

Citation for published version:

Gillison, FB, Greaves, C, Stathi, A, Ramsay, R, Bennett, P, Taylor, G, Francis, M & Chandler, R 2012, 'Waste the waist': the development of an intervention to promote changes in diet and physical activity for people with high cardiovascular risk', *British Journal of Health Psychology*, vol. 17, no. 2, pp. 327-345.
<https://doi.org/10.1111/j.2044-8287.2011.02040.x>

DOI:

[10.1111/j.2044-8287.2011.02040.x](https://doi.org/10.1111/j.2044-8287.2011.02040.x)

Publication date:

2012

Document Version

Peer reviewed version

[Link to publication](#)

This is the peer reviewed version of the following article: F. Gillison, C. Greaves, A. Stathi, R. Ramsay, P. Bennett, G. Taylor, M. Francis and R. Chandler. 'Waste the Waist': the development of an intervention to promote changes in diet and physical activity for people with high cardiovascular risk' in *British Journal of Health Psychology*, Vol. 17, Issue 2, pp. 327 - 345, May 2012, which has been published in final form at [10.1111/j.2044-8287.2011.02040.x](https://doi.org/10.1111/j.2044-8287.2011.02040.x). This article may be used for non-commercial purposes in accordance with Wiley Terms and Conditions for Self-Archiving.

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Running head: Waste the waist

“Waste the waist”: The development of an intervention to promote changes in diet and physical activity for people with high cardiovascular risk.

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Word count (exc. figures/tables): 3731

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Acknowledgements: With support from the Pan Bath and Swindon Primary Care Research Consortium.

Abstract

Objectives: To identify an evidence-based intervention to promote changes in diet and physical activity and adapt it for a UK primary care setting for people with high cardiovascular risk.

Design: A three stage mixed-methods design was used to facilitate a strategic approach to programme selection and adaptation.

Method

Stage 1: Criteria for scientific quality and local appropriateness were developed for the selection /adaptation of an intervention to promote lifestyle change in people of high cardiovascular risk through; (i) patient interviews, (ii) a literature search to extract evidence-based criteria for behavioural interventions, and (iii) stakeholder consultation. Stage 2: Potential interventions for adaptation were identified and ranked according to their performance against the criteria developed in Stage 1. Stage 3: Intervention mapping techniques were used to (i) specify the behavioural objectives that participants would need to reach in order to attain programme outcomes, and (ii) adapt the selected intervention to ensure that evidence-based strategies to target all identified behavioural objectives were included.

Results: Four of 23 potential interventions identified met the 11 essential criteria agreed by a multi-disciplinary stakeholder committee. Of these, the Greater Green Triangle programme (Laatikainen et al., 2007) was ranked highest and selected for adaptation. The intervention mapping process identified 13 additional behaviour change strategies that were used to adapt the intervention for the local context.

Conclusions: Intervention mapping provided a useful set of techniques for the systematic adaptation of an existing lifestyle intervention to a new population and context, and facilitated transparent working processes for a multi-disciplinary team.

Background

Recent calls have been made for researchers who are developing and evaluating behavioural interventions to provide greater detail about the intervention content and theoretical basis (Abraham, Kelly, West & Michie, 2009; Michie, 2008). By breaking down complex interventions into their constituent parts and specifying the *processes* of behaviour change that are to be targeted greater transparency in intervention design and evaluation can be provided. Without this detailed information, we cannot identify which of the elements within an intervention contribute to the final outcome (i.e. which are the necessary or sufficient contributors to success). In a similar manner, calls have been made to document why a particular intervention design is chosen, reflecting the practical, theoretical and socio-political considerations that direct decision making (Schaalma & Kok, 2009). Poor intervention specification limits our ability to a) replicate useful strategies in future work b) monitor and manage the quality with which interventions are delivered (intervention fidelity) (Craig, Dieppe, Macintyre, Michie, Nazareth & Petticrew, 2008), c) develop an evidence base from which to draw from in subsequent intervention design, and d) understand how best to translate findings from research trials into practice. With this in mind, the present paper reports on the process of identifying and adapting an intervention to promote change in diet and physical activity in people with high cardiovascular (CV) risk. We aim to provide a case study demonstrating how the technique of intervention mapping (IM) can be used to aid the systematic specification of locally required interventions, and in particular how it may be helpful in adapting high quality existing interventions to other contexts. Addressing these issues helps to move the science of behaviour change forward and is particularly important if health psychologists are to be able to respond to consultation on what constitutes “best practice” in the design and selection of interventions for use in health-care practice.

The present study was triggered by a local general practitioner (GP) who approached a team of health psychologists for assistance in providing behavioural support to patients diagnosed with metabolic syndrome (a combination of central obesity and other CV risk factors) for whom significant lifestyle changes are recommended (e.g. improved diet, physical activity and stopping smoking) (British Cardiac Society, 2005; NICE, 2006). This is not just a local problem. Indeed, the need for effective and cost-effective interventions for managing high CV risk is highlighted and will become more widespread following the initiation of a national programme in England to screen all adults aged 40-74 to identify and treat people with high CV risk (NHS Health Checks; Department of Health [DH], 2009).

In accordance with evidence-based guidelines (NICE, 2006; Paulweber, Valensi, Lindström, Lalic, Greaves, McKee, et al., 2010), the Department of Health guidance for NHS Health Checks recommends that people with CV risk of 20% or more and people with impaired glucose regulation should receive “intensive lifestyle intervention” to modify diet and physical activity (DH, 2009). However, the GPs charged with identifying patients at risk and delivering these recommendations have limited resources and training to provide the necessary behavioural support. GPs have reported being deterred from recommending lifestyle change to patients by a lack of confidence about what advice should be given, and a perceived lack of access to effective services to support the advised behavioural changes (e.g. Ampt, Amoroso, Harris, McKenzie, Rose & Taggart 2009). Therefore, in order to meet the government’s aim of providing intensive lifestyle intervention (DH, 2008) it is important that we identify interventions that are appropriate and cost-effective for a UK population.

CV risk is defined in terms of a combination of risk factors, including excess weight, sedentary behaviour, elevated blood glucose (especially non-diabetic hyperglycaemia or ‘pre-diabetes’) (Paulweber et al., 2010; Roden, Paulweber, Valensi, Lindström, Lalic, Greaves et al., in press), blood lipid levels and blood pressure (Davies, Khunti, Chauhan, Stribling,

Goyder, Farooqi et al., 2008; British Cardiac Society, 2005). Approximately 15% of UK adults aged over 40 have non-diabetic hyperglycaemia, and around 20% have a CV risk score of over 20% (Davies et al., 2008). Importantly, a number of CV risk factors are reversible through changes in diet and physical activity (Avenell, Broom, Brown, Poobalan, Aucott, Stearns et al., 2004; Knowler, Barrett-Connor, Fowler, Hamman, Lachin, Walker et al., 2002; Laatikainen, Dunbar, Chapman, Kilkkinen, Vartiainen, Heistaro et al., 2007). For example, it is estimated that 120 to 180 minutes of moderate-intensity physical activity per week may substantially reduce cardiovascular risk (Physical Activity Guidelines Advisory Committee, 2008) and achievable changes in diet (e.g. adoption of a diet high in whole grain, fruit, nuts and olive oil) have been demonstrated to lead to a reduction in CV risk factors including insulin resistance, body weight, and serum high-sensitivity C-reactive protein (Esposito, Marfella, Ciotola, Di Palo, Giugliano, Giugliano et al., 2004).

Given the burden on society and health services attributable to diabetes and heart disease, the development of effective interventions that assist patients in making lifestyle changes has great potential for public health benefit; a cost-modelling exercise has estimated that if the NHS Health Checks programme is fully implemented in the UK, the NHS should save £55.3 billion over a 20 year timeframe (DH, 2008). However, achieving this optimistic target depends on the assumption that pragmatic lifestyle intervention programmes, as delivered in real-world UK healthcare settings, can deliver similar levels of effectiveness to results seen in other countries and in highly controlled research settings (Tuomilehto, Lindstrom, Eriksson, Valle, Hamalainen, Ilanne-Parikka et al., 2001; Knowler et al., 2002; Espeland, Pi-Sunyer, Blackburn, Brancati, Bray, Bright et al., 2007).

The present study therefore aimed to a) identify an evidence-based intervention to promote changes in diet and physical activity, and b) adapt it for use in a UK primary care setting for people with high CV risk. Although there are other modifiable health behaviours

that contribute significantly to CV risk such as smoking and adherence to medication, the present intervention focused on changing diet and physical activity behaviours. This was because a) nationwide evidence-based stop smoking services are already available to which GPs can readily refer their patients (Croghan, 2011), b) there was a clear demand from our NHS stakeholders (GPs and PCT managers) for an intervention focused on diet and physical activity to address this perceived major gap in current care provision and to address the recommendation of "intensive lifestyle intervention" as part of the care pathway for people identified by NHS Health Checks as having high CV risk or pre-diabetes (DoH, 2008), and c) medication adherence was considered to be in the domain of medically trained healthcare professionals and it would not be appropriate to cover this in detail without qualified professionals present. However, recommendations to stop smoking and take medication as prescribed are reinforced in the resulting programme, with signposting to relevant NHS services.

Method

Design/Strategy for Programme Specification.

A significant body of research exists reporting on the efficacy of dietary and physical activity change interventions. Therefore, rather than developing an intervention from first principles, we set out to identify an existing high quality intervention to act as a platform for further development. A three-stage strategy was used to inform this programme selection and adaptation. This involved;

- 1) systematically investigating and defining the criteria that an intervention would need to fulfil in order to meet the objectives of the present study (i.e. producing a detailed intervention specification),
- 2) systematically reviewing and comparing existing interventions against these criteria to select a 'best available' intervention as a basis, and

3) adapting the selected intervention for the local context.

An intervention mapping (IM) approach was employed at each step of the process both to facilitate the specification of requirements, and to provide a detailed content analysis of existing interventions. IM is based on the premise that an intervention is most likely to be effective if it is appropriately grounded in the practical problem and the context /population to be targeted (Bartholomew, Parcel, Kok & Gottlieb, 2001). It is an 'ecological' model (Bronfenbrenner, 1979) which considers intervention processes, barriers to implementation and pragmatic issues at the organisational and societal level as well as at the individual level, and provides a systematic approach to the development of intervention strategies working back from the expected programme outcomes (e.g. what health-related behaviour changes will be achieved). It involves the detailed specification of performance objectives (what a person will need to do in order to meet the programme outcomes), identification of the determinants of these behaviours or behaviour changes, and finally mapping intervention methods and strategies to modify these determinants (Bartholomew, Parcel, Kok & Gottlieb, 2006).

Six steps in the IM process have been identified (although as IM is designed to be an iterative process the order in which they are conducted may vary); (1) needs assessment, (2) preparing matrices of change objectives, (3) selecting theory-informed intervention methods and practical strategies, (4) producing programme components and materials, (5) planning programme adoption, implementation and sustainability, and (6) planning for evaluation (Bartholomew et al., 2006). Preparing matrices of change objectives (Step 2) is an iterative process that involves setting out what it is a person will need to do [proximal performance objectives; PPOs] in order to achieve the overarching aims of the intervention [programme outcomes; POs]. A more specific set of *programme* objectives (i.e. what the programme needs to provide to facilitate the achievement of PPOs) is then generated through a

consideration of the theoretical modifiable determinants of each PPO. Steps 2 to 4 are represented in an intervention matrix which makes explicit the translation of programme objectives to specific strategies and intervention techniques (Bartholomew et al. 2001).

Stage 1: Defining criteria for successful intervention

A needs assessment exercise was conducted with two main objectives. First, a set of general criteria were required that would enable us to identify existing high quality interventions that were potentially appropriate for the local target population. Second, more detailed criteria on the intervention content were required to ensure that the needs of the present target population would be met. This second group of criteria formed the basis of the intervention adaptation through the specification of programme outcomes (POs) and proximal performance objectives (PPOs).

The needs assessment process included (a) interviews with people diagnosed with metabolic syndrome, (b) a review of the literature on dietary and physical activity interventions and (c) stakeholder consultation:

(a) Eleven in-depth individual interviews were conducted with patients recently diagnosed with metabolic syndrome from a single primary care practice. This sub-group of patients with cardio-vascular risk were selected in line with the intervention's original aims, as the scope of the target group was not expanded to all patients at high CV risk until later in the development process. Semi-structured interviews followed a topic guide covering; the impact and importance of diagnosis, the meaning patients and those around them associated with the diagnosis, changes in behaviour since receiving the diagnosis (especially diet or physical activity) and patients' wishes for lifestyle change support. Transcripts were coded and analysed by two qualitative researchers using constant comparison methods to extract basic themes and categories. This involved patient feedback both in-vivo and post analysis.

We also considered the findings of previous qualitative work which elicited the needs of patients with pre-diabetes (Evans, Greaves, Winder, Fearn-Smith, & Campbell, 2007; Penn, Moffatt & White, 2008) and other at risk populations (Stathi, McKenna & Fox, 2010) in relation to supporting lifestyle change.

(b) Literature searches were conducted to identify best practice guidelines for supporting people to change their diet and /or level of physical activity. Three key guidelines were selected to provide evidence-based recommendations on which specific intervention components are associated with increased effectiveness for weight loss and /or increased physical activity (including both the specific content of interventions in terms of strategies employed, and/or characteristics of delivery such as duration/intensity of support). Three reviews were selected on the basis of providing an up-to-date and comprehensive coverage of the evidence base and having a clear focus on interventions to support change in diet and physical activity; the National Institute for Health and Clinical Excellence guidelines on managing obesity (NICE, 2006), a review of reviews underpinning the EU guidelines for diabetes prevention (Paulweber et al, 2010) and recommendations of the US Preventive Services Task Force (McTigue, Harris, Hemphill, Lux, Sutton, Bunton et al., 2003).

c) Stakeholder consultation was facilitated through the establishment of a multi-disciplinary steering group who met quarterly. The group comprised two GPs, two patient representatives, two health psychologists, an exercise psychologist, a statistician, a consultant endocrinologist, a Research and Development support manager, the local Director of Public Health and the research officer. The steering group provided a broad range of expertise and local knowledge including local referral pathways, facilities for physical activity, and forthcoming Primary Care Trust (PCT) investment.

Consolidation of information sources:

Each arm of the needs assessment contributed to both the suggested intervention selection criteria, and to defining the content of the adapted intervention (through contributing to the specification of programme outcomes [POs] and specific proximal performance objectives [PPOs]). The initial selection criteria were finalised by a meeting of the steering group, during which data from all sources were synthesised to derive a list of essential (i.e. basic minimum qualities necessary) and desirable (i.e. preferable qualities) criteria. To be included as “essential”, a consensus was required among the members of the committee that the criterion was necessary to the success or the implementation of the intervention programme. This included both objective evidence-based scientific requirements generated from the literature review, and pragmatic necessities dictated by local public health and funding priorities (i.e. criteria that if not met, would limit sustainability as future support/funding would be unlikely). All other identified criteria were retained as “desirable”.

Stage 2: Reviewing existing interventions

To identify candidate interventions, we extracted those that met all of the essential criteria from evidence tables in the three guideline documents on supporting changes in diet and /or physical activity (i.e. NICE, 2006; Greaves, Sheppard, Abraham, Evans, Roden, Schwarz et al, 2008; McTigue et al, 2003). We also asked all stakeholders (and relevant colleagues) to identify other possible interventions. Identified interventions were then reviewed by two investigators against the inclusion criteria generated in Stage 1, and all those that met the essential criteria were shortlisted. Shortlisted interventions were then ranked based on their performance against each criterion relative to other interventions (e.g., how cost effective, or how large an effect size beyond the minimum for inclusion), and according to pragmatic considerations, and the pros and cons behind the rankings recorded. Ranking was conducted independently by an intervention design sub-group of the steering committee comprising exercise and health psychologists, a GP and a medical statistician. Individual ranking

outcomes were then shared and discussed until a consensus was reached. The selected intervention was then reported back to and approved by the main steering group.

Stage 3: Adapting the selected intervention

Before adaptation, IM techniques were used to deconstruct the selected intervention into a matrix of its component parts. Copies of the participant and facilitator handbooks, and detailed programme specification were obtained from the intervention's authors for this purpose. While we used the standard techniques from the IM approach (Schaalma & Kok, 2009; van Oostrom, Anema, Terluin, Venema, de Vet & van Mechelen, 2007), these were somewhat modified to suit our purposes. Specifically, we used steps 2 to 4 of the IM approach to;

- (i) Identify the specific intervention strategies, PPOs, modifiable determinants and overall programme outcomes targeted in our selected intervention (i.e. working backwards from the existing intervention specification /manuals). This process was conducted independently by two investigators, and finalised through discussion with the design sub-group.
- (ii) Contrast the matrix generated from the candidate intervention with the list of PPOs generated in Stage 1 to identify gaps in provision (i.e. PPOs or modifiable determinants that were not already addressed by the intervention).
- (iii) Systematically identify evidence-based strategies to address identified gaps. The choice of behaviour change strategies /techniques to target these additional POs and PPOs were based on a) evidence presented in key reviews (e.g. NICE, 2006; Roden et al. 2010; Greaves et al, 2010), b) consistency with the theoretical approach of the existing programme, and c) considerations of fit with the structure of the existing programme (e.g. additional time demands or production of materials), negotiated by members of the design sub-group.

Results

Stage 1: Defining criteria for intervention selection

The main themes emerging from the interviews are summarised in Table 1. Patients reported difficulty in initially understanding their diagnosis and what it meant for them, and perceived a lack of support (from both family/friends and health-care providers) for making recommended changes to their diet and physical activity.

Table 1

The three components of the needs assessment resulted in a checklist of 11 essential, and five desirable criteria for assessing the suitability of candidate interventions (Table 2). The essential criteria included those relating to the intervention content, research quality (reflecting a minimum degree of quality in both intervention content and its reporting), practical considerations, and size of the intervention's reported effects. Cut-off values for each criterion were established from published evidence where available, and otherwise agreed through expert consultation.

As part of this process, the stakeholders agreed that the intervention should be expanded to provide treatment for all patients with a high CV risk, rather than only those diagnosed with metabolic syndrome. This decision in part reflected the introduction of NHS Health Checks national programme (DH, 2009), in that allowing referral following health checks without requiring additional tests for metabolic syndrome would streamline the referral process.

Table 2

The PPOs derived from all three arms of the needs assessment, reflecting the objectives for our final adapted intervention are set out Table 3.

Table 3

Stage 2: Reviewing existing interventions

Twenty-three interventions were initially screened for inclusion against the criteria set out in Table 2. Of these, only four interventions met all objective essential criteria and were shortlisted (Bo, Ciccone, Baldi, Benini, Dusio, Forastiere et al., 2007; Esposito et al., 2004; Laatikainen et al., 2007; Stevens, Obarzanek, Cook, Lee, Appel, Smith West et al., 2001). The authors of each study were contacted to seek further clarification as necessary, and permission to use and adapt their intervention in principle. Following the ranking process and subsequent discussions a single intervention was unanimously selected (Greater Green Triangle [GGT] Diabetes Prevention Project; Laatikainen, et al., 2007).

The GGT was ultimately selected as in addition to meeting all the essential criteria, it; (i) promoted generic rather than prescriptive changes in diet (e.g. participants could choose what types of food they ate), (ii) was one of the lowest cost interventions (estimated £355 per person), (iii) required a feasible level of staff input (six weekly sessions delivered by health promotion/nursing level staff), (iv) reported positive findings for weight loss which were sustained at 30 months (Laatikainen, et al., 2007), and (v) had already been demonstrated to be adaptable in different countries, namely Finland (Lindstrom, Ilanne-Parikka, Peltonen, Aunola, Eriksson, Hemio et al., 2006) and Australia (Laatikainen, et al., 2007). Furthermore, materials were available in English, and the intervention's authors were willing for it to be adapted and to act as consultants to this process. The GGT was originally designed using the Health Action Process Approach (HAPA) (Schwartzler, 1992) as summarised in Figure 1. The HAPA proposes that behaviour changes through a motivational phase, and a volitional phase (involving the phases of planning, action and maintenance), for which self-efficacy, perceptions of risk and outcome expectancies are identified as primary mediators of change during different phases. The GGT programme consists of six two-hour group sessions facilitated by trained public health nurses or equivalents, using a patient-centred style based on empowerment ideology (Rappaport, 1987) which emphasises the client's responsibility for

making decisions and self-regulation. Sessions 1 and 2 of the programme target the ‘motivation’ stages of the model, namely increasing self-efficacy, setting realistic positive outcome expectations, and setting accurate risk perceptions, all of which contribute to the formation of intentions. Sessions 3 to 6 target the action and maintenance stages: helping participants to make concrete plans to change (i.e, providing training in individual goal setting), providing support for initial steps, promoting behaviour maintenance and helping participants to deal with recovery from slips and lapses.

Figure 1

Stage 3: Refining selected intervention

Matrices linking PPOs, behavioural determinants and behavioural programme objectives were constructed for the GGT intervention (an example is provided in Supplementary Table 1). The matrices generated for promoting change in diet and physical activity were very similar as both were based on the same theoretical constructs (e.g. enhancing self-efficacy and promoting self-monitoring were applicable to both behaviours). Thirteen behaviour change strategies were added to the existing GGT programme, to address PPOs that were not considered to be fully met (Table 4): Five were added to improve client engagement through strategies introduced at the point of referral (strategies 1-3) and during the intervention (strategies 4 and 5). Two additional strategies were included to promote greater initial behaviour changes (strategies 7 and 8), and six to promote the maintenance of behaviour changes beyond the programme itself focusing on increasing available social support (strategies 10 to 13), and self-monitoring (strategies 5 and 6). Finally, the action planning activities included in the GGT were extended to include coping planning for when goals are not achieved (strategy 9). Materials supporting the new strategies were included in the participant manual.

Table 4

The resulting adapted intervention was named the Waste the Waist (WtW) programme, to distinguish it from the original GGT. The WtW programme was designed to be delivered by lifestyle coaches (i.e. people experienced in providing behavioural support, such as fitness coaches or health trainers, but not health professionals) in a community setting, with referrals from primary care (post NHS Health Checks). The initial six session GGT programme was extended with three maintenance sessions to provide support for up to nine months.

Discussion

The present paper documents a systematic process for the selection and adaptation of a behavioural intervention to promote health behaviour changes for patients with high CV risk. The process drew on local needs assessment, expert opinion of relevant stakeholders (including patient representatives), and the existing evidence base for behavioural interventions to promote changes in diet and physical activity. A key strength of the project was the innovative use of IM techniques. This systematic and rigorous approach is usually only applied to the development of new interventions. However, through effectively applying IM backwards to deconstruct an existing programme into its constituent parts, this enabled us to use a similar systematic approach for the selection and adaptation of an existing intervention by comparing its objectives and targeted behavioural determinants with those identified by our own needs assessment. As such, the present work provides an example of a systematic process of adapting and updating an intervention to a new setting.

Through using the process described, we identified an intervention that a) should produce a mean weight loss of at least 2.5Kg over 24 months in people with elevated CV risk, b) should modify other CV risk factors (plasma glucose, cholesterol, triglycerides, blood pressure), c) can be successfully delivered on a large scale, d) is within a cost threshold set by our primary care stakeholders, e) can be adapted to include intervention components recommended by relevant systematic reviews (NICE, 2006; Paulweber et al, 2010; McTigue,

et al., 2003), f) can be adapted in line with local priorities, and g) has/retains a clearly defined theoretical basis.

Adapting existing high-quality successful interventions to new contexts rather than developing completely new interventions each time is important in promoting scientific development by building on best practice (Michie, 2008; Tortolero, Markham, Parcel, Peters, Escobar-Chaves, Basen-Engquist et al, 2005). Not only does it save time and resources, but it is also argued that this phase of adaptation is essential in translating effective but resource-intensive research interventions into those that are affordable and feasible in a community setting (Ackermann & Marrero, 2007); this was one of the *a priori* aims of the present study. In the UK at least, with an increased emphasis on the localisation of health services (DH, 2010b), strategies that facilitate the translation of programmes across settings with the expectation of making local adaptations are likely to become increasingly important. Using a framework to direct the process of adaptation more systematically may help to retain programme fidelity and prevent the inadvertent loss of essential elements.

There is further support for the present approach in other areas of public health. For example, in the USA the Centre for Disease Control (CDC) has set out a five step process (assess, select, prepare, pilot and implement) for the adaptation of evidence-based behavioural interventions for use by practitioners/commissioners in preventing and treating AIDS and HIV (McKleroy, Galbraith, Cummings, Jones, Harshbarger, Collins et al, 2006; Wingood & DiClemente, 2008). The model has some similarities to the approach used in the present example; the CDC guidelines state that interventions should be based on an initial needs assessment (i.e. *assess*) as is the case with IM, including the practical constraints organisations face in addition to the needs of the target population. Similarly, it recommends selecting existing evidence-based interventions for adaptation rather than developing new programmes (i.e. the *select* stage). However, there is little guidance on how practitioners /

commissioners should go about adapting existing interventions (i.e. in the *prepare* stage) beyond stipulating that all “core” elements should be maintained, and all decisions regarding adaptations are recorded and available for scrutiny by other potential users. IM, as applied in the present study could therefore provide a useful framework to provide greater guidance within the CDC process guidelines for a more systematic *preparation* phase.

We are aware of only one other example of IM being used in this manner, in which a similar process was followed to translate a sexual education intervention to a new community (Tortolero et al., 2005). Tortolero et al., used IM to map the existing programme and then substitute behaviour change strategies that were considered to be more appropriate to a different population/context (e.g. they adjusted the format of sessions to reflect that they were working with less able students than those for whom the original intervention was developed). The present study provides a further example of the use of IM for purposes of adaptation in a different context, but also adds an example of how the IM framework can facilitate a systematic process of intervention selection.

Strengths and Limitations of using Intervention Mapping for programme adaptation

While an undoubtedly useful and systematic approach, IM is not without its challenges. Predominantly, this is because it can be laborious and time consuming, resulting in extensive matrices that are difficult to view or conceptualise as a whole. It is impractical to list every possible link between performance objectives, determinants and strategies without the matrix becoming too complex to be useful and, inevitably, decisions have to be made as to how to limit this. One way to do so is to focus on general processes rather than trying to apply every possible process to every possible micro-behaviour. For example the process of encouraging an increase in physical activity might involve; exploring and enhancing motivations for the general concept of getting some more activity, followed by a focus on individual-specific action-planning (and an examination of confidence for the

specific actions selected). In contrast, trying to repeat motivational techniques for every possible type of physical activity (running, walking, going to the gym) before deciding which to do would be more complex and wasteful. Hence, considering the strategic ordering of intervention elements or the "process model" at an early stage may be beneficial.

A further potential limitation is the inevitably subjective nature of the phases of intervention selection and adaptation directed by a particular stakeholder group. While it is important for local stakeholders to have an input in order to foster ownership and commitment, different groups of stakeholders may generate different selection criteria and make different intervention choices. Within the present study we attempted to reduce the impact of this potential bias by including primary evidence-based essential criteria to ensure that as a minimum requirement any intervention that the group selected would be valid on the grounds of being supported by research evidence. However, as the purpose of stakeholder involvement is to select an intervention that will be not only effective but also appropriate for a particular context, allowing the views of local stakeholders to influence the desirable criteria is a valid approach.

Finally, IM can add complexity to interventions if the adaptation process results in the addition of strategies; the present adaptation resulted in the addition of 13 strategies. However, the impact of this can be minimised if new strategies are either blended to extend the themes already addressed in the intervention rather than introducing new concepts, or if they are substituted for existing strategies that they may supersede. For example, in the present study we added a number of strategies to promote social support (from friends, family but also health professionals), as the outcome of the needs assessment suggested that the existing provision was not sufficient. However, this was achieved by a) substituting a structured activity for a more general discussion, b) including revision of social support plans alongside other goal planning activities, and c) adjusting referral processes to and from the

programme requiring no additional session, and only a brief extension of time allocated to the topic at the relevant stage of the candidate intervention.

Overall in the present study we considered the benefits of the approach to outweigh its limitations. First, the process was still less time consuming than developing an intervention from scratch, and despite the limitations is more systematic and available to scrutiny than more *ad hoc* methods. Second, the process facilitated the constructive engagement of stakeholders in the design and decision making of an intervention through providing demonstrable means of accounting for the input of people from a range of lay and professional backgrounds (e.g., in setting criteria, and ranking candidate interventions) . Such genuine and visible involvement has the potential to increase the acceptability and feasibility of a programme for both participants and service delivery personnel (Brodie, Cowling, Nissen, Ellis Paine, Jochum, Warburton et al., 2009). Finally, as a result of the systematic approach reported here, we can also better assess intervention fidelity and conduct process evaluation work to inform further development of the intervention and its underlying theoretical basis.

Limitations of the present study

A limitation of the present study is that initial interviews were conducted with only a sub-group of the target population (patients diagnosed with metabolic syndrome). This was the intended recipient group of our intervention until its scope was broadened following discussion with the steering group. While we expect these patients to be representative of participants with other CV risk factors combinations, we acknowledge that some of the needs or concerns of other groups may differ. Secondly, the reviews used as a basis for identifying candidate interventions were based on expert opinion rather than a systematic review process. In particular, as our focus centred on the reduction in measurable risk factors, this was oriented towards interventions resulting in significant weight loss in similar patients rather

than studies that promoted diet and physical activity behaviour change per se. As such, some alternative useful interventions for adaptation may have been overlooked. Finally, our intervention has targeted only diet and physical activity, rather than including smoking cessation and medication adherence which are also important in CV risk reduction. This was in order to avoid replicating services already available through the NHS, however participants are signposted to existing NHS services to support these behaviours within our intervention.

Future Directions

Having completed the specification of the WtW lifestyle programme for reducing CV risk, the next goal is to test its efficacy in a UK population. This will involve developing detailed manuals and materials (i.e. step four of the IM framework), and pilot the adapted intervention in its intended setting. To this end, funding has been obtained from the National Institute of Health Research to test the feasibility and acceptability of the amended intervention protocol to patients and health care providers, test methods for assessing intervention fidelity and inform the planning of a full-scale randomised controlled trial. The pilot work also includes significant process evaluation work (both qualitative and quantitative) which will help to confirm and (if necessary) refine the process model developed through Intervention Mapping.

Conclusions

Intervention mapping provided a useful set of techniques which could be adapted for the systematic selection and adaptation of an existing lifestyle intervention to a new population and context. The present study has implications for intervention development practice as it presents a worked example of how practitioners and researchers can work together to select and adapt existing interventions for new populations and settings.

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Table 1 Themes extracted from interviews with patients diagnosed with metabolic syndrome.

| Themes | Theme content |
|--|---|
| Understanding a diagnosis | <ul style="list-style-type: none"> - Tendency to focus only on one salient element, namely weight. - Perception that a diagnosis is not serious (as many other people are overweight) <ul style="list-style-type: none"> <i>“It sounded like a technical term for being fat....I don’t think there’s anything wrong with me”</i> - Overweight perceived to be hereditary rather than behaviourally determined <ul style="list-style-type: none"> <i>“My parents and on both sides of my parent’s family, my grandparents, are all overweight. I don’t know whether that’s why I am. I have a suspicion that that’s possibly why.”</i> |
| Perceived barriers to behaviour change | <ul style="list-style-type: none"> - Long working hours - Lack of enjoyment of healthy behaviours <ul style="list-style-type: none"> <i>“If you go out for a meal somewhere I wouldn’t choose the one which is the low calorie one, I would choose the one that I liked...I don’t really know if the sacrifice is worth making...I mean, how long do I want to live for?”</i> <i>“When I am walking up hills with friends ... I become breathless and go red in the face and sweat and my friends sometimes comment on this which embarrasses me.”</i> - Restriction of social activities <ul style="list-style-type: none"> <i>“We have lots of family get-togethers, we’re a huge family ... and we have great big meals together so all our celebrations</i> |

are lots of food and so that's still going on now celebrating, having lots of food."

- Availability of high calorie foods at home

"There's lots of kinds of snacky things in the house, to sort of keep the children going ...so I open a cupboard and ... then again I'm in the sweet shop scenario"

Factors participants envisage would facilitate behaviour change

- Support from other members of the household, e.g., in determining what food is in the house, meal preparation
 - Having someone to exercise with
 - Setting and monitoring firm targets; being answerable if targets are not met
 - Greater availability of advice and information
-

Table 2 Initial selection criteria for studies considered as a basis for the Waste the Waist intervention

| Essential Criteria | Exclusion criteria | Source |
|---|--|---|
| Intervention content | | |
| 1. Focus on both dietary and physical activity behaviour change | Sole focus on changing only diet or physical activity (i.e., not both) | Literature review, NICE guidelines 2006 |
| 2. Relevant population (i.e., high CV risk) | Not tested on adults of both sexes with risk factors for CVD | Stakeholder consultation |
| 3. Clearly defined causal model | No identification of theoretical behavioural determinants or behaviour change techniques to address specific behavioural determinants. | Literature review /Expert consultation |
| Research Quality | | |
| 4. Adequate sample size | Exclusion if; < 50/group | Literature review /Expert consultation |
| 5. Study quality | Evidence of bias assessed through application of the <i>Cochrane risk of bias assessment criteria</i> (Higgins & Green, 2008) | Literature review |
| Implementation issues | | |
| 6. Affordable | Estimated from reported data on intervention time*: - excluded if \geq £800 /patient /year | Stakeholder consultation |

| | | |
|---------------------------------------|--|-----------------------------|
| | <ul style="list-style-type: none"> - medium cost classified as £400-£800 - low cost \leq £400/patient /year | |
| 7. Acceptable to patients | <p>Exclusion if;</p> <ul style="list-style-type: none"> - \geq 30% attrition at 12 months - serious adverse effects - negative evaluation by participants | Stakeholder consultation |
| 8. Acceptable to health professionals | <p>Exclusion if;</p> <ul style="list-style-type: none"> - reported difficulty in engaging /recruiting health professionals, - high dropout rate for practices - negative evaluation by health professionals | Stakeholder consultation |
| 9. Feasible within primary care | <p>Excluded if;</p> <ul style="list-style-type: none"> - reliant on expert personnel, or specialist equipment that would make it impractical for widespread local adoption. - Cost $>$£800 per person | Stakeholder consultation |

Intervention outcomes

| | | |
|--|--|---|
| 10. Clinically meaningful effects on targeted outcomes | <p>Exclusion if effect size</p> <ul style="list-style-type: none"> - for weight, $<$ 2.5 kg weight loss <i>or</i> $<$ 20% absolute increase in proportion achieving 5% weight loss at 12 months | Literature review /Stakeholder consultation |
|--|--|---|

| | | |
|--|--|---|
| | - <30 mins 3 x week moderate intensity PA <i>or</i> 20% absolute increase in proportion achieving 150 mins /week moderate intensity PA at 12 months | |
| 11. Sustained effects | Excluded if the intervention led to; <ul style="list-style-type: none"> - < 2.0Kg weight loss or <60 additional minutes /week moderate activity at 12 months, or - < 20% absolute increase in participants achieving 5% weight loss or 150 minutes /week of moderate activity | Literature review /Stakeholder consultation |
| <hr/> Desirable criteria <hr/> | | |
| 12. Further evidence for effectiveness since initial intervention trial (e.g., different population, or applied in practice) | | Stakeholder consultation |
| 13. Provision of ongoing support and interest from health professionals | ≤ 1 session with health professionals | Literature review /Needs assessment interviews |

| | |
|---|--|
| <p>14. Evidence that skills for delivery can be taught to a wide range of practitioners (e.g. nurses, health visitors, trained lay people or health care assistants) with minimal additional training</p> | <p>Stakeholder consultation</p> |
| <p>15. Contains, or could be modified to contain, strategies to enhance social support from significant others</p> | <p>NICE (2006), IMAGE guideline / stakeholder consultation</p> |
| <p>16. Contains, or could be modified to contain, behaviour change techniques aimed at supporting maintenance</p> | <p>NICE (2006), IMAGE guidelines**</p> |

Notes: * costs calculated as: intervention cost per person/per year, doubled (for oncosts) + £100 for recruitment costs; **for IMAGE guidelines see Paulweber et al (2010); PA – physical activity

Table 3: Proximal performance objectives for intervention content generated by initial needs assessment

PROGRAMME OUTCOME 1: ENGAGE IN THE PROGRAMME

- To perceive the programme as important**/****
- To engage openly with health professionals*/**
- To engage with the group***†

PROGRAMME OUTCOME 2: INCREASE PHYSICAL ACTIVITY

- To accurately identify one's own baseline physical activity level **
 - To relate physical inactivity to health consequences (i.e. establish risk awareness)*/**
 - To develop an awareness of personal risk (in relation to physical activity level)*/**
 - To establish realistic outcome expectancies for increasing physical activity **
 - To identify acceptable opportunities within daily life/activities for increasing physical activity*/**
 - To be motivated to initiate change**
 - To plan specific changes in physical activity*/**
 - To be able to act on personalised feedback in relation to physical activity**
 - To develop self-motivation to continue with increased physical activity*/**
 - To be able to cope with set-backs in achieving increased physical activity levels*/**
 - To obtain social support from the home environment*/**/****
 - To obtain social support from within the programme*/**
-

PROGRAMME OUTCOME 3: EAT A HEALTHIER DIET

- To accurately identify one's own dietary intake**
- To relate diet to health consequences (i.e. establish risk awareness)*/**
- To develop an awareness of personal risk (in relation to dietary habits)*/**
- To establish realistic outcome expectancies of a healthier diet**
- To be motivated to initiate dietary change**
- To plan for changes in diet*/**
- To be able to act on personalised feedback in relation to diet**
- To develop self-motivation to continue dietary change*/**
- To be able to cope with set-backs in dietary changes*/**
- To obtain social support from the home environment*/**/**
- To obtain social support from within the programme*/**

PROGRAMME OUTCOME 4: MAINTAIN BEHAVIOUR CHANGES BEYOND

THE PROGRAMME

- To obtain ongoing social support from the home environment*/**/**
- To obtain ongoing social support from within the programme*/**
- To have agreed an action plan/agenda for continued behaviour change and maintenance **

Notes: * denotes PPO/determinant identified through qualitative (needs assessment (Stage 1a); ** denotes PPOs are based on the literature search of good practice evidence base (Stage 1b), ***denotes PPO/determinant contributed expert panel member relating to local/target population (Stage 1c); † denotes PPO added once a group-based intervention had been decided on.

Table 4: Additional behaviour change strategies included following adaptation

| Point of Delivery | Strategy* |
|--|---|
| At referral (i.e. respected, known authority figure) | <ol style="list-style-type: none"> 1. Referral from GP (i.e. respected, authority figure) 2. Acknowledgement of concerns, reassurance that secondary prevention is achievable 3. Acknowledgement of potential concerns of joining group sessions, and presentation of a rationale for group format. |
| During programme: | <ol style="list-style-type: none"> 4. Provision of specific information about the process of heart disease. 5. Facilitate self-assessment of CV risk (e.g. weight, smoking status, physical activity level and dietary content). 6. Provision of pedometers for use in self-monitoring 7. Provision of information on the behaviour-health link 8. Acknowledgement of emotional barriers to behaviour change 9. Development of a written coping plan 10. Use of a social support mapping tool as a planning aid 11. Include interactive tasks with peers to facilitate reciprocal support |
| Before programme conclusion; | <ol style="list-style-type: none"> 12. Arrange follow up with Primary Care team |
| Following programme | <ol style="list-style-type: none"> 13. Arrange for the provision of feedback on CV risk status (e.g. at 6 months then every 12 months) |

Note: * some strategies were mapped to multiple Programme Outcomes (e.g., change in diet and physical activity).

Figure 1: Model adopted by the Greater Green Triangle programme

