

A causal modelling approach to the development of theory-based behaviour change programmes for trial evaluation

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Abstract

Theory-based intervention programmes to support health-related behaviour change aim to increase health impact and improve understanding of mechanisms of behaviour change. However, the science of intervention development remains at an early stage. We present a causal modelling approach to developing complex interventions for evaluation in randomized trials. In this approach a generic model links behavioural determinants, causally through behaviour, to physiological and biochemical variables, and health outcomes. It is tailored to context, target population, behaviours and health outcomes. The development of a specific causal model based on theory and evidence is illustrated by the *ProActive* programme, supporting increased physical activity among individuals at risk of Type 2 diabetes. The model provides a rational guide to appropriate measures, intervention points and intervention techniques, and can be tested quantitatively. Causal modelling is critically compared to other approaches to intervention development and evaluation, and research directions are indicated.

Introduction

Interventions supporting changes in health-related behaviours can contribute significantly to preventing a range of common chronic conditions, such as cardiovascular disease, Type 2 diabetes and some cancers. However, the science of intervention development and evaluation remains at an early stage (Ory *et al.*, 2002). Interventions may be carefully developed, but weakly evaluated, or elegant trial designs used to evaluate poorly specified interventions. This highlights the need to link intervention development with evaluation and design issues during early phases of intervention development. This linkage is particularly important when the intervention is complex, as in most behaviour change programmes.

Complex interventions are those that consist of a number of components that may act both independently and inter-dependently (Medical Research Council, 2000). A framework for the development and evaluation of complex interventions has recently been developed by the UK Medical Research Council (MRC) (Campbell *et al.*, 2000; Medical Research Council, 2000), and emphasizes the importance of the early phases of developing the intervention, measures and trial design (Table I). Details of how to achieve phase 1 (review of theory and evidence) and phase 2 (modelling) of the framework are lacking. This paper presents a causal modelling approach to the development of theory-based interventions for randomized controlled trial evaluation, focusing on the first two phases. We use the term ‘causal modelling’ to mean the development of a specific causal model to guide the design of a programme to support behaviour change for

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Table I. Framework for the development and evaluation of complex interventions [adapted from (Campbell et al., 2000; Medical Research Council, 2000)]

Phases	Methods
1. Pre-clinical/theoretical	Review relevant theory and evidence to ensure (i) best choice of intervention, and (ii) predict major confounders and strategic design issues
2. Modelling	Identify (i) intervention components, and (ii) how intervention components interrelate and relate to surrogate or final health outcomes
3(a) Operationalization	Describe components of a replicable intervention
3(b) Piloting exploratory trials ^a	Describe a feasible trial protocol for comparing the intervention to an appropriate alternative
4. Definitive randomized controlled trial	Compare a fully defined theory-based intervention to an appropriate alternative, using a protocol that is reproducible and adequately controlled in a study with appropriate statistical power
5. Long-term implementation and monitoring	Determine whether the intervention and results can be reliably replicated in uncontrolled settings over the long term

^aOperationalization of the intervention may occur within a pilot randomized trial or within a feasibility study of the intervention before the pilot trial.

trial evaluation. The specific causal model can then be populated with data from the trial or from other relevant studies, and tested quantitatively. This paper describes the development and application of a specific causal model.

A range of approaches to intervention development and evaluation have been described from public health and social science perspectives. They employ mapping techniques of various kinds to guide intervention development, including logic models (Conrad *et al.*, 1999), and matrices for objectives, intervention methods and strategies (Bartholomew *et al.*, 2001). Causal models that span behavioural determinants, behaviours, health outcomes and their correlates may complement these approaches.

A comprehensive causal modelling approach starts with a simple generic model (Table II) linking behavioural and disease determinants in a causal pathway. It contains four levels: behavioural determinants, behaviour, physiological and biochemical variables, and health outcomes.

The generic model is further specified for each application. Appropriate intervention and measurement points and behaviour change techniques are indicated in one graphical representation. The specific model is tailored to characteristics of the target population, social context, target behaviour and health or disease outcomes. Theory and evi-

dence are used to guide the selection of behavioural determinants, intervention and measurement points, and behaviour change techniques. However, existing intervention studies rarely justify the theory selected and we therefore formulated criteria to inform this important step.

The approach is illustrated by a case study of the primary-care-based *ProActive* programme, aimed at increasing physical activity among individuals at high risk of Type 2 diabetes and currently under trial in Cambridgeshire, UK (Williams *et al.*, 2004). The questions posed in developing the programme were: what intervention techniques might be most effective in supporting increases in physical activity and how could their efficacy be tested?

Methods

Development of the *ProActive* model drew iteratively on epidemiology and psychology. The methods used in developing the causal model are summarized in Table III.

Contribution of epidemiology

Epidemiology informed the causal model from behaviour to health outcome in four ways:

Table II. *Generic causal model*

Level	
1	Behavioural determinants (e.g. psychological, social, geographical) ↓
2	Behaviour ↓
3	Physiological and biochemical variables ↓
4	Health outcomes (health and quality of life)

- (1) Defining the health outcome (Type 2 diabetes), its importance and its predictors.
- (2) Defining the target group.
- (3) Identification of the target behaviour and the likely impact of achievable behaviour change on physiological and biochemical variables, and health outcome.
- (4) Development and validation of precise objective measures of the target behaviour.

The main method used to inform the causal model was a review of epidemiological evidence.

Contribution of psychology

Psychology informed the causal model from behavioural determinants to behaviour, and contributed in four ways:

- (1) Defining theory-based behavioural determinants.
- (2) Defining intervention points.
- (3) Defining techniques to support behaviour change.
- (4) Developing measures of change in behavioural determinants.

A range of methods was used, which are outlined below.

Defining theory-based behavioural determinants

- *Expert meetings.* At the first of two expert meetings the project team (authors), psychologists, a sociologist, epidemiologists and primary

care practitioners considered the applicability of a wide range of theories from sociology, social, health and clinical psychology to *ProActive*. After the meeting five criteria were defined for theory selection: (1) use in interventions aimed at similar target behaviours, (2) applicability to the target group, (3) clear definition of causal, testable pathways between behavioural determinants and behaviour, (4) strength of evidence about predictive validity, and (5) clear guidelines for measurement.

- *Systematic reviews.* To inform the first criterion, systematic reviews were conducted of interventions aimed at weight gain prevention and family-based interventions to prevent and treat obesity (Hardeman *et al.*, 2000; McLean *et al.*, 2003).
- *Focus groups and individual consultations.* To inform the second criterion, focus groups and interviews were conducted with seven individuals at risk of Type 2 diabetes, aged 30–45 years.
- *Team meetings.* At several project meetings the utility of a range of theories was reviewed in relation to all five criteria.

Defining intervention points

Selection of intervention points to facilitate behaviour change and habit formation was informed by both the selected theory and a review of evidence by psychologists at the second expert meeting.

Defining techniques to support behaviour change

Selection of behaviour change techniques was based on (1) the underlying theory, (2) techniques used in other interventions aimed at similar target behaviours and (3) a review of evidence about effectiveness of techniques. We reviewed techniques proposed by authors of the selected theory and conducted systematic reviews (Hardeman *et al.*, 2000, 2002; McLean *et al.*, 2003). Clinical, social and health psychologists also reviewed empirical evidence for effective behaviour change techniques at a second expert meeting, without detailed consideration of underlying theories.

Table III. *Methods used in the development of the causal model in the ProActive case study*

General methods	Specific methods followed in the <i>ProActive</i> case study
Defining the health outcome and its importance	Review of epidemiological evidence about the importance of Type 2 diabetes, e.g. disease burden, and clinical and psychological consequences
Specifying physiological and biochemical variables	Review of epidemiological evidence about physiological and biochemical risk factors of Type 2 diabetes First expert meeting with epidemiologists and primary care practitioners
Defining the target population	Review of epidemiological evidence of determinants of Type 2 diabetes (weight gain, family history) Development of a feasible and acceptable strategy to identify individuals in the target group from the population First expert meeting with epidemiologists and primary care practitioners
Developing objective measures of the target behaviour	Development of objective measures of energy expenditure
Identifying the target behaviour	Review of epidemiological evidence of behavioural determinants of Type 2 diabetes (physical inactivity) Consultations with the target group about acceptability of changing specific behaviours
Specifying theory-based behavioural determinants	Development of criteria for the selection of theory Two expert meetings with social, health and clinical psychologists, sociologist, epidemiologists, and primary care practitioners Systematic reviews (Hardeman <i>et al.</i> , 2000, 2002; McLean <i>et al.</i> , 2003) Focus groups and interviews with the target group Project meetings
Specifying intervention points	Second expert meeting with clinical, social and health psychologists
Specifying behaviour change techniques	Systematic reviews (Hardeman <i>et al.</i> , 2000, 2002) Second expert meeting with clinical, social and health psychologists
Developing measures to assess change in behavioural determinants	Review of available measures Pilot study of salient beliefs towards increasing physical activity among 213 people, aged 35–75 years (Sutton <i>et al.</i> , 2003) Development of a theory of planned behaviour-based questionnaire to assess determinants of physical activity ($N = 213$) (French <i>et al.</i> , 2005; Sutton <i>et al.</i> , 2003)

Developing measures of change in behavioural determinants

A pilot study was conducted among 213 participants aged 35–75 years in the Ely observational cohort study into Type 2 diabetes, to identify salient beliefs and predictors of intention towards increasing physical activity (Sutton *et al.*, 2003). Subsequently, a questionnaire was developed to assess change in salient beliefs over time.

Results

Epidemiology

Defining the health outcome and its importance

Type 2 diabetes is a common and burdensome chronic disease. Its prevalence is well over 5% in many developed countries and is rising (Williams *et al.*, 2002). The disorder is managed by a regimen

including dietary change, increase in physical activity and taking multiple medication, which may include injections of insulin. Effective management of hyperglycaemia and related abnormalities including hypertension and dyslipidaemia can reduce the complications of diabetes, including premature cardiovascular disease, retinopathy and nephropathy (UK Prospective Diabetes Study Group, 1998; Gaede *et al.*, 2003). Labelling, treatment and complications can impact on functional status, well-being and quality of life (Johnston *et al.*, 1984; de Grauw *et al.*, 1999; UK Prospective Diabetes Study Group, 1999). The incidence of diabetes can be predicted by various anthropometric, physiological and biochemical variables, including age, family history, blood glucose, insulin and proinsulin (Wareham *et al.*, 1999), and these risk predictors were included in the causal model.

Defining the target group

Adults with a family history of Type 2 diabetes constitute a high-risk population, identifiable through inclusion of their parents with diabetes on GP registers. They have a 3-fold increased risk of developing diabetes compared to those without a family history. This risk is magnified by physical inactivity, weight gain and aging. At least 40% of the excess risk associated with weight gain might be avoided if Body Mass Index did not exceed 30 kg/m² (Sargeant *et al.*, 2000). The study therefore recruited at-risk individuals by virtue of their family history, sedentary lifestyle and middle age. As family members may share disease risk, which could indicate shared behaviours, environmental or genetic determinants (Hippisley-Cox *et al.*, 2002), we intervened on all willing family members living together, so that more family members might potentially benefit from the programme.

Identifying the target behaviour, and its impact on physiological and biochemical variables, and health outcome

Physical inactivity accounts for at least 11.7% of all deaths in developed countries (Murray and Lopez, 1996) and the rise in obesity in many countries is associated with a decline in physical activity.

Physical activity can make a clinically important impact on the prevention of diabetes. A consistent direct relationship exists between sedentary living and risk of Type 2 diabetes (Hamman, 2002). Three trials among individuals with impaired glucose tolerance in China (Pan *et al.*, 1997), Finland (Tuomilehto *et al.*, 2001) and the USA (Diabetes Prevention Program Research Group, 2002) have established that intensive approaches to change lifestyle, including physical activity, can delay or prevent progression to diabetes by up to 58% over 3 years (Diabetes Prevention Program Research Group, 2002) and possibly longer (Pan *et al.*, 1997), and are cost-effective relative to pharmacological therapy (Herman *et al.*, 2003). While these trials focused on structured activity, the Ely observational cohort study suggested that an increase in overall energy expenditure was beneficial: an increase equivalent to 0.5 hours walking per day was associated with a reduction in risk of the metabolic cardiovascular syndrome (physiological and biochemical variables) of about one-third (Wareham *et al.*, 1998) and of undiagnosed diabetes or impaired glucose tolerance of about one-fifth (Wareham *et al.*, 2000). The relationship is continuous with no threshold. Such increases in physical activity are achievable in sedentary populations in community settings (Hillsdon *et al.*, 1995; Simons-Morton *et al.*, 1998; Sallis and Owen, 1999). Interventions aimed at unsupervised physical activity, emphasizing leisure physical activity of low intensity, can be associated with large effects (Dishman and Buckworth, 1996). At consultations our target group preferred unorganized activities above structured, formal activities such as going to the gym.

Development and validation of objective measures of the target behaviour

Most behavioural studies rely on self-report of exercise. In trials this may inflate differences between groups due to recall bias or reduce the study's power to detect a difference between groups due to imprecision of measurement. Furthermore, self-reports tend to focus on leisure-time exercise and do not quantify changes in overall energy expenditure (Wareham and Rennie, 1998). Valid

estimation of total energy expenditure is possible in free-living individuals using heart rate monitoring with individual calibration (Wareham *et al.*, 1997). This method increases the precision of measuring the quantitative link between physical activity and different diseases, and was used in the Ely study which demonstrated the importance of overall daily activity, rather than fitness alone. Overall physical activity in the causal model was measured by individually calibrated heart rate monitoring over 4 days preceded by submaximal VO₂ fitness testing (Wareham *et al.*, 2000) and by self-report (Wareham *et al.*, 2002). Objectively measured physical activity was expressed as the Physical Activity Ratio (PAR) (Schutz *et al.*, 2001).

Psychology

Theory-based behavioural determinants

The systematic reviews identified no commonly used theory to inform choice of behavioural determinants. Underlying theories were varied and rarely specified.

Focus groups and interviews with at-risk individuals showed that few were aware that family history increased their risk of developing diabetes and Pierce (Pierce, 1996) reported that 66% of people with a parental history perceived little risk of developing diabetes themselves. Experts proposed at their first meeting that the theory should specify determinants of intention to change, as risk awareness and associated motivation to adopt preventative measures could not be assumed among the offspring of people with diabetes. Behavioural models (e.g. operant theory) and cognitive-behavioural models (e.g. cognitive-behavioural therapy) were not selected as the organizing theory, because they do not clearly specify how to strengthen motivation and primarily focus on problem behaviours. Social cognition models that specify determinants of motivation were chosen for further consideration.

After the expert meeting the project team reviewed the social cognition theories in more detail. The Theory of Planned Behaviour [TPB (Ajzen, 1991)] was selected to underpin the causal model, as it clearly specifies causal links between determinants

of intention and behaviour, there is good evidence to support the theory's predictive validity, and construct measurement is clearly specified, which allows testing of the theory's causal pathways (Godin and Kok, 1996; Sutton, 1998; Armitage and Conner, 2001). In a population of similar age, the model's three main components (attitude, subjective norm and perceived behavioural control) explained 48% of the variance in intention to increase physical activity and this intention was on average only moderately strong (French *et al.*, 2005). In a meta-analysis, intention and perceived behavioural control explained on average 27% of the variance in physical activity (Hagger *et al.*, 2002).

Intervention points

Informed by the TPB, the beliefs predicting intention to change were defined as the first intervention point. According to the theory, change in these beliefs would lead to changes in intention and behaviour. As the intervention was delivered to individuals in family groups, it was possible to identify and target individual salient beliefs rather than working with the modal salient beliefs of the target group, which did not adequately represent those of the individual (Sutton *et al.*, 2003). Thus, the TPB was used in a novel, although theoretically appropriate, way. The importance of building on individuals' own reasons for change was corroborated by interviews with at-risk individuals.

Experts identified a limitation of the TPB: a strong intention alone does not always lead to behaviour change (Sheeran, 2002; Sutton, 2004). Thus, intention and behaviour were identified as further intervention points.

Techniques to support behaviour change

The authors of the TPB propose persuasive messages as the main technique to change beliefs (Ajzen and Fishbein, 1980). In *ProActive*, information is provided about the potential to prevent diabetes by increases in physical activity. TPB-based interventions in the literature used a wide range of techniques, but their choice was rarely justified (Hardeman *et al.*, 2002). At the second meeting experts identified additional techniques

with evidence of effectiveness to change beliefs: reinforcing positive beliefs and problem solving in relation to negative beliefs.

To bridge the 'gap' between intention and behaviour, other techniques, not informed by the TPB, were selected to impact directly on intention and behaviour. Systematic reviews identified goal setting, self-monitoring, reinforcement (Hardeman *et al.*, 2000) and building family support (McLean *et al.*, 2003) as potentially effective techniques. The experts identified additional techniques to support individuals in moving from intention to action: action planning (Gollwitzer, 1996), building social support, facilitating habit formation (Aarts *et al.*, 1997) and preventing relapse (Marlatt and Gordon, 1985). These techniques can be effectively applied to support increased physical activity (Dishman *et al.*, 1996; Sallis *et al.*, 1999).

Measures of change in behavioural determinants

Salient beliefs towards increasing physical activity were identified in the Ely pilot study, to inform a TPB-based questionnaire assessing change in behavioural determinants (Sutton *et al.*, 2003).

The final causal model, including intervention points, behaviour change techniques and associated measures, is shown in Table IV. Behavioural determinants are derived from the TPB and the model specifies that change in specific physical activity behaviours will affect total objectively measured physical activity, which in turn will impact on physiological and biochemical variables, either directly via increased energy expenditure or fitness, or indirectly via weight gain prevention. Changes in these variables would result in lower risk of developing Type 2 diabetes.

Discussion

This paper has presented a causal modelling approach to the development of a theory-based programme for evaluation in a randomized controlled trial. It outlined the steps followed in the translation of a generic causal model into a specific

model, in the context of a particular disease and behavioural programme for its prevention in a high-risk group. The specific model shows causal pathways, intervention components and measures in one graphical representation. The case study used theories and evidence from psychology and epidemiology. Psychological determinants of the target behaviour (physical activity, measured as energy expenditure) were identified from the TPB. Prior trial evidence was available for causal links from target behaviour to outcomes, but evidence for the pathways from psychological determinants to behaviour came mainly from cross-sectional studies among people unrepresentative of our target population and are therefore hypothesized causal pathways to be tested in the trial and against other data sets.

Patient-centred measures of well-being and quality of life are also being assessed as important outcomes in their own right (Kinmonth *et al.*, 1998). Impact on well-being may occur through many pathways, e.g. relating to anxiety about risk status (Shaw *et al.*, 1999) or the burden of physical activity, or to reassurance from engaging in preventative activity or the social and physiological effects of exercise (Fox, 1999).

Comparison with other approaches

Most published approaches to intervention development and evaluation are comprehensive and best compared to the overall MRC framework, of which causal modelling is only a component. The MRC framework has a strong clinical trials focus and includes five phases (see Table I) representing a continuum of increasing evidence. The RE-AIM evaluation model (Glasgow *et al.*, 1999) focuses on public health impact of interventions, and includes reach, efficacy, adoption, implementation and maintenance, which are considered in MRC phases 3–5. Other approaches describe phases of intervention development, implementation and evaluation, each with particular strengths. Precede–Proceed (Green and Kreuter, 1999) specifies phases of needs assessment that map onto MRC phase 1. Intervention Mapping (Bartholomew *et al.*, 2001)

Table IV. ProActive causal model: application to a population (30-50 years old) at risk of type 2 diabetes, due to family history and physical inactivity

Intervention points and behaviour change techniques	Causal model	Measures for evaluation
	<p><i>LEVEL 1</i></p> <p>Past behaviour</p> <p>↓</p>	Physical Activity Questionnaire (baseline, past year) (Wareham <i>et al.</i> , 2002)
<p>Information about disease risk and preventive behaviour</p> <p>Identifying salient beliefs towards behaviour change</p> <p>Reinforcing positive beliefs</p> <p>Problem solving in relation to negative beliefs</p> <p>→</p>	<p>Attitude towards behaviour</p> <p>Subjective norm</p> <p>Perceived behavioural control</p> <p>↓</p>	Theory of Planned Behaviour Questionnaire (Sutton <i>et al.</i> , 2003)
<p>Setting achievable goals</p> <p>→</p>	<p>Behavioural intention</p> <p>↓</p>	Theory of Planned Behaviour Questionnaire
<p>Action planning (prompts, social support)</p> <p>Self-monitoring</p> <p>Self-reinforcement</p> <p>Goal review</p> <p>Building new habits</p> <p>Preparing for and dealing with setbacks</p> <p>→</p> <p><i>LEVEL 2</i></p>	<p>Specific behaviours to increase physical activity</p> <p>↓</p>	Physical Activity Questionnaire (1 yr follow-up, past year)
	<p><i>LEVEL 3</i></p> <p>Energy expenditure (total physical activity)</p> <p>↓</p> <p>Fitness</p> <p>↓</p> <p>Biochemical and physiological variables</p> <p>↓</p>	<p>Objective measures of overall physical activity: Physical Activity Ratio (PAR) parameters (Schutz <i>et al.</i>, 2001)</p> <p>↓</p> <p>Cardiorespiratory fitness (submaximal VO₂ max)</p> <p>Weight, height, distribution of body fat</p> <p>↓</p> <p>Fasting plasma glucose, insulin, lipids, glycosylated haemoglobin, blood pressure, electrocardiogram</p>
	<p><i>LEVEL 4*</i></p> <p>Incidence of Type 2 diabetes</p>	Modelling of PAR on diabetes risk

*Well-being and quality of life are also measured, but this model does not specify a causal path (see Discussion).

describes five phases of programme development, from definition of proximal programme objectives to anticipation of process and effect evaluation, and Logic Models (Conrad *et al.*, 1999) link inputs and

activities to programme products and outcomes, while communicating the logic (theory) behind the programme. The last two approaches describe activities for MRC phases 1–4.

The causal modelling approach is most similar to the Four-Model Approach (Bauman *et al.*, 1991), which works from a theoretical model to an implementation model for the programme. The causal modelling approach differs from this by specifying steps involved in developing causal models and specifying measures along the causal pathways. The modelling described in this paper includes steps used in most approaches, e.g. needs assessment, use of theory and evidence from epidemiology and social and behavioural sciences, and specification of techniques and measures. It varies from other approaches in terms of working towards a concise, one-page representation of theory- and evidence-based causal pathways linked to intervention components and measures, and an explicit focus on statistical modelling.

Causal models extend the MRC framework and other approaches in four ways.

- (1) They guide the choice of intervention points and measures along hypothesized causal pathways. This helps to avoid the common problems of measuring variables that could not logically be affected by the intervention and omitting those that could.
- (2) They assist in the choice of behaviour change techniques, indicating how they are hypothesized to impact on behaviour and its determinants, and allowing quantitative hypothesis testing along the causal path. This makes it possible to examine why interventions are effective or not.
- (3) They inform the assessment of fidelity to theories, e.g. to what extent intervention providers targeted the behavioural determinants and applied specified techniques.
- (4) They enable statistical modelling of the relationships between measured behaviours and distant health outcomes. In *ProActive*, 1-year follow-up does not allow assessment of the relationship between physical activity and incidence of Type 2 diabetes. However, epidemiological studies using similar measures of physical activity in comparable populations have estimated quantitatively the association

between energy expenditure and diabetes risk (Wareham *et al.*, 1997). This allows the effect of the intervention on diabetes incidence to be modelled from its effect on physical activity.

Importance of multidisciplinary working

The approach highlights the importance of a multidisciplinary perspective. In the case study, theories, intervention points, techniques and measures were drawn from social, health and clinical psychology. Target groups at risk of common chronic diseases that might be prevented by behaviour change were identified from epidemiology. Studies with objective measures of overall physical activity provided quantitative evidence that everyday activities (walking, cycling) were important target behaviours in terms of public health impact on diabetes risk (Wareham *et al.*, 2000). Broad epidemiological studies can also inform environmental, social, political, economic and geographical determinants of behaviours, and in the future will inform genetic determinants of risk.

Theoretical issues

There are no clearly agreed criteria for choosing theories to inform interventions. A wide range of theories exists with substantial overlap in terms of constructs (Fishbein *et al.*, 2001; Nigg *et al.*, 2002; Sutton, 2003). We therefore developed a set of five criteria (see Methods), and future studies might develop them in relation to disease group (acute, chronic), stage in disease trajectory (asymptomatic, symptomatic, relapse), target group (volunteers, those seeking help), target behaviour (adopting healthy behaviours, decreasing addictive behaviours) and setting (primary care, specialist setting). Links between behaviour change techniques and behavioural determinants are also poorly developed. Intervention development may therefore draw on theories that specify causal pathways to inform psychological determinants of behaviour and more dynamic theories of behaviour change (e.g. self-regulation theory) to inform intervention techniques.

Operationalization

Moving from a specific causal model to an intervention for evaluation in a trial requires further significant work to bridge the gap between theory and practice. In *ProActive*, the causal model was applied in an action research model, working with 15 volunteer high-risk individuals and their families. Intervention protocols and fidelity measures were developed, and the feasibility and acceptability of the intervention tested. Two versions of a year-long intervention, an intensive face-to-face intervention (delivered at participants' homes and by phone) and less intensive distance intervention (delivered by phone and correspondence), were developed and are being tested in the trial against brief advice about physical activity. The practicalities of an intervention are determined by feasibility of the underlying health service model and trial design, considerations that are part of the wider MRC framework. The health service model and trial design inform additional measures in a trial, such as questionnaires to assess satisfaction with the programme and to inform health economic analysis.

Conclusion

As a rational approach to intervention development and evaluation, the causal modelling approach indicates testable pathways from behavioural determinants to health outcomes and logical intervention points, and links the pathways to behaviour change techniques and measures in the context of a specific target group, health outcome and target behaviour. The approach is generalizable to other target groups and interventions. Its utility needs to be tested in a range of contexts, and future research needs to build on the steps required to design specific causal models and develop a comprehensive framework for theory selection.

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References

- Aarts, H., Paulussen, T. and Schaalma, H. (1997) Physical exercise habit: on the conceptualization and formation of habitual health behaviours. *Health Education Research*, **12**, 363–374.
- Ajzen, I. (1991) The Theory of Planned Behavior. *Organizational Behavior and Human Decision Processes*, **50**, 179–211.
- Ajzen, I. and Fishbein, M. (1980) *Understanding Attitudes and Predicting Social Behavior*. Prentice Hall, Englewood Cliffs, NJ.
- Armitage, C.J. and Conner, M. (2001) Efficacy of the Theory of Planned Behaviour: a meta-analytic review. *British Journal of Social Psychology*, **40**, 471–499.
- Bartholomew, L.K., Parcel, G.S., Kok, G. and Gottlieb, N.H. (2001) *Intervention Mapping: Designing Theory- and Evidence-based Health Promotion Programs*. Mayfield, Mountain View.
- Bauman, L.J., Stein, R.E.K. and Ireys, H. (1991) A framework for conceptualizing interventions. *Sociological Practice Review*, **2**, 241–251.
- Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A.L., Sandercock, P., Spiegelhalter, D. and Tyrer, P. (2000) Framework for design and evaluation of complex interventions to improve health. *British Medical Journal*, **321**, 694–696.
- Conrad, K.J., Randolph, F.L., Kirby, M.W.J. and Bebout, R.R. (1999) Creating and using logic models: four perspectives. *Alcoholism Treatment Quarterly*, **17**, 17–31.
- de Grauw, W.J., van de Lisdonk, E.H., Behr, R.R., van Gerwen, W.H., van den Hoogen, H.J. and van Weel, C. (1999) The impact of type 2 diabetes mellitus on daily functioning. *Family Practice*, **16**, 133–139.

- Diabetes Prevention Program Research Group (2002) Reduction in the incidence of Type 2 diabetes with lifestyle intervention or metformin. *New England Journal of Medicine*, **346**, 393–403.
- Dishman, R.K. and Buckworth, J. (1996) Increasing physical activity: a quantitative synthesis. *Medicine and Science in Sports and Exercise*, **28**, 706–719.
- Fishbein, M., Triandis, H.C., Kanfer, F.H., Becker, M., Middlestadt, S.E. and Eichler, A. (2001) Factors influencing behavior and behavior change. In Baum, A., Revenson T.A. and Singer, J.E. (eds), *Handbook of Health Psychology*. Erlbaum, Mahwah, NJ, pp. 3–17.
- Fox, K.R. (1999) The influence of physical activity on mental well-being. *Public Health Nutrition*, **2**, 411–418.
- French, D.P., Sutton, S., Hennings, S.J., Mitchell, J., Wareham, N.J., Griffin, S., Hardeman, W. and Kinmonth, A.L. (2005) The importance of affective beliefs and attitudes in the Theory of Planned Behavior: predicting intentions to increase physical activity. *Journal of Applied Social Psychology*, in press.
- Gaede, P., Vedel, P., Larsen, N., Jensen, G.V.H., Parving, H.-H. and Pedersen, O. (2003) Multifactorial intervention and cardiovascular disease in patients with Type 2 diabetes. *New England Journal of Medicine*, **348**, 383–393.
- Glasgow, R.E., Vogt, T.M. and Boles, S.M. (1999) Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *American Journal of Public Health*, **89**, 1322–1327.
- Godin, G. and Kok, G.J. (1996) The Theory of Planned Behavior: a review of its applications to health-related behaviors. *American Journal of Health Promotion*, **11**, 87–98.
- Gollwitzer, P.M. (1996) The volitional benefits of planning. In Gollwitzer, P.M. and Bargh, J.A. (eds), *The Psychology of Action. Linking Cognition and Motivation to Behavior*. Guilford Press, New York, pp. 287–312.
- Green, L.W. and Kreuter, M.W. (1999) *Health Promotion Planning: An Educational and Ecological Approach*, 3rd edn. Mayfield, Mountain View, CA.
- Hagger, M.S., Chatzisarantis, N.L.D. and Biddle, S.J.H. (2002) A meta-analytic review of the theories of reasoned action and planned behavior in physical activity: predictive validity and the contribution of additional variables. *Journal of Sport and Exercise Psychology*, **24**, 3–32.
- Hamman, R.F. (2002) Prevention of Type 2 diabetes. In Williams, R., Herman, W., Kinmonth, A.L. and Wareham, N.J. (eds), *Evidence Base for Diabetes Care*. Wiley, Chichester, pp. 75–176.
- Hardeman, W., Griffin, S., Johnston, M., Kinmonth, A.L. and Wareham, N.J. (2000) Interventions to prevent weight gain: a systematic review of psychological models and behaviour change methods. *International Journal of Obesity and Related Metabolic Disorders*, **24**, 131–143.
- Hardeman, W., Johnston, M., Johnston, D.W., Bonetti, D., Wareham, N.J. and Kinmonth, A.L. (2002) Application of the theory of planned behaviour in behaviour change interventions: a systematic review. *Psychology and Health*, **17**, 123–158.
- Herman, W.A., Brandle, M., Zhang, P., Williamson, D.F., Matulik, M.J., Ratner, R.E. and Engelgau, M.M. on behalf of the Diabetes Prevention Program Research Group (2003) Costs associated with the primary prevention of type 2 diabetes mellitus in the diabetes prevention program. *Diabetes Care*, **26**, 36–47.
- Hillsdon, M., Thorogood, M., Anstiss, T. and Morris, J. (1995) Randomised controlled trials of physical activity promotion in free living populations: a review. *Journal of Epidemiology and Community Health*, **49**, 448–453.
- Hippisley-Cox, J., Coupland, C., Pringle, M., Crown, N. and Hammersley, V. (2002) Married couples' risk of same disease: cross sectional study. *British Medical Journal*, **325**, 636–640.
- Johnston, M.E., Gibson, E.S., Terry, C.W., Haynes, R.B., Taylor, D.W., Gafni, A., Sicurella, J.I. and Sackett, D.L. (1984) Effects of labelling on income, work and social function among hypertensive employees. *Journal of Chronic Disease*, **37**, 417–423.
- Kinmonth, A.L., Woodcock, A., Griffin, S., Spiegel, N., Campbell, M.J. on behalf of the Diabetes Care From Diagnosis Research Team (1998) Randomised controlled trial of patient centred care of diabetes in general practice: impact on current wellbeing and future disease risk. *British Medical Journal*, **317**, 1202–1208.
- Marlatt, G.A. and Gordon, J.R. (1985) *Relapse Prevention: Maintenance Strategies in the Treatment of Addictive Behaviors*. Guilford Press, New York.
- McLean, N., Griffin, S., Toney, K. and Hardeman, W. (2003) Family involvement in weight control, weight maintenance and weight loss interventions: a systematic review of randomised trials. *International Journal of Obesity and Related Metabolic Disorders*, **27**, 987–1005.
- Medical Research Council (2000) *A Framework for the Development and Evaluation of RCTs for Complex Interventions to Improve Health*. Medical Research Council, London.
- Murray, C.J.L. and Lopez, A.D. (1996) *The Global Burden of Disease*. Harvard University Press, Cambridge, MA.
- Nigg, C.R., Allegrante, J.P. and Ory, M. (2002) Theory-comparison and multiple-behavior research: common themes advancing health behavior research. *Health Education Research*, **17**, 670–679.
- Ory, M.G., Jordan, P.J. and Bazarre, T. (2002) The Behavior Change Consortium: setting the stage for a new century of health behavior-change research. *Health Education Research*, **17**, 500–511.
- Pan, X., Li, G., Hu, Y., Wang, J., Yang, W., An, Z., Hu, Z., Lin, J., Xiao, J., Cao, H., Liu, P., Jiang, X., Jiang, Y., Wang, J., Zheng, H., Zhang, H., Bennett, P.H. and Howard, B.V. (1997) Effect of diet and exercise in preventing NIDDM in people with impaired glucose tolerance. *Diabetes Care*, **20**, 537–543.
- Pierce, M.B. (1996) Non-insulin dependent diabetes and its complications: beliefs, perceptions and prospects for risk reduction. *MD Thesis*, University of London.
- Sallis, J.F. and Owen, N. (1999) *Physical Activity and Behavioral Medicine*. Sage, Thousand Oaks, CA.
- Sargeant, L., Wareham, N.J. and Khaw, K.T. (2000) Family history of diabetes identifies a group at increased risk for the metabolic consequences of obesity and physical inactivity in EPIC-Norfolk: a population-based study. *International Journal of Obesity and Related Metabolic Disorders*, **24**, 1333–1339.
- Schutz, Y., Weinsier, R.L. and Hunter, G.R. (2001) Assessment of free-living physical activity in humans: an overview of currently available and proposed new measures. *Obesity Research*, **9**, 368–379.
- Shaw, C., Abrams, K. and Marteau, T.M. (1999) Psychological impact of predicting individuals' risks of illness: a systematic review. *Social Science and Medicine*, **49**, 1571–1598.

- Sheeran, P. (2002) Intention-behavior relations: a conceptual and empirical review. *European Review of Social Psychology*, **12**, 1–36.
- Simons-Morton, D.G., Calfas, K.J., Oldenburg, B. and Burton, N.W. (1998) Effects of interventions in health care settings on physical activity or cardiorespiratory fitness. *American Journal of Preventive Medicine*, **15**, 413–430.
- Sutton, S. (1998) Predicting and explaining intentions and behavior: how well are we doing? *Journal of Applied Social Psychology*, **28**, 1317–1338.
- Sutton, S. (2003) Using theories of behaviour change to develop and evaluate sexual health interventions. In Stephenson, J.M., Imrie, J. and Bonell, C. (eds), *Effective Sexual Health Interventions*. Oxford University Press, Oxford, pp. 51–66.
- Sutton, S. (2004) Determinants of health-related behaviours: theoretical and methodological issues. In Sutton, S., Baum, A. and Johnston, M. (eds), *The Sage Handbook of Health Psychology* Sage, London, pp. 94–126.
- Sutton, S., French, D., Hennings, S.J., Mitchell, J., Wareham, N.J., Griffin, S., Hardeman, W. and Kinmonth, A.L. (2003) Eliciting salient beliefs in research on the theory of planned behaviour: the effect of question wording. *Current Psychology*, **22**, 234–251.
- Tuomilehto, J., Lindstrom, J., Eriksson, J.G., Valle, T.T., Hamalainen, H., Ilanne-Parikka, P., Keinanen-Kiukkaanniemi, S., Laakso, M., Louheranta, A., Rastas, M., Salminen, V., Uusitupa, M. for the Finnish Diabetes Prevention Study Group (2001) Prevention of Type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *New England Journal of Medicine*, **344**, 1343–1350.
- UK Prospective Diabetes Study Group (1998) Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet*, **352**, 837–853.
- UK Prospective Diabetes Study Group (1999) Quality of life in type 2 diabetic patients is affected by complications but not by intensive policies to improve blood glucose or blood pressure control (UKPDS 37). *Diabetes Care*, **22**, 1125–1136.
- Wareham, N.J. and Rennie, K.L. (1998) The assessment of physical activity in individuals and populations: why try to be more precise about how physical activity is assessed? *International Journal of Obesity and Related Metabolic Disorders*, **22**, S30–S38.
- Wareham, N.J., Hennings, S.J., Prentice, A.M. and Day, N.E. (1997) Feasibility of heart-rate monitoring to estimate total level and pattern of energy expenditure in a population-based epidemiological study: the Ely Young Cohort Feasibility Study 1994–5. *British Journal of Nutrition*, **78**, 889–900.
- Wareham, N.J., Hennings, S.J., Byrne, C.D., Hales, C.N., Prentice, A.M. and Day, N.E. (1998) A quantitative analysis of the relationship between habitual energy expenditure, fitness and the metabolic cardiovascular syndrome. *British Journal of Nutrition*, **80**, 235–241.
- Wareham, N.J., Byrne, C.D., Williams, R., Day, N.E. and Hales, C.N. (1999) Fasting proinsulin concentrations predict the development of type 2 diabetes. *Diabetes Care*, **22**, 262–270.
- Wareham, N.J., Wong, M.-Y. and Day, N.E. (2000) Glucose intolerance and physical inactivity: the relative importance of low habitual energy expenditure and cardiorespiratory fitness. *American Journal of Epidemiology*, **152**, 132–139.
- Wareham, N.J., Jakes, R.W., Mitchell, J., Hennings, S.J. and Day, N.E. (2002) Validity and repeatability of the EPIC-Norfolk physical activity questionnaire. *International Journal of Epidemiology*, **31**, 168–174.
- Williams, K., Prevost, A.T., Griffin, S., Hardeman, W., Hollingworth, W., Spiegelhalter, D., Sutton, S., Ekelund, U., Wareham, N. and Kinmonth, A.L. (2004) The ProActive trial protocol—a randomised controlled trial of the efficacy of a family-based, domiciliary intervention programme to increase physical activity among individuals at high risk of diabetes [ISRCTN 61323766]. *BMC Public Health*, **4**, 48–59.
- Williams, R., Herman, W., Kinmonth, A.L. and Wareham, N.J. (2002) *Evidence Base for Diabetes Care*. Wiley, Chichester.

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