A systematic review of intervention studies using Health Action Process Approach (HAPA) model components to target behaviours for preventing and managing chronic diseases

PROTOCOL 23/5/13

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Overview

The purpose of this systematic review is to *describe* how the Health Action Process Approach (HAPA) model and HAPA-like approaches have been applied in intervention studies that aim to change behaviours directly linked to the onset or progression of chronic diseases. It also aims to *determine the effectiveness* of these interventions, and explore factors influencing effectiveness. To our knowledge, no systematic reviews of the HAPA model have been conducted to date. The specific focus of our review is on: (1) intervention studies, rather than observational studies examining the predictive value of HAPA components, and on (2) behaviours linked to chronic disease. This focus stems from the anticipated nature of the bulk of high quality, synthesisable evidence in the field, similar approaches taken in other reviews of behaviour change models (e.g. Hardeman et al, 2002; Bridle et al, 2007) and the need to limit the scope of this (unfunded)

review to link with the related on-going research of the core review team primarily concerned with behaviour change interventions for chronic disease prevention (e.g. diabetes, cardiovascular disease) and management (e.g. asthma).

Background

Chronic disease: definitions and problem

Chronic, or non-communicable, diseases generally progress slowly and are of long duration (WHO, 2011), and at present they can only be controlled, not cured (DoH, 2004). The risk and incidence of chronic diseases increase with age and their prevalence is increasing in the UK and worldwide (DoH, 2004; WHO 2011). In 2008, 36 million people died from a chronic disease, representing 63% of the total global deaths. The main contributors to this figure were cardiovascular diseases, diabetes, cancers and chronic respiratory diseases (WHO, 2011). Together, chronic diseases are estimated to account for over 70% of the total health and social care spending in England (DoH, 2012).

Behavioural risk factors for chronic disease

Virtually all chronic diseases have certain behaviours that are key modifiable risk factors for their development and/or progression. Much of the resultant morbidity and mortality could therefore be reduced by modifying these behaviours. The UK Department of Health (DoH, 2010) estimate that 50% of deaths from circulatory diseases, 30% of cancers and most cases of type 2 diabetes could be avoided by reducing obesity, smoking and physical inactivity and improving diet. In the US, nearly 40% of all deaths are estimated to be attributable to smoking, poor diet, physical inactivity, alcohol consumption, unsafe sexual practices and illicit drug use, with poor diet and physical inactivity being the fastest growing risk factors (Mokdad et al, 2004). These and other behaviours (e.g. adherence to medication) are also central to the effective secondary prevention and management of chronic diseases. Despite this, nearly two-thirds of adults in the UK are overweight or obese, less than 40% participate in adequate levels of physical activity, nearly a quarter drink alcohol at levels considered to pose at least a moderate risk to health, over a fifth continue to smoke, and a majority consume diets high in salt and saturated fat, and low in fruit and vegetables (DoH, 2010). In those with existing conditions, poor adherence to medications (DiMatteo, 2004) and other self-care behaviours (Greaves & Campbell, 2007) is also a significant problem.

Due to the strong and continually emerging evidence that changing health-related behaviours can have a favourable impact on disease prevention and management, lifestyle and behaviour change interventions have great potential to alter health patterns and disease epidemiology. For example, in a large scale clinical trial the US Diabetes Prevention Programme (Diabetes Prevention Programme Research Group, 2002) demonstrated that participants who followed the lifestyle intervention of reducing saturated fat intake, increasing fibre intake, increasing physical activity and losing 5% of baseline body weight had a 58% reduction in their chances of developing type 2 diabetes. On the basis of such evidence, public health initiatives to promote health-related behaviour changes at individual and societal level have increasingly been recommended in guidelines (e.g. NICE, 2006; 2007; Paulweber et al, 2010) and implemented by national and local governments (e.g. DoH, 2009). However, in spite of this, as recognised at a recent high level meeting of the United Nations General Assembly (UN, 2011), chronic conditions continue to have a

significant burden on national health-care systems and people's lives (WHO, 2011). More effective approaches to changing people's behaviours to prevent and control them are therefore needed.

Changing health-related behaviour

With this in mind, there has been a great deal of research over recent decades investigating the determinants of health-related behaviour change. This has increasingly focused on modifiable psychological factors, particularly social-cognitive determinants as the most mutable and proximal influences on patterns of behaviour. Many different theories or models which incorporate social-cognitive determinants, such as people's motivation to change and their beliefs about a behaviour, its consequences and their ability to perform it, have been developed and used to understand and predict changes in health-related behaviours. Well-known examples of these so-called "social-cognition models" are the Health Belief Model (Rosenstock, 1974), the Theory of Reasoned Action (Fishbein & Ajzen, 1975), the Theory of Planned Behaviour (Ajzen, 1985), Social Cognitive Theory (Bandura, 1985), and the Transtheoretical (Stages of Change) Model (Prochaska & DiClemente, 1983). Approaches to tackling chronic disease prevention and management have increasingly drawn on such psychological theories of behaviour change, since they provide an understanding of the determinants of behaviour and therefore can guide the development of interventions to change them (Baranowski et al, 2003; Leventhal et al, 2008).

However, there is disagreement in the literature about whether one single theory or model is superior (Noar & Zimmerman, 2005), and the rationale for the choice of theory used within behaviour change interventions is often unclear (Hardeman et al, 2005). Systematic reviews have examined interventions based on some of these psychological theories. For example, Hardeman et al (2002) examined use of the Theory of Planned Behaviour (TPB) in behaviour change interventions and Bridle et al (2005) reviewed the effectiveness of health-related behaviour change interventions based on the Transtheoretical Model. Both found inconclusive evidence in support of the respective model. However, there is uncertainty regarding the extent to which interventions purporting to be based on a particular theory are actually based on the theory. For example, some studies included in Hardeman et al's review failed to examine whether interventions were properly implemented, and others used additional theories or models alongside the TPB in the development and/or evaluation of interventions. Behaviour change interventions also frequently fail to assess or target using appropriate change techniques all components of the theoretical model from which they are purportedly derived. Developing definitions and taxonomies of behaviour change techniques (e.g. Abraham & Michie, 2008; Michie et al, 2011) increasingly provide a way to describe the extent to which supposedly theory-based interventions are actually designed to modify all determinants of behaviour suggested by a particular model.

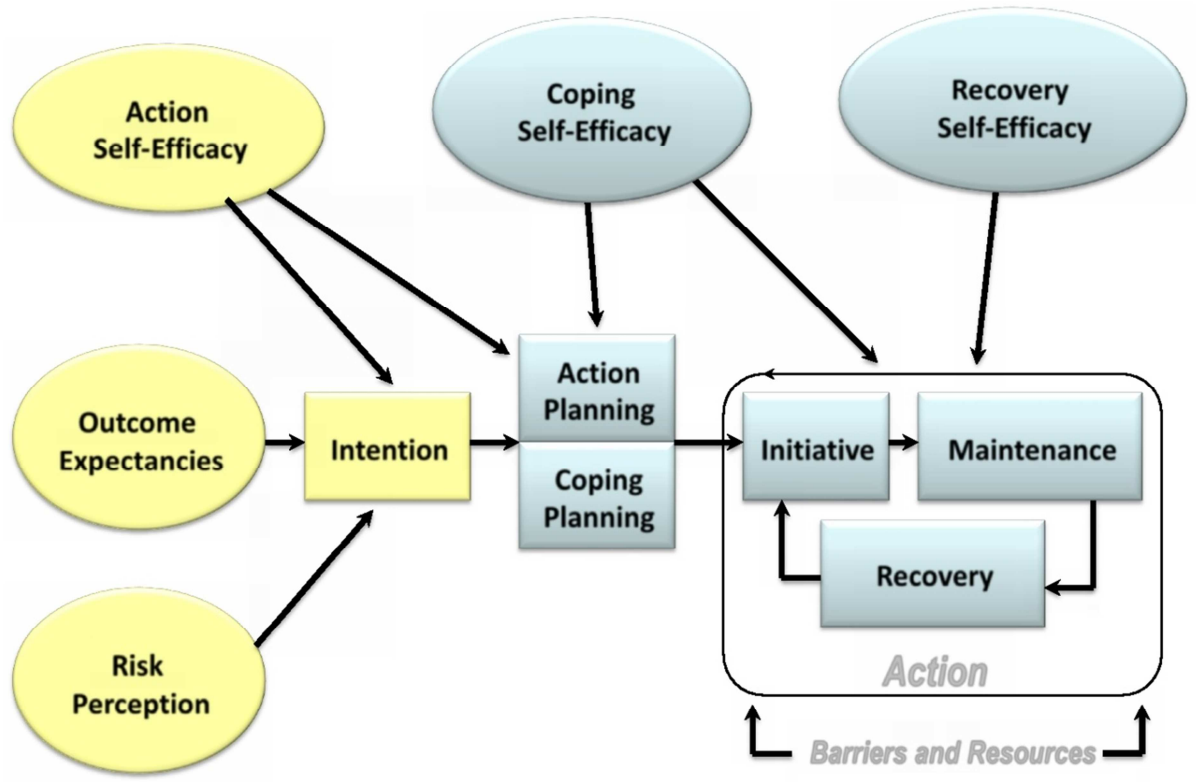
In addition to difficulties with being reliably and comprehensively applied in designing and evaluating interventions, a further problem with social cognition models such as the Theory of Planned Behaviour, is that they suggest that people form intentions to change a behaviour and it is those intentions which lead an individual to act, such that intention is the best predictor of behaviour. Yet research has shown that forming an intention is often not sufficient to warrant actual behaviour change and that there are additional factors that moderate between the intention and behaviour change outcome (Sheeran, 2002). This is known as the "intention-behaviour gap" (Sniehotta et al, 2005). The aforementioned social cognition models primarily focus on motivational factors important in forming an intention (i.e. goal setting) and do not incorporate so-called "volitional" or "action" components that facilitate translation of an intention into actual behaviour (i.e. goal pursuit). Recent research efforts to decrease the 'intention-behaviour gap' and

enhance behaviour change have centred on processes such as detailed goal setting, planning and self-monitoring, which seem to be important in ensuring that once people are motivated, intended behaviour changes are acted upon and maintained (Sniehotta et al, 2005). Targeting these components in health-related behaviour change interventions in addition to motivational factors, or in people who are already motivated, has potential to make them more effective (Michie et al, 2009; Greaves et al, 2011). More recent approaches to understanding and influencing behaviour change have recognised this by extending social cognitive models to incorporate modifiable volitional, as well as motivational, components.

The HAPA model and HAPA-like approaches

A more recently developed behaviour change model which recognises the importance of motivational and volitional processes is the Health Action Process Approach (HAPA) (Figure 1). Building on Social Cognitive Theory, the HAPA was developed in 1992 by Ralf Schwarzer in an attempt to provide a more complete model that overcomes the limitations of earlier ones whilst incorporating some of the strengths of each (Schwarzer, 1992). The model suggests that an individual first passes through a motivational phase which concludes with forming an intention and then, in preparation for performing the behaviour, they enter a volitional phase which is concerned with translating motivation into action (Armitage and Arden, 2010). In the motivational phase, as an individual forms an intention to change their behaviour, the influencing factors are identified as self-efficacy, risk perceptions and outcome expectancies. This is similar to other models of behaviour change, but with outcome expectancies potentially encompassing some factors (e.g. social norms) that appear separately in models such as the TPB. The volitional phase can be further subdivided into a planning stage, an action stage and a maintenance stage, unlike most other social cognition models, highlighting the processes an individual must go through in order to translate their intentions into behaviour and maintain those changes over time. Other extended (e.g. using implementation intentions alongside the TPB, Orbeil et al, 1997) and integrated social cognition models (e.g. the Integrated or I-Change model, De Vries et al 2005; the Process Model of Lifestyle Behaviour Change, Greaves et al, 2010) incorporate similar motivational and volitional components and can be considered “HAPA-like”.

Figure 1. The Health Action Process Approach Model



R Schwarzer **http://userpage.fu-berlin.de/~health/hapa.htm**

Research on the HAPA model and its components

Many cross-sectional and longitudinal observational studies have used the HAPA model and combinations of its key components in a range of populations to examine and predict health-related behaviours. These include physical activity (e.g. Barg*et al*. 2011; Perrier, Strachan & Latimer-Cheung, 2012; Caudriot, Stephan & Scanff, 2010; Schwarzer *et al* 2007), smoking (e.g. Radtke et al, 2011), alcohol consumption (e.g. Murgraff, 2003) and healthy eating (e.g. Mullan et al, in press; Scholz *et al*, 2009; and Schwarzer *et al*. 2007). These have generally supported the importance of HAPA model motivational and volitional components as predictors of behaviour change, but with some conflicting results. For example, the importance of planning when tested as a volitional component of the HAPA model has not consistently been supported (e.g. Scholz *et al* 2009; Barg*et al*. 2011; Caudriot et al, 2010; Mullan et al, in press; Radtke et al, 2011), potentially highlighting the importance of automaticity in many behaviours, whereby planning is not always enough to overcome impulsive control and break ingrained habits (Verplanken & Aarts, 1999). However, there is much research outside the context of the HAPA model in which planning (especially coping planning) has been shown to independently predict behaviour change (e.g. Hagger *et al,* 2011; Weidemann *et al,* 2004; Pakpour, 2011; Luszczynska et al, 2007; Sneihotta et al, 2006). Other findings also suggest that interventions adopting both motivational and volitional components have more effect on changing health-related behaviours such as physical activity (Milne et al, 2002), than those implementing motivational or volitional components alone (Hagger *et al*. 2011). Planning and self-regulatory processes appear to be important in maintaining behaviour changes over the longer-term, and the effects of including these in interventions in addition to targeting motivational components as the HAPA would propose, is therefore a particular area for further research.

HAPA-based behaviour change interventions

In light of research on the ability of HAPA components to predict behaviour change, studies have begun to use the HAPA model, or combinations of its key motivational and volitional components, as the basis for the development of interventions. For example, in the field of type 2 diabetes mellitus (T2DM) prevention with which the review team is familiar, the Greater Green Triangle (GGT) Diabetes Prevention Project (Laatikainen *et al*, 2007); the GOAL implementation study (Absetz *et al* 2007); and our on-going Norfolk Diabetes Prevention Study (Murray et al, 2011) all state in published papers that the development of the intervention was based on the HAPA model. For example, in the Norfolk Diabetes Prevention Study (NDPS), the HAPA model stages of motivation, action and maintenance are mirrored closely in the framework for the intervention sessions and its overall structure. Appropriate behaviour change techniques (Abraham & Michie, 2008) are used to probe and target participants' risk perceptions, outcome expectancies and intentions early on. Use of the HAPA volitional components of action planning, coping planning and self-monitoring of behaviour then form a core part of attempts to support self-regulation and maintenance of behaviour change over the longer-term.

As well as using the HAPA model as the basis for developing the intervention, the GGT in Australia and NDPS programmes in England have also measured HAPA variables (e.g. outcome expectancies, intention formation, self-efficacy, use of action and coping planning) to examine via process evaluations their influence on behavioural outcomes (physical activity and healthy eating) and weight related risk factors, and in doing so provide a test of the model. We are also aware of similar comprehensive HAPA-based intervention studies in other areas, such as cardiovascular risk reduction (e.g. Waste the Waist, Gillison et al, 2011). We also anticipate there being studies that although they do not explicitly cite the HAPA model, use HAPA-like approaches in the development and/or evaluation of a behaviour change intervention. The PREPARE programme (Yates et al, 2008), which states that the intervention was a theory-driven group-based structured programme and mentions the importance of volitional and motivational components, is an example of such a study in the diabetes prevention field. Unlike in these studies, however, research in this area commonly fails to provide a detailed description of how the model has been applied, and the extent to which this is the case will be further explored in the proposed review.

Summary and context for this review

In the 20 years since its inception, we anticipate that an increasing number of published studies such as the examples above have reported using the HAPA model or HAPA-like approaches incorporating its key motivational and volitional components, as the basis for designing and evaluating interventions to change health-related behaviours. There is some evidence to suggest that the HAPA model might be superior to traditional social cognition models due to the addition of the planning and self-regulatory components (Armitage and Connor, 2007). However, unlike several other models including the Theory of Planned Behaviour (Hardeman, 2002), the Transtheoretical Model (Bridle, 2007; Riemsma, 2003) and the Health Belief Model (Brewer, 2007), the HAPA model and intervention studies incorporating multiple HAPA components to support health-related behaviour change to our knowledge do not appear to have been the subject of a systematic review. Hence, there is a need to review evidence on how the HAPA model and combinations of its components have been applied in intervention studies. Furthermore, it is important to establish the overall effectiveness of such interventions in terms of their ability to alter behaviours that

increase a person's risk of developing a chronic disease or complications in an established disease, and factors influencing their effectiveness.

Searches of the Cochrane library and York Centre for Reviews and Dissemination Database of Abstracts of Reviews of Effectiveness, and Medline and PsycInfo databases[1] did not reveal any existing reviews of the HAPA model up to May 2012. We also confirmed with two of the originators of the model (Ralf Schwarzer, Falko Sniehotta) in May 2012 that they were not aware of any existing or on-going reviews.

As per Hardeman et al's (2002) review of the TPB, we initially also considered synthesising evidence on the predictive value of HAPA motivational and volitional variables for successful health-related behaviour change, in other words to examine which constructs of the model account for most of the changes in behaviours. However, after consultation, it was agreed that synthesis of such literature would be difficult and beyond the scope and resources of the current (unfunded) review. It will be possible, though, to document included intervention studies that explore the predictiveness of HAPA components via process evaluations, for potential examination in a separate review. On the basis of the approach taken in similar reviews of other models of behaviour change (e.g. Hardeman et al, 2002; Bridle et al, 2007) and in order to limit the scope of the review to link with the bulk of our own related on-going research (e.g. in chronic disease prevention and self-management) it also focusses only on health-related behaviours directly linked to chronic disease prevention and management. Such behaviours are defined further below.

Aims, review questions and scope

The aims of this study are similar to those in Hardeman et al's (2002) review of the application of the Theory of Planned Behaviour in behaviour change interventions, but in this case applied to the HAPA model. We will use standard systematic review methods (CRD, 2008) to identify, describe and synthesise evidence from relevant intervention studies (see below) to address the following questions:

(1) How often and in what ways have the HAPA model, and HAPA-like approaches incorporating multiple motivational and volitional components, been applied:

   (a) in the development of interventions aimed at changing behaviours related to chronic disease prevention/management, and/or

   (b) the evaluation of these interventions?

(2) What behaviour change techniques (e.g. Michie et al, 2011) have been used to target the various components of the model?

(3) Are interventions based on the HAPA model, and HAPA-like approaches, effective in changing health outcomes, health-related behaviours (primary outcomes) and targeted HAPA components (e.g. perceived risk, outcome expectancies, self-efficacy, intention, planning)?

With regards to questions three, where possible, we will examine the effectiveness of the interventions in influencing:

[1] On Medline and PsycInfo the terms (review or meta-anal$) and (theory or model) and (intervention$) were searched for in titles of references.

(a) impacts on health and initiation of behaviour change in the short-term (e.g. up to 6 months)[2];
(b) health impacts and behaviour change over the longer-term (e.g. 6 months and beyond)[2];
(c) and maintenance of health impacts and behaviour change from one follow up point to another (e.g. 6-12 months)[2].

Assessment of the effectiveness of interventions will inevitably take account of the different comparisons made in included studies (e.g. no intervention/routine care, minimal/information only interventions, other active interventions), with a primary focus being on comparisons of interventions using HAPA components, compared to no intervention or routine care.

To explore factors influencing the effectiveness of interventions (heterogeneity), the following pre-specified sub-questions will also be assessed if there are a sufficient numbers of studies:

(d) Does the number of HAPA components used, and "quality" or extent of their application (e.g. as per Michie & Prestwich, 2010 coding scheme for judging the degree to which interventions are theory-based) influence effectiveness?

(e) What proportion of the identified studies are authored by persons involved in the development of the HAPA and does their involvement influence reported effectiveness?

The influence of other characteristics related to the participants, behaviours and diseases targeted, type and nature of the interventions (e.g. provider, format, intensity, components) and study designs will be further explored (e.g. via meta-regression, sub-group or sensitivity analyses) as far as possible.

Given the complexity of the review in terms of the populations, interventions, comparisons and outcomes, refinements may need to be made to the scope and questions during the course of the review. In particular, if a much larger than anticipated evidence base is identified the proposed broad scope may need to be refined by agreement of the review team. Decisions leading to any changes made will be carefully documented.

Plan for review

The review will proceed as follows:

1. Two reviewers (KB and NM) will **search** for all possibly relevant studies using pre-defined search terms and sources determined following scoping searches undertaken in an attempt to balance specificity and sensitivity (see 'Search strategy').

2. Two reviewers (KB and NM) will **screen** titles obtained from searches to exclude obviously irrelevant studies and identify all possibly relevant studies for which an abstract will be saved/obtained (see 'Study screening'). Studies considered potentially relevant by either reviewer will be retained for further review.

[2] Final definitions for the timeframes used in relation to (a) - (c) will be guided by parallel work on initiation and maintenance of behaviour change being undertaken by the PhD students involved in the review (KB and NM respectively) and any commonalities initially identified in follow up times across included studies.

3. One reviewer (KB or NM) will **review study abstracts** for exclusion or initial inclusion and full text review, with a sub-sample and abstracts for any excluded studies being assessed independently by a second reviewer (KB or NM) (see 'Study selection').

4. Full texts of all studies selected for initial inclusion by either reviewer, or over which there are uncertainties will then be obtained and reviewed independently by two reviewers (out of KB, NM, JS) to **confirm inclusion/exclusion**. Reference to a third reviewer will be sought if there are uncertainties or disagreements regarding inclusion and the final decisions will be discussed and agreed (see 'Study selection').

5. To address review question 1 and provide a description of the extent and nature of relevant research, two reviewers (out of KB, NM, JS) will initially **categorise** included studies along a number of dimensions related to their use of the HAPA model/components, study design and the behaviour(s) and disease(s) targeted (see 'Study categorisation and prioritisation'). Advice from a third reviewer will be sought if there is disagreement or a need for clarification regarding categorisations.

6. If there are a large number of included studies (>50), categorisation of studies undertaken at step 5 will be used to **prioritise** the most relevant and/or highest quality (in terms of study design) studies for data extraction (see 'Study categorisation and prioritisation'). The categorisations will also be used to divide up the subsequent data extraction and synthesis work between reviewers (KB and NM).

7. **Descriptive data** on general study characteristics, participants, interventions, comparators, outcomes, follow up timepoints, reported study findings and study quality characteristics from selected studies will be extracted by one reviewer (KB or NM) who will also check the data extraction undertaken by the other reviewer (see 'Data extraction'). Again, reference to a third reviewer (JS or CG) will be made if there is disagreement or if further clarification is needed in relation to data extraction and a third reviewer (JS or CG) will check data extraction for 10% of studies.

8. If there are a sufficient number of controlled studies (>2) addressing similar questions and reporting adequate data on behavioural and health outcomes, one reviewer (KB or NM) will extract **outcome data** from allocated studies and check the data extraction undertaken by the other reviewer (see 'Data extraction'). Reference to a third reviewer (JS or CG) will again be made if there are disagreements or further clarification is needed, and they will check data extraction for 10% of studies.

9. Descriptive, and where possible, quantitative **syntheses of findings** will be separately undertaken and written up by KB and NM (see 'Data synthesis') under the guidance of JS and CG prior to a combined paper(s) reporting on all aspects of the review being drafted.

Scope and definitions

Inclusion criteria

The review will only include studies that meet <u>all</u> of the following inclusion criteria:

Study and publication type

Criterion 1. Is a primary research study

Criterion 2. Is reported in a fully published form in English after 1992

Population:

Criterion 3. Targets adults (16 years and over) from a healthy population, group at-risk of, or with, a chronic physical disease or presents analyses separately for a sub-group of such adults within a mixed age sample.

Intervention:

Criterion 4. Evaluates one or more intervention to change on-going health-related behaviour(s) (i.e. not once-off behaviour) directly associated with the prevention and/or management of a chronic physical disease. A chronic physical disease is defined as a long-term, non-communicable physical illness that cannot usually be cured (e.g. diabetes, cardiovascular disease, cancers, respiratory disease and liver diseases,).

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Criterion 5.

Mentions the HAPA model or cites a relevant publication on the HAPA model as the basis for the development/design and/or evaluation of the intervention in the abstract, introduction or methods of the paper (as per Hardeman et al, 2002 review).

OR

Uses a HAPA-like model that includes (1) **self-efficacy**, and at least **four out of six other pre-specified HAPA components**, at least one of which is (2) **a motivational component**, and one of which is (3) **a volitional component** in the context of the development/design and/or evaluation of the intervention. The required number and type of components must all be mentioned in the context of the development/design OR all in relation to evaluation, or both, and not split across the two (e.g. 2 components included in design, 2 in evaluation), in order to meet this criterion for inclusion. The HAPA components are defined, and will be identified, as follows:

(1) Self-efficacy

> **Self-efficacy**, derived from Bandura's (1977) social cognitive theory, is defined as a belief in one's ability, capability or competence to succeed, or perform a particular action or behaviour required to achieve a desired goal or outcome (Albery & Munafo, 2008; Connor & Norman, 2005). This is sometimes described as a person's **confidence** in their ability to undertake a particular action or perform a behaviour. It is closely related (arguably identical) to the concept of **perceived behavioural control** in the Theory of Planned Behaviour, representing how much control a person believes they have over a certain behaviour, i.e. whether a particular behaviour is perceived as being under their control and they have the ability to perform it (Albery & Munafo, 2008). In the HAPA model, self-efficacy is seen to be important in intention formation and in the initiation and maintenance of behaviour change, with different types of self-efficacy in relation to each phase in the behaviour change process (action, coping

and recovery self-efficacy) sometimes distinguished (Schwarzer, 1992). Self-efficacy beliefs are usually considered situation specific, however, a broader concept referred to as generalised self-efficacy (i.e. a general set of beliefs in one's ability to perform a variety of behaviours across a number of situations to achieve desired outcomes, Albery & Munafo, 2008) can also be identified. This is similar to the concept of **perceived control**, which refers to the extent to which something is *believed* to be (rather than is actually) under control, or more specifically the extent to which an individual believes something to be under *their* control (Walker, 2001). Perceived control over outcomes equates to the concept of **locus of control,** and perceived control over action to self-efficacy, and so it is not clearly a separate construct (Walker, 2001; Wallston, 1992). Broad beliefs about one's capability to perform relevant actions are also sometimes referred to as "**perceived competence**" or "**mastery**". For the purposes of this review, explicit mention of any of these **control beliefs** in the context of designing or evaluating an intervention will be considered sufficient for meeting this criterion for inclusion, and searches will use terms to identify the key overlapping constructs highlighted.

(2) Motivational components included in the HAPA model are as follows:

(2a) Outcome expectancies. These are defined as the **perceived consequences** (e.g. health-related, emotional, social, environmental) of a planned action, specifically the belief that in a given situation a particular behaviour will alter an outcome (**action outcome expectancy**) that would otherwise occur in the absence of action (**situation outcome expectancy**) (Connor & Norman, 2005). Before deciding whether to change behaviour, people weigh up the perceived **pros and cons** (benefits and costs) of doing so, entertaining both positive and negative outcome expectancies. A person is more likely to form an intention to change a behaviour if they expect more positive (and/or fewer negative) consequences (Schwarzer *et al,* 2003). In this review, explicit mention of targeting or assessing beliefs about any consequences or outcomes of a behaviour (including pros and cons) will be considered sufficient for the identification of outcome expectancies in a study, and a range of terms will be used to pick up related concepts in searches.

(2b) Risk perception. This is defined as the **perceived susceptibility** to a health **threat** in terms of both **perceived vulnerability** (probability of being affected by the threat) and **perceived severity** (seriousness of the threat if left unattended or no preventive action is taken) (Schwarzer *et al,* 2003). It has also been referred to as **risk awareness** (Schwarzer *et al,* 2003) and **threat–severity/vulnerability** (Schwarzer, 1992) in earlier versions of the HAPA model. In order for an individual to think about the benefits of taking action and begin to form intentions to change their health behaviours, a minimum level of threat or concern must be present (Schwarzer *et al,* 2003). Weinstein (1988) specified three stages of risk perception: 1) people are unaware of the health threat; 2) people are aware of the threat but have not accepted that it is relevant to them; and 3) people acknowledge that the health threat is personally relevant and begin to think about taking health-protective action. Other factors are then taken into consideration to determine whether or not the person decides to act. Risk perception by itself is not enough to enable the formation of intentions, but it does encourage the person to think about the consequences of taking or not taking action (outcome expectancies), and their competencies (self-efficacy) to change their behaviour (Schwarzer, 2008), which can influence the formation of intentions (Schwarzer, 1992). It works in combination with the other motivational components of the HAPA as higher risk perceptions will generally lead to the development of more positive outcome expectancies (Sutton, 2005). A range of terms will be used to search for studies including one or more of the above concepts related to risk perception and explicit mention of any of these in the design or evaluation of an intervention will be sufficient for identification of risk perception in a study.

(2c) **Intention.** Intentions relate to the **goals**, **aims** or **targets** that people set themselves, with intention formation usually considered synonymous with **goal setting** (Triandis, 1980). Intention has been regarded as the most important and direct predictor of action (Schwarzer *et al,* 2003; Sheeran *et al,* 2005). Both direction and intensity of the **motivation** towards achieving a set goal or target make up a person's intention. Intention represents a combination of the attitudes and beliefs that a person holds about the specific behaviour and the possible outcomes of performing it (Gibbons *et al,* 2000), with increasing risk perceptions, outcome expectancies, and perceived task self-efficacy as per above, influencing the development of an intention to change health-related behaviours. Intentions represent the end of the motivational phase of the HAPA (Schwarzer *et al,* 2003) and must be formed before attempts to perform the action can be made (Schwarzer, 1992). Clear behavioural intentions are considered necessary for changes in behaviour to occur (Schwarzer *et al,* 2003). Variations on the terms intention, intend and motivation will be used in searching and mention of targeting or assessing intentions will be sufficient to identify the presence of this component in a study.

(3) **Volitional components** included in the HAPA model are as follows:

(3a) **Action planning**. The simplest definition of "action planning", as provided by Leventhal et al (1965) is stating "where, when and how to act", with Van Osch *et al* (2009) agreeing that "…simply, action planning involves setting goals and planning actions to meet these goals by specifying when, where and how to act". The term "**implementation intention**" has sometimes been used interchangeably with, and seen as equivalent to, action planning (Luszczynska et al, 2007; Wiedemann et al, 2011; Gerber et al, 2010), for example, with Michie et al (2004) stating that "...action plans have been studied under a different name, that of implementation intentions". However, a quote from Pakpour et al (2011) highlights that not all agree, noting that "…action planning and implementation intentions are not the same". More specifically, implementation intentions are formulated if there is a format where an "IF" (situational cue) precedes a "THEN" (behavioural response), whereas, action plans are broader and simply define the when, where and how of a behavioural response (i.e. not necessarily in an IF-THEN manner) (Gollwitzer 1999). Sneihotta (2009) concurs by stating that not all action plans are implementation intentions. They can simply be considered a specific, constrained and often pre-specified type of action plan. In summary, for the purposes of this review, "action planning" will be identified in its broadest sense where there is some specification or assessment of how one will meet a set goal and enact a behaviour, typically in terms of the elements of what, when, where and how to act, whether or not this includes an IF-THEN element (situational cue).

(3b) **Coping planning**. Definitions of coping plans include "…internal and external barriers which are linked to strategies for the inhibition of undesired responses…" (Wiedemann et al, 2011); and anticipating strategies to **overcome barriers** and setbacks (Gerber et al, 2010). Sneihotta *et al* (2005) state that "…coping planning can help a person to overcome obstacles and to cope with difficulties by anticipating risk situations and planning coping responses in detail". They are therefore critical to **relapse prevention** and **behavioural maintenance** over the longer term. **Implementation intentions** have been used in relation to coping planning, as well as action planning as described above, with Sneihotta *et al* (2005) using the IF-THEN layout described by Pakpour et al (2011) in coping plans, for example, "IF I wanted to go running, but I am tired, THEN I won't let myself sit down but start running at once" (Sneihotta *et al*, 2005). In summary, use of plans that deal with planning regarding particular outcomes following action, i.e. after behavioural enactment, for example to overcome anticipated barriers or **solve problems** encountered will be identified as coping plans in this review (Sneihotta *et al*, 2006).

Regarding the definitions and usage of the terms “action planning”, “coping planning” and “implementation intentions”, Sneihotta (2009) states that there has been some confusion relating to the terminology applied in describing these concepts and this requires disentangling. Essentially, action plans and coping plans can have similar structures (e.g. the inclusion of an if-then component) but they have different purposes (Wiedemann et al, 2011), with action planning facilitating initial performance of a behaviour and behavioural action, and coping planning being equivalent to problem solving, that is barrier focused and based on pairing anticipated risks/problems with solution responses following initiation of a behaviour**.** A range of broad terms related to goals, plans and implementation intentions will be used in this review to identify relevant planning concepts and the difference in purpose will be used to identify each type of planning in studies.

(3c) **One or more other self-regulatory process** aimed at maintenance of behaviour change. Self-regulation is often defined as efforts by human beings involving actions, thoughts, feelings and desires to reach their goals (Vohs & Baumeister 2004). Therefore, self-regulation sees the individual as an active agent and decision maker in striving to obtain their goals. Individuals must continually evaluate their behaviour and monitor their actions to determine whether they are on track with reaching a stated goal or if further implementation of self-regulation is needed. Phrased differently, Webb et al (2010) agree that “depending on their progress, individuals can adjust their efforts to self-regulate their behaviour”. Central to all self-regulation models of behaviour is the concept of goals. A common feature of self-regulation is an interactive system of setting goals, developing strategies and techniques to deal with those goals, reviewing progress and revising those goals accordingly (de Ridder & de Wit, 2006). Self-regulatory strategies incorporating goal setting, planning, self-monitoring, reviewing progress and problem-solving aim to facilitate this process of ‘learning from experience’ (Sniehotta et al, 2006) and seem to be important in ensuring that intended behaviour changes are acted upon and maintained (Sniehotta et al, 2005). In terms of this review, a range of terms to identify self-regulation, key self-regulatory strategies and concepts related to **maintenance** of behaviour change will be used in searches, and targeting or assessment of any one or more self-regulatory process (other than action or coping planning already considered above) in the design or evaluation of an intervention will lead to this component being identified.

One area of potential overlap between the motivational and volitional components as described above, which needs careful consideration in this review in terms of making judgements about whether any particular study meets the inclusion criteria of including the required number and type of HAPA components, is in relation to the term ‘goal setting’. As specified, ‘goal setting’ (e.g. I want to lose some weight) or assessment of motivation (e.g. how strong is your goal/intention) alone is considered equivalent to forming or measuring an intention, and therefore a motivational component. Action planning, which is a volitional component, involves goal setting but in addition requires some specification of how a goal will be pursued or achieved, involving more detailed context-specific planning. It is important, therefore, to consider what would need to be included in a paper to consider something to count as action planning rather than just goal setting. After discussion amongst the review team and consultation with Prof Schwarzer as the originator of the HAPA model, it was agreed that:

1. When initially reviewing papers for inclusion/exclusion, if goal setting is undertaken or assessed in some form it will be considered to indicate the presence of a motivational OR volitional component until the paper is reviewed in more depth to decide whether the goal setting was just that, or could be considered action planning.

2. When reviewing papers in depth, efforts will be made to distinguish between goal setting and action planning (and thus whether the description of what was done indicated there being a motivational AND volitional component) using the distinctions highlighted above and definitions being developed by the Behaviour Change Technique Taxonomy project (see Appendix 1 for these and a discussion of related issues). Inclusion decisions would then be reviewed as necessary.

3. If the intervention description is so poor that this distinction cannot be made and the intervention contains no additional volitional or no additional motivational component (i.e. if goal setting would be the only volitional or motivational component), then the study will be excluded from the review.

As highlighted above, there are also some uncertainties surrounding definitions of, terminology for, and overlaps between, the volitional components of the HAPA model. This will potentially make study selection decisions related to inclusion of these components difficult. However, as highlighted below (see 'Study Selection') all uncertainties and disagreements regarding selection, particularly in situations where this is the only criterion on which a selection decision rests, will be discussed and agreed. It is anticipated that the studies identified in the review will provide a valuable source of information on terminology and definitions of action planning, coping planning, self-regulatory processes and related concepts and behaviour change techniques which will be explored as the review progresses, and in an iterative manner used to refine definitions and inclusion decisions as necessary.

As long as they incorporate the specified combination of the above components, interventions can take any format e.g. face-to-face, technology-based, self-delivered, individual or group-based, and be undertaken in any setting, with any intervention provider.

Comparator:

No exclusions will initially be made on the basis of any comparison groups or conditions to which interventions are compared, however, only controlled trials with a no intervention, minimal intervention or usual care control group will be included in any meta-analyses.

Outcomes:

Criterion 6. Included studies will report quantitative data on a **physical health outcome** or one or more on-going (i.e. not once-off) **health-related behaviour** directly associated with the prevention and/or management of a **chronic physical disease,** whether or not the behaviour is actually targeted in the context of chronic disease prevention or management. Relevant outcome data will need to be comparative, that is reported for at least two timepoints (e.g. a baseline and follow up) or at a follow up timepoint for two or more groups, or be presented in terms of a change over time or difference between groups. Examples of relevant physical health outcomes include disease or risk states (e.g. weight, blood pressure, cholesterol levels, symptoms), general health status or health-related quality of life. Relevant behaviours include physical activity, dietary behaviour, smoking, alcohol use, sunscreen use, medication adherence, and self-monitoring of symptoms/physiological states. All included studies will need to report objective or self-report measures of one or more of these outcomes.

Exclusion criteria

We will exclude studies that meet any of the following exclusion criteria:

Study type/design:

Is a conference abstract, unpublished thesis, review, discussion paper, editorial, policy article or epidemiological, cross-sectional, longitudinal observational or qualitative study that does not evaluate an intervention.

Population:

Targets children (under 16 years of age) or adults only in their role as health professionals, parents or carers responsible for the care of the population of interest, rather than as the population itself.

Intervention:

No further exclusion criteria.

Outcomes:

Reports data only for one timepoint/group, qualitative data, data on a once-off behaviour (e.g. screening attendance) or behaviour not linked to the prevention or management of chronic disease, only to infectious disease, acute illness, injury or mental illness alone (e.g. seeking treatment, wearing seatbelts, use of cycle helmets).

Search strategy

We will adopt a combination of search strategies consisting of both standard bibliographic database and other searching methods as detailed below. This mixed approach is justified and necessary as all relevant studies are unlikely to be identified using only traditional search methods because the HAPA, or relevant components applied, may not be mentioned in the fields searched such as the abstracts of papers. Instead, generic terms for behaviour-change approaches might be used to describe the design or evaluation of an intervention, particularly if the study is focusing on behavioural or health outcomes rather than psychological or cognitive indicators and processes. Professionals in the research area will also be contacted via mailing lists and targeted emails for information on relevant studies. Hand searching of reference lists from relevant publications and websites will be undertaken.

Search sources

The following bibliographic databases will be searched using Ovid software:

- Medline (life sciences and biomedical literature with a US focus)
- EMBASE (other international biomedical literature)
- PsycINFO (psychology literature).

The following bibliographic databases will be separately searched:

- CINAHL (Cumulative Index to Nursing and Allied Health Literature)
- ISI Web of Knowledge Science & Social Science Citation Indices
- SportDiscus

In addition to the above:

- References listed on the personal websites of Ralf Schwarzer and other key HAPA researchers (e.g. Sniehotta, Luszczynska, Lippke, Scholz) will be checked for relevant studies.
- Citation searching for studies citing Schwarzer's key references (e.g. 1992 book chapter, 1998 journal article) will be undertaken via the Web of Knowledge (e.g. 1998 article), PsycInfo (e.g. 1992 chapter and 1998 article), Medline and EMBASE.
- Relevant mailing lists (DHP, EHPS, UKSBM, PsyPAG) will be emailed to inquire about relevant studies.
- The reference lists of articles obtained will be handsearched to identify any further potentially relevant studies.

Search terms and limits

Complex combinations of search terms related to the review dimensions of Study type/design (i.e. intervention studies), Population, Intervention and Outcomes will be combined using Boolean operators to search electronic databases. Further limits will be placed on the search. Firstly, a language filter will be used to select only studies published in English, to expedite inclusion decisions and data extraction and because, although the originator of the model is German, most of his and his colleagues' work are anticipated to be published in English-language journals. Secondly, since the HAPA was not developed until 1992, we will limit the search to studies published from 1992 onwards.

An example search refined to balance sensitivity and specificity following a scoping exercise on Medline is shown in Appendix 2. Terms, subject headings and operators will be adapted for each database searched as necessary.

Searches will initially be conducted in late November/early December 2012 and re-run in March 2013 to ensure that recently published studies are not missed and the review is up to date as at the end of February 2013.

Study screening

Titles obtained from searches initially will be screened to exclude obviously irrelevant papers, and any papers that possibly appear to fulfil the inclusion criteria will be retained, guided by the following questions:

- Does the paper appear to report on a primary study of an intervention (i.e. not a discussion paper, secondary research or purely observational study without an intervention)?
- Does the study appear to target a relevant health-related behaviour in adults?
- Is there potential for the study to have used the HAPA model or a similar approach?

If the answer to all of the above questions on screening of titles is either 'yes' or 'unclear', the citation will be retained. If the answer to any one of the above questions is 'no' the citation will not be considered further. Emphasis will be placed on the need to be inclusive at this stage to ensure that no potentially relevant articles are missed.

All selected records from each search and their abstracts will be, where possible, downloaded directly into an EndNote reference management database specific to that search, with additional references identified entered manually as necessary. The total number of references identified and number of references downloaded from each data source will be recorded. Once this has been done the databases containing references from each of the data sources will be combined, overlapping references noted and duplicates removed for final study selection and the total unique number of references obtained from each of the data sources searched will be documented (to allow construction of a flow chart as per PRISMA guidelines, http://www.prisma-statement.org/).

Study selection

Examining abstracts of studies identified from searches, one reviewer (KB or NM) will decide whether a study retained from the search is excluded or initially included for full text review on the basis of the above inclusion/exclusion criteria. The flowchart in Appendix 3 outlines how the study selection criteria will be applied. A sub-sample and abstracts for any excluded studies will be assessed independently by a second reviewer (KB or NM). An electronic study selection checklist comprising an Excel spreadsheet in which the references of all studies identified as potentially relevant from searches will be listed with columns alongside for each of the selection criteria will be used to document decisions and record any queries or notes (see Appendix 4). Full texts of all studies selected for initial inclusion by either reviewer, or over which there are uncertainties will be obtained and will be further reviewed independently by two reviewers (out of KB, NM, JS) to confirm eligibility. Reference to a third reviewer will be sought if there are uncertainties or disagreements regarding selection, and the final decisions will be discussed and agreed. Only studies that clearly meet all of the inclusion criteria and none of the exclusion criteria will ultimately be included in the review.

References for included studies will be tagged in the EndNote database to indicate its status in the review, for example excluded, unclear, included. The number of studies retained, and excluded/included by each researcher at the stages of study screening, reviewing abstracts and reviewing full text will be documented for inclusion in a PRISMA flowchart (http://www.prisma-statement.org/) and levels of agreement (kappa) will be calculated and reported.

Multiple publications of the same data

The sources for each study will be carefully checked to match up multiple reports of the same data and/or intervention. Papers that describe relevant interventions but report no outcome data (including study protocols) will be retrieved to supplement information in any linked reports found on evaluations of these interventions and all linked publications will be used during data extraction and study quality assessment.

Study categorisation and prioritisation

Two reviewers (out of KB, NM, JS) will initially independently categorise included studies, alongside assessment for inclusion where possible, along the following dimensions:

1. Whether they explicitly mention the HAPA model (labelled "HAPA") or do not mention the HAPA model but otherwise meet the inclusion criteria by including multiple HAPA components as specified above (labelled "HAPA-like").

2. Whether they used the HAPA model or its components in: (1) designing or delivering the intervention alone (labelled "intervention"), (2) in the evaluation of the intervention alone (labelled "evaluation"), or (3) in designing/delivering AND evaluating the intervention (labelled "intervention + evaluation"). HAPA components included in the design/delivery and evaluation in each study will also be recorded.

3. According to study design, that is whether they are a (1) "before-after study" (i.e. no control group), (2) "controlled observational study" (i.e. using a naturally occurring control group), (3) "controlled trial" (i.e. allocating participants to groups in a non-random way), (4) "randomised controlled trial" (i.e. allocating participants to groups randomly). The nature of any control group(s) will also be documented (i.e. no treatment, usual care, information-only, other psychologically-based intervention, other active intervention).

4. According to the behaviour(s), physical health outcome(s) and any disease(s) targeted.

Relevant details on the above will be recorded for each study in a spreadsheet designed for this purpose (see Appendix 5). Where there are uncertainties or disagreements regarding categorisation, advice will be sought from a third reviewer and a consensus sought. Agreement between reviewers regarding the categorisation of studies will be assessed and a kappa score calculated.

The categorisation will allow a broad assessment to be made by the review team, prior to detailed data extraction and viewing of results, regarding the quantity, nature and broad quality (in terms of study design) of evidence available. The volume of studies in each category and the number of times each HAPA component is included in studies will be described to address review question 1.

This information can also potentially be used to prioritise and possibly limit extraction of data to the most relevant and highest quality studies if a large number of eligible studies (e.g. >50) are identified. For example, further selection of studies may be undertaken on the basis of: (1) their use of HAPA and HAPA components in designing/delivering interventions only (rather than in evaluations alone), (2) study design (i.e. to select only controlled studies), and/or (3) the outcomes targeted, to select only those behaviours/health outcomes which are most relevant to our related research (e.g. physical activity and diet) or for which there are a sufficient number of studies to allow meaningful synthesis of results. The

classifications will also be used to divide up the subsequent data extraction and synthesis work between reviewers (KB and NM).

Data extraction

Descriptive data extraction

Descriptive data will be systematically extracted from each of the included studies using a data extraction template. Data will be extracted by one of the researchers (KB or NM) and checked by the other. The template will include:

- General study characteristics (publication year, country, setting, aims)
- Participant characteristics (number, age, gender, any disease diagnosis, risk status or other inclusion criteria)
- Details of intervention(s) and any control groups, including:
    - Provider(s) and relevant characteristics (e.g. additional training received, gender)
    - Setting (e.g. hospital, workplace, home)
    - Number, duration and frequency of sessions, plus total duration
    - Format (individual, group)
    - Delivery (face-to-face, web-based etc)
    - Number and type of HAPA components included (to check details from study categorisation as above)
    - Nature and frequency of behaviour change techniques used and their mapping to HAPA components
    - "Quality"/extent of HAPA application (see below for assessment methods)
    - Whether intervention fidelity was checked

  For further details on relevant intervention characteristics to be extracted see WIDER recommendations (Michie et al, 2009)
- Health and behaviour change outcomes reported and details of outcome measures used
- HAPA component outcomes reported and details of measures used to assess these
- Other outcomes reported
- Follow up timepoints, divided into short, medium and long-term (definitions to be confirmed as per discussion in 'Aims, review questions and scope' section)
- Study findings as reported in relation to changes in health outcomes, behaviours, and HAPA components, including significance values and an indication of whether sufficient outcome data is reported for potential quantitative synthesis (e.g. n/N for binary outcomes, point estimate and variability for continuous outcomes)
- Study design and comparison group (if any) (to supplement details from study categorisation as above)
- Study quality characteristics as per checklist (see below)

In terms of the intervention, to further describe the nature of the research in this area, a 19-item coding scheme devised by Michie and Prestwich (2010) to examine the extent to which interventions are theory-based will be examined to determine whether this can be applied to assess the "quality" of the application of the HAPA model and its components (i.e. number and extent components applied, whether additional components are considered). To address review question 2, as a further descriptive exercise, the most

recent version of the taxonomy of behaviour change techniques devised by Abraham and Michie (2008) will be applied (see http://www.ucl.ac.uk/health-psychology/BCTtaxonomy/), and an assessment of the links between these techniques and the HAPA components as per Michie et al (2008) will be conducted.

Studies for which data are missing will be included in the review as far as possible.

Extracted data will initially be summarised in separate tables describing (1) General study and participant characteristics, (2) various aspects of interventions, (3) outcomes, measures, timepoints and description of reported results, (4) study design and quality characteristics.

Study quality/validity assessment

The Cochrane Handbook specifies a preference for the assessment of risk of bias rather than an assessment of methodological quality. Therefore, a checklist incorporating the *Cochrane Collaboration's tool for assessing risk of bias* and a tool used in a previous review including a range of study designs (Smith et al, 2007) (see Appendix 6) will be developed and applied by one reviewer to included studies selected for full data extraction, and checked by a second reviewer. The Cochrane tool addresses the six domains of sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and 'other issues'. It is divided into two parts of which the first involves describing what the study reported to have happened. The second part requires the researcher to answer a pre-specified question about the adequacy of the study and make a judgment of the overall risk of bias (Higgins & Green, 2008). The checklist used in the previous review (Smith et al, 2007) covers additional issues related to internal validity (randomisation/selection of comparators, allocation, blinding of outcome assessors), external validity (inclusion/exclusion criteria stated, participation rate, sample size and retention, comparability of non-participants and withdrawals, intention-to-treat analysis), quality of reporting (analyses, appropriate data), and other issues (primary outcome and endpoint specified, power calculation, baseline comparability).

Any disagreements between the data extractors will again be referred to the third reviewer to make a decision on the risk of bias of the study or studies in question.

Outcome data extraction

If, on the basis of study categorisations and review of the outcomes reported, there appear to be a sufficient number of similar good quality studies reporting adequate data on similar outcomes, numerical outcome data will be extracted from these to allow quantitative synthesis (meta-analysis) of findings regarding our primary health or behavioural outcomes (see below). Where possible, data on health outcomes and behaviour change in the short-term, and longer-term and in relation to maintenance of change from one timepoint to another (definitions to be confirmed as per discussion in 'Aims, review questions and scope' section), will be extracted.

Data Synthesis

Descriptive data synthesis

Descriptive data on participants, interventions, study quality and study findings will be tabulated and summarised in an accompanying narrative review and using descriptive statistics where appropriate. This will describe the extent and nature of the research in different categories, how the HAPA model and HAPA components have been used in these studies (review question 1), and the behaviour change techniques applied in interventions (review question 2). It will also describe findings regarding the effectiveness of interventions across different studies (review question 3), at different timepoints (questions 3a-c) and for different interventions (3d), comparisons, participant groups, and considering different outcomes (health outcomes and behaviours). Further effects of clinical and methodological diversity on the patterns of results and variations amongst them will also be described where possible. In interpreting findings and drawing conclusions from this descriptive synthesis, weight will be given to the better designed studies, with lowest risk of bias that are most relevant to addressing the review questions about effectiveness.

Quantitative data synthesis (Meta-analyses)

The appropriateness of undertaking quantitative data synthesis (meta-analysis) will be assessed by the review team based on tabular summaries of study characteristics. This will determine whether it is appropriate, and practical, to pool studies on the basis that they appear to be sufficiently similar in terms of participants, interventions, comparisons, outcomes and study designs, or large enough in number to divide into pre-specified subgroups given variations in the outcomes assessed and comparisons made. Only data extracted from higher quality studies would be included in a meta-analysis with a focus on randomised controlled trials. The number of these studies included in the review and their similarity is thus also likely to influence the decision over whether a meta-analysis is conducted. Meta-analysis for selected outcomes (e.g. weight loss, health-related behaviours) will be performed if there are sufficient data. Effectiveness results will be summarised via Forest plots showing individual study results and confidence intervals along with a weighted average and confidence intervals across studies. Standardised mean differences will most likely be presented for continuous data reflecting changes over time or group differences at an endpoint and relative risks or odds ratios for binary data (displayed as log RR, OR). Consideration will be given by the review team to the relative benefits of the different methods used to calculate and pool weights for studies (e.g. generic inverse variance method to maximise the type of data and study designs that can be pooled).The relative merits of RevMan or other meta-analytic software (e.g. STATA) to conduct analyses will also be investigated.

Care will be taken to include only one outcome per participant per meta-analysis if multiple timepoints and outcomes are reported in studies, so that individual studies are not given undue weight in any single analysis. Where studies report multiple outcomes (e.g. different behaviours) and timepoints, consideration will be given to the various options for handling multiplicity, such as conducting a separate meta-analysis for each timepoint and outcome, choosing the last available timepoint, picking one primary outcome, and discarding timepoints or outcomes. Special attention will also be given to any crossover and cluster RCTs where unit of analysis errors are common.

Observation of the Forest plot and statistical tests of heterogeneity will be used to assess the extent of variability in the study results (effect sizes) and, in the case of statistical tests, whether this statistical heterogeneity is greater than that expected by chance. If there is large statistical heterogeneity, particularly if the results are varying both directions (i.e. qualitatively different), a meta-analysis may be considered inappropriate. Alternatively a random effects meta-analysis will be conducted and factors documented

during data extraction (e.g. study design, participant characteristics, nature and quality of interventions) influencing statistical and clinical heterogeneity in the results will, depending on study numbers, be explored with subgroup analysis (separate pooling of different studies), meta-regression or sensitivity analyses. Specifically, as per review question 3, where possible the pre-specified effects of differences in the nature and quality of the intervention (3d) and authorship of studies (3e) will be examined. Further analyses of factors influencing effectiveness will be considered exploratory and hypothesis generating. In conducting them, consideration will be given to whether the differences identified between studies are: clinically important, statistically significant, hypothesised, limited in the number investigated, within or between studies, consistent across studies and supported by indirect evidence.

Publication bias

If there are a sufficiently large number of studies (i.e. greater than 10) of varying sizes included in a meta-analysis a funnel plot will be produced to examine the potential for publication bias and the likely impact of this on any meta-analytic results.

Assessment of threats to validity

The findings of this systematic review are dependent on the quality of the included studies. It is unlikely that we will find enough randomised controlled trials of relevant interventions to limit assessment to these, and therefore other intervention studies of lower quality will likely be included. We will also include studies covering a variety of health outcomes and behaviours and using different types of intervention, introducing additional heterogeneity which may limit the scope for meaningful meta-analyses to be conducted. The quality of the application of the HAPA model to the development or evaluation of interventions is likely to threaten the validity of the review, for example some studies may use the whole model and others might only use certain components, whereas other studies could use a modified version of the HAPA. This along with the studies' reporting of the techniques used to measure the components may make it difficult to accurately assess the contribution of the model to behaviour change. The recruitment and drop-out rates of studies may also threaten the validity of the findings, as will the quality of the studies' reporting of methods and results, however, these will be documented and explored in terms of their effects on findings where possible.

Reporting

Write up of this review will be based on the PRISMA checklist, and further guidance on reviews of behaviour change interventions and complex interventions (CRD, 2008). Individual write-ups by NM and KB will focus on specific aspects relevant to their PhDs, for PhD transfer panels and other purposes (e.g. NM's Stage 2 Health Psychology training). The target audience for this systematic review is public health and health psychology researchers and practitioners. We plan to publish the completed systematic review in a

relevant health psychology journal (e.g. Health Psychology, Psychology & Health, Health Psychology Review).

Timeline

Protocol: First draft of combined version by early October 2012.

Initial literature searching: November - December 2012.

Initial study selection and retrieval of full texts: December 2012 - January 2013.

Pilot final study selection and categorisation: February - March 2013

Update searches to end February 2013: March 2013

Finalise protocol, complete study selection and initial categorisation: April - May 2013.

Finalise data extraction and study quality assessment templates: June 2013

Data extraction: June - July 2013.

Data synthesis and analysis: July - August 2013

Individual write up for PhD theses: August - September 2013

Draft full paper of main findings: September - October 2013

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Appendix 1 - Definitions of goal setting, action planning and coping planning (= problem solving) behaviour change techniques from the Behaviour Change Technique Taxonomy Project (http://www.ucl.ac.uk/health-psychology/BCTtaxonomy/) **Dec 2012**

Behaviour Change Technique	**Definition**	**Examples**
Goal setting (behaviour)	Set or agree a goal defined in terms of the behaviour to be achieved *Note: only code guidelines if set as a goal in an intervention context; if goal unspecified or a behavioural outcome,* *code **Goal setting (outcome)**; if the goal defines a specific context, frequency, duration or intensity for the behaviour, also code **Action planning***	Invite the person to propose a daily walking goal (e.g. to walk for at least 30 minutes every day) and reach agreement about the goal Set the goal of eating 5 pieces of fruit per day as specified in public health guidelines
Goal setting (outcome)	Set or agree a goal defined in terms of a positive **outcome** of wanted behaviour *Note: only code guidelines if set as a goal in an intervention context; if goal is a behaviour, code **Goal setting (behaviour)**; if goal unspecified code **Goal setting (outcome)***	Invite the person to set a weight loss goal (e.g. 0.5 kilogram over one week) as an outcome of changed eating patterns
Action planning	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 *'**Implementation Intentions**'*) *Note: evidence of action planning does not necessarily imply goal setting, only code latter if sufficient evidence*	Following prompting, plan to carry condoms when going out socially at weekends Plan the performance of a particular physical activity (e.g. running) at a particular time (e.g. before work) on certain days of the week
Problem solving	Analyse factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators (includes '***Relapse Prevention***' *and* '***Coping Planning***') *Note: barrier identification without solutions is not sufficient. If the BCT does not include analysing the behavioural problem, consider **Avoidance/changing exposure to cues for the behaviour, Restructuring the physical environment, Restructuring the social environment,** or **Reduce negative emotions***	Identify specific triggers (e.g. being in a pub, feeling anxious) that generate the urge/want/need to drink and develop strategies for avoiding environmental triggers or for managing negative emotions, such as anxiety, that motivate drinking

During recent training on using the taxonomy, there was debate about what counted as "context, frequency, duration and intensity" in terms of the action planning definition, and a general feeling that this was rather loose e.g. if someone specifies that they are going to exercise daily for a month, does the goal

incorporate information about frequency, and therefore count as action planning? There was a suggestion that the definition should be tightened to require inclusion of more than one of these details.

Related to the above, some of the examples for goal setting in the table could be argued to meet the definition for action planning (e.g. specifying frequency, duration), so the distinction is not clear! Is there some contradiction between the “also code action planning” statement under goal setting, and “note: evidence of action planning does not necessarily imply goal setting” under action planning. Can you have an action plan without setting a goal?!

There appears to be scope for these definitions to be tightened/improved, particularly in the context of this review/the HAPA model in terms of using them to make distinctions about the presence of motivational and volitional processes. The papers from the review could provide a source of information to describe and develop these issues related to definitions. It is hoped that one of the PhD students involved (Nikki Murray) who is looking at action planning in her thesis can explore these further.

Appendix 2 – Example Medline search (on OvidSP)

CATEGORY	NO.	TERM/SUBJECT HEADING	HITS	NOTES
Study design terms	1.	exp Intervention Studies/	5687	
	2.	exp Clinical Trial/	705846	
	3.	exp Clinical Trials as Topic/	264111	
	4.	exp Evaluation Studies/	175492	
	5.	exp Evaluation Studies as Topic/	946939	
	6.	exp Longitudinal Studies/	804371	
	7.	(pretest adj posttest).mp	1455	
	8.	(pre-test adj post-test).mp	436	
	9.	(before adj3 after).mp.	199129	
	10.	(repeated adj measure$).mp.	23371	
	11.	(random$ adj3 trial).mp.	368668	
	12.	(control$ adj3 trial).mp.	443725	
	13.	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12	2397141	
~~**Population terms**~~		~~Adult/~~		
		~~exp Young Adult/~~		
		~~exp Adolescent/~~		
		~~adult?.mp.~~		
		~~adolescen$.mp.~~		
		~~student?.mp.~~		
		~~male?.mp.~~		
		~~female?.mp.~~		
		~~men.mp.~~		
		~~women.mp.~~		
		~~14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23~~		
Intervention terms - general	14.	intervention?.mp.	460577	
	15.	program$.mp.	600232	
	16.	initiative.mp.	22083	
	17.	strategy.mp.	226687	
	18.	education.mp.	521854	
	19.	rehabilitation	108095	
	20.	Exp rehabilitation/	142154	
	21.	14 or 15 or 16 or 17 or 18 or 19 or 20	1716008	
- HAPA related	22.	"health action process approach".mp.	31	
	23.	HAPA.mp.	126	
	24.	Schwarzer.mp.	47	
	25.	22 or 23 or 24	179	
- self-efficacy components	26.	(self adj efficac$).mp.	16272	
	27.	confiden$.mp.	270938	
	28.	Mastery.mp	3394	
	29.	(control adj3 belie$).mp.	1667	
	30.	(control adj3 perceiv$).mp.	3050	
	31.	(control adj3 perception?).mp.	1656	
	32.	(competenc$ adj3 belie$).mp.	109	
	33.	(competence$ adj3 perceiv$).mp.	1169	
	34.	(competence$ adj3 perception?).mp	469	
	35.	(capab$ adj3 belie$).mp	125	
	36.	(capab$ adj3 perceiv$).mp	137	
	37.	(capab$ adj3 perception?).mp	89	

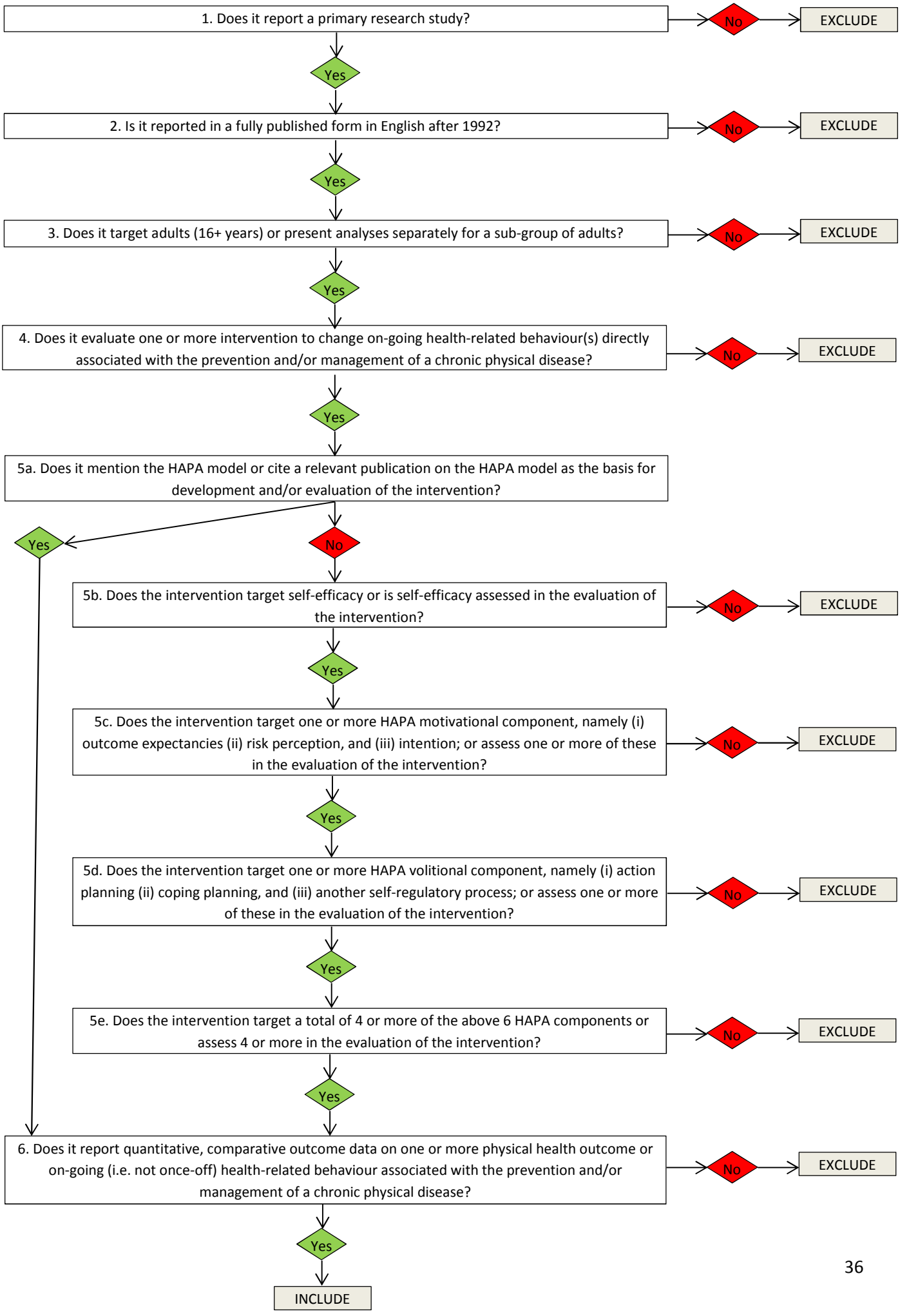
	38.	26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37	294814	
- motivational components	39.	intention$.mp.	44878	
	40.	intend$.mp.	46803	
	41.	motivat$.mp.	94773	
	42.	(outcome? adj3 expect$).mp.	4685	
	43.	(Pros adj3 cons).mp	3871	
	44.	(Benefit$ adj3 cost$).mp	64844	
	45.	(advantage£ adj3 disadvantage$).mp	15519	
	46.	(consequence$ adj3 belie$).mp	243	
	47.	(consequence$ adj3 perceiv$).mp	412	
	48.	(consequence$ adj3 perception$)	195	
	49.	(outcome$ adj3 belie$).mp	598	
	50.	(outcome$ adj3 perceiv$).mp	948	
	51.	(outcome$ adj3 perception$).mp	850	
	52.	(risk? adj3 belie$).mp.	973	
	53.	(risk? adj3 perceiv$).mp.	4054	
	54.	(risk? adj3 perception?).mp.	4393	
	55.	(risk? adj3 aware$).mp.	3274	
	56.	(threat? adj3 belie$).mp.	68	
	57.	(threat? adj3 perceiv$).mp.	832	
	58.	(threat? adj3 perception?).mp.	315	
	59.	(threat? adj3 aware$).mp.	106	
	60.	(vulnerab$ adj3 belie$).mp.	72	
	61.	(vulnerab$ adj3 perceiv$).mp.	359	
	62.	(vulnerab$ adj3 perception?).mp.	205	
	63.	(vulnerab$ adj3 aware$).mp.	64	
	64.	(susceptib$ adj3 belie$).mp.	156	
	65.	(susceptib$ adj3 perceiv$).mp.	601	
	66.	(susceptib$ adj3 perception?).mp.	146	
	67.	(susceptib$ adj3 aware$).mp.	54	
	68.	(severity adj3 belie$).mp.	154	
	69.	(severity adj3 perceiv$).mp.	1008	
	70.	(severity adj3 perception?).mp.	491	
	71.	(severity adj3 aware$).mp.	86	
	72.	39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71	281585	
- volitional components	73.	volition$.mp.	4784	
	74.	action.mp.	569610	
	75.	enaction.mp.	11	
	76.	goal$.mp.	183642	
	77.	plan.mp.	69000	
	78.	plans.mp.	55556	
	79.	planning.mp.	214161	
	80.	maintenance.mp.	197892	
	81.	maintain$.mp.	391806	
	82.	(relapse? adj prevent$).mp.	1878	
	83.	(relapse? adj manag$).mp	40	
	84.	(implement$ adj3 intend$).mp	168	
	85.	(implement$ adj3 intention$).mp.	253	

	86.	(self adj regulat$).mp.	5525	
	87.	(self adj monitor$).mp.	6961	
	88.	(self adj control$).mp.	3535	
	89.	(self adj reinforce$).mp.	430	
	90.	(progress adj evaluat$).mp	62	
	91.	(progress adj review$).mp.	105	
	92.	(problem$ adj3 solv$).mp	44320	
	93.	(problem$ adj3 solution$).mp	10121	
	94.	(autonom$ adj regulat$).mp.	1627	
	95.	feedback.mp.	88919	
	96.	(impulse? adj control$).mp.	3053	
	97.	(learn$ adj3 experien$).mp	6834	
	98.	73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97	1681804	
- combined components	99.	25 or (38 and 72 and 98)	4211	
~~**Outcome terms (behaviours)**~~		~~exp Drinking Behavior/~~		
		~~exp Alcoholism/~~		
		~~exp Alcoholic Intoxication/~~		
		~~exp Drug-Seeking Behavior/~~		
		~~exp Smoking/~~		
		~~exp Smoking Cessation/~~		
		~~exp "Tobacco Use Cessation"/~~		
		~~exp Food Habits/~~		
		~~exp Food Preferences/~~		
		~~exp Diet/~~		
		~~exp Eating/~~		
		~~exp Overweight/~~		
		~~exp Obesity/~~		
		~~exp Exercise/~~		
		~~exp Health Behavior/~~		
		~~exp Illness Behavior/~~		
		~~exp risk reduction behavior/~~		
		~~exp Self Care/~~		
		~~behavio?r$.mp.~~		
		~~alcohol$.mp.~~		
		~~drink$.mp.~~		
		~~smok$.mp.~~		
		~~tobacco.mp.~~		
		~~diet$.mp.~~		
		~~eat$.mp.~~		
		~~nutrition$.mp.~~		
		~~food.mp.~~		
		~~(energy adj intake).mp.~~		
		~~(energy adj expenditure?).mp.~~		
		~~weight.mp.~~		
		~~overweight.mp.~~		
		~~obes$.mp.~~		
		~~exercis$.mp.~~		
		~~(physical$ adj activ$).mp.~~		

		~~inactiv$.mp.~~		
		~~fitness.mp.~~		
		~~adhere$.mp.~~		
		~~complian$.mp.~~		
		~~comply.mp.~~		
		~~(self adj manag$).mp.~~		
		~~(self adj care).mp.~~		
		~~lifestyle.mp.~~		
		~~(life adj style).mp.~~		
		~~90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123 or 124 or 125 or 126 or 127 or 128 or 129 or 130 or 131 or 132~~		
All PICO terms combined	100.	13 and 21 and 99	1214	
With limits	101.	Limit 134 to (english language and yr="1992 -Current")	1133	

NB: Population and outcome terms were excluded after scoping searches to increase sensitivity but are shown for completeness here

Appendix 3 – Flowchart outlining application of inclusion/exclusion criteria



Appendix 4 - Study selection checklist

Selection criteria

1 Does the reference report a **primary research** study (i.e. not a review, discussion paper, editorial)?

2 Is the study reported in a **fully published** form in **English** after 1992 (i.e. not a conference abstract, thesis, foreign language publication)?

3 Does the study target **adults** aged 16 years or over (not solely in their role as parents/carers) or present analyses separately for a sub-group of adults within a mixed age sample?

4 Does the study evaluate **an intervention to change on-going health-related behaviour(s)** associated with the **prevention and/or management of a chronic physical disease**?

5 Does the study report use of the **HAPA model OR** include **self-efficacy plus 4 out of 6 HAPA components** (at least 1 motivational and 1 volitional[1]) in the design/delivery and/or evaluation[2] of the intervention?

6 Does the study report **comparative** (i.e. across 2+ groups or timepoints) **quantitative outcomes for a relevant health outcome or behaviour**?

NOTES ***1 MOTIVATIONAL COMPONENTS*** *Risk Perception; Outcome Expectancies, Intention* ***VOLITIONAL COMPONENTS*** *Action Planning; Coping planning; Self Regulation* ***AND SELF-EFFICACY***

2 THE 4+ COMPONENTS PLUS SELF-EFFICACY MUST ALL BE MENTIONED IN THE CONTEXT OF DESIGN OR EVALUATION OF THE INTERVENTION (OR BOTH) AND NOT SPLIT ACROSS THE TWO I.E IF 2 ARE LINKED TO DESIGN ONLY, AND 2 EVALUATION ONLY, THIS WOULD NOT BE SUFFICIENT FOR INCLUSION

REFER TO PROTOCOL FOR FULL DEFINITIONS AND TERMS RELATED TO HAPA COMPONENTS

Indicate Y (Yes), N (No) or U (Unclear) in response to questions 1-6.

If ALL questions answered Y: Decision = I (Include)

If ANY questions answerd N: Decision = E (Exclude)

If ANY questions answered U: Decision = U (Unclear)

Reviewer Initials

Study ID	Author	Year	Other ID	1	2	3	4	5	6	*Reviewer* Decision	*Reviewer Notes*	etc	AGREED Y / N	FOR INCLUSION
												etc		

Appendix 5 - Draft study categorisation form

				USE OF HAPA & COMPONENTS				
				Use of HAPA in intervention			Model	Self efficacy
				Design	Evaluation	Design + evaluation	referenced	check
Include	Study ID	Author	Year	0 = No, 1 = Yes	0 = No, 1 = Yes	1 = No, 2 = Yes (autofilled)	0 = No, 1 = Yes	1 = yes (if no exclude)

continues below

USE OF HAPA & COMPONENTS								
Motivational components				Volitional components				Total HAPA components
Outcome expectancies	Risk perception	Intention	Total motivational 1-3	Action planning	Coping planning	Self regulation	Total volitional 1-3	0-6
0 = No, 1 = Yes	0 = No, 1 = Yes	0 = No, 1 = Yes	(exclude if 0 & no HAPA ref)	0 = No, 1 = Yes	0 = No, 1 = Yes	0 = No, 1 = Yes	(exclude if 0 & no HAPA ref)	(exclude if <4 & no HAPA ref)

continues below

STUDY DESIGN					
Study type		Control treatment		Latest follow up	
1=RCT, 2=CCT, 3=COS, 4= B4 after, 5=other	Details if other (free text)	0=No int, 1=usual care, 2=Info only/minimal 3=Other psych-based, 4=other active, 5=other	Details if other (free text)	Number 1-52	Unit w=weeks, m=months, y=years

continues below

STUDY AIMS				PARTICIPANT CHARACTERISTICS					
Aim of intervention			Disease(s) or risk factor(s) targeted	Health status			Age		
Prevention	Management	Other		Healthy	At-risk	Chronic disease	Young (16-29)	Adults (30-65)	Elderly (>65)
0 = No, 1 = Yes	0 = No, 1 = Yes	Specify (free text)	Specify (free text)	0 = No, 1 = Yes	0 = No, 1 = Yes	0 = No, 1 = Yes	0 = No, 1 = Yes	0 = No, 1 = Yes	0 = No, 1 = Yes

continues below

BEHAVIOUR(S) TARGETED Indicate all that apply								
Diet	Physical activity	Smoking	Alcohol	Illicit drug	Med adherence	Self-monitoring	Other	Notes
0 = No, 1 = Yes	0 = No, 1 = Yes	0 = No, 1 = Yes	0 = No, 1 = Yes	0 = No, 1 = Yes	0 = No, 1 = Yes	0 = No, 1 = Yes	Specify (free text)	Free text

Appendix 6 – Draft study quality/validity assessment items

(a) The following is taken from Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* version 5.0.0 (updated February 2008).

Table 1. The Cochrane Collaboration's tool for assessing risk of bias

Domain	Description	Review authors' judgement
Sequence generation.	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Was the allocation sequence adequately generated?
Allocation concealment.	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	Was allocation adequately concealed?
Blinding of participants, personnel and outcome assessors *Assessments should be made for each main outcome (or class of outcomes).*	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Was knowledge of the allocated intervention adequately prevented during the study?
Incomplete outcome data *Assessments should be made for each main outcome (or class of outcomes).*	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Were incomplete outcome data adequately addressed?
Selective outcome reporting.	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Are reports of the study free of suggestion of selective outcome reporting?
Other sources of bias.	State any important concerns about bias not addressed in the other domains in the tool.	Was the study apparently free of other problems that could put it at a high risk of bias?

Domain	Description	Review authors' judgement
	If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry.	

Source: Higgins & Green (2008)

(b) The following list of methodological and reporting quality characteristics was taken from Smith et al (2007), a systematic review which incorporated various study designs and involved review of complex interventions and samples (psycho-educational interventions in severe/difficult asthma).

Randomisation/selection of comparison group (as appropriate)

i) Method for randomisation/selection of comparison group? *To state/Not stated*
ii) Concealed allocation of randomisation sequence? *Yes/No/Not stated/Not applicable*
iii) Concealment method? *To state/Not stated/Not applicable*

Outcome assessment

iv) Blinded outcome assessment? *Yes/No/Not stated*
v) Single primary outcome specified/reported? *Yes/No*
vi) Single primary endpoint specified/reported? *Yes/No*

Study sample and attrition

vii) Total sample size? *To state/Unclear*
viii) Clear selection criteria described? *Yes/No*
ix) Power calculation conducted/reported? *Yes/No*
x) Participation rate? *%/Not stated*
xi) Comparability of non-participants checked/reported? *Yes/No + Note any differences*
xii) Baseline comparability of groups checked/reported? *Yes/No + Note any differences*
xiii) Minimum follow-up? *%/Not stated*
xiv) Comparability of withdrawals checked/reported? *Yes/No + Note any differences*

Analysis and reporting of results

xv) Provided details of analysis? *Yes/No*
xvi) Specified ITT analysis? *Yes/No*
xvii) Adequate outcome reporting (numerator and denominator for binary outcomes, point estimates plus measures of variability for continuous data)? *Yes/No*