

National
Obesity
Observatory

NHS



Standard Evaluation Framework for weight management interventions

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Foreword

The topic of evaluation can sometimes seem quite daunting, full of jargon and with a baffling variety of different methodologies. But evaluation is actually quite simple: it is judging the value of something and looking at the extent to which a programme or project has achieved its objectives.

Evaluation is particularly important in the area of interventions that aim to tackle the issue of overweight and obesity. Across the world we are witnessing unprecedented increases in rates of overweight and obesity, which require an effective and 'industrial-scale' public health response. We need to know as much as possible about which approaches are likely to yield results, and to do this we need to be able to compare results across settings, populations and types of intervention. We can then focus public health investment appropriately.

This is why I welcome this ambitious initiative from England's National Obesity Observatory. The document presents a list of essential and desirable criteria that should be collected as part of any evaluation of a weight management intervention. This should go some way towards ensuring that core information is collected in a standardised way across the country, helping to increase our understanding of the impact that public health approaches are having in combating the obesity epidemic.

As readers may be at different points in their understanding of evaluation methods, the lists of criteria are preceded by a basic guide to evaluation which presents the main concepts, approaches and some theoretical context. Many readers may be familiar with these basic concepts, but they are presented here to ensure readers are all starting at the same point.

I hope this guide will help to encourage innovative, evidence-based approaches to weight management interventions, and will contribute to raised standards of evaluation and support development of the evidence base.

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1. Introduction

This document aims to guide the reader through the process of using the Standard Evaluation Framework (SEF). It introduces the concepts of evaluation, describes the SEF, and provides guidance on how to use it.

The document is split into distinct sections:

Section two introduces the basic concepts of evaluation. This is aimed at people working on weight management interventions who may have little or no experience of evaluation, but wish to improve their knowledge and understand the basic principles and some of the key evaluation challenges. This provides the foundation and context for the SEF. After reading section two they should be better able to use the SEF.

If you understand the basics of evaluation go straight to **section three**. It presents a simple table showing the key essential and desirable criteria.

Section four is a guide to using the table, and an explanation of each criterion.

The target audience for the SEF is:

- **Primary care trust commissioners:** sections three and four can help you commission well-evaluated weight management interventions, assess how effective they are and identify any gaps in provision.
- **Primary care trust obesity leads:** section two can help improve your knowledge about the essentials of evaluation, and sections three and four can help you commission and run well-evaluated weight management interventions.
- **Organisations running weight management interventions:** section two can improve your knowledge about the essentials of evaluation, and sections three and four can help you understand what data to collect when evaluating weight management interventions.
- **Evaluators:** sections three and four can help you understand what data to collect when evaluating weight management interventions.

1.1 What is the Standard Evaluation Framework (SEF)?

The SEF is a list of data collection criteria and supporting guidance for collecting high quality information that supports the evaluation of weight management interventions across England.

In this document, the term *weight management intervention* refers to any intervention that explicitly sets out to manage or reduce body weight (including the primary prevention of weight gain). This includes projects focusing on diet, physical activity, or both in combination. It is intended to be applicable to a range of approaches including interventions conducted with individuals on a one-to-one basis or in groups, and in clinical or community settings. However, the SEF is not intended for use with:

- medical interventions such as surgery and medications;
- wider environmental interventions such as changes to the built environment (although the SEF could support the evaluation of such interventions alongside wider evaluation criteria).

The SEF aims to support high-quality, consistent evaluation of weight management interventions in order to increase the evidence base.

Objectives:

- Increase the proportion of weight management interventions that are evaluated.
- Increase the quality of evaluations.
- Contribute to the development of a core dataset to increase the consistency and comparability of evaluations.
- Provide wider evaluation support.

The list of criteria in section three is divided into two parts. Essential criteria are presented as the minimum recommended data for evaluating a weight management intervention. Desirable criteria are additional data that would enhance the evaluation. The supporting guidance, in section four, describes why particular criteria have been categorised as essential and desirable, and gives further information on collecting data.

1.2 Why do we need this framework?

At present there is a lack of high quality evidence on effective weight management interventions. In August 2008, a study by the EPPI-Centre at the University of London focused on schemes to promote healthy weight in overweight and obese children.¹ It found that whilst interventions are being commissioned by a variety of organisations, data informing the relative 'success' of the interventions, in terms of the intended health outcomes, was patchy and inconsistent.

In order to maximise collective learning and ensure increasingly effective interventions over time, it is important that individual interventions are assessed for their effectiveness (including cost-effectiveness), and that interventions can be compared with one another.

In evidence-based medicine, randomised controlled trials (RCTs) are usually considered to be the 'gold standard' for a scientifically robust assessment of whether an intervention is effective. *The Consolidated Standards of Reporting Trials* (CONSORT) statement provides guidelines for how RCTs should be reported for evaluation purposes.² An extension to the CONSORT statement in December 2008, provides similar guidance about the reporting of 'pragmatic' trials which are intended to inform decisions about whether an intervention works in 'normal' practice.³

However, RCTs are often not practical or are too expensive for evaluating public health interventions and other research designs may be more appropriate in many cases. In addition, community-based programmes are often more complex than RCTs. Typically, RCTs evaluate a specific single intervention and its effects on specified outcomes. By contrast, community programmes often have multiple elements, complex partnerships and may be less amenable to strictly scientific evidence generation.

The Medical Research Council's *Developing and evaluating complex interventions: new guidance* updates its guidelines from 2000 and includes non-experimental methods and complex interventions outside the health service.⁴ It recognises that there are methodological and practical constraints to carrying out complex interventions that need to be considered when carrying out an evaluation. The TREND statement has general guidance and a checklist, similar to the CONSORT statement, for the evaluation of non-RCTs and other types of research design.⁵

The Consort Statement, Medical Research Council guidance and TREND statement have all been consulted and referenced in the development of this document.

This document does not set out to be over-prescriptive or stifle innovation. Evaluation is not a fixed or stand alone process: it needs to be flexible and adaptable to the needs of the intervention being studied. It is hoped that this document will provide an evidence-based framework that will help to improve the quality of evaluation and development of relevant policies.

1.3 Consultation processes in the development of the SEF

The SEF has been developed in consultation with academic experts and representatives from public health observatories, government offices, primary care trusts and other relevant organisations.

An initial draft list of essential and desirable criteria was developed following a broad literature search. This list was disseminated to members of the scientific advisory panel, the cross-governmental obesity team, primary care trust obesity leads, government office obesity leads, public health observatory obesity leads and directors of public health with an online questionnaire for consultation. Comments were also invited from a number of academics in the field.

Revised criteria were considered at a consultation workshop in November 2008. Following feedback from this workshop, the criteria were further reviewed and the supporting guidance document drafted.

The SEF is an ongoing project: it will be revised and updated following evaluation of this first draft.

If you have any comments or suggestions, please email them to info@noo.org.uk

2. An introduction to evaluation

This section introduces the concept of evaluation. It draws extensively on a number of other evaluation guidance documents.^{6,7,8} Readers interested in finding out more about evaluation methods could look at one of the core texts on the topic.^{9,10}

2.1 Evaluation: what's it all about?

Evaluation is about judging the value of an activity and assessing whether or not it has achieved what it set out to do. In health promotion, an evaluation determines the extent to which a programme has achieved its objectives, and will assess how different processes contributed to achieving these objectives.¹¹

A health promotion initiative should have three components:

- planning;
- implementation;
- evaluation.

Evaluation is key to good project management and is just as important as setting clear aims and objectives. Evaluation should not be a stand-alone activity, nor should it occur only at the end of a project: it should be considered an integral part of the overall project planning, ideally beginning before a project is implemented.¹² It should be closely linked to setting the project's objectives. At its most simple, evaluation answers the question:

"Has the project achieved its objectives?"

Answering this relies on the project having had defined, clear, measurable and achievable objectives from the outset. There is more information on this in section 2.5.

Evaluation also contributes to determining *how* a project worked as well as *whether or not* it worked. The EPPI-Centre report, *Schemes to promote healthy weight among obese and overweight children in England*, identifies three key points to consider when carrying out an evaluation:

1. Why might we expect the project to work?
2. Does the project work?
3. How does the project work?¹³

Evaluation should be closely related to the *logic model* of a project. A logic model sets out the way a project is predicted to progress and the processes of change that might take place (see section 2.8). Discussing and agreeing a logic model is a critical stage in a project's development because it reveals what needs to be measured at each stage of the project.

2.2 Why evaluate?

Evaluation is important for:

- finding out whether a project's aims and objectives have been achieved;
- assessing what else has been achieved;
- finding out what went well and what could be improved;
- influencing a project's development;
- feeding back progress to everyone involved including funding bodies and supporters;
- monitoring progress;
- demonstrating that resources are well-allocated;
- sharing experiences with others including potential funding bodies and key decision makers.

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Evaluating a project is often forgotten, particularly if focus is centred on actually running the project. However, without some form of evaluation it is difficult to find out if a project has done what it set out to do, met any funding conditions or benefited a targeted group.

Evaluation indicates what was successful as well as what could be improved next time. This is particularly important if an objective is to repeat the project.

2.3 Who wants to know?

Many weight management interventions have multiple partners and funding agencies, representing a diverse range of interests. For example, a project may be funded by a primary care trust but delivered by a local authority or private company.

Each funding body may have quite different reasons for becoming involved in the project. For example, a primary care trust may be interested in reducing prescribing budgets and meeting health improvement targets; a local authority may be focused on increasing the use of their leisure and sport facilities; and academic institutions may want to contribute to the evidence base in peer-reviewed publications. These different motivators or 'drivers' can lead to different perspectives about the best way to evaluate a project.

Finding out what these drivers are can prompt a common question or questions to ask about your project. One of the most important first steps is to find out what you, your organisation, your funders and your participants value about the project. This, in turn, will influence the decisions you make about:

- what defines success;
- what is seen as the project's strength and weakness;
- how these can be measured;
- who does the measuring;
- who pays for the evaluation;
- who analyses the information;
- how the results are shared.

Different interested parties may also have different perspectives on how they define success. For example, some may focus on objective quantifiable results and will want to see results such as:

- the numbers of participants receiving the intervention;
- percentage of these with measured change in a key indicator (such as level of physical activity or nutritional intake) perhaps compared to a control group;
- percentage of participants who have reduced their body weight.

Others may be more focused on qualitative information and measure success in terms of:

- what actually happened and how it was delivered;
- involvement of other parties or agencies;
- quotes or interview data from participants.

These different perspectives should be taken into account when designing the intervention and how it is evaluated.

An evaluation cannot be done in isolation: it is best done in conjunction with others, particularly those who have an interest in learning from a project's successes and failures.

2.4 What is evaluation NOT? Some myths

Many people think evaluation is something mysterious and technical that takes years of training. Evaluation often gets confused with carrying out academic research.

Evaluation of a project:

- does not always involve extensive questionnaires;
- does not have to mean employing expensive consultants;
- is not simply about counting everything;
- does not necessarily have to involve comparing one group with a control group;
- is not something that can be tagged onto the end of a project.

Nutbeam and Bauman define the key differences between an evaluation conducted primarily from the perspective of practitioners, and an evaluation conducted for scientific purposes.¹⁴ Although, in reality, there is not a clear distinction between the two perspectives, table one does help to illuminate possible differences.

Table 1: the similarities and differences between practitioner and scientific evaluations of health promotion programmes. Adapted from Nutbeam and Bauman.¹⁵

Function	Practitioner perspective	Scientific/researcher perspective
Funding	Controlled by managers or other stakeholders.	Usually grants from academic funders.
Purpose of evaluation	To implement and improve programmes.	To generate scientific evidence.
Research methods	Pragmatic. Often a mix of quantitative and qualitative methods. May include perspectives of users and other stakeholders.	Tends towards quantitative methods Use of advanced statistical techniques and methodologies. Aim to reduce bias.
Level of evaluation	Emphasis on formative evaluation and process evaluation.	Emphasis usually on the project's impacts. May extend to outcome evaluation, to provide evidence of project's effect.
Research design	Flexible and pragmatic.	Tightly controlled.
Use of results	To improve (or perhaps abandon) the programme. To disseminate to others so they can use them in settings or communities.	Publication that contributes to scientific knowledge. Dissemination to encourage replication to 'test' in other settings or communities.

Evaluation or audit?

In the context of healthcare and health services, auditing a project assesses performance management, service improvement and cost effectiveness. An audit gathers information for monitoring quality and value for money, and may encourage changes to current practice. Consequently, it tends to focus on monitoring and evaluating processes rather than their impact. An audit may form part of an evaluation, and some of the information collected may be the same, but an evaluation goes further

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than an audit in that it attempts to assess why any changes may have occurred.

At this point, it may be useful to look at the difference between monitoring and evaluating. Monitoring describes the collection of routine information, such as attendance figures and drop-out rates, to check the extent to which a project is proceeding according to plan. Monitoring is, therefore, part of the evaluation process. *It is not a substitute for evaluation.*

2.5 Relating an evaluation to the aims and objectives

As stated in section 2.1, projects need clear objectives that describe what they are aiming to do and how they will do it. In general, the clearer the objectives, the easier they will be to measure. If it is not clear what the project is trying to achieve, it will not be possible to measure whether or not it has been successful.¹⁶

This is why evaluation needs to be considered right at the start, and built into a project's logic model (see section 2.8). A simple way to set objectives is to use SMART objectives:

- **Specific:** objectives should specify what you want to achieve;
- **Measurable:** measure whether or not objectives are being met;
- **Achievable:** are the objectives achievable and attainable?
- **Realistic:** can the objectives be realistically achieved with the available resources?
- **Time-bound:** when should the objectives be met?

As an example, compare these two objectives and how well they can be evaluated:

1. to reduce the proportion of residents of a borough aged 45–54 with a BMI of 30+ by 10 per cent by January 2020;
2. to promote physical activity to residents across a borough.

Objective one is measurable and clear about what is to be achieved and by when. Objective two is vague and could be 'achieved' by putting on a single exercise class, or launching a multi-million pound integrated programme. If objectives are SMART, the evaluation stands a greater chance of providing meaningful results.

2.6 What types of evaluation? Some definitions

There are three main types of evaluation: formative, process and impact/outcome.

- **Formative evaluation** starts during a project's development stages and uses theory to develop and plan the project's components, development and pilot testing. It informs the direction a project will take. Pre-testing is a type of formative evaluation and involves trying out some of a project's parts before it is launched in full. It assesses a project's relevance to identified health problems, and the practicality of different intervention methods.¹⁷
- **Process evaluation**, also known as implementation evaluation, begins at the start of a project. It assesses implementation and delivery, and identifies factors and conditions relating to how a project is being implemented. It aims to see why a project does or does not meet its aims and objectives, and can show whether the project deviated from the original plan.
- **Impact/outcome evaluation** focuses on whether a project met its aims and objectives. This might be in terms of health outcomes, such as obesity, or impacts on health behaviours such as increased physical activity or better nutrition.

Formative, process and impact/outcome evaluations seek to answer different types of question about the project. None is superior to the others. Rather, they complement each other and, ideally, should all be conducted at the appropriate stages in a project's cycle. Often an evaluation will seek to answer both process and impact/outcome questions.

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In a hypothetical weight management intervention using counselling in primary care, the different types of evaluation would look at the following.

A formative evaluation might identify features from a literature search that support a particular approach. For example, motivational interviewing, combined with reinforcement and follow-up. This information can be used to develop the best possible project for this setting. A pilot study with a small sample of GP patients could test the evaluation and this lead to refinements to the project. For example, patients from the pilot study might say they prefer to have detailed discussions about their diet with a dietician rather than a GP. This could lead to changes to the project's structure or format before it is launched in full.

Process evaluation starts after the full programme is launched and might reveal the dieticians are finding it hard to stick to the motivational interviewing approach and are drifting towards giving more direct advice. This would indicate it is difficult to implement the project exactly as intended.

An impact evaluation might show x per cent of patients reporting they have changed their diet (by reducing total fat intake by y percent or by z grams per day) following the counselling.

An outcome evaluation could say what proportion of patients reduced their Body Mass Index following the intervention.

In practice, an equal amount of time cannot be spent on each of the different types of evaluation. The amount of attention given to each depends on the type of project, its aims, and the perspectives of the stakeholders concerned.

Quantitative and qualitative evaluations are different ways data can be used to inform evaluations, see the definitions below. Another important distinction to make is between evaluation, monitoring and research, and these are also defined below.

- **Quantitative evaluations** give numerical results. For example, the percentage of participants still exercising six months after completing a cardiac rehabilitation programme. Quantitative methods are most often used to assess a project's effects.
- **Qualitative evaluations** use narrative or descriptive data rather than numbers. For example, a description of the views and attitudes of those completing a cardiac rehabilitation programme, and their thoughts on how it could be improved. Qualitative methods are most often used in a formative evaluation to aid a project's planning stage and when assessing participants' needs.
- **Monitoring** checks the extent to which a project is proceeding according to plan. For example, looking every week to see if there is a drop-off in attendance. It is really a subset of evaluation and should not be used as a substitute for a full evaluation.
- **Research** is not the same as evaluation. The two are very different activities – see table one. In research projects, an intervention tends to be designed and controlled by researchers who aim to ensure that it is delivered in a standardised way. When evaluating a project in real-life, the challenge is to investigate a project that is usually being delivered by other people in a real-life settings. This tends to lead to more varied results and requires a pragmatic approach to evaluation. An aim of health promotion research is to show those health promotion interventions that are 'effective'. Strictly speaking, effectiveness can only be demonstrated through controlled research designs which are expensive and time-consuming. This is explored in more detail below.

2.7 Evaluation designs

This section is an introduction to the wide range of different types of evaluation design. Suggested further reading is offered throughout this section for more detailed information.

In general, a stronger evaluation design increases the confidence with which conclusions can be drawn from findings. In particular, a strong evaluation can indicate that a project's outcomes were

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caused by the project itself rather than by chance. However, in health promotion projects, there are often multiple stakeholders, multiple intervention elements, and it may be impossible to use the optimal scientific evaluation design. The project context, functioning of the partnerships in the community, and population reached and engaged with may be more important elements in some community weight management programme evaluations, than the need to generate scientific proof of weight loss attributable to the intervention. It is therefore critical to choose the most appropriate evaluation design.

Experimental designs

It is generally acknowledged that the strongest scientific evidence comes from experimental designs, and specifically randomised controlled trials (RCT).¹⁸ Participants or groups of people are randomly allocated to receive an intervention (intervention group) or not (control group). Changes in the intervention group are compared against measures in the control group. This reduces the possibility that the changes occurred by chance, and increases confidence that they were caused by the intervention itself rather than an external factor.

RCTs are not the focus of this document, as they are primarily used by academic researchers who are able to control most of the elements of the intervention, which is generally conducted in a research rather than real-life setting.

Quasi-experimental designs

These types of designs tend to be more feasible in evaluations of projects in real-life settings. Quasi-experimental designs may use a control group but, unlike the RCT, do not randomly allocate participants to either the intervention or control groups. So, for example, in a community-based weight control programme, the findings might be compared to a community, group or setting where there was not an intervention. This increases the risk of changes in outcomes being due to the differences between two communities. Although there may be something different about the comparison community that was not an outcome of the project, it does make the evaluation much more manageable.

Comparisons could also be made with earlier measures in the same population, rather than from a control group. This is a time-series design in which multiple measures are taken at different time points before the project, and then multiple measures taken afterwards. In this way, we can see whether the project made a difference to the prevailing trend. This is relevant to obesity interventions as groups of people seldom lose weight without intervention; if anything, secular changes point to group increases in weight. Therefore, if this trend has been reversed it is more likely to have been specifically due to an intervention.

Pre-experimental designs

These types of studies provide the weakest evidence and should only be used when all other possibilities have been explored.¹⁹ Pre-experimental designs include a pre-post study (where data are collected before and after an intervention). This is a design that can be used for very large evaluations, for example, evaluating a national programme. In areas like obesity management, these can still be informative, as observed and significant weight loss does not occur by itself, and is likely to be due to a project, even limited to a pre-post assessment.

The weakest design is a post-intervention only study in which data are collected after the project has taken place. This type of design cannot be used for assessing a project's effects, although it can provide some useful information such as participants' satisfaction. *Post-only evaluations should never be used for assessing a project's effectiveness or impact because there is no measure prior to the intervention and change cannot be assessed.*

In all evaluations, the designs used will be determined by the resources available including available budget and the skills of those involved. The perspectives and needs of the project stakeholders should also be taken into account. In most cases, a mixture of designs will be most appropriate.

2.8 Measuring key indicators

A crucial part of any evaluation is agreeing a set of core measures. These are things that it is hoped will change following the project's implementation. These may be qualitative, such as feelings of satisfaction with an obesity service, but they are more likely to be quantitative such as time spent being active per week.

The *Healthy weight, healthy lives: a toolkit for developing local strategies* lists national indicators relevant to obesity and related issues.²⁰ The indicators include obesity prevalence, healthy food choices, physical activity participation and mortality. These indicators provide an important context for local projects because they describe some of the key behavioural and health outcomes that projects are likely to be aiming to change.

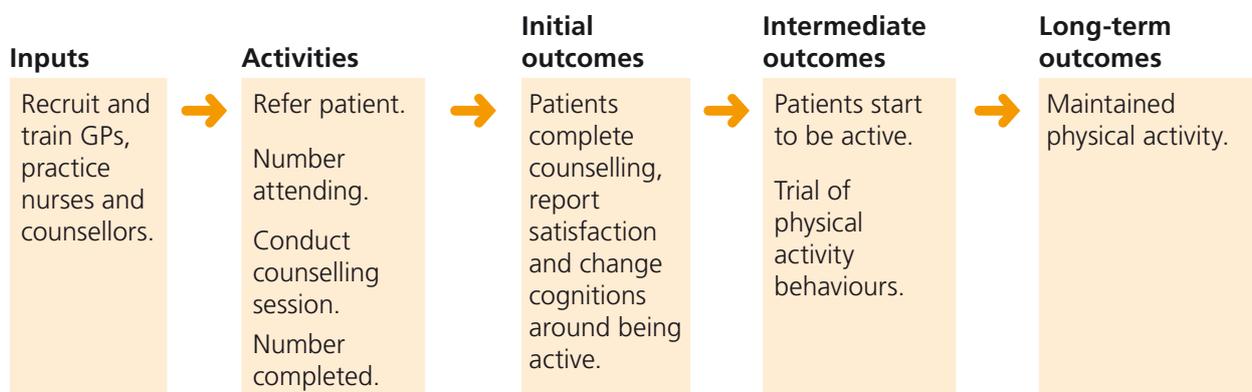
It is important to be realistic about the impact a project can have on these key indicators. In most cases, weight management interventions have the ultimate aim of reducing or maintaining body weight (usually expressed as Body Mass Index (BMI) – see sections three and four). It may be unlikely a project will have a measurable impact on BMI in the short term but it may change one or more of the other determinants of obesity such as eating behaviour and physical activity. In this instance, while data on height and weight (and hence BMI) should be collected, the key measure would not be BMI but a measure of food intake or physical activity behaviour.

Logic models

A logic model is useful for focusing on an intervention's likely impact. A logic model describes the relationships between each element in a project or intervention, and the likely direction of change. A logic model should be developed before a project begins, and set out expected actions with their expected impact and outcomes. It provides a logical roadmap that anticipates how each project element will work, what the result will be, and how the sequence of elements will lead to the expected outcomes. This enables the evaluator to focus on taking key measures at each stage, and relating these measures to the overall project. This, in turn, can be related to more complex models that map the relationships between obesity and its determinants.²¹

The US Centers for Disease Control and Prevention's *Physical activity evaluation handbook* has a good logic model for physical activity.²² An example logic model for a physical activity-based intervention is shown in figure one.

Figure 1: a simplified example of a logic model for primary care physical activity counselling



In this example, an evaluation would not only measure whether patients have sustained physical activity, the main outcome variable, but also initial outcomes such as patients' intentions to be active and initial trials of physical activity after the counselling session.

2.9 Budgets

A critical part of project planning is securing the budget. This should include adequate funds for an evaluation. There is not a general consensus on an appropriate scale for evaluations, the World Health Organisation (WHO) suggests at least 10 per cent of a health promotion's total project should be dedicated to its evaluation.²³

Having adequate resources for an evaluation results in having a greater choice about which elements of a project can be evaluated.

2.10 Methods for collecting data

An evaluation is likely to contain a mixture of methods for collecting the different types of information it needs. Some of the data will be objective such as height and weight and can be measured directly. Some cannot be observed or collected directly and have to be indirectly collected through other collection methods. The most common method is a questionnaire survey, completed either by an interviewer or directly by the participants. It is important to seek expert advice on questionnaire design as there are many issues that can affect the quality of data collected, and the ease of analysis. For example, open-ended questions can yield valuable qualitative information but are difficult to analyse.

One of the most important issues to consider when using an indirect measurement tool, such as a questionnaire, is whether or not its reliability and validity have been tested. The tool has to be tested for the extent to which it measures the same thing each time it is used and the extent to which it reflects the 'truth' of what it is measuring. Appendix A outlines some validated tools for measuring physical activity and nutrition behaviour.

Qualitative information is usually collected through semi-structured face-to-face or telephone interviews, or focus groups. Again, it is important to seek help from someone experienced in qualitative methods before starting to collect data.

2.11 Analysis and reporting

A common situation with health promotion interventions is that evaluation systems are set up and data collected, but the data are never analysed, so there is no ongoing feedback or learning about the project. It is critical that the data are analysed at key stages in the project. This may simply be at the project's completion or it may be at agreed times throughout the project to allow for interim feedback.

Even basic monitoring of data can be extremely useful if fed into a project's development. For example, the monthly analysis of attendance at a weight management intervention may show changing patterns in attendance due to an external factor that can be easily rectified.

The type of analysis needs to be closely related to the study design and the appropriate statistical tests chosen (for quantitative analysis) or the appropriate analytical analysis method (for qualitative studies). There are a number of texts available to help choose the most appropriate analysis according to study design.^{24,25}

The style of reporting should also be related to the readers' needs and the evaluation's aims. For example, a manuscript for an academic journal reporting on the results of a controlled trial will have a very different style to a report to a project board on participants' views. The same evaluation data may be used for different purposes, providing reports are suitably adapted.

2.12 Ethics

An important part of any research or evaluation study is the consideration of ethical issues. These are issues that may have an impact on the rights, safety, dignity and well-being of all actual or potential participants in a study.²⁶

In the NHS, ethical considerations are governed by the National Research Ethics Service (NRES). This service: 'works with colleagues in the UK to maintain a UK-wide system of ethical review that protects the safety, dignity and well being of research participants, whilst facilitating and promoting ethical research within the NHS.' It is comprised of the former Central Office for Research Ethics Committees (COREC) and Research Ethics Committees (RECs) in England.²⁷

The NRES manages a formal process of approval for research in the NHS. Most research involving NHS patients must be formally approved by a research ethics committee before it can begin. Evaluators should check with the NRES to see if their project requires approval. There are exceptions if a project is a 'clinical audit' or a 'service evaluation' rather than research. Guidance is available on the NRES website.²⁸

A key source for guidance and standards for research ethics is the Department of Health's *Research governance framework for health and social care: second edition* and the *Second edition, 2005 – annex*.²⁹ It applies to all research undertaken by or within health and social care agencies. It aims to ensure that core principles and relevant legislation relating to issues such as ethics, patient information, health and safety, informed consent and intellectual property rights are adhered to in order to safeguard the health and well-being of the public. How these principles should be applied in a research project will differ according to its design, context and method.

2.13 Evaluation: who can help?

Practitioners may find there is a lack of people available to offer hands-on help with an evaluation. Some projects rely on external consultants or academic bodies to support their evaluation design and, even, undertake the evaluation. This can be a good option although it is unlikely to be the cheapest. It may be worthwhile finding out if any expertise or support is available locally from, for example, a school, college or university, the local authority, primary care trust, voluntary groups or health promotion unit. They may have students, volunteers or employees available to help design or implement your evaluation. Such support can add to a shared vision of an evaluation and the possible benefits of a project.

An evaluation partnership is a recommended approach. Project managers and evaluators work together in a true partnership that aims to evaluate a project and make sure it continuously improves as learning is fed back into its development. This is the opposite of the approach where the team running a project view the evaluators as 'the enemy' or 'snoopers' who have come to check on their progress.

2.14 Some general principles: DOs and DON'Ts

DO

- Set a budget for evaluation.
- Build evaluation into the start of a project.
- Bring all stakeholders together and agree aims and objectives.
- Set out how the project will achieve its objectives.
- Find out what stakeholders think a successful project will look like.
- Agree what will be measured and how it can be measured.
- Use data collection methods which are appropriate to the available resources and will help answer the key evaluation questions.
- Consider the value of both quantitative and qualitative information, if possible.
- Scope out timing and logistical issues, and consider the impact they will have on the evaluation.
- Think creatively: there is no single way to evaluate a project.
- Keep evaluations simple and useful.
- Share your findings as widely as possible.

DON'T

- Start the project without collecting baseline data.
- Try to measure everything.
- Only have one person responsible for the evaluation.
- Spend so long designing a questionnaire that you do not have the time to use it.
- Collect data that will not be used.
- Construct a comprehensive evaluation plan then forget it as soon as you get the funding.
- Make claims from the evaluation that cannot be substantiated.

2.15 Measuring the broader effects

An evaluation can reveal unintended consequences. These are outcomes, both positive and negative, that might arise but were not originally intended. For example, a healthy eating project targeting children in schools may influence family eating habits as the children bring home their materials or discuss what they have learned. It is therefore important to consider wider possible outcomes when designing the project and its evaluation. Aim to measure and assess some of the wider, often unplanned, possible outcomes. The ability to do this will be limited by project resources but can lead to a richer understanding of a project's achievements. For example, when considering possible negative outcomes, the potential psycho-social consequences of an intervention should not be overlooked. An intervention targeting overweight or obese children may lead to them feeling stigmatised and have a negative impact on their self-esteem. This would not be identified without having the appropriate baseline and follow-up data. Psycho-social measures are discussed in more detail in sections three and four.

2.16 A step by step guide to evaluation

Step 1: What would you like to know?

- Who is the evaluation for?
- What does your project aim to achieve?
- What information do you need to collect?
- What are the outcomes of your project?
- What processes will your project go through from start to finish?
- What are the aims and objectives of your project?
- What funding exists for doing your evaluation?
- What style of evaluation will be appropriate?

Step 2: How are you going to find out what you need to know?

- What is the best way for your project to collect the information you need?
- Who will collect this information?
- What additional skills, resources or training are needed to do the evaluation?
- Do you have the appropriate people, time and evaluation methods?
- How are you going to analyse this information?
- Do stakeholders know the sort of information you will find out from the evaluation?
- Will the evaluation have any consequences, good or bad, for the way the project is designed and run?

Step 3: Find it out

- Are you checking the information you need is being collected?
- Are you on time for completing your evaluation?

Step 4: Look at the answers so you can make your judgement

- What do the results say?
- What did you expect them to say?
- Are there any unexpected results from your project?
- How will the results be used to change the project?
- Do the results indicate that the project should be stopped?

Step 5: Tell the people who need to know

- How are you going to share your project evaluation with others?

3. Standard Evaluation Framework for weight management interventions

This section presents the core elements of the standard evaluation framework. Essential criteria are presented as the minimum recommended data for evaluating a weight management intervention. Desirable criteria are additional data that would enhance the evaluation. The supporting guidance, in section four, describes why particular criteria have been categorised as essential and desirable, and gives further information on collecting data. *Click on a cell to be taken to corresponding explanation.*

	ESSENTIAL	DESIRABLE
Part one: intervention details		
1. Title/name of intervention		
2. Aims and objectives (including primary and secondary outcomes)		
3. Intervention timescale (exposure, quantity and duration)		
4. Intervention delivery dates		
5. Duration of funding (including dates)		
6. Location and setting		
7. Description of intervention: <ul style="list-style-type: none"> • target population; • content; • delivery method; • deliverer; • unit of delivery; Details of quality assurance mechanisms		
8. Rationale for intervention (including theoretical basis)		
9. Core staff competencies required		
10. Equipment and resources required		
11. Incentives for attendance		
12. Details of training needs (including quality assurance of training)		
13. Method of recruitment and referral		
14. Participant consent mechanism		
15. Participant admission/exclusion criteria		
16. Cost of intervention per participant		
17. Cost to participant		
18. Detailed breakdown of cost		
19. Type of evaluation and evaluation design		
20. Details of equality impact assessment		
21. Relevant policy and performance context		
22. Details of health needs assessments that have been conducted		
23. Contact details		
24. Commissioner(s) of the intervention and sources of funding		
25. Declaration of interest		
26. Details of type and extent of any clinical involvement		

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	ESSENTIAL	DESIRABLE
Part two: demographics of individual participants		
27. Age		
28. Sex		
29. Ethnicity		
30. Disability		
31. Measure of socio-economic status		
32. Additional information including marital status, medical history, smoking status, parity and family make-up		
33. Details of parental weight status (for children)		
Part three: baseline data		
34. Height and weight (to calculate Body Mass Index)		
35. Additional proxy measures for adiposity		
36. Measure(s) of dietary intake and behaviour		
37. Measure(s) of physical activity levels and behaviour		
38. Potential facilitators of, and barriers to, lifestyle change		
Part four: follow-up data		
Impact evaluation		
39. Follow-up data: minimum of three follow-up points, including at one year		
40. Follow-up data on key measures (height, weight, physical activity and diet) over a greater term than one year		
41. Follow-up data on additional proxy measures for adiposity (if collected at baseline)		
42. Additional proxy measures for adiposity		
43. Dietary intake and behaviour		
44. Physical activity levels and behaviour		
45. Follow-up measures on potential facilitators of, and barriers to, lifestyle change (if collected at baseline)		
Process evaluation		
46. Number invited		
47. Number recruited		
48. Number attended each session or contact point		
49. Number completed		
50. Number of participants at each follow-up point		
51. Methods of data collection and timings		
52. Reasons for opt-out (where applicable)		
53. Details of any unexpected outcomes and/or deviations from the intended intervention design and the reasons why		
54. Participants' satisfaction with the intervention		
55. Plans for sustainability		
Part five: analysis and interpretation		
56. Summary of results compared to baseline (for primary and secondary outcomes)		
57. Details of any further analyses and statistical methods used		
58. Limitations and generalisability		

4. Explanatory notes

The list of criteria above is separated into essential and desirable.

Essential criteria are the minimum data and information required to do a basic evaluation of an intervention that sets out to manage or reduce body weight including the primary prevention of weight gain.

Desirable criteria are recommended to improve the quality of the evaluation so that practitioners, commissioners and evaluators can:

- understand more about what went well and what did not go well when carrying out the intervention;
- understand whether or not the delivery of the evaluation needs to be modified;
- be confident about conclusions that are drawn from any analysis and interpretation of collected data.

Part one: intervention details

1. Title/name of intervention

ESSENTIAL

A record of the name or title of the intervention, for example, *Get fit and healthy*.

2. Aims and objectives (including primary and secondary outcomes)

ESSENTIAL

What does the intervention aim to do? Does it have a primary weight management target such as reducing body weight? Does it have a secondary outcome target such as increasing self-esteem? These are the key outcomes which need to be carefully measured, and against which the intervention will be evaluated. It may be helpful to refer to section 2.8 on logic models.

Aims and objectives need to be as clear as possible and, ideally, SMART, that is specific, measurable, achievable, realistic and time-bound. See section 2.5 for more detail.

3. Intervention timescale (exposure, quantity and duration)

ESSENTIAL

How long will the intervention run for each group of participants? How many sessions, episodes or events will be delivered? How long is the intervention intended to last? For example, 'the intervention was delivered in 20 two-hour sessions, twice a week for ten weeks'. Please note, the intervention's duration may differ from the duration of the funding.

4. Intervention delivery dates

ESSENTIAL

This includes dates for the initial recruitment, first point of contact and any follow-ups.

5. Duration of funding (including dates)

DESIRABLE

What are the start and finish dates for the overall programme? The intervention may be run a number of times throughout the duration of a programme.

6. Location and setting

ESSENTIAL

Where is the intervention taking place? It could be in a GP surgery, school or community centre. It may be that it takes place in several settings and they should all be included here. It may be useful to add any transport that is being provided.

7. Description of intervention**ESSENTIAL**

The headings below are only intended as a guide. It may be that these points are described differently for a particular intervention.

Target population

What is the intervention's target population? From which population are the participants recruited? For example, 'Bangladeshi women from Xtown aged 45–55 with a BMI of 30 or over'; or 'children aged 7–13 from the Ytown area who are overweight or obese'.

Content

Clearly state what the intervention is going to do, and how it is going to do it. List all of its major project activities and outputs. For example, 'The intervention will include giving dietary advice, demonstrations of healthy cooking, motivational interviewing and interactive physical activity sessions. Each two-hour session will be split between an hour of nutrition and healthy eating advice, and either physical activity or motivational interviewing.'

Delivery method

How will the intervention be delivered? For example, face-to-face meetings, by telephone or online.

Deliverer

Who is delivering the intervention? For example, school nurse, community nutritionist, health trainers, health professional or teachers.

Unit of delivery

Who is the intervention aimed at? For example, individuals, families or particular groups.

Details of quality assurance mechanisms

What mechanisms are in place to ensure the intervention is being delivered in the way in which it was planned? This is particularly important if the intervention sets out to use a particular delivery method or style such as motivational interviewing.

Examples of quality assurance mechanisms are spot-checks carried out by an external assessor, self-assessment check-lists that can be used by the deliverer of the programme, and participants' satisfaction questionnaires.

Include details of any relevant health and safety checks, risk assessments and Criminal Record Bureau checks, if applicable (that is, if the intervention is with children).

8. Rationale for intervention (including theoretical basis)**DESIRABLE**

It is very helpful to state the reasoning behind the design of the intervention and the methods that will be used. State the theories or scientific evidence the intervention is based on. What is the theoretical or scientific basis that suggests the intervention will be successful in its aims and objectives? This could be peer reviewed research studies, NICE guidance on obesity interventions, or theories about health promotion and behaviour change.

9. Core staff competencies required**DESIRABLE**

What are the core skills needed by everyone involved in delivering the intervention. For example, facilitation skills, cooking skills, experience in working with children or young people, communication skills, and basic knowledge of nutrition or physical activity. This can be very useful if others want to replicate the approach taken by this intervention.

10. Equipment and resources required

DESIRABLE

Is a particular type of venue required? For example, one with a kitchen or gym. Are specific resources needed such as pictures of 'eat-well' plates, specific physical activity equipment, cooking equipment, food and measurement tools such as pedometers and calibrated scales? There is more information on measurement equipment that may be needed in points 34 and 37.

11. Incentives for attendance

DESIRABLE

Have any incentives been provided for encouraging individuals to take part in the intervention and, if so, what are they? Have incentives been provided for first attendance or completion of the intervention? If incentives have been used, please outline any assessment that has been made on potential outcomes as incentives may have an impact on the success of the intervention and the sustainability of any behaviour change.

12. Details of training needs (including quality assurance of training)

DESIRABLE

Are those delivering the intervention required to be trained in certain aspects of the intervention such as basic nutrition, counselling or childcare and youth work. Do they have to have a qualification in fitness training? Do they have to be trained to a specific level?

13. Method of recruitment and referral

ESSENTIAL

How have participants been recruited to the intervention? What percentage of those that are eligible have been recruited? Has there been a referral process or was it self-selection? For example, have participants been referred by a GP or have leaflets and posters been used to advertise in GP surgeries? Please give brief details here of any sampling process that was undertaken. Was there any targeting of particular groups by, for example, advertising the intervention in certain communities or at specific locations? The method by which people have been recruited should be taken into account when carrying out the evaluation. For example, a self-selected group of participants may be more motivated than referred participants.

14. Participant consent mechanism

DESIRABLE

The appropriate mechanism for gaining participant consent must be considered. The nature of consent will vary for different groups of people. For example:

- those able to consent for themselves;
- those with parental responsibility and consenting on behalf of a child or young person under the age of 16;
- those who lack the capacity to consent.

Policy guidance on seeking consent from different groups and consent forms for children, older people, people in prison, and people with learning difficulties is available from the Department of Health website.³⁰

If a potential participant does not have the capacity to make decisions, health professionals should follow the Department of Health guidance, *Reference guide to consent for examination or treatment*. It is available to download from the Department of Health website.³¹

The *Data Protection Act 1998* must be adhered to when collecting personal data from individuals. A data protection statement should be given to participants before any personally identifiable data is collected. It should explain exactly which personal data is being held, why, where it will be held, and who will have access to the data. This is particularly important when collecting sensitive data

such as ethnicity and socio-economic status. More information about the requirements of the Data Protection Act 1998 can be found on the Office of Public Sector Information website.³²

15. Participant admission/exclusion criteria

ESSENTIAL

Participants who have been referred or have self-referred should meet pre-defined criteria. For example, the target population may be overweight and obese children aged 7–13 from a particular location. However, the admission criteria should ensure that the intervention is appropriate for the needs of the target group. For example, children with particular or complex needs, such as those with learning or educational difficulties, significant or serious obesity-related morbidity, or a suspected underlying medical cause of obesity may need more intensive or specific types of therapy.

16. Cost of intervention per participant

ESSENTIAL

This describes the cost of running the intervention as either an estimate or true cost in terms of actual expenditure and cost of people's time. This information is important for an economic analysis of whether or not the intervention is good value for money. It enables commissioners to judge whether the resources required to run the intervention are available.

17. Cost to participant

DESIRABLE

It should be noted if participants are charged for any part of the intervention. This is often the case for exercise referral schemes.

18. Detailed breakdown of cost

DESIRABLE

A detailed breakdown of an intervention's costs is important for an economic analysis of the entire intervention and judging whether or not it is good value for money. Take into account costs during the planning stages as well during the delivery and evaluation stages. Some examples of input costs are staff time, transport, venue hire, equipment, publicity and incentives. It is especially important to factor in 'invisible' costs. For example, a room in a local authority leisure centre may be hired free of charge as part of a partnership agreement with the local primary care trust. However, this cost needs to be taken into account so that, if the intervention is repeated, financial resources can be planned accurately.

19. Type of evaluation and evaluation design

ESSENTIAL

The way in which an evaluation is designed to collect data, and the method by which data may be compared with any control population, should be recorded here. For example, is the evaluation using mainly qualitative or quantitative data? See section 2.6 for a more detailed explanation of evaluation designs.

20. Details of equality impact assessment

ESSENTIAL

Public bodies have a duty to undertake equality impact assessments (EIA) under race, gender and disability equality legislation. It is useful to provide an intervention's equality impact assessment as part of its overall evaluation. It can give valuable information if particular outcomes are seen in different groups. An equality impact assessment provides a systematic way of ensuring legal obligations are met. It is also a 'practical way of examining new and existing policies and practices to determine what effect they may have on equality for those affected by the outcomes.'³³

21. Relevant policy and performance context**DESIRABLE**

It may be useful to show how an intervention fits into any strategic policies or is a priority service as outlined in, for example, a local area agreement, joint strategic needs assessment,³⁴ or plans supporting World Class Commissioning.

For example, two indicators directly relating to obesity levels are included in: the national indicator set,³⁵ the NHS operational plans 2008/09–2010/2011,³⁶ and the core dataset of indicators produced by the Department of Health and Association of Public Health Observatories to support joint strategic needs assessment (JSNA) processes. These are:

- NI55 – Obesity in primary school age children in Reception Year;
- NI56 – Obesity in primary school age children in Year 6.

The Department of Health, *Healthy weight, healthy lives: a toolkit for developing local strategies* has further advice on setting local goals, developing local obesity strategies and World Class Commissioning.³⁷

Further information is available on the Department of Health website about JSNAs.³⁸ And further information on World Class Commissioning is on the NHS World Class Commissioning website.³⁹

22. Details of health needs assessments that have been conducted**DESIRABLE**

Has a health needs assessment been conducted that identifies a gap in this service being provided for the target population? Information may come from a specific needs assessment conducted for the intervention or it may be available from other sources. For example, data relating to health inequalities and gaps in service provision may already be available from policy documents such as *Joint strategic needs assessments* or *Children and young people's plans*.

If information is not readily available from these documents, datasets from sources such as the Quality and Outcomes Framework, Health Survey for England, Active Peoples Survey, Local Place Surveys, National Diet and Nutrition Survey, Index of Multiple Deprivation, Health Profiles and the Census may be helpful. Useful data, signposting and further information can be found on a range of websites including those for the Association of Public Health Observatories, with links to each of the regional Public Health Observatories,⁴⁰ The UK Statistics Authority,⁴¹ NHS The Information Centre,⁴² and The National Obesity Observatory.⁴³

When using data to identify gaps in service provision and to justify resource allocation, it is important to assess the quality of the data being used. For example, how robust are the data at the geographical level at which you wish to use it? How old are the data? How well validated is the tool used to collect the data? If it is estimated data, how has it been modelled and how accurate an estimate is it likely to be? A more robust approach could be to use findings from a number of different data sources and supporting these by carrying out localised research. For example, by using local health and well-being questionnaires, focus groups or face-to-face interviews with the target population or community.

23. Contact details**ESSENTIAL**

Give a list of the key people involved in the intervention's planning, delivery and evaluation. This should include all contact details and details of staff positions as staff may change jobs during the course of the intervention.

24. Commissioner(s) of the intervention and sources of funding**DESIRABLE**

Where has the funding come from to commission the intervention and who has commissioned it? For example, 'the funding has come from the regional government office and the intervention has been commissioned by the primary care trust.'

25. Declaration of interest**DESIRABLE**

This covers any potential conflicts of interest in carrying out the intervention and is particularly important if the evaluation is funded by an agency that could be perceived as wanting to influence the results for commercial reasons.

NICE has produced a clear statement covering different categories of potential conflicts of interest that should be declared, including pecuniary interests (where a financial payment or other benefit has been received) and a non-pecuniary interest (where someone may have publicly expressed a clear opinion on the intervention in question, and this may influence their impartiality).⁴⁴

In general, it is best to declare any potential conflicts even if they do not appear to be important. Perceived conflicts of interest do not necessarily mean the intervention should not go ahead as planned; it may be acceptable to state how potential conflicts are going to be avoided.

26. Details of type and extent of any clinical involvement**DESIRABLE**

Will any clinicians be involved at any stage of the intervention? This includes during development, delivery and carrying out quality assurance of the delivery. In some cases it may be appropriate for the provider to inform GPs that their patients are participating in an intervention.

Part two: demographics of individual participants**27. Age****ESSENTIAL**

It is essential to record the age of all participants in the intervention.

Examples of age categories from national population surveillance studies that could be used for comparative purposes are:

- Census 2001 used: 0–4, 5–9, 10–14, 15–19, 16 or 19–24, 25–34, 35–44, 45–54, 55–64, 65–74 and 75+;
- Health survey for England use: 2–10, 11–15 and 2–15 and adults are classed as 16 and over;
- National Child Measurement Programme uses: children in reception year (aged 5–6) and in year 6 (aged 10–11).

If the intervention is being carried out with children and/or adolescents, pubertal status is an important, potentially confounding, factor to consider because the onset of puberty has a significant impact upon body fat distribution and growth. It should be accounted for as a confounding factor during data analysis. However, it can be difficult to control for given gender and age differences in onset. The impact of pubertal status has been demonstrated particularly in girls,⁴⁵ and the onset of puberty is often earlier in overweight children.

In boys, pubertal changes begin between 10 and 14 years and are complete at between 15 and 17 years. Peak height velocity is reached between the ages of 12 and 17 years and during stage four of the Tanner Stages of pubertal status. In girls, puberty can start a year earlier, between the ages of 9 and 13 and is completed between 12 and 16 years.⁴⁶ Peak height velocity is reached between the ages of 10 and 13. The Tanner self-assessment scale could be used if the age group is reaching puberty.

28. Sex**ESSENTIAL**

Record the sex of all participants. This is useful for identifying whether or not the intervention tends to be more effective for males or females.

29. Ethnicity

ESSENTIAL

It is standard practice in healthcare interventions to record the ethnic origin of participants. If the intervention is targeted at a specific ethnic group, then a record of ethnic origin is essential for screening participants for eligibility. If the intervention is not targeted in this way, it is still important information for raising understanding about the extent to which response to the intervention may vary between different ethnic groups.

For example, if the intervention is aimed at women aged 45–55 in a local community which has 25 per cent of its population made up of Bangladeshis and, in a rolling programme of interventions, less than two per cent of the participants are Bangladeshi, it can be concluded that there is something about either the intervention itself or the publicity for the intervention that is not engaging with the Bangladeshi population. In this case, further research and community development work may be needed to engage with these communities and the intervention or publicity amended accordingly. This is particularly important as there are particular ethnic groups with a higher than average prevalence of obesity.⁴⁷

In addition, there is a legal requirement to carry out ethnic monitoring. *The Race Relations (Amendment) Act 2000* requires public bodies, including local authorities, primary care trusts and their partners to take account of race equality in policy making and service delivery. Ethnic monitoring demonstrates that policies for equality are working in practice. It is a way of identifying potential discrimination and whether policies promoting equality of opportunity and good relations between different racial groups are being implemented. For further information on this, please see the Equalities and Human Rights Commission's website.⁴⁸

The commission recommends public authorities and their partners use the following *Census 2001* categories for ethnic monitoring in England and Wales:⁴⁹

White

- British
- Irish
- Any other white background

Mixed

- White and Black Caribbean
- White and Black African
- White and Asian
- Any other mixed background

Asian or Asian British

- Indian
- Pakistani
- Bangladeshi
- Any other Asian background

Black or Black British

- Caribbean
- African
- Any other Black background

Chinese or other ethnic group

- Chinese
- Any other Chinese background

30. Disability

ESSENTIAL

It is standard practice in healthcare interventions to record the disability status of participants. The *Disability Discrimination Act* defines a disabled person as: 'someone who has a physical or mental impairment that has a substantial and long-term adverse effect on his or her ability to carry out normal day-to-day activities.' Detailed guidance on the interpretation of this definition can be found on the archived Disabilities Rights Commission's website.⁵⁰

The *Disability Equality Duty* came into force in December 2006 and requires all public bodies, including NHS trusts and boards, to actively look at ways of ensuring that people with disabilities have equal access to service provision. It may be particularly important to consider this duty if an intervention has been commissioned by an external provider. More information is on the *Disability Equality Duty* website,⁵¹ the Equality and Human Rights Commission website⁵², and the Office of Public Sector Information website.⁵³

In the context of obesity, monitoring of disability is important as physical or learning difficulties in adults and children can confound the outcome of a weight management intervention. There is increasing evidence to suggest that many disabling conditions such as arthritis, mental health disorders, learning difficulties and back ailments increase the risk of obesity. Children with learning or physical difficulties may be at a higher risk of obesity.⁵⁴ This may be related to genetic or metabolic complications associated with a particular disorder or practical issues related to inappropriate eating or physical activity.⁵⁵ It is unclear whether or not obesity is the cause or the result of these disabilities.

The white paper *Choosing health: making healthy choices easier*, highlights the need to address health inequalities by tailoring services and information for particular groups.⁵⁶ This may be relevant for obese individuals with disabilities whose needs are different from that of standard practice. For example, NICE suggests: 'referral to an appropriate specialist should be considered for children who are overweight or obese and have co-morbidity or complex needs (for example, learning or educational difficulties)'. NICE also suggests a specialist referral should be considered for adults that have 'complex (disease states or) needs that cannot be managed in primary or secondary care.'⁵⁷

31. Measure of socio-economic status

ESSENTIAL

An indicator of socio-economic status should be recorded. There is clear evidence associating lower socio-economic status with the likelihood of children and adults being overweight or obese. Evidence from the *Health survey for England* shows a relationship between obesity and socio-economic status (or 'social class' as it was previously categorised).⁵⁸ The survey also indicates an increased risk of obesity in girls from families in the lowest income quintile and in children from semi-routine and routine households.⁵⁹

There is currently only a limited understanding of the reasons for this association, making it important to build evidence of effectiveness among different socio-economic groups. It is also useful to monitor uptake of interventions by different socio-economic groups, to ensure they are not systematically excluding any groups through their design, delivery, recruitment or referral methods.

The standard indicator of socio-economic status, as used in the *Census 2001*, uses the National Statistics Socio-Economic Classifications (NS-SEC). It is a structured, occupationally-based classification that also includes categories for the non-employed. The NS-SEC categories are:

- Employers in large organisations
- Higher managerial occupations
- Higher professional occupations
- Lower professional and higher technical occupations
- Lower managerial occupations
- Higher supervisory occupations
- Intermediate occupations

- Employers in small organisations
- Own account workers
- Lower supervisory occupations
- Lower technical occupations
- Semi-routine occupations
- Routine occupations
- Never worked
- Long term unemployed
- Full time student
- Occupation not stated or inadequately described
- Unclassifiable

Further information on these classifications and how they have been derived is available on the Office for National Statistics (ONS) website.⁶⁰

Interventions for children should, where possible, collect this information about their parents and guardians.

In many cases it may not be practical to collect the data needed to derive NS-SEC categories (as described on the ONS website, above). In these cases, other proxy indicators of socio-economic status can be used. It is advised that a minimum of two of the following indicators are collected:

1. Postcode for Index of Multiple Deprivation

The Index of Multiple Deprivation combines a number of indicators covering a range of economic, social and housing issues and creates a single deprivation score for each small area in England. This allows areas to be ranked according to their level of deprivation and can be derived from postcodes. These rankings have been produced at Lower Super Output Area level, of which there are 32,482 in the country. Lower Super Output Areas can be mapped against postcode which allows an individual's address to be given a general IMD ranking. Any ranking given is 'modelled' against a number of criteria and relates to an overall ranking for an area which may not necessarily be indicative of the characteristics of an individual household.

2. Educational attainment level

The *Census 2001* categorised the population, aged 16–74, in terms of recorded levels of education:

- Level 1: 1+ 'O' level passes; 1+CSE/GCSE any grades; NVQ level 1; Foundation GNVQ
- Level 2: 5+ 'O' level passes; 5+ CSEs (grade 1); 5+ GCSEs (grades A-C); School Certificate; 1+ 'A' levels/AS levels; NVQ level 2; Intermediate GNVQ
- Level 3: 2+'A' levels; 4+ AS levels; Higher School Certificate; NVQ level 3; Advanced GNVQ
- Level 4/5: First degree; Higher degree; NVQ levels 4 and 5; HNC; HND; Qualified Teacher
- Status; Qualified Medical Doctor; Qualified Dentist; Qualified Nurse; Midwife; Health Visitor

3. Housing tenure

Census 2001 housing tenure categories were as follows:

- Owner occupied: owned outright
- Owner occupied: owns with mortgage or loan
- Owner occupied: shared ownership
- Social rented: rented from council
- Social rented: other social rented
- Private rented: private landlord or letting agency
- Private rented: employer or a household member
- Private rented: relative or friend of a household member
- Private rented: other
- Living rent free

Other relevant indicators might be:

- Household income
- Free school meals status
- Household composition
- Household amenities
- Number of cars per household

Analysis of these data can be a complex issue so it may be necessary to seek specialist help. Local public health analysts or researchers may be able to assist with this type of analysis. Further information about the Index of Multiple Deprivation is available on the Communities and Local Government website.⁶¹

32. Additional information including marital status, medical history, smoking status, parity and family make-up

DESIRABLE

Additional information can enhance the evaluation and give an indication of possible confounders when analysing results.

Marital status/cohabitation

This is a useful indicator as there is a significant amount of evidence indicating that the BMIs of married people tend to be correlated.⁶² There is also some evidence that people gain weight when married and lose weight when no longer married.⁶³ It is therefore useful not only to collect data on whether the subject is married (or cohabitating) but also the weight and height of the subject's partner.

Medical history:

This can indicate confounders such as a participant taking steroids or having an existing clinical syndrome that is known to be linked with obesity such as thyroid dysfunction.

Smoking status:

Smoking has been shown to be correlated with obesity. For example, the *Health survey for England 2006* identifies smoking status as a increasing the risk of obesity in boys aged 8–15.⁶⁴

Parity:

There is evidence to indicate that the incidence of maternal obesity at the start of pregnancy is increasing and accelerating.⁶⁵

Family make-up:

There is some evidence indicating that children raised by single parents are more likely to be overweight than those in two-parent families.

33. Details of parental weight status (for children)

DESIRABLE

A number of studies have shown children are more likely to be overweight or obese if one or both of their parents are overweight or obese.⁶⁶

Part three: baseline data

For all weight management interventions, the key long-term health outcome will be to reduce the risk of health-related conditions associated with obesity which can lead to premature mortality and obesity-related morbidity. Given that it is impractical to track very long-term health outcomes, it may be necessary to use intermediate or shorter-term health outcomes or markers such as changes in food choices, increased physical activity and decreased sedentary behaviour, and sustained improvements in weight status.

It is extremely important to collect baseline data *before* an intervention begins. It is quite common

for health promotion projects to begin without collecting any baseline data. This creates a significant challenge for any evaluation as it is extremely difficult to look back and collect data with any confidence.

34. Height and weight (to calculate Body Mass Index)

ESSENTIAL

It is essential to collect the height and weight of participants, in order to calculate their Body Mass Index (BMI). Even if changing BMI is not the primary objective of the intervention, or BMI is not expected to change in the short term, height and weight should be measured throughout any weight management intervention to assess any changes in BMI in the long term.

BMI is defined as the person's weight in kilograms divided by the square of their height in metres, and is one of the most common ways of estimating whether a person is overweight. It is used because, for most people, it correlates with their proportion of body fat.⁶⁷ It is also a relatively easy, cheap and non-intrusive method for establishing weight status. However, BMI is only an index of body fatness and other factors such as fitness (muscle mass), your ethnic origin and puberty can alter the relation between BMI and body fatness must be taken into consideration. There are also additional measurements such as waist circumference and skin thickness which can be collected.

For all adults, 18 years and over, the BMI ranges for under-weight, healthy weight, overweight and obesity do not change with age and are the same for both men and women. However, because children and teenagers are still growing, BMI as an indicator of adiposity is different for boys and girls and changes with age. For children and teenagers, the amount of body fat also differs between boys and girls, and BMI must also take gender into account. It is therefore not possible to use the adult BMI categories or calculator for people under 18 years old. In the UK, the government uses the UK 1990 growth charts to group BMI values for children and young people between two and 18 years old.

The UK 1990 growth charts were compiled from measurements on boys and girls collected during 11 British surveys carried out between 1978 and 1990. They show the growth patterns of these UK children. A child's BMI and age can be plotted on these charts to work out the BMI centile. The centile is the most commonly used method of interpreting an individual child's BMI and indicates the relative position of the child's BMI as compared with a reference population of children of the same age and sex. For example, a child with a BMI centile of 95 has a BMI higher than 95 per cent of children of the same age and sex, and only five per cent of children of the same age and sex have a higher BMI. If a child's BMI is lower than the second centile, it means that only two per cent of children have a BMI less than they do.

Information about how to purchase the full UK growth charts and a BMI calculator for individual height and weight measurements is available on the Harlow Healthcare website.⁶⁸

Measurement protocols and standards

It is important to ensure that standardised, easily reproducible protocols are used for measuring height and weight so that inaccuracies and inconsistencies are minimised. Ethical considerations should also be taken into account, particularly when weighing and measuring children. The *National Child Measurement Programme* (NCMP) and the *Health survey for England* have established basic standards for these procedures including using standardised weighing and measuring equipment, and ensuring the consistent posture and head positioning of participants when measuring height.

There is more detailed guidance in the *National Child Measurement Programme guidance for PCTs: 2008/09 school year* which is available on the Department of Health website.⁶⁹

The key points about weighing and measuring from these surveillance programmes are summarised below.

Eligibility

Some of these issues may already have been covered in the inclusion criteria for the intervention.

Chair-bound participants and those with difficulty standing

They should not have their height and weight measured. If a participant is too unsteady on their feet for these measurements, do not attempt to take them. If they find it painful to stand or stand straight, do not attempt to measure height.

Small children

Measure small children whilst they are being held by an adult. To weight the child, the adult is weighed first, and then the adult and child are weighed together and the difference calculated.

Site

It is strongly advised, if possible, to measure height and weight on a floor which is level and not carpeted.

Equipment

Portable stadiometers are advised. This is a collapsible device with a vertical rule and a sliding head plate or paddle.

General points about measuring adult and children's height

1. Take measurement without shoes on.
2. Check that stadiometer is assembled correctly.
3. Participant should stand with their feet flat against the base with their back as straight as possible against the rule but not leaning on it. They should be facing forwards with their arms at their sides.
4. Move the participant's head so that the Frankfort Plane is in a horizontal position (Frankfort Plane is an imaginary line passing through the external ear canal and across the top of the lower bone of the eye socket, immediately under the eye. Use the diagram in the NCMP guidance to identify this.⁶⁹ This position is important for an accurate reading. An additional check is to ensure that the measuring arm rests on the crown of the head, that is the top back half.
5. If the measurement has been done correctly, the participant should be able to step off the stadiometer without ducking.
6. Height should be recorded in centimetres and millimetres.

General points for weighing adults and children

1. Participant should remove their shoes and any heavy clothing, outer garments or heavy jewellery.
2. The participant should stand with their feet together in the centre of the scales.
3. The *Health survey for England* stipulates the use of Soehnle electronic bathroom scales.
4. Measure weight in kilograms.

35. Additional proxy measures for adiposity**DESIRABLE**

There are a number of other proxy measures for adiposity or body fatness. Alternative estimates from height and weight are the Ponderal or Rohrer's Index (which is weight/height³) or Benn's Index (weight/height^p where p is determined by analysis of the population being investigated). Each have their own advantages and disadvantages, and they are sometimes used in specific instances, such as for newborns or in research studies, but by far the most common anthropometric measure for published prevalence figures is the Body Mass Index (BMI).

Waist circumference measurement can be used to assess a patient's abdominal fat content or 'central' fat distribution.⁷¹ Central obesity is linked to a raised risk of type 2 diabetes and coronary heart disease. NICE recommends that waist circumference may be used, in addition to BMI, to assess risk in people with a BMI of less than 35kg/m².⁷² It is likely that in a clinical context, consideration of both BMI and waist circumference for adults provides a better indication of increased risk of obesity-related

ill health than either measure alone. Although other measures of central adiposity may be equally good indicators of increased risk of obesity-related ill health, in the absence of evidence based cut-offs to classify individuals as being at increased risk, it is not recommended that waist circumference is routinely used alone. The absence of readily available age-specific cut offs or growth charts for children, means the same applies to measures of central adiposity for children.

Waist-hip ratio is another measure of body fat distribution. It is defined as waist circumference (in metres) divided by hip circumference (in metres). There is no consensus about appropriate waist-hip ratio thresholds. However, a raised waist-hip ratio is commonly taken to be 1.0 or more in men and 0.85 or more in women. NICE does not recommend the use of waist-hip ratio as a standard measure of overweight or obesity.⁷³

Skin fold thickness-measures, using skin fold callipers on multiple sites, can be used to estimate the subcutaneous fat mass and distribution. This method requires some basic training and is more invasive than other measures, but the equipment is relatively inexpensive and portable. However, as with all anthropometric measurements, the possibility of measurement error is high without standardised equipment, measurement protocol and training. In addition, prediction models need to be used in order to derive percentage body fat value.⁷⁴

Bio-impedance is an indirect measure of lean tissue mass, estimated by passing a low-level electrical current through the body and measuring voltage changes given lean tissue mass conducts and fat mass insulates.⁷⁵ There are a variety of equations for different instruments and for different age groups, that can be used to estimate body composition.

Other measures such as bone length measures or head circumference can sometimes be used as an indicator of adiposity for newborns.

Measuring intermediate health outcomes

The SEF criteria in section three list measures of dietary and physical behaviour change as essential to evaluating the success of a weight management intervention. NICE recommends weight management programmes follow best practice which is being: 'multi-component, addressing both diet and activity and offering a variety of approaches.' However, the SEF can be used to evaluate any intervention that aims to address determinants of obesity and improve weight status, either as an intermediate or long term-health outcome. Where an intervention focuses on either diet or physical activity, only the relevant health outcome should be treated as a primary outcome measure.

36. Measure(s) of dietary intake and behaviour

ESSENTIAL

Obesity is caused by an imbalance between energy intake and energy expenditure. NICE guidance recommends that validated methods should be used to estimate dietary intake and physical activity. In principle, all instruments used to assess behaviour indirectly, should be tested for reliability and validity. In this context, reliability refers to how likely it is that the same thing will be measured, each time it is used, either within the same or a different participant. Validity refers to how accurately the measurement reflects the actual behaviour. An instrument can therefore be reliable but not valid as it could measure the wrong thing, but do so consistently.⁷⁶ There are a number of ways of testing for reliability and validity.

Ideally, overall energy intake, broken down by food types would be measured during the intervention and at follow-up. However, dietary intake is a very complex and difficult thing to measure.⁷⁷ The 'gold standard' objective measure of energy intake is the 'doubly labelled water' method.⁷⁸ However these measurements are impractical and expensive for interventions outside a research setting and are usually used as a validation method for other, indirect but more practical measures.

As a result, dietary intake measurement frequently relies on self-report instruments such as food frequency questionnaires. Self-reporting can result in recall errors, over- and under-reporting of portion sizes and dishonest reporting. Through a phenomenon known as 'social desirability bias',

participants are more aware of behaviours promoted by health promotion campaigns in the media, and report their behaviour to be more aligned with these messages, particularly for behaviours such as drinking alcohol.⁷⁹ This can be unconsciously or consciously done. There is also evidence from doubly labelled water validated studies to show that under-reporting is more common and most severe in obese subjects compared to people of normal weight.⁸⁰

Self-report instruments to measure dietary intake fall into two categories; those that measure current diet such as 24-hour recall and food diaries; and those that assess food histories and habits such as food frequency questionnaires (FFQs). The most reliable of these instruments is a 7-day weighed food diary. However these are time consuming to the participant and there is evidence to show that the accuracy of reporting decreases over the 7-day period.⁸¹ They also require a substantial amount of analytical expertise in order for estimates of nutrient and energy intake to be derived. Some studies have investigated the use of web-based or electronic tools to collect dietary intake data more accurately, particularly with children. One example of these uses 24-hour recall methodology with a web-based, children-friendly interface.⁸² Other studies have used mobile phone technology and hand-held personal digital assistants to record dietary intake.⁸³

Interventions should aim to measure the aspect of the diet that is the focus of the intervention. For example, if an intervention is focusing on reducing consumption of fatty foods, then it would be important to measure fat consumption at baseline and follow-up. However, most projects are likely to focus on reducing overall energy consumption, and measurement of this is highly problematic. A review by the East Midlands Public Health Observatory⁸⁴ and further consultation during the development of this document has indicated that there are no validated, simple instruments available for measuring dietary intake that do not require highly specialist analysis or are onerous and time consuming for the participant. This therefore remains a significant research challenge: to ensure that validated tools are available for collecting dietary intake data that are relevant and indicative of improvements in weight status.

Some interventions may focus on increasing fruit and vegetable intake. This can be a valid approach, as the low energy density of the vast majority of fruits and vegetables may mean that high fruit and vegetable consumption is as an indicator of low obesity risk. There are some tools available that provide a measure of fruit and vegetable consumption, including the FACET⁸⁵ and CADET⁸⁶ tools. While both of these tools have been validated, they were found to either over- or under-estimate some aspects of fruit and vegetable consumption, and have not been validated to show that they are sensitive to change. They therefore should only be used with caution.

In some cases it might be useful and appropriate to collect information about dietary behaviour and eating patterns. Unhealthy meal patterns and snacking behaviour have been associated with obesity.⁸⁷ Questionnaires such as the Golan Family Eating and Physical Activity Habits questionnaire⁸⁸ attempts to understand whether eating patterns are, in fact as a result of hunger.

37. Measure(s) of physical activity levels and behaviour

ESSENTIAL

If an intervention aims to increase physical activity as part of its approach to preventing or reducing obesity, then a measure of physical activity is an important aspect of the evaluation. Appropriate tools for measuring physical activity are outlined below.

Physical activity can be measured either by using objective methods or by using a questionnaire or other self-assessment tool. Objective measurements of activity include measures using motion sensors (which measure body movement in two or three planes) or pedometers (which measure number of steps taken). These can be used to calculate total energy expenditure over a day or week. These have the advantage of being well-validated and are generally accurate which overcomes some of the problems of recall bias found in surveys.

Issues to consider when using objective methods to measure physical activity include the storage of data, and the importance of using only tools that have been well-validated. Cheaper pedometers may

be useful as motivations or promotional devices but they are unlikely to provide accurate measures of physical activity.⁸⁹

More expensive motion sensors allow data to be uploaded to a computer, sometimes remotely. Some models have seven-day memories. If the unit has no memory, participants will need to record their steps each day, which may reduce the quality of the data.⁹⁰

However, objective measures can be costly to use at a population level, and do not always provide data of the appropriate level of detail. For example, motion sensors cannot provide data on the mode of activity. For this reason, the focus here is on using self-assessment methods.

The National Obesity Observatory has conducted a rapid review on the most appropriate tools for measuring physical activity in local level weight management interventions.⁹¹ It recommends the following tools: the Stanford 7-day Recall, the International Physical Activity Questionnaire, the New Zealand Physical Activity Questionnaire, and the Seven Day Physical Activity Diary. More details about these tools can be found in Appendix A.

38. Potential facilitators of, and barriers to, lifestyle change

DESIRABLE

Examples of potential facilitators of, and barriers to, lifestyle change are:

- health literacy: health-related knowledge, attitude, motivation, behavioural intentions, personal skills and self-efficacy;⁹²
- social action and influence such as social norms and public opinion;
- other environmental influence such as workplace and home;
- other psycho-social outcomes such as self-esteem, confidence, body image, positivity and improved quality of life.

There is a wide range of theories, concepts and accounts of behaviour and behaviour change that may be considered when evaluating the intervention. Psycho-social models of behaviour change allow determinants such as socio-economic and cultural context, physical environment, attitudes, knowledge, self-perception and social norms to be identified and taken into account at baseline and follow-up. This type of information may help to tailor particular aspects of the intervention, or to explain why the intervention has worked in the way it has for certain individuals. This approach is supported by NICE in *Behaviour change at population, community and individual levels*. It suggests planning and prioritising interventions that are 'tailored to tackle the individual beliefs, attitudes, intentions, skills and knowledge associated with the target behaviours.'⁹³

In addition, psycho-social measures can be useful indications of the likelihood of positive behaviour changes being sustained beyond follow-up. For example, there is evidence to show that low self-esteem in obese children is associated with a lack of desire to take part in physical activity. In addition, a child's perception of their competence to take part in physical activity will also have an impact on their motivation to do so.⁹⁴ A measure of children's psychological well-being can ensure there are no adverse effects from the intervention on their psychological well-being as a result of, for example, stigmatisation.

The first table in Appendix B summarises some of the key health behaviour change theories and the broad information requirements associated with them.

Part four: follow-up data**Impact evaluation**

39. Follow-up data: minimum of three follow-up points, including at one year

ESSENTIAL

41. Height and weight (to calculate Body Mass Index)

ESSENTIAL

43. Dietary intake and behaviour

ESSENTIAL

44. Physical activity levels and behaviour

ESSENTIAL

Section three described the minimum data that should be collected at baseline, before an intervention begins.

These key indicators (including height and weight) should ideally be measured at least three times after the intervention has taken place. Typically this will be at the end of the intervention, then six and 12 months later. Although measures from two data points can give some indication for an estimate of change, it is not sufficient for accurate measurement of trends.

Also at the end of an intervention, the impact is likely to be greatest. Only to measure at this point might give an artificially inflated indication of the intervention's impact. This is related to the statistical issue regression to the mean.⁹⁵ Behaviour change needs to be sustained to have health impacts. It is important to see if behaviours that change at six months are maintained in the longer term.

Where additional indicators have been collected, such as psycho-social health outcomes, these two should be collected at defined follow-up points.

40. Follow-up data on key measures (height weight; physical activity; diet) over a greater term than one year

DESIRABLE

42. Follow-up data on additional proxy measures for adiposity (if collected at baseline)

DESIRABLE

45. Follow-up measures on potential facilitators of and barriers to lifestyle change (if collected at baseline)

DESIRABLE

Process evaluation

46. Number invited

ESSENTIAL

A critical aspect of evaluating an intervention is to determine the flow of participants through the project. How many individuals were invited to attend the intervention? If this was through GP referrals or referral from a school nurse, state the number of people who were advised to attend the intervention, or state if invitation was through leaflets, posters and other general publicity.

47. Number recruited

ESSENTIAL

How many participants were found to be eligible for the intervention and enrolled?

48. Number attended each session or contact point**ESSENTIAL**

How many participants attended each exposure, episode, session or contact point? For example, if an intervention is run twice a week for 10 weeks, how many participants attended each of these sessions?

49. Number completed**ESSENTIAL**

How many participants completed the final follow-up stage? The definition of what is meant by 'completed', should be consistent to understand whether those who complete an intervention are more likely to benefit compared with those with poor attendance or who do not complete. Some trials have suggested the definition of 'completion' be based on 75 per cent attendance.⁹⁶ Whilst certain types of intervention may find it appropriate to develop their own definition of completion, this should be clearly defined.

50. Number of participants at each follow-up point

How many participants attended each of the follow-up points and had the required data collected?

51. Methods of data collection and timings**DESIRABLE**

At what stages of the intervention are the follow-up points, for example, week six, month three, year one? How are the data collected at each of these contact points, for example, in person at an event or session, by telephone, by home visit, or online?

52. Reasons for opt-out (where applicable)**ESSENTIAL**

Whilst this information is not always the easiest to gather, it is vitally important to understand why participants might opt out of an intervention. This is particularly useful if the intervention is going to be run more than once as part of a rolling programme. This sort of information can be collected in a number of ways and is similar to gathering information on participants' overall satisfaction with the intervention (see below). The difference, here, is that participants may have to be contacted directly. This needs to be handled sensitively so they do not feel like they are being chased. It is advisable to let people know at the beginning of the intervention that, if they choose to opt-out, they will be contacted for feedback which will be used to improve how the intervention is delivered in the future.

53. Details of any unexpected outcomes and/or deviations from the intended intervention design and the reasons why**DESIRABLE**

Were there any unexpected side effects or outcomes from the intervention? For example, did participants gain weight or did they have lower self-esteem by the end of the intervention? Unexpected outcomes, however, do not necessarily have to be negative and there can be unexpected positive health outcomes.

It is important to include any deviations from the intended delivery or concept, such as amendments to the content, that may have had an effect on the outcomes.

54. Participants' satisfaction with the intervention**ESSENTIAL**

Satisfaction questionnaires are frequently used as part of evaluations. If participants are dissatisfied with the way in which an intervention is being delivered, or unhappy with an element of the overall design of the intervention, it is unlikely they will continue to attend. Consequently, the intervention is less likely to achieve its defined outcomes.

When undertaking research into participants' satisfaction, it should be noted that it is often very difficult to glean unbiased opinions from participants if there have been problems and difficulties. Therefore, any research of this nature should be carefully and sensitively conducted. To identify strengths and weaknesses of the intervention, it can be more useful to use qualitative methods of research such as focus groups or semi-structured interviews. It may also be advisable for the deliverer of the intervention not to carry out the research. Participants may feel more able to be honest with another person that they have not previously encountered as part of the delivery team.

55. Plans for sustainability**DESIRABLE**

Consider whether plans have been made to ensure participants are offered the opportunity to continue with the intervention in another way. This will help the intervention's effect to be sustained over time. There may be resource implications for this type of long-term planning, and these should be included in the evaluation.

Part five: analysis and interpretation

No matter how good the quality of the data collected, it is important to ensure correct analysis and interpretation. Otherwise, they will not produce useful and robust information about the intervention. It is beyond the scope of this document to give detailed guidance on data analysis. Readers should either seek the advice of a statistician or analyst, or consult one of the many good textbooks on study design and statistical methods.

**56. Summary of results compared to baseline
(for primary and secondary outcomes)****ESSENTIAL**

The bare minimum is to show whether primary and secondary outcomes have changed over the course of the intervention. The method for analysing and presenting results from the evaluation will depend on the study design. This in turn will determine the degree of confidence in the results. Section 2.7 described the main study designs used for evaluations, and these all have appropriate analysis methods.

In **experimental designs**, such as randomised controlled trials (RCT), results are presented as a change in the intervention group compared to changes in the control group. If the difference between the intervention and control group is statistically significant (usually expressed as a p value of < 0.05), there can be confidence this was caused by the intervention itself, and not by some external factor. So, for example, in an RCT of a self-help intervention to promote active commuting, Mutrie et al. found that the intervention group was almost twice as likely to increase walking to work as the control group at six months.⁹⁷ This was expressed as an odds ratio of 1.93 (meaning the odds of walking to work in the intervention group are 1.93 times the odds of the control group walking to work). Thus, there is confidence the intervention was effective in increasing walking.

Quasi-experimental designs usually use a control group. Unlike the RCT, they do not randomly allocate individuals to intervention or control. Like the RCT, results are stated in terms of differences between intervention and control. The main limitation is the lack of certainty that the difference between intervention and control group was due to the intervention. For example, in a pilot study of obesity prevention counselling for children, Kubik et al. compared counselling in one primary care

practice with the usual care provided by a control practice.⁹⁸ Following the pilot it was found that more intervention than control parents reported they intended to give their child five or more servings of fruits and vegetables on most days during the next 30 days (25 per cent of intervention parents versus nine per cent of control parents; $p=0.049$). This indicates that the intervention was successful, with the limitation that there might have been something different about the 'usual care' practice that influenced the results.

As stated in section 2.7, **pre-experimental designs** provide the weakest evidence and should only be used when other possibilities have been explored.⁹⁹ Like experimental designs, data from pre-post studies is usually presented as difference between data before and after the intervention. The limitation here is that we cannot be sure that any change would not have happened anyway, as there was not a control group. For example, an intervention on physical activity may have found an increase in behaviour following the intervention, but this may have been prompted by other external factors such as another programme or campaign, or simply due to secular trends.

57. Detail of any further analyses or statistical methods used

DESIRABLE

It is beyond the remit of this document to detail the statistical methods that could be used in the analysis of collected data and the nature of the statistical methods used will very much depend on the research and evaluation study design. However, below are some key points about data analysis which may assist the evaluation.

Change in BMI Z score

When evaluating interventions it is preferable to measure the change in a child's BMI using the BMI Z score rather than the BMI centile. A BMI Z score or Standard Deviation Score indicates how many units of the standard deviation a child is above or below the average BMI value for their age group and sex. For instance, a Z score of 1.5 indicates a child is 1.5 standard deviations above the average value and a Z score of -1.5 indicates a child is 1.5 standard deviations less than the average value. Approximately 95 per cent of children will lie within two standard deviations from the average BMI. This is due to the fact that the BMI centile is relative to the reference population and a reduction in a child's BMI will not be consistent across the entire scale. For example, a change from the 98th to the 95th centile will typically be a larger reduction in actual BMI than a change from the 68th to the 65th centile. However, using the BMI Z score, any reductions in a child's BMI Z score will be consistent within each reference population, that is their age group and sex, regardless of their original BMI value.

Statistical significance

This describes the extent to which we can be certain that a result did not occur by chance. Statistical significance is usually expressed as a p value, often shown to be $p<0.05$. This means that there is a five per cent possibility that the result occurred due to chance, and was not as a result of the intervention.

Statistical significance is related to the power of a study, which can be determined through *sample size calculations*. These should be conducted before the study begins, and calculate how many people are needed in the study to enable measurements that will be statistically significant. It is important to seek the advice of a statistician before a study commences to ensure that it is large enough, and that the sample is constructed correctly.

Confidence intervals

These describe the range of possible values around an observed outcome. So, for example, there may be a mean change in body weight of one kilogram following an intervention, with 95 per cent confidence intervals stated as 0.2 to 1.8. This means there is a 95 per cent likelihood that the true amount of weight loss lies between 0.2 and 1.8.

58. Limitations and generalisability

DESIRABLE

The generalisability of the intervention is how likely it is that the results of the intervention would be reproduced if the intervention were carried out in another group or in the whole population. When assessing generalisability, it is important to take into account the following: the target population, nature of the intervention, nature of sampling and recruitment methods, length of follow-up, settings and resources needed.

The more tightly controlled the intervention is, that is the higher the internal validity, the less likely it is that the results would be reproduced unless the intervention was conducted and controlled in the same way.

5. Conclusions

We hope this document has been helpful to those considering an evaluation of a weight management intervention. Our aim has been to establish the beginnings of a consensus on the minimum data that need to be collected for an evaluation to be effective and to help raise standards of evaluation. This should contribute towards the long-term aim of advancing knowledge on what works in combating the rise in obesity in this country.

We welcome any comments on this document and invite input into all our work.
Please email info@noo.org.uk

Glossary

Aim

A broad statement of intent setting out the purpose of the project. For example, 'the project aims to reduce obesity through counselling of obese children and their families.'

Evaluation

Establishing whether a project has achieved what it set out to do.

Focus group

A group of people who discuss an issue, led by a researcher. This generates qualitative data, usually in the form of transcripts. Sometimes used in preference to individual interviews, as some researchers believe that the 'group processes' involved will reveal more about people's beliefs and attitudes.

Indicator

A measure of something which demonstrates a change in a particular outcome. For example the number of people attending a weight control session.

Interviews

A discussion between a researcher and subject(s), usually using a script or pre-designed list of questions, prompts and topics. Interviews can be face to face or on the phone, structured (with fixed questions) or semi-structured (where discussion can be more flexible).

Milestone

A marker of progress, usually used to monitor whether a course of action is on track. Like a milestone on the road it tells you whether you are on the right track, how far you have travelled and how far you still have to go.

Monitoring

Collection of routine data that helps you assess whether projects are proceeding to plan. A sub-set of evaluation.

Outcome

A visible or practical result, effect or product. It highlights the change or impact a project will have on the target population. For example, 'an average reduction of 2cm in waist circumference among project participants within six months.'

Outputs

Things that the project produces or activities that occur through the use of the resources in the project. For example, distribution of 300 leaflets to the target population.

Process evaluation

Evaluation which focuses on the process used throughout a project: it aims to see why the project meets or does not meet its aims and objectives; what went right and what went wrong; what can be learnt for future projects.

Qualitative research

Information that is reported in narrative form or which is based on descriptive information, such as diaries, open ended responses to questions and field notes.

Quantitative research

Information that is reported in numerical form, such as number of people attending and drop out rates.

Reliability

How likely it is that a measurement instrument will measure the same thing each time it is used.

Target population

People who the project aims to reach. These may be segmented by a number of factors including age, gender and social class.

Validity

How well something measures the 'truth'. For example, to what extent a self-report food frequency questionnaire reflects the actual dietary intake. In the context of a research study validity can be either 'internal' or 'external'. Internal validity is the extent to which differences between a study and a control intervention are real rather than a product of bias. External validity is the extent to which the results of the study can be made general for the wider population.

Appendix A: physical activity measurement tools

Tool 1: Stanford 7-day recall

What it measures	Respondents are asked about the number of hours spent in sleep, moderate, hard, and very hard activities during the preceding week. Examples of the types of activities in each category are provided, and the week is separated into weekend days and weekdays. The remaining amount of time is presumed to have been spent in light activities. A formula is available for the calculation of daily energy expenditure in kilocalories, and norms are available from the Stanford Heart Disease Prevention Program.
Validation	The instrument was originally developed for the Five Cities Project. It has acceptable reliability and validity. Validity has also been assessed against doubly labelled water, indicating that the instrument provides a reasonable estimate of daily energy expenditure. It has been used in numerous intervention studies including the Activity Counselling Trial (ACT).
Key Reference	Blair et al., 1985 ¹⁰⁰ Mahabir et al., 2006 ¹⁰¹ Blair et al., 1998 ¹⁰²
Population	Adults
Caveats/Limitations	
Administration Method/ Practical Application	Interview administered and takes approximately 15 minutes to complete.
Copyright/Ownership/Location	http://www.drjamesallis.sdsu.edu/sevendayparprotocol.pdf [Accessed February 2009]

Tool 2: International Physical Activity Questionnaire (IPAQ) Long Version

What it measures	<p>Recall questionnaire for past 7 days.</p> <p>Short form: frequency, duration of time spent on walking/vigorous/moderate intensity/sedentary activity (sitting)</p> <p>Long form: domains unspecified: household/yard work, occupational, self-powered transport, leisure time related physical activity as well as sedentary activity (sitting on a weekday/weekend day); pace of walking/cycling.</p>
Validation	<p>There are varying reports of validity.¹⁰³ Some authors have found over-reporting of physical activity.¹⁰⁴ Low criterion validity results were found between IPAQ and an accelerometer¹⁰⁵ whereas Ekelund et al¹⁰⁶ found similar criterion validity scores for the short IPAQ, suggesting that the specificity to correctly classify people achieving 30 minutes of physical activity per day was sound.</p> <p>IPAQ (long version) has been validated against doubly labelled water and provides an acceptable estimate of daily energy expenditure.</p>
Key Reference	<p>Craig et al., 2003¹⁰⁷</p> <p>Maddison et al., 2007¹⁰⁸</p>
Population	Population level. Validated for use in 15–69 year olds.
Caveats/Limitations	The IPAQ is a population level instrument designed for surveillance and for cross-national monitoring of PA/inactivity. It was not initially designed for evaluating intervention studies.
Administration Method/ Practical Application	Telephone or self administered
Copyright/Ownership/Location	http://www.ipaq.ki.se/ipaq.htm [Accessed February 2009].

Tool 3: New Zealand Physical Activity Questionnaire

What it measures	A short self-completion recall (approximately 10 minutes to complete) that uses show cards to prompt people to recall moderate and vigorous activities they have been undertaken in the last 7 days.
Validation	Validated against doubly labelled water. The instrument has been used in a primary care based randomised controlled trial in New Zealand that showed a significant difference between intervention and control groups. In studies the self-completion has been supervised by a researcher.
Key Reference	Maddison et al., 2007 ¹⁰⁹ Lawton et al., 2008 ¹¹⁰
Population	Middle aged adults (40–79)
Caveats/Limitations	Not commonly used in UK
Administration Method/ Practical Application	7-day recall
Copyright/Ownership/Location	See references above

Tool 4: 7-day physical activity diary

What it measures	This is a self-completion diary that requires participants to 'tick' 15 minute blocks of activity as they occur over the course of each day, for 7 consecutive days. It includes occupational, leisure time and sports activity.
Validation	The validity is good although reliability is unclear. A validity study using double-labelled water indicates that the measure is a reasonable estimate of daily energy expenditure.
Key Reference	Koebnick et al., 2005 ¹¹
Population	Adults
Caveats/Limitations/	The measure was designed for use in epidemiological studies so its usefulness in intervention studies is unknown.
Administration Method/ Practical Application	7-day diary
Copyright/Ownership/Location	http://www.dife.de/en/presse/erhebungsinstrumente/erhebungsinstrumente.php#1 [Accessed February 2009].

Appendix B: health behaviour change models

Theory	Key elements	Suggested information that may be useful in evaluation if adopting this model	Key references
Health Belief Model	<p>An individual will take action related to a specific health problem based on a number of beliefs:</p> <ul style="list-style-type: none"> • perceived susceptibility to problem; • perceived seriousness of the consequences of the problem; • perceived benefits of a particular course of action; • perceived barriers to taking action; • perceived ability to carry out the specified action. <p>Subsequent theorists pointed out that this model does not take account of social, economic and environmental conditions which may also effect behaviour change.</p>	<p>Information collected through questionnaire or interview relating to each individuals perceptions of the health problem, the intervention itself and their perceived competency in being able to participate in the action promoted by the intervention (at baseline and follow-up points).</p>	<p>Becker, M.H.(ed.), 1974. The health belief model and personal health behavior, <i>Health Education Monography</i>. 2, 324-473.</p> <p>Janz, N.K. Becker, M.H., 1984. The health belief model: a decade later, <i>Health Education Quarterly</i>. 11, 1-47.</p>

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<p>Theories of Reasoned Action and Planned Behaviour</p>	<p>Individuals make a rational decision about their behavioural intentions based on:</p> <ul style="list-style-type: none"> • attitudes towards the behaviour (based on perceptions of whether the behaviour will achieve desired short and long-term outcomes, for example, reduced BMI, and therefore improvements in health); • subjective norms (based on an individual's perception of how other people think they should act and how motivated they are by this perception); • perceived behavioural control (based on their own perception of how much power they have to control their own behaviour). 	<p>Information collected through questionnaire or interview from the participants relating to:</p> <ul style="list-style-type: none"> • what their beliefs are about the outcomes of the intervention (short- and long-term); • their beliefs about their social networks and how supportive or otherwise this is of their proposed behaviour change; • to what extent they are motivated by the latter; • how they feel about their own power and ability to change their behaviour. 	<p>Ajzen, I. & Fishbein, M., 1980. <i>Understanding attitudes and predicting social behaviour</i>. New Jersey: Prentice-Hall.</p> <p>Ajzen, I., 1991. The theory of planned behavior, <i>Organisational Behavior and Human Decision Processes</i>, 50, 179-211.</p> <p>Montano, D.E. & Kasprzyk, D., 2002. <i>The theory of reasoned action and theory of planned behavior</i>. In Glanz, K. et al. <i>Health behavior and health education: theory, research and practice</i>. 3rd ed. California: Jossey-Bass.</p>
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<p>Stages of Change Model</p>	<p>Individuals go through a process related to behaviour change which has a number of stages. The stages are not necessarily linear and individuals can start the process or leave it at any stage.</p> <ul style="list-style-type: none"> • pre-contemplation: the individual is not considering changing their behaviour or, indeed, has the intention not to change their behaviour; • contemplation: the individual is considering changing their behaviour; • determination (preparation): the individual has made a decision to change and is committed to the decision; • action: the individual starts to take action to change their behaviour; • maintenance: the individual sustains the change in behaviour and achieves benefits in health outcomes (or relapse). <p>Termination has been suggested as a further stage for addictive behaviours such as smoking. Here the individual has reached a stage where they would have been had they never had the habit.</p>	<p>Information collected through questionnaire or interview from participants relating to the stage of change they are at. For example, whether they have previously considered or tried to do anything about their weight. This could indicate whether or not an individual is ready to take part in a certain type of intervention. It may also help to gauge the sort of intervention that would be likely to be most successful in supporting them to the next stage of behaviour change. For example, if an individual is at the pre-contemplation stage, it is unlikely they will commit to, or succeed in, a twice-weekly community-based programme for 10 weeks.</p>	<p>Prochaska, J.O. & DiClemente, C.C., 1984. <i>The transtheoretical approach: crossing traditional boundaries of therapy</i>. Illinois: Dow Jones Irwin.</p> <p>Prochaska, J.O. et al., 1994. Stages of change and decisional balance for twelve problem behaviours, <i>Health Psychology</i>, 13</p> <p>Prochaska, J.O. Redding, C.A., & Evers, K.E., 2002. <i>The transtheoretical model and stages of change</i>. In Glanz, K. et al. <i>Health behavior and health education: theory, research and practice</i>. 3rd ed. California: Jossey-Bass.</p>
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<p>Social Cognitive Theory</p>	<p>An individual, their environment and behaviour continuously interact and influence each other. This relationship is reinforced by observational learning (association of the behaviour with desired rewards), expectations (beliefs and motivations held about the short and long terms effects of the behaviour), self-efficacy (belief in your own ability to perform a behaviour). The interaction between all these characteristics and the environment are dynamic. For example someone may have high self-efficacy in their ability to eat a healthy, low fat diet when she is at home, but may be less confident when out for a meal with friends. This theory avoids focusing interventions on behaviour in isolation from the environment.</p>	<p>This model acknowledges individual beliefs, values and self confidence and the importance of social norms and environmental influences and the dynamic relationship between the individual and the environment.</p> <p>Information about the individuals feelings of self efficacy in different environments e.g. work, home, pub, with friends could be useful here as well as a measure of what individual beliefs are about the health problem and what the views are of those closest to them.</p>	<p>Bandura, A., 1986. <i>Social foundations of thought and action: a social cognitive theory</i>. Englewood Cliffs, New Jersey: Prentice Hall.</p> <p>Bandura, A., 1995. <i>Self-efficacy in changing societies</i>. New York: Cambridge University Press.</p> <p>Baranowski, T. Perry, C.L. & Parcel, G.S., 2002. <i>How individuals, environments and health behaviour interact</i>. In Glanz, K. et al. <i>Health behavior and health education: theory, research and practice</i>. 3rd ed. California: Jossey-Bass.</p>
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Source of information: Nutbeam and Harris, *Theory in a Nutshell*, 2004.¹¹²

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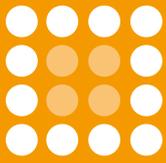
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