also involves ensuring that the intervention does not have unintended side-effects.

Table 6 summarises the options for testing DBCIs and the concepts behind them or their components. Most of these options are considered in more detail in a paper by Michie and colleagues (10). Clearly there is much more to say about each of these options but that is beyond the scope of this guide. The list is divided into methods that involve original research in which data are gathered from potential or actual users, and methods that involve evidence synthesis. Both of these are important.

² Testing is used here to mean any kind of data gathering to assess the functioning and functionality of an intervention or intervention concept, including evaluation in relation to the APEASE criteria.

Table 6: Options for testing DBCIs

Original research	
Interviews with users	Talking to users with or without props using a structured or semi-structured interview schedule.
Think-aloud	Asking users to articulate their thoughts as they use an intervention or part of one, or a mock up.
Observation of use	Observing users and recording their behaviour as they interact with the intervention.
'Dog-fooding'	This involves developers using their own products to identify bugs and gain a personal sense of whether it is achieving its goals.
N-of-1 studies ¹	These are formal studies in which data are collected over a period of time at frequent intervals and temporal trends are tested as a function of introduction of changes to the user's environment or the product being tested; they may be randomised.
Sequential A-B testing ¹	This involves establishing a baseline for a key set of variables and then making a change to the product and determining what effect this has.
Concurrent A-B testing ¹	This involves giving different versions of a product to different groups of users and establishing what difference this makes.
Uncontrolled quantitative evaluation	Measurement of key outcome and process parameters in a sample of users, typically accompanied by assessment of associations between user characteristics and those measures.
Factorial or fractionated factorial experiments ¹	Experimental studies in which components of an intervention are varied in an orthogonal manner across different randomly allocated groups of users so that they are not confounded with each other and can be evaluated as though they were in separate experiments as long as there are not higher order interactions between them; interactions can also be evaluated.
Non-randomised comparisons	Comparison between users of the product and a comparison group without allocation to the

	groups being random, or between products that contain different features or components.
SMART designs ¹	Sequential Multiphase Adaptive Randomised Trials (SMART) are ones in which individuals are randomised to receive different products or a product with different features. Then, according to a decision rule, those who respond well are allocated to a new comparison as are those who respond less well or not at all. This process may continue in order to identify efficient and effective interventions for different subgroups.
Trials of Intervention Principles ¹	The concept here is to use experimental studies to compare features of interventions based on the principles underlying them, allowing variation in implementation of these features so that generalisations are made about the features rather than their specific implementation (85).
Cost-impact evaluations	These studies usually use an experimental study to measure the effect of an intervention relative to a comparator and cost information and assumptions about the benefits arising from the effect observed to arrive at a cost-impact assessment.
Randomised controlled trials ¹	This involves randomly allocating users of an intervention, usually with their consent, to receive different versions of an intervention or an intervention versus one or more comparators, and assessing the differences in one or more outcome measures. RCTs usually involve assessment of process variables as well in order to assess the mechanism of action.
Evidence synthesis	
Expert review	This involves gathering views from experts, often with discussion, on a set of ideas or proposals.
Meta-analyses	This involves combining data from multiple studies to estimate an overall effect size with confidence intervals on the assumption that the intervention, context and measures of outcome are sufficiently similar to be able to draw general conclusions

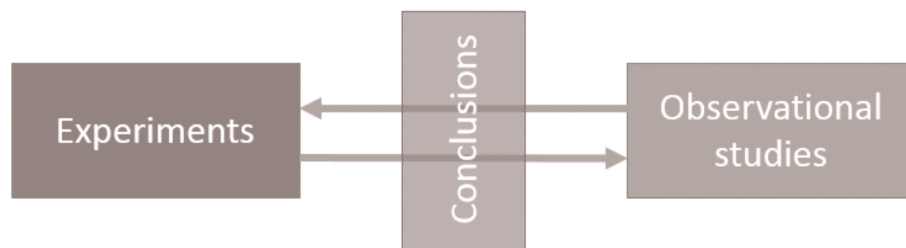
	about the categories of interventions, populations, settings and behavioural outcomes specified. Effect sizes always need to be expressed in terms of defined comparators.
Meta-regression	This involves attempting to explain heterogeneity in effect sizes found in meta-analyses by examining how far these are associated with components of the intervention (e.g. BCTs), differences in the target population, setting or outcome measure. These analyses need to take into account differences in study design and quality.
Classification and regression trees	These are a form of exploratory data analysis in which predictor variables are chosen one at a time to partition the respondents in terms of their outcomes with the process being applied iteratively to each partition. This in theory has the ability to detect interactions between predictor variables.
Content synthesis	This method identifies the content or other features of interventions that have been found to be effective.

¹Denotes experimental designs in which a researcher introduces variation and observes the result

Considerations when choosing a method of testing

When it comes to evaluating effectiveness of an intervention, a trade-off often has to be made between internal and external validity: that is, confidence that an apparent effect of an intervention is truly attributable to the intervention versus ability to generalise beyond the study to the population and setting of interest. There are also practical and ethical considerations that can rule out some kinds of study design. In general, the approach recommended is to combine experimental and observational methods to arrive at confident generalisable conclusions (Figure 8). It should be noted, however, that experimental methods do not necessarily provide internal validity (i.e. the presumption that the intended differences between the experiences of the participants is what caused the difference in outcome). In fact they only do so under a limited set of circumstances which are rarely met (Table 7) (86).

Figure 8: Combining experimental and observational methods in intervention evaluation



The focus of testing is usually on evaluating effectiveness, but all the APEASE criteria are potentially relevant (see Section 6). Acceptability to potential users is clearly particularly important. Therefore any testing with users should involve, not just measures of effect but also of engagement.

Table 7: Conditions under which experiments guarantee internal validity

Guaranteed internal validity requires ...	Explanation
Successful random allocation and assignment	Random allocation does not guarantee that groups being compared are equivalent. If either the randomisation or the implementation of the randomisation leads to imbalances in variables that could affect outcomes this undermines confidence that outcomes were due to the intended difference between the conditions.
No loss of participants to the study after randomisation	If participants drop out of the study after they have been randomised and before enactment of the intervention, any differences in outcome may be due this difference.
Complete engagement with the experimental and comparison interventions	Where take-up or engagement differs from what has been specified, and potentially differs between conditions being compared, differences in measured outcomes may in part be due to this.
Successful and complete delivery of the intervention and comparison conditions	Where the intervention and control conditions have not been delivered completely as specified it is not possible to guarantee that the outcome comparison reflect the intended experimental variation.

Similar contexts across intervention and comparison conditions	When allocation to one or other condition leads participants to be exposed to different contexts, observed findings may arise from this.
No co-occurrence of specified intervention features and another variable	An intervention or comparator may be linked by chance or through a causal chain to another variable (e.g., expectation of success) that contributes to any difference in outcome.
No contamination between intervention and comparison conditions	If participants in the intervention condition and control condition are exposed to another condition, this undermines conclusions that can be drawn based on comparison of the outcomes.
No loss to follow up	Where the outcome cannot be assessed in all participants, differences in measured outcomes may in part be due to differential loss to follow up in factors related to outcome.

It is also important to remember that part of the purpose of the testing process is to generate new knowledge. This will often involve measuring the impact of the intervention or its components and/or its putative mechanisms of action.

Testing may involve any of the multitude of different features of an intervention in terms of its content or delivery. Testing specific features of delivery such as 'dose' may require particular types of study design (87).

Choice of comparator(s) in effectiveness testing

Effectiveness testing is likely to be required at some point since it can almost never be assumed that a DBCI is having the required effect without direct evidence. This testing needs to include both process and outcome measures and should include qualitative research to help understand the quantitative data produced.

A major issue when it comes to effectiveness testing is the choice of comparator. There are several options, none of which is ideal. Table 8 shows the options and the strengths and limitations of each one. In terms of trying to estimate an effect size for a given population in a setting for a given target behaviour the best option is to test against the 'minimum credible intervention'. This is the DBCI equivalent of the placebo. It should have enough features that it is judged by users that it could be effective but it should omit key active ingredients. Deciding what constitutes a minimum credible intervention is clearly a difficult judgement and if resources permit should be informed by research with the user group of interest.

Table 8: Comparators for effectiveness testing

No intervention	This is suitable for estimating the effect of a DBCI where there is nothing else that users could access that would perform this function. In many cases, users do have access to and may well use another intervention if they know that they have been allocated to this condition which reduces confidence in the interpretation of the findings. It can also lead to participants dropping out or failing to engage with the study. In non-randomised comparison studies and studies where participants in all conditions are receiving another active intervention this may be less of an issue.
Active comparator	This involves testing the DBCI against another DBCI or another type of intervention to permit a judgement of relative effectiveness. This could be important when one is trying to develop an intervention that improves on what is already available in terms of effectiveness, reach, efficiency or side-effects.
Minimum credible intervention	This is the equivalent of the placebo in pharmacological trials. It is useful where the aim is to estimate the overall effectiveness of a DBCI but cannot test it against no intervention because of the ethical or practical constraints, or when one needs to be confident that the effect was not due to expectancy effects.

Data analysis

There are important choices to be made about analysing data from DBCI testing. Often descriptive quantitative statistics are sufficient.

Qualitative analysis can involve a range of different approaches depending on what one wants to learn as summarised by Neale (88).

When it comes to inferential statistics (generalising conclusions about associations and differences from samples to populations), the traditional 'frequentist' approach is being superseded by Bayesian methods. The frequent approach is based on the view that probability represents 'long run' frequency. Thus, saying that the probability of rolling a 3 with a standard die is $1/6^{\text{th}}$ because over an extended series of throws a 3 will come up 1 in 6 times. In the Bayesian view, probability represents an appropriate strength of belief that an event will occur and this belief should be continually updated as new evidence become available. Bayesian statistics have many advantages over frequentist methods. One important advantage for DBCI testing is that data can be scrutinised in an ongoing manner until a point is reached where one is confident that there is or is not a particular effect. This means that one does not have to specify sample sizes in advance and use of data is much more

efficient. A recent article by West provides a brief introduction and an indication as to where to go for further information (89).

Information to be recorded and reported in evaluations

In order to be able to contribute to generalisable conclusions about intervention effectiveness, it is essential to provide full details of crucial aspects, not only of the intervention (content and delivery), but also usage (including uptake and engagement), context (including population and setting), and putative mechanisms of action. This is needed to be able to build an 'ontology' that can form the basis for the accumulated science of behaviour change (see Section 7).

It is early days in the development of systems for specifying aspects of an ontology of behaviour change interventions. However, the taxonomy BCTTv1 forms an important component of such an ontology, specifying intervention content, and a start has been made in terms of mode of delivery, setting (90) and target behaviour (91-93).

Criteria other than effectiveness

Although the focus on most evaluations is on effectiveness and cost-effectiveness, the APEASE criteria (Section 5) include other crucial factors that need to be considered. In pharmaceutical interventions safety sits alongside effectiveness as a key factor because it is recognised that drugs can have serious side effects that need to be weighed against the benefits. There is an assumption with DBCIs that the side-effects will be minimal and these are rarely mentioned or assessed. Yet clearly there will be occasions when a DBCI could have unwanted adverse effects, and proposals have been made for how these should be assessed (94).

Apart from effectiveness and safety, it will be important to build assessment of DBCIs against other APEASE criteria into routine practice. Affordability will have to consider how the intervention will be sustained after the initial development phase, both in terms of regular updates which are always necessary and with server, promotion and ongoing evaluation costs. Practicability will need to address issues of access by the target population and ones that arise when platform providers keep making updates that undermine the functionality of a program. Acceptability will be a continuing challenge and may vary over time and across cultures. Equity also remains a crucial factor. DBCIs may enhance equity if they increase access to low cost, effective support but they may also undermine it if the DBCIs are designed in such a way that they require high levels of intellectual functioning or social capital to be effective.

Section 12 provides a simple template for applying the APEASE criteria to proposed interventions or their components.

9. Implementing DCBIs

Implementation of a DCBI may take place at any point once a viable product has been developed. It often occurs before testing has clearly indicated that it has a benefit. Even if it occurs after rigorous testing for effectiveness, it will usually still be necessary to continue to test after implementation. This serves to ensure that the intervention remains effective, to check for unwanted side-effects and to provide information that can lead to further development.

Server options

Implementation options include private servers, commercial servers, public organisation servers and digital distribution platforms. It is important when using any of these servers to ensure that they have the bandwidth to handle the expected traffic.

Variation in devices and operating systems

One of the biggest challenges for implementation is the variety of operating systems and devices on which the application may be used. Having established that a DCBI is effective for one kind of device with a limited set of operating systems, it can be expensive, time-consuming and difficult to translate it to other devices or operating systems.

Sustainability

A critical issue for DCBIs is sustainability. The social context is such that interventions of this kind cannot be developed and then left unchanged. They will quickly look dated and users will come to expect different ways of interacting with them depending on what functionalities and aesthetics are dominant at the time. This should be planned and budgeted for in programmes of work.

10. Promoting DBCIs

Promotion of DBCIs is important both for recruitment in the development and evaluation of DBCIs and in longer-term implementation. DBCIs can be promoted in many ways. It is not possible to capture all of these in this guide but there are some that are widely used. These are briefly described below.

Paid-for advertising: It can be worthwhile paying for advertising through traditional media such as TV, posters and periodicals, or through digital and social media (e.g. Google ads, Twitter and Facebook or highly visited websites). It is not clear what the cost-effectiveness is of these methods. Anecdotal evidence suggests that it can be highly variable, but it is not clear what factors relate to getting a good response.

Digital distribution platforms: Making smartphone applications available on the Apple App Store and Google Play can be effective in promoting use. There are ways of maximising the visibility of apps on these platforms. One of the most important considerations is to get the app as high as possible in the search listing. There is an extremely steep drop-off in terms of downloads as the search ranking decreases. There are other digital distribution platforms for apps of a more specialised nature and it seems likely that more use of these will be made in the future because they can be more effectively curated, thus potentially providing users with a mark of quality.

Search engines: One of the most important ways of promoting a DBCI is to ensure that it is discovered on the major search engines. As with digital distribution platforms, there is a very steep fall off with ranking in the search engine and therefore search engine optimisation has become a major field of expertise.

Public Relations: As with any product, the opportunity arises for unpaid publicity by engaging directly with journalists and sections of the media. This can be done through stories, press releases and events. For DBCIs there is the opportunity to publicise the findings of major trial results or the launch of a DBCI that has been based on major trial findings.

Websites: Being promoted on websites that attract a lot of visitors can be a highly effective way of promoting DBCIs. Some governmental agencies have health-related websites that receive many millions of visitors each week. A link to a DBCI prominently displayed on one of these websites can generate a lot of use at minimal cost.

Use of organisational databases: Organisations such as large employers may have databases that could be used as a basis for contacting potential users of DBCIs. This has potential advantages in terms of targeting individuals most likely to benefit from DBCIs, but there are also significant barriers to gaining the necessary permissions.

Workplace promotion: Related to the above, employers or groups of employers may wish to be involved in promoting the DBCI to their workforce.

11. Templates for development and evaluation of DBCIs

The development and evaluation process

Drawing the elements of this guide together, we have created a simple template summarising the process, the decisions that have to be made along the way and the justification for those decisions.

The idea is that when one is considering developing a DBCI, one completes as much of the table as possible in as much detail as possible, giving the proposed choices as discussed in this guide and the rationale for those choices. This document becomes a master document that is updated as the project progresses.

Item	Details
Title	
Context	
Goals	
Opportunities	
Constraints	
Stakeholders	
Collaborators	
Risks	
Activities	
Concept	
Knowledge	
Development	
Testing	
Implementation	
Promotion	

Applying the APEASE criteria

The grid below can be used as a simple way to structure discussion and record and update judgements relating to the criteria used for determining the suitability of an intervention or intervention component.

Criterion	Evidence and analysis	Judgement
Acceptability		
Practicability		
Effectiveness/cost effectiveness		
Affordability		
Safety/side effects		
Equity		

12. Appendix 1: Behaviour Change Techniques

(From Michie et al (9)) See www.bct-taxonomy.com

No.	Label	Definition
1.1*	<i>Goal setting (behaviour)</i>	<p>Set or agree on a goal defined in terms of the behaviour to be achieved</p> <p><i>Note: only code goal-setting if there is sufficient evidence that goal set as part of intervention; if goal unspecified or a behavioural outcome, code 1.3, Goal setting (outcome); if the goal defines a specific context, frequency, duration or intensity for the behaviour, <u>also</u> code 1.4, Action planning</i></p>
1.2*	<i>Problem solving</i>	<p>Analyse , or prompt the person to analyse, factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators (includes '<u>Relapse Prevention</u>' and '<u>Coping Planning</u>')</p> <p><i>Note: barrier identification without solutions is not sufficient. If the BCT does not include analysing the behavioural problem, consider 12.3, Avoidance/changing exposure to cues for the behaviour, 12.1, Restructuring the physical environment, 12.2, Restructuring the social environment, or 11.2, Reduce negative emotions</i></p>
1.3*	<i>Goal setting (outcome)</i>	<p>Set or agree on a goal defined in terms of a positive outcome of wanted behaviour</p> <p><i>Note: only code guidelines if set as a goal in an intervention context; if goal is a behaviour, code 1.1, Goal setting (behaviour); if goal unspecified code 1.3, Goal setting (outcome)</i></p>
1.4*	<i>Action planning</i>	<p>Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive) (includes '<u>Implementation Intentions</u>')</p> <p><i>Note: evidence of action planning does not necessarily imply goal setting, only code latter if sufficient evidence</i></p>

1.5*	<i>Review behaviour goal(s)</i>	Review behaviour goal(s) jointly with the person and consider modifying goal(s) or behaviour change strategy in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of (or in addition to) the first, or no change <i>Note: if goal specified in terms of behaviour, code 1.5, Review behaviour goal(s), if goal unspecified, code 1.7, Review outcome goal(s); if discrepancy created consider also 1.6, Discrepancy between current behaviour and goal</i>
1.6	<i>Discrepancy between current behaviour and goal</i>	Draw attention to discrepancies between a person's current behaviour (in terms of the <i>form, frequency, duration, or intensity</i> of that behaviour) and the person's previously set outcome goals, behavioural goals or action plans (goes beyond self-monitoring of behaviour) <i>Note: if discomfort is created only code 13.3, Incompatible beliefs and <u>not</u> 1.6, Discrepancy between current behaviour and goal; if goals are modified, also code 1.5, Review behaviour goal(s) and/or 1.7, Review outcome goal(s); if feedback is provided, <u>also</u> code 2.2, Feedback on behaviour</i>
1.7*	<i>Review outcome goal(s)</i>	Review outcome goal(s) jointly with the person and consider modifying goal(s) in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of, or in addition to the first <i>Note: if goal specified in terms of behaviour, code 1.5, Review behaviour goal(s), if goal unspecified, code 1.7, Review outcome goal(s); if discrepancy created consider also 1.6, Discrepancy between current behaviour and goal</i>
1.8	<i>Behavioural contract</i>	Create a written specification of the behaviour to be performed, agreed on by the person, and witnessed by another <i>Note: <u>also</u> code 1.1, Goal setting (behaviour)</i>
1.9	<i>Commitment</i>	Ask the person to affirm or reaffirm statements indicating commitment to change the behaviour <i>Note: if defined in terms of the behaviour to be achieved <u>also</u> code 1.1, Goal setting (behaviour)</i>

2.1*	<i>Monitoring of behaviour by others without feedback</i>	Observe or record behaviour with the person's knowledge as part of a behaviour change strategy <i>Note: if monitoring is part of a data collection procedure rather than a strategy aimed at changing behaviour, do not code; if feedback given, code only 2.2, Feedback on behaviour, and <u>not</u> 2.1, Monitoring of behaviour by others without feedback; if monitoring outcome(s) code 2.5, Monitoring outcome(s) of behaviour by others without feedback; if self-monitoring behaviour, code 2.3, Self-monitoring of behaviour</i>
2.2*	<i>Feedback on behaviour</i>	Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g. form, frequency, duration, intensity) <i>Note: if Biofeedback, code only 2.6, Biofeedback and <u>not</u> 2.2, Feedback on behaviour; if feedback is on outcome(s) of behaviour, code 2.7, Feedback on outcome(s) of behaviour; if there is no clear evidence that feedback was given, code 2.1, Monitoring of behaviour by others without feedback; if feedback on behaviour is evaluative e.g. praise, also code 10.4, Social reward</i>
2.3*	<i>Self-monitoring of behaviour</i>	Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy <i>Note: if monitoring is part of a data collection procedure rather than a strategy aimed at changing behaviour, do not code; if monitoring of outcome of behaviour, code 2.4, Self-monitoring of outcome(s) of behaviour; if monitoring is by someone else (without feedback), code 2.1, Monitoring of behaviour by others without feedback</i>
2.4	<i>Self-monitoring of outcome(s) of behaviour</i>	Establish a method for the person to monitor and record the outcome(s) of their behaviour as part of a behaviour change strategy <i>Note: if monitoring is part of a data collection procedure rather than a strategy aimed at changing behaviour, do not code ; if monitoring behaviour, code 2.3, Self-monitoring of behaviour; if monitoring is by someone else (without feedback), code 2.5, Monitoring outcome(s) of behaviour by others without feedback</i>
2.5*	<i>Monitoring outcome(s) of behaviour by others without feedback</i>	Observe or record outcomes of behaviour with the person's knowledge as part of a behaviour change strategy

		<p><i>Note: if monitoring is part of a data collection procedure rather than a strategy aimed at changing behaviour, do not code; if feedback given, code only 2.7, Feedback on outcome(s) of behaviour; if monitoring behaviour code 2.1, Monitoring of behaviour by others without feedback; if self-monitoring outcome(s), code 2.4, Self-monitoring of outcome(s) of behaviour</i></p>
2.6	<i>Biofeedback</i>	<p>Provide feedback about the body (e.g. <i>physiological or biochemical state</i>) using an external monitoring device as part of a behaviour change strategy</p> <p><i>Note: if Biofeedback, code only 2.6, Biofeedback and <u>not</u> 2.2, Feedback on behaviour or 2.7, Feedback on outcome(s) of behaviour</i></p>
2.7*	<i>Feedback on outcome(s) of behaviour</i>	<p>Monitor and provide feedback on the outcome of performance of the behaviour</p> <p><i>Note: if Biofeedback, code only 2.6, Biofeedback and <u>not</u> 2.7, Feedback on outcome(s) of behaviour; if feedback is on behaviour code 2.2, Feedback on behaviour; if there is no clear evidence that feedback was given code 2.5, Monitoring outcome(s) of behaviour by others without feedback; if feedback on behaviour is evaluative e.g. praise, also code 10.4, Social reward</i></p>
3.1*	<i>Social support (unspecified)</i>	<p>Advise on, arrange or provide social support (e.g. <i>from friends, relatives, colleagues, 'buddies' or staff</i>) or non-contingent praise or reward for performance of the behaviour. It includes encouragement and counselling, but only when it is directed at the behaviour</p> <p><i>Note: attending a group class and/or mention of 'follow-up' does not necessarily apply this BCT, support must be explicitly mentioned; if practical, code 3.2, Social support (practical); if emotional, code 3.3, Social support (emotional) (includes 'Motivational interviewing' and 'Cognitive Behavioural Therapy')</i></p>
3.2*	<i>Social support (practical)</i>	<p>Advise on, arrange, or provide practical help (e.g. <i>from friends, relatives, colleagues, 'buddies' or staff</i>) for performance of the behaviour</p> <p><i>Note: if emotional, code 3.3, Social support (emotional); if general or unspecified, code 3.1, Social support (unspecified) If only restructuring the physical environment or adding objects to the environment, code 12.1, Restructuring the physical environment or 12.5, Adding</i></p>

		<i>objects to the environment; attending a group or class and/or mention of 'follow-up' does not necessarily apply this BCT, support must be explicitly mentioned.</i>
3.3	<i>Social support (emotional)</i>	Advise on, arrange, or provide emotional social support (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour <i>Note: if practical, code 3.2, Social support (practical); if unspecified, code 3.1, Social support (unspecified)</i>
4.1*	<i>Instruction on how to perform a behaviour</i>	Advise or agree on how to perform the behaviour (includes ' <u>Skills training</u> ') <i>Note: when the person attends classes such as exercise or cookery, code 4.1, Instruction on how to perform the behaviour, 8.1, Behavioural practice/rehearsal <u>and</u> 6.1, Demonstration of the behaviour</i>
4.2	<i>Information about antecedents</i>	Provide information about antecedents (e.g. social and environmental situations and events, emotions, cognitions) that reliably predict performance of the behaviour
4.3	<i>Re-attribution</i>	Elicit perceived causes of behaviour and suggest alternative explanations (e.g. external or internal and stable or unstable)
4.4	<i>Behavioural experiments</i>	Advise on how to identify and test hypotheses about the behaviour, its causes and consequences, by collecting and interpreting data
5.1*	<i>Information about health consequences</i>	Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour <i>Note: consequences can be for any target, not just the recipient(s) of the intervention; emphasising importance of consequences is not sufficient; if information about emotional consequences, code 5.6, Information about emotional consequences; if about social, environmental or unspecified consequences code 5.3, Information about social and environmental consequences</i>

5.2	<i>Saliency of consequences</i>	Use methods specifically designed to emphasise the consequences of performing the behaviour with the aim of making them more memorable (goes beyond informing about consequences) <i>Note: if information about consequences, also code 5.1, Information about health consequences, 5.6, Information about emotional consequences or 5.3, Information about social and environmental consequences</i>
5.3*	<i>Information about social and environmental consequences</i>	Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behaviour <i>Note: consequences can be for any target, not just the recipient(s) of the intervention; if information about health or consequences, code 5.1, Information about health consequences; if about emotional consequences, code 5.6, Information about emotional consequences; if unspecified, code 5.3, Information about social and environmental consequences</i>
5.4	<i>Monitoring of emotional consequences</i>	Prompt assessment of feelings after attempts at performing the behaviour
5.5	<i>Anticipated regret</i>	Induce or raise awareness of expectations of future regret about performance of the unwanted behaviour <i>Note: <u>not</u> including 5.6, Information about emotional consequences; if suggests adoption of a perspective or new perspective in order to change cognitions <u>also</u> code 13.2, Framing/reframing</i>
5.6	<i>Information about emotional consequences</i>	Provide information (e.g. written, verbal, visual) about emotional consequences of performing the behaviour <i>Note: consequences can be related to emotional health disorders (e.g. depression, anxiety) and/or states of mind (e.g. low mood, stress); <u>not</u> including 5.5, Anticipated regret; consequences can be for any target, not just the recipient(s) of the intervention; if information about health consequences code 5.1, Information about health consequences; if about social, environmental or unspecified code 5.3, Information about social and environmental consequences</i>
6.1*	<i>Demonstration of the behaviour</i>	Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film,

		pictures, for the person to aspire to or imitate (includes ' <u>Modelling</u> '). <i>Note: if advised to practice, <u>also</u> code, 8.1, Behavioural practice and rehearsal; If provided with instructions on how to perform, <u>also</u> code 4.1, Instruction on how to perform the behaviour</i>
6.2	<i>Social comparison</i>	Draw attention to others' performance to allow comparison with the person's own performance <i>Note: being in a group setting does not necessarily mean that social comparison is actually taking place</i>
6.3	<i>Information about others' approval</i>	Provide information about what other people think about the behaviour. The information clarifies whether others will like, approve or disapprove of what the person is doing or will do
7.1*	<i>Prompts/cues</i>	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 <i>Note: when a stimulus is linked to a specific action in an if-then plan including one or more of frequency, duration or intensity <u>also</u> code 1.4, Action planning.</i>
7.2	<i>Cue signalling reward</i>	Identify an environmental stimulus that reliably predicts that reward will follow the behaviour (includes ' <u>Discriminative cue</u> ')
7.3	<i>Reduce prompts/cues</i>	Withdraw gradually prompts to perform the behaviour (includes ' <u>Fading</u> ')
7.4	<i>Remove access to the reward</i>	Advise or arrange for the person to be separated from situations in which unwanted behaviour can be rewarded in order to reduce the behaviour (includes ' <u>Time out</u> ')
7.5	<i>Remove aversive stimulus</i>	Advise or arrange for the removal of an aversive stimulus to facilitate behaviour change (includes ' <u>Escape learning</u> ')
7.6	<i>Satiation</i>	Advise or arrange repeated exposure to a stimulus that reduces or extinguishes a drive for the unwanted behaviour
7.7	<i>Exposure</i>	Provide systematic confrontation with a feared stimulus to reduce the response to a later encounter

7.8	<i>Associative learning</i>	Present a neutral stimulus jointly with a stimulus that already elicits the behaviour repeatedly until the neutral stimulus elicits that behaviour (includes ' <u>Classical/Pavlovian Conditioning</u> ') <i>Note: when a BCT involves reward or punishment, code one or more of: 10.2, Material reward (behaviour); 10.3, Non-specific reward; 10.4, Social reward, 10.9, Self-reward; 10.10, Reward (outcome)</i>
8.1*	<i>Behavioural practice/rehearsal</i>	Prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill <i>Note: if aiming to associate performance with the context, <u>also</u> code 8.3, Habit formation</i>
8.2	<i>Behaviour substitution</i>	Prompt substitution of the unwanted behaviour with a wanted or neutral behaviour <i>Note: if this occurs regularly, <u>also</u> code 8.4, Habit reversal</i>
8.3	<i>Habit formation</i>	Prompt rehearsal and repetition of the behaviour in the same context repeatedly so that the context elicits the behaviour <i>Note: <u>also</u> code 8.1, Behavioural practice/rehearsal</i>
8.4	<i>Habit reversal</i>	Prompt rehearsal and repetition of an alternative behaviour to replace an unwanted habitual behaviour <i>Note: <u>also</u> code 8.2, Behaviour substitution</i>
8.5	<i>Overcorrection</i>	Ask to repeat the wanted behaviour in an exaggerated way following an unwanted behaviour
8.6	<i>Generalisation of a target behaviour</i>	Advise to perform the wanted behaviour, which is already performed in a particular situation, in another situation
8.7	<i>Graded tasks</i>	Set easy-to-perform tasks, making them increasingly difficult, but achievable, until behaviour is performed
9.1*	<i>Credible source</i>	Present verbal or visual communication from a credible source in favour of or against the behaviour <i>Note: code this BCT if source generally agreed on as credible e.g., health professionals, celebrities or words used to indicate expertise or leader in field and if the communication has the aim of persuading; if information</i>

		<p>about health consequences, <u>also</u> code 5.1, Information about health consequences, if about emotional consequences, <u>also</u> code 5.6, Information about emotional consequences; if about social, environmental or unspecified consequences <u>also</u> code 5.3, Information about social and environmental consequences</p>
9.2	<i>Pros and cons</i>	<p>Advise the person to identify and compare reasons for wanting (pros) and not wanting to (cons) change the behaviour (includes '<u>Decisional balance</u>') <i>Note: if providing information about health consequences, <u>also</u> code 5.1, Information about health consequences; if providing information about emotional consequences, <u>also</u> code 5.6, Information about emotional consequences; if providing information about social, environmental or unspecified consequences <u>also</u> code 5.3, Information about social and environmental consequences</i></p>
9.3	<i>Comparative imagining of future outcomes</i>	<p>Prompt or advise the imagining and comparing of future outcomes of changed versus unchanged behaviour</p>
10.1	<i>Material incentive (behaviour)</i>	<p>Inform that money, vouchers or other valued objects <i>will be</i> delivered if and only if there has been effort and/or progress in performing the behaviour (includes '<u>Positive reinforcement</u>') <i>Note: if incentive is social, code 10.5, Social incentive if unspecified code 10.6, Non-specific incentive, and <u>not</u> 10.1, Material incentive (behaviour); if incentive is for outcome, code 10.8, Incentive (outcome). If reward is delivered also code one of: 10.2, Material reward (behaviour); 10.3, Non-specific reward; 10.4, Social reward, 10.9, Self-reward; 10.10, Reward (outcome)</i></p>
10.2	<i>Material reward (behaviour)</i>	<p>Arrange for the delivery of money, vouchers or other valued objects if and only if there <i>has been</i> effort and/or progress in performing the behaviour (includes '<u>Positive reinforcement</u>') <i>Note: If reward is social, code 10.4, Social reward, if unspecified code 10.3, Non-specific reward, and <u>not</u> 10.1, Material reward (behaviour); if reward is for outcome, code 10.10, Reward (outcome). If informed of reward in advance of rewarded behaviour, also code one of: 10.1, Material incentive (behaviour); 10.5, Social incentive; 10.6, Non-</i></p>

		<i>specific incentive; 10.7, Self-incentive; 10.8, Incentive (outcome)</i>
10.3	<i>Non-specific reward</i>	<p>Arrange delivery of a reward if and only if there <i>has been</i> effort and/or progress in performing the behaviour (includes '<u>Positive reinforcement</u>') <i>Note: if reward is material, code 10.2, Material reward (behaviour), if social, code 10.4, Social reward, and <u>not</u> 10.3, Non-specific reward; if reward is for outcome code 10.10, Reward (outcome). If informed of reward in advance of rewarded behaviour, also code one of: 10.1, Material incentive (behaviour); 10.5, Social incentive; 10.6, Non-specific incentive; 10.7, Self-incentive; 10.8, Incentive (outcome)</i></p>
10.4	<i>Social reward</i>	<p>Arrange verbal or non-verbal reward if and only if there <i>has been</i> effort and/or progress in performing the behaviour (includes '<u>Positive reinforcement</u>') <i>Note: if reward is material, code 10.2, Material reward (behaviour), if unspecified code 10.3, Non-specific reward, and <u>not</u> 10.4, Social reward; if reward is for outcome code 10.10, Reward (outcome). If informed of reward in advance of rewarded behaviour, also code one of: 10.1, Material incentive (behaviour); 10.5, Social incentive; 10.6, Non-specific incentive; 10.7, Self-incentive; 10.8, Incentive (outcome)</i></p>
10.5	<i>Social incentive</i>	<p>Inform that a verbal or non-verbal reward <i>will be</i> delivered if and only if there has been effort and/or progress in performing the behaviour (includes '<u>Positive reinforcement</u>') <i>Note: if incentive is material, code 10.1, Material incentive (behaviour), if unspecified code 10.6, Non-specific incentive, and <u>not</u> 10.5, Social incentive; if incentive is for outcome code 10.8, Incentive (outcome). If reward is delivered also code one of: 10.2, Material reward (behaviour); 10.3, Non-specific reward; 10.4, Social reward, 10.9, Self-reward; 10.10, Reward (outcome)</i></p>
10.6	<i>Non-specific incentive</i>	<p>Inform that a reward <i>will be</i> delivered if and only if there has been effort and/or progress in performing the behaviour (includes '<u>Positive reinforcement</u>') <i>Note: if incentive is material, code 10.1, Material incentive (behaviour), if social, code 10.5, Social incentive and <u>not</u> 10.6, Non-specific incentive; if incentive is for outcome code</i></p>

		10.8, Incentive (outcome). If reward is delivered also code one of: 10.2, Material reward (behaviour); 10.3, Non-specific reward; 10.4, Social reward, 10.9, Self-reward; 10.10, Reward (outcome)
10.7	Self-incentive	Plan to reward self in future if and only if there has been effort and/or progress in performing the behaviour Note: if self-reward is material, <u>also</u> code 10.1, Material incentive (behaviour), if social, <u>also</u> code 10.5, Social incentive, if unspecified, <u>also</u> code 10.6, Non-specific incentive; if incentive is for outcome code 10.8, Incentive (outcome). If reward is delivered also code one of: 10.2, Material reward (behaviour); 10.3, Non-specific reward; 10.4, Social reward, 10.9, Self-reward; 10.10, Reward (outcome)
10.8	Incentive (outcome)	Inform that a reward <i>will be</i> delivered if and only if there has been effort and/or progress in achieving the behavioural outcome (includes <u>Positive reinforcement</u>) Note: this includes social, material, self- and non-specific incentives for outcome; if incentive is for the behaviour code 10.5, Social incentive, 10.1, Material incentive (behaviour), 10.6, Non-specific incentive or 10.7, Self-incentive and <u>not</u> 10.8, Incentive (outcome). If reward is delivered also code one of: 10.2, Material reward (behaviour); 10.3, Non-specific reward; 10.4, Social reward, 10.9, Self-reward; 10.10, Reward (outcome)
10.9	Self-reward	Prompt self-praise or self-reward if and only if there <i>has been</i> effort and/or progress in performing the behaviour Note: if self-reward is material, <u>also</u> code 10.2, Material reward (behaviour), if social, <u>also</u> code 10.4, Social reward, if unspecified, <u>also</u> code 10.3, Non-specific reward; if reward is for outcome code 10.10, Reward (outcome). If informed of reward in advance of rewarded behaviour, also code one of: 10.1, Material incentive (behaviour); 10.5, Social incentive; 10.6, Non-specific incentive; 10.7, Self-incentive; 10.8, Incentive (outcome)
10.10	Reward (outcome)	Arrange for the delivery of a reward if and only if there <i>has been</i> effort and/or progress in achieving the behavioural outcome (includes <u>Positive reinforcement</u>) Note: this includes social, material, self- and non-specific rewards for outcome; if reward is for the behaviour code 10.4, Social reward, 10.2, Material reward (behaviour),

		10.3, Non-specific reward or 10.9, Self-reward and <u>not</u> 10.10, Reward (outcome). If informed of reward in advance of rewarded behaviour, also code one of: 10.1, Material incentive (behaviour); 10.5, Social incentive; 10.6, Non-specific incentive; 10.7, Self-incentive; 10.8, Incentive (outcome)
10.11	<i>Future punishment</i>	Inform that future punishment or removal of reward will be a consequence of performance of an unwanted behaviour (may include fear arousal) (includes <u>Threat</u>)
11.1	<i>Pharmacological support</i>	Provide, or encourage the use of or adherence to, drugs to facilitate behaviour change <i>Note: if pharmacological support to reduce negative emotions (i.e. anxiety) then <u>also</u> code 11.2, Reduce negative emotions</i>
11.2	<i>Reduce negative emotions^b</i>	Advise on ways of reducing negative emotions to facilitate performance of the behaviour (includes <u>Stress Management</u>) <i>Note: if includes analysing the behavioural problem, <u>also</u> code 1.2, Problem solving</i>
11.3	<i>Conserving mental resources</i>	Advise on ways of minimising demands on mental resources to facilitate behaviour change
11.4	<i>Paradoxical instructions</i>	Advise to engage in some form of the unwanted behaviour with the aim of reducing motivation to engage in that behaviour
12.1*	<i>Restructuring the physical environment</i>	Change, or advise to change the physical environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour (other than prompts/cues, rewards and punishments) <i>Note: this may also involve 12.3, Avoidance/reducing exposure to cues for the behaviour; if restructuring of the social environment code 12.2, Restructuring the social environment; if only adding objects to the environment, code 12.5, Adding objects to the environment</i>
12.2	<i>Restructuring the social environment</i>	Change, or advise to change the social environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour (other than prompts/cues, rewards and punishments)

		<i>Note: this may also involve 12.3, Avoidance/reducing exposure to cues for the behaviour; if also restructuring of the physical environment also code 12.1, Restructuring the physical environment</i>
12.3	<i>Avoidance/reducing exposure to cues for the behaviour</i>	Advise on how to avoid exposure to specific social and contextual/physical cues for the behaviour, including changing daily or weekly routines <i>Note: this may also involve 12.1, Restructuring the physical environment and/or 12.2, Restructuring the social environment; if the BCT includes analysing the behavioural problem, <u>only</u> code 1.2, Problem solving</i>
12.4	<i>Distraction</i>	Advise or arrange to use an alternative focus for attention to avoid triggers for unwanted behaviour
12.5*	<i>Adding objects to the environment</i>	Add objects to the environment in order to facilitate performance of the behaviour <i>Note: Provision of information (e.g. written, verbal, visual) in a booklet or leaflet is insufficient. If this is accompanied by social support, also code 3.2, Social support (practical); if the environment is changed beyond the addition of objects, also code 12.1, Restructuring the physical environment</i>
12.6	<i>Body changes</i>	Alter body structure, functioning or support directly to facilitate behaviour change
13.1	<i>Identification of self as role model</i>	Inform that one's own behaviour may be an example to others
13.2	<i>Framing/reframing</i>	Suggest the deliberate adoption of a perspective or new perspective on behaviour (e.g. its purpose) in order to change cognitions or emotions about performing the behaviour (includes ' <u>Cognitive structuring</u> '); <i>If information about consequences then code 5.1, Information about health consequences, 5.6, Information about emotional consequences or 5.3, Information about social and environmental consequences instead of 13.2, Framing/reframing</i>
13.3	<i>Incompatible beliefs</i>	Draw attention to discrepancies between current or past behaviour and self-image, in order to create discomfort (includes ' <u>Cognitive dissonance</u> ')

13.4	<i>Valued self-identity</i>	Advise the person to write or complete rating scales about a cherished value or personal strength as a means of affirming the person's identity as part of a behaviour change strategy (includes ' <u>Self-affirmation</u> ')
13.5	<i>Identity associated with changed behaviour</i>	Advise the person to construct a new self-identity as someone who 'used to engage with the unwanted behaviour'
14.1	<i>Behaviour cost</i>	Arrange for withdrawal of something valued if and only if an unwanted behaviour is performed (includes ' <u>Response cost</u> '). Note if withdrawal of contingent reward code, 14.3, <i>Remove reward</i>
14.2	<i>Punishment</i>	Arrange for aversive consequence contingent on the performance of the unwanted behaviour
14.3	<i>Remove reward</i>	Arrange for discontinuation of contingent reward following performance of the unwanted behaviour (includes ' <u>Extinction</u> ')
14.4	<i>Reward approximation</i>	Arrange for reward following any approximation to the target behaviour, gradually rewarding only performance closer to the wanted behaviour (includes ' <u>Shaping</u> ') <i>Note: also code one of 59-63</i>
14.5	<i>Rewarding completion</i>	Build up behaviour by arranging reward following final component of the behaviour; gradually add the components of the behaviour that occur earlier in the behavioural sequence (includes ' <u>Backward chaining</u> ') <i>Note: also code one of 10.2, Material reward (behaviour); 10.3, Non-specific reward; 10.4, Social reward, 10.9, Self-reward; 10.10, Reward (outcome)</i>
14.6	<i>Situation-specific reward</i>	Arrange for reward following the behaviour in one situation but not in another (includes ' <u>Discrimination training</u> ') <i>Note: also code one of 10.2, Material reward (behaviour); 10.3, Non-specific reward; 10.4, Social reward, 10.9, Self-reward; 10.10, Reward (outcome)</i>
14.7	<i>Reward incompatible behaviour</i>	Arrange reward for responding in a manner that is incompatible with a previous response to that situation (includes ' <u>Counter-conditioning</u> ')

		<i>Note: also code one of 10.2, Material reward (behaviour); 10.3, Non-specific reward; 10.4, Social reward, 10.9, Self-reward; 10.10, Reward (outcome)</i>
14.8	<i>Reward alternative behaviour</i>	Arrange reward for performance of an alternative to the unwanted behaviour (includes <u>Differential reinforcement</u>) <i>Note: also code one of 10.2, Material reward (behaviour); 10.3, Non-specific reward; 10.4, Social reward, 10.9, Self-reward; 10.10, Reward (outcome); consider also coding 1.2, Problem solving</i>
14.9	<i>Reduce reward frequency</i>	Arrange for rewards to be made contingent on increasing duration or frequency of the behaviour (includes <u>Thinning</u>) <i>Note: also code one of 10.2, Material reward (behaviour); 10.3, Non-specific reward; 10.4, Social reward, 10.9, Self-reward; 10.10, Reward (outcome)</i>
14.10	<i>Remove punishment</i>	Arrange for removal of an unpleasant consequence contingent on performance of the wanted behaviour (includes <u>Negative reinforcement</u>)
15.1	<i>Verbal persuasion about capability</i>	Tell the person that they can successfully perform the wanted behaviour, arguing against self-doubts and asserting that they can and will succeed
15.2	<i>Mental rehearsal of successful performance</i>	Advise to practise imagining performing the behaviour successfully in relevant contexts
15.3	<i>Focus on past success</i>	Advise to think about or list previous successes in performing the behaviour (or parts of it)
15.4	<i>Self-talk</i>	Prompt positive self-talk (aloud or silently) before and during the behaviour
16.1	<i>Imaginary punishment</i>	Advise to imagine performing the unwanted behaviour in a real-life situation followed by imagining an unpleasant consequence (includes <u>Covert sensitisation</u>)
16.2	<i>Imaginary reward</i>	Advise to imagine performing the wanted behaviour in a real-life situation followed by imagining a pleasant consequence (includes <u>Covert conditioning</u>)

16.3	<i>Vicarious consequences</i>	<p>Prompt observation of the consequences (including rewards and punishments) for others when they perform the behaviour</p> <p><i>Note: if observation of health consequences, also code 5.1, Information about health consequences; if of emotional consequences, <u>also</u> code 5.6, Information about emotional consequences, if of social, environmental or unspecified consequences, <u>also</u> code 5.3, Information about social and environmental consequences</i></p>
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