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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

PUBLIC HEALTH DRAFT GUIDELINE

Exercise referral schemes to promote physical activity

What is this guideline about?

This guideline makes recommendations on exercise referral schemes to promote physical activity for people aged 19 and older. It is an update of recommendation 5 in 'Four commonly used methods to increase physical activity' (NICE public health guidance 2).

In this guideline, exercise referral schemes consist of:

- an assessment involving a primary care or allied health professional to determine that someone is 'inactive', that is, they are not meeting the current <u>UK physical activity guidelines</u> (Department of Health 2011)
- a referral by a primary care or allied health professional to a physical activity specialist or service
- an assessment involving a physical activity specialist or service to determine what programme of physical activity to recommend
- an opportunity to participate in a physical activity programme.

This guideline does not consider exercise referral schemes designed for, or that include, management of, or rehabilitation for, specific diseases. This includes cardiac or pulmonary rehabilitation programmes. For NICE's recommendations on exercise schemes to support people with specific conditions see:

Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin
 (NICE technology appraisal guidance 159)

- <u>Selection of prostheses for primary total hip replacement</u> (NICE technology appraisal guidance 2)
- Crohn's disease: management in adults, children and young people (NICE clinical guideline 152).

See the scope for more details.

Physical activity is important for health and can help prevent and manage conditions such as coronary heart disease, type 2 diabetes, stroke, mental health problems, musculoskeletal conditions and some cancers. It can also have a positive effect on mental wellbeing including mood, sense of achievement, relaxation and release from daily stress.

Recommendation 5 in 'Four commonly used methods to increase physical activity' stated: 'Practitioners, policy makers and commissioners should only endorse exercise referral schemes that are part of a properly designed and controlled study to evaluate their effectiveness.'

This recommendation was based on limited evidence that exercise referral schemes led to small but significant effects in the short term (6–12 weeks). These did not persist into the medium (6 months) or longer term (1 year). This update identified additional evidence that such schemes have a positive effect on people's physical activity levels. However, the additional benefits were only small compared with giving people brief advice about physical activity.

Exercise referral schemes are also relatively expensive compared with other primary care interventions aimed at encouraging physical activity. The cost per quality adjusted life year (QALY) was estimated to be above NICE's usual threshold for cost effectiveness – and considerably higher than other interventions that increase physical activity.

Therefore, NICE does not recommend exercise referral schemes for the **sole** purpose of increasing people's physical activity levels.

However, NICE acknowledges that not all the potential benefits of these schemes could be captured in the economic model. Further, there were considerable uncertainties about the correct parameters to use. The guideline details the issues considered and makes a number of research recommendations.

The guideline is for primary care practitioners and policy makers, commissioners and practitioners with physical activity as part of their remit and working in local authorities and the NHS. It is particularly aimed at those responsible for commissioning, developing, managing and delivering exercise referral schemes. This includes those responsible for 'exit' strategies that help participants to be physically active in the long term. In addition, it may be of interest to members of the public.

See <u>About this guideline</u> for details of how the guideline was developed and its current status.

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1 Draft recommendations

This guideline replaces <u>recommendation 5</u> in 'Four commonly used methods to promote physical activity', NICE public health guidance 2 (2006).

Recommendation 1 Commissioning interventions to increase physical activity

Policy makers and commissioners with a remit for increasing physical activity levels should:

- Continue to support people to be physically active as part of their daily life using:
 - modifications to the physical environment (see <u>Physical activity and the</u> <u>environment</u>, NICE public health guidance 8)
 - interventions to encourage walking and cycling (see <u>Walking and cycling</u>, NICE public health guidance 41).
- Implement NICE's recommendations on 'Physical activity: brief advice for adults in primary care' (NICE public health guidance 44). Specifically:
 - Recommendation 3 Incorporating brief advice in commissioning.
 - Recommendation 4 Systems to support brief advice.
 - Recommendation 5 Providing information and training.
- Not commission exercise referral schemes for the sole purpose of getting
 people to be more active. The only exception is for schemes that collect a
 minimum data set and make it available for analysis, monitoring and
 research to inform future practice. As a minimum, schemes should collect
 details on:
 - inclusion and exclusion criteria for participation, physical activity options
 and plans for remaining physically active beyond the end of the scheme
 - participant characteristics, including disease risk factors and reason for referral

- costs, including the primary care practitioner's time spent making referrals, the cost of the physical activity programme and costs for participants
- the intensity, duration and frequency of physical activity at baseline, during the scheme and afterwards (up to 1 year after the programme ends)
- reasons why people drop out, and action taken by providers and commissioners to get them involved in physical activity again
- changes to health-related quality of life associated with being physically active, for example, as measured by the <u>EQ-5D questionnaire</u> or another validated questionnaire
- mental and physical health benefits associated with participating in the exercise referral scheme, such as changes in blood pressure, respiratory functioning, mobility, sedentary behaviour, body mass index (BMI) and anxiety levels.

Recommendation 2 Encourage inactive adults to be more physically active

Primary care practitioners should:

- Implement NICE's recommendations on giving adults brief advice on physical activity (NICE public health guidance 44). Specifically:
 - Recommendation 1 Identifying adults who are inactive.
 - Recommendation 2 Delivering and following up on brief advice.
- Not refer people to exercise referral schemes for the sole purpose of getting them to be more active.

2 Context

Introduction

Increasing how much physical activity someone does can significantly improve both their physical and mental wellbeing and reduce illnesses and disease throughout life. It can also improve life expectancy.

For example, physical activity can help prevent and manage more than 20 conditions and diseases including coronary heart disease, some cancers, diabetes, musculoskeletal disorders, mild to moderate depression and obesity (The public health responsibility deal, Department of Health 2011). Evidence also indicates that being sedentary is an independent risk factor for certain diseases such as coronary heart disease and type 2 diabetes, even when achieving the recommended physical activity levels (Lee et al. 2012).

Most adults and many children in England do not meet the national recommended levels of physical activity. In 2008, based on self-reporting, 39% of men and 29% of women aged 16 and older met the recommended minimum (Health survey for England 2008: physical activity and fitness, Health and Social Care Information Centre 2009).

In 2013, The Health Survey for England re-analysed the 2008 data using the revised national recommendations published in 2011 (see 'National guidelines, resources and indicators' below). It estimated that 65–66% of men and 53–56% of women were meeting the new recommendations in 2008 – and probably continued to do so up to 2012 (Health Survey for England 2012: Is the adult population in England active enough?).

Physical activity levels vary according to income, gender, age, ethnicity and disability. Generally, women are less active than men and people tend to be less active as they get older. Leisure time physical activity levels are also lower among certain minority ethnic groups, people from lower socioeconomic groups and people with disabilities (<u>The public health responsibility deal</u>, Department of Health 2011).

During 2007/08, an estimated 300 million consultations took place with primary care practitioners, with the average patient attending 5.4 consultations (QRESEARCH and Health and Social Care Information Centre 2008). Every consultation provides an opportunity to promote physical activity (Boyce et al. 2008).

Lack of physical activity: the costs

Public Health England's <u>Health impact of physical inactivity</u> estimates that not being physically active enough could be the cause of up to 36,815 premature deaths in England a year.

In 2006/07 physical inactivity cost the NHS an estimated £0.9 billion, based on the occurrence of diseases that can be prevented by being physically active (Scarborough et al. 2011). This is a conservative estimate because other health problems, such as osteoporosis and poor mental health, can also be exacerbated by a lack of exercise. There are also wider economic costs, for example sickness absence from work, estimated at £5.5 billion per year.

In 2008 the Department of Health's <u>Be active, be healthy</u> estimated that the average cost of physical inactivity for every primary care trust in England was £5 million.

National guidelines, resources and indicators

In 2001, the Department of Health developed the National quality assurance framework for exercise referral. It focuses primarily on schemes that take place in leisure centres or gyms and involve supervised exercise programmes. This framework aimed to improve existing schemes and help develop new ones. It is currently being updated.

In 2010 the British Heart Foundation National Centre for Physical Activity and Health published an <u>exercise referral toolkit</u> as a blueprint for how exercise referral schemes should be designed, implemented and evaluated.

In 2011, the Chief Medical Officers of England, Scotland, Wales and Northern Ireland issued joint UK physical activity guidelines for people of all ages (<u>Start active</u>, stay active: a report on physical activity from the four home countries' chief medical officers, Department of Health 2011).

For adults, the guidelines recommend being active daily and accumulating at least 150 minutes of moderate-intensity activity, or 75 minutes of vigorous activity, in bouts of 10 minutes or more during each week. The guidelines also

recommend avoiding being sedentary for prolonged periods (such as sitting for long periods of time). There are additional recommendations on strength for all groups, and to help improve balance among older people.

To help achieve the recommendations, the Department of Health has recently updated its <u>Let's get moving</u> physical activity care pathway. This is a systematic approach to identifying and supporting adults who are not currently meeting the national recommended level of physical activity. Exercise referral is cited as a specific intervention that primary care practitioners can use with people who are inactive and have certain clinical needs.

In 2011 there were 2 additions to the cardiovascular disease quality outcomes framework menu of indicators (NM36 and NM37). Both relate to the use of the general practice physical activity questionnaire (GPPAQ) and assessment of physical activity levels in primary care as a way of helping prevent cardiovascular disease (NICE menu of indicators).

The revised Department of Health <u>Public health outcomes framework for England, 2013–2016</u> also highlights the importance of encouraging physical activity and reducing sedentary behaviour (see domain 2).

3 Considerations

This section describes the factors and issues the Public Health Advisory Committee (PHAC) considered when developing the recommendations. Please note: this section does not contain recommendations. (See Recommendations.)

Background

3.1 The PHAC noted that many of those involved in commissioning, developing and delivering exercise referral schemes believe they are an effective use of public money. This is evident in the number of schemes, the popularity of referrals and anecdotal reports of an increase in physical activity levels and other health benefits among participants. However, the economic analyses demonstrated that these schemes are less cost effective than giving brief advice, as

recommended in <u>Physical activity: brief advice for adults in primary</u> <u>care</u> (NICE public health guidance 44). That is because they have a very small additional effect and are relatively expensive. See 3.9–3.16 for further details.

- 3.2 The PHAC acknowledged that a number of different types of exercise referral schemes have been set up in the UK since the publication of Four commonly used methods to increase physical activity. There was insufficient evidence to assess the relative cost effectiveness of the different types of schemes. Overall, the new evidence identified does not support exercise referral schemes for the sole purpose of getting people physically active (see 3.4 below for other benefits of such schemes).
- 3.3 The PHAC noted that a number of factors may influence effectiveness. These include: the intensity, length and frequency of the exercise referral scheme; and the experience, skills and knowledge of people who provide or deliver it. However, the evidence on these factors was very limited.
- 3.4 The PHAC noted that the overall aim of exercise referral schemes is to improve health and that an increase in physical activity is not always the primary outcome. Other outcomes, such as an increased sense of belonging and social interaction ('social capital') may be important. But these have not been measured in most studies and were not specifically considered here.

Evidence of effectiveness

- 3.5 The PHAC was disappointed at the relatively small number of studies identified for this update.
- 3.6 The PHAC noted that, compared with brief advice, the 'relative risk' of exercise referral schemes is 1.08. This would result in only 1 extra person out of every 36 people who participated in these

- schemes meeting the Chief Medical Officers' (CMOs') recommended level of physical activity.
- 3.7 Members noted that the evidence on the medium- or long-term health benefits associated with exercise referral schemes was very limited.
- 3.8 Members noted that data collected via self-reporting methods may overestimate how physically active each participant has been compared with more objective measures of physical activity.

Economic modelling

- 3.9 The PHAC noted that exercise referral schemes are only marginally more effective than brief advice and lead to a very small additional gain in quality-adjusted life years (QALYs). However, there were considerable uncertainties about the correct parameters to use for the economic modelling and members noted that the model does not capture all the potential benefits.
- 3.10 Using the base case assumptions, the incremental intervention cost of £217 led to an incremental cost-effectiveness ratio (ICER) between £72,748 and £113,931 per QALY gained. Even in the best case scenario, the estimated incremental cost effectiveness ratio was £31,009 per QALY gained. NICE normally considers that any interventions over a threshold of £20,000–£30,000 per QALY are not cost effective. However, because current evidence to inform the assumptions in the model was insufficient, members did not feel they could recommend disinvestment in such schemes. Further, some schemes may be cost effective, or may only be cost effective for some subgroups. Again, however, there was insufficient evidence to make recommendations on this.
- 3.11 The PHAC noted that if exercise referral schemes collected more detailed data, this would allow commissioners to make a more informed decision on future investment. Such a decision would take

- into account the prevailing local priorities, the nature of the schemes and evidence of effectiveness.
- 3.12 The PHAC noted that set up costs have not been considered in the economic model and that their inclusion would increase the incremental cost-effectiveness ratio.
- 3.13 The PHAC noted that, if the relative risk of exercise referral schemes (compared with usual practice) is 1.08, schemes costing more than £150 would not be considered cost-effective at a threshold of £20,000–£30,000 per QALY. However, there was no evidence on how a reduction in costs would affect effectiveness so it was not possible to recommend a cap on the cost of such schemes.
- 3.14 The PHAC noted that the full cost to participants (including travel and childcare costs) was not considered in the economic model.
- 3.15 The PHAC noted that any increase in physical activity is associated with positive health benefits. But unless people achieved the CMOs' recommended levels of activity, these benefits were not captured in the economic modelling. This means that the true gains from exercise referral schemes are likely to be underestimated by the model. However, the economic model used is comparable to that used to assess the cost effectiveness of brief advice to increase physical activity. The latter is often used as the comparator in many of the included studies. So the finding that exercise referral schemes cost considerably more per QALYs than brief advice is likely to be valid.
- 3.16 The PHAC discussed the importance of additional, health-related quality of life gains and the 'feel good' factor ('process utility') gained from being physically active .Both feature as inputs of the model. However, there was uncertainty around the magnitude of the process utility and how long it would last. This meant that the PHAC was unable to agree or disagree on this key assumption in

- the cost effectiveness model. This added to the uncertainty about estimates of cost effectiveness.
- 3.17 The PHAC was aware that the economic modelling to determine the long-term health benefits of exercise referral schemes was based on cohort studies limited to coronary heart disease, stroke and type 2 diabetes. The PHAC agreed that the other benefits of physical activity are not captured by the model (for example, alleviation of mental health problems, musculoskeletal conditions and some cancers). Taking these into account could lower the ICER, but the magnitude of this effect was unclear.
- 3.18 The PHAC noted that the economic model over-simplifies the clinical situation. That is because it does not allow for someone having more than 1 of the 3 health conditions in the model (coronary heart disease, stroke or type 2 diabetes). Members also noted that the model does not consider that the presence of 1 'comorbidity' may affect the likelihood of experiencing another. These limitations mean that the cost effectiveness of exercise referral schemes may be underestimated.

Scenarios of effectiveness

- 3.19 The PHAC agreed that some exercise referral schemes may be more effective and cost effective than others. Some approaches may be cheaper to deliver (see 3.20). Others may be more effective for specific subgroups (see 3.19). Effectiveness is greater if a high percentage of participants regularly attend the programme, if few people drop out and if participants continue to be physically active afterwards (see 3.21).
- 3.20 The PHAC felt that exercise referral schemes may be cost effective in encouraging physical activity among specific groups. For example, it may help people with multiple disease risk factors such as hypertension, obesity or poor mental health, or those who would not otherwise have access to supervised exercise programmes.

Members also noted that the people who appear to benefit most from these programmes may gain similar benefits from brief physical activity advice. However, because of a lack of evidence the PHAC was unable to make specific recommendations for specific groups.

- 3.21 The PHAC noted that cost effectiveness and effectiveness varied according to the type of exercise referral scheme. There was a feeling that more 'simplistic' models could be effective and more cost effective for certain subgroups. Such models consist of more self-directed and less resource-intensive activities (such as walking and cycling), rather than gym-based activities. No review evidence was identified to verify this assumption.
- The PHAC discussed the importance of increasing adherence throughout the duration of an exercise referral scheme and boosting ongoing participation in physical activity beyond the end of the programme. For example, it agreed that helping participants to develop the skills they need to be physically active on their own, or providing social support during the intervention, might encourage adherence to the scheme and in turn, this might increase the chances of participants being physically active in the longer term.

Barriers to success

3.23 The PHAC noted that poor referral practices affect the overall effectiveness of schemes. These could be due to the initial assessment or the type of activity someone has been referred to. The participant may not be interested in a particular type of activity, or may not be able to complete it because of their current fitness level. Or it could be due to a general lack of consideration of participants' motivation and ability. Members noted that better use of triage or a 'stepped approach' that includes brief physical activity advice (NICE public health guidance 44) may overcome these problems. However, no evidence was identified to substantiate this assumption.

- 3.24 The PHAC noted that a lack of focus on relapse prevention and sustainability impacts on effectiveness. Alongside improving referral practices (see 3.23), members discussed the need for improved follow-up to identify why people drop out and how this might inform development of future schemes. Members also discussed the importance of following up participants who have completed a scheme and supporting them to continue to increase or maintain their activity.
- 3.25 The PHAC considered how staff training affects the effectiveness of exercise referral schemes. Members noted the training outlined in the Department of Health's National Quality Assurance Framework and British Heart Foundation exercise referral tool kit. Members also noted that this training could help alleviate concerns about possible litigation issues. The latter was highlighted as a significant barrier to referral in review 2 undertaken for this guideline.
- 3.26 The PHAC noted that the range of physical activities provided is a key factor in whether or not someone adheres to a scheme. Those offering alternatives to gym-based activities, that are less expensive and give a degree of personal choice, seem to improve adherence.

This section will be completed in the final document.

4 Recommendations for research

The Public Health Advisory Committee (PHAC) recommends that the following research questions should be addressed. It notes that 'effectiveness' in this context relates not only to the size of the effect, but also to the duration of effect and cost effectiveness. It also takes into account any harmful or negative side effects.

All the research should aim to identify differences in effectiveness among groups, based on characteristics such as socioeconomic status, age, gender and ethnicity.

- 4.1 What models of exercise referral are effective and cost effective and for which groups? Factors to consider include: choice of activity; adherence to the scheme; whether or not the costs are subsidised; and whether it is commissioned and delivered by an NHS, non-NHS or community-based organisation.
- 4.2 What support do primary care professionals need to help them choose the most effective physical activity intervention for an individual? This includes knowing how and when to refer people who can most benefit from an exercise referral scheme.
- 4.3 What factors encourage uptake of, and adherence to, an exercise referral scheme? What factors influence physical activity levels in the long term (at 1 year and beyond)?
- 4.4 What factors encourage under-represented groups to take part in an exercise referral scheme? What factors prevent these groups from participating? Under-represented groups include: people from black and minority ethnic groups, people with disabilities and those from lower socioeconomic groups.
- 4.5 What outcome measures should be used to judge the effectiveness of exercise referral schemes? For example: absolute increases in physical activity levels (above and below the Chief Medical Officers' recommendations); or other health, mental health and social wellbeing outcomes?

More detail identified during development of this guideline is provided in <u>Gaps</u> in the evidence.

5 Related NICE guidance

Published

 <u>Behaviour change: individual approaches</u>. NICE public health guidance 49 (2014)

- Managing overweight and obesity among children and young people. NICE public health guidance 47 (2013)
- BMI and waist circumference black, Asian and minority ethnic groups.
 NICE public health guidance 46 (2013)
- <u>Physical activity brief advice in primary care</u>. NICE public health guidance 44 (2013)
- Walking and cycling. NICE public heath guidance 41 (2012)
- Preventing type 2 diabetes: risk identification and interventions for high risk individuals. NICE public health guidance 38 (2012)
- Preventing type 2 diabetes population and community interventions.
 NICE public health guidance 35 (2011)
- Depression in adults. NICE clinical guideline 90 (2011)
- Weight management before, during and after pregnancy. NICE public health guidance 27 (2010)
- <u>Prevention of cardiovascular disease</u>. NICE public health guidance 25
 (2010)
- Occupational therapy and physical activity interventions to promote the mental wellbeing of older people in primary care and residential care. NICE public health guidance 16 (2008)
- Identifying and supporting people most at risk of dying prematurely. NICE public health guidance 15 (2008)
- Promoting physical activity in the workplace. NICE public health guidance
 13 (2008)
- <u>Physical activity and the environment</u>. NICE public health guidance 8
 (2008)
- Behaviour change: the principles for effective interventions. NICE public health guidance 6 (2007)
- Four commonly used methods to increase physical activity. NICE public health guidance 2 (2006)
- Obesity. NICE clinical guideline 43 (2006)

Under development

- Overweight and obese adults: lifestyle weight management. NICE public health guidance. Publication expected May 2014.
- Maintaining a healthy weight and preventing excess weight gain among children and adults. NICE public health guidance. Publication expected March 2015.
- Older people: independence and mental wellbeing. NICE public health guidance. Publication expected September 2015.

6 Glossary

Brief advice

'Brief advice' means verbal advice, discussion, negotiation or encouragement, with or without written or other support or follow-up. It can vary from basic advice to a more extended, individually focused discussion (see NICE public health guidance 44).

Duration of activity

'Duration of activity' refers to the length of time for which an activity or exercise is performed. Duration is generally expressed in minutes. The Department of Health's <u>UK physical activity guidelines</u> (2011) define a bout of physical activity as lasting at least 10 minutes. Coupled with frequency and intensity, duration provides a way to measure a person's level of physical activity against the recommendations.

Frequency of activity

'Frequency of activity' refers to the number of bouts (lasting at least 10 minutes) of physical activity over a fixed period. Coupled with duration and intensity, frequency provides a way to measure a person's level of physical activity against the Department of Health's UK physical activity guidelines.

Inactivity

'Inactive' refers to people not currently meeting the Department of Health's <u>UK</u> <u>physical activity guidelines</u>.

Intensity of activity

'Intensity of activity' refers to the rate of energy expenditure that an activity demands – in other words, how hard a person is working. The rate of energy expenditure ('absolute intensity') is usually measured in either kcals/kg per minute or in METs (metabolic equivalents). Coupled with duration and frequency, intensity provides a way to measure a person's level of physical activity against the Department of Health's UK physical activity guidelines.

Process utility

People benefit psychologically from physical activity. This short-term 'feel good' factor is referred to in economic terms as 'process utility'.

7 References

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Murphy SM, Edwards RT, Williams N et al. (2012) An evaluation of the effectiveness and cost effectiveness of the National Exercise Referral Scheme in Wales, UK: a randomised controlled trial of a public health policy initiative. Journal of Epidemiology & Community Health 66: 745–53

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Scarborough P, Bhatnagar P, Wickramasinghe KK et al. (2011). The economic burden of ill health due to diet, physical inactivity, smoking, alcohol and obesity in the UK: an update to 2006–07 NHS costs. Journal of Public Health 33: 527–35

8 Summary of the methods used to develop this guideline

Introduction

The reviews include full details of the methods used to select the evidence (including search strategies), assess its quality and summarise it.

The minutes of the Public Health Advisory Committee (PHAC) meetings provide further detail about the Committee's interpretation of the evidence and development of the recommendations.

Guideline development

The stages involved in developing public health guidelines are outlined in the box below.

- 1. Draft scope released for consultation
- 2. Stakeholder comments used to revise the scope
- 3. Final scope and responses to comments published on website
- 4. Evidence reviews and economic modelling undertaken and submitted to PHAC
- 5. PHAC produces draft recommendations

- 6. Draft guideline (and evidence) released for consultation (and for fieldwork)
- 7. PHAC amends recommendations
- 10. Final guideline published on website
- 11. Responses to comments published on website

Key questions

The key questions were established as part of the <u>scope</u>. They formed the starting point for the reviews of evidence and were used by the PHAC to help develop the recommendations. The overarching questions were:

Question 1: How effective and cost effective are exercise referral schemes? What are the most important factors that influence effectiveness and cost effectiveness?

Question 2: What factors influence referral to an exercise referral scheme?

Question 3: What factors influence attendance at, and successful completion of, an exercise referral scheme?

Question 4: What factors influence longer-term participation in physical activity following attendance on an exercise referral scheme?

The subsidiary questions included:

- 1. What factors influence the effectiveness of exercise referral schemes (for example, age, gender or socioeconomic status)?
- 2. How aware are health practitioners of exercise referral schemes?
- 3. Are there any adverse or unintended effects from exercise referral schemes (for example, unintentional injuries)?
- 4. Are exercise referral schemes available to, and accessible by, different populations?

- 5. How are initial assessments and medical records transferred from primary care to physical activity services for people attending exercise referral schemes?
- 6. What 'exit strategies' are in place for people once they have completed an exercise referral scheme?

These questions were made more specific for each review.

Reviewing the evidence

Review of effectiveness, uptake and adherence

An effectiveness, uptake and adherence review was commissioned by the National Institute for Health Research Health Technology Appraisal programme (NIHR HTA).

This review is an update of a systematic review commissioned by NIHR HTA and carried out by Pavey et al. in 2011. It was specifically commissioned to inform NICE's guidance. NICE set out the parameters and protocols for the review but it is based on the NIHR's methods (summarised below). The review also includes an economic model. For more details see <u>A systematic review and economic evaluation of exercise referral schemes in primary care:</u> a short report.

Identifying the evidence

Several databases were searched in September 2013 for randomised control trials published since October 2009 (the date of the previous searches by Pavey et al. 2011).

Selection criteria

Studies were included in the review if they:

- were based on randomised controlled trials
- included adults (aged 18 or older) without a medical diagnosis and for whom an exercise referral scheme was deemed appropriate

- included counselling (face-to-face or by telephone), written materials or supervised exercise training
- included outcomes on: physical activity, physical fitness, health, adverse events, and uptake and adherence to the scheme.

Studies were excluded if:

- they focused exclusively on people with a medical diagnosis
- interventions were not part of an exercise referral scheme
- interventions did not include a clear assessment of physical activity levels and a clear referral process.

Details can be found in: <u>A systematic review and economic evaluation of</u> exercise referral schemes in primary care: a short report.

Quality appraisal

Included papers were assessed for methodological rigour and quality using the Cochrane <u>risk of bias tool</u> to assess study quality. Study quality was checked against the following factors:

- method of randomisation
- · allocation concealment
- blinding
- numbers of participants randomised, excluded and lost to follow up.
- whether intent to treat analysis has been performed
- methods for handling missing data
- baseline comparability between groups.

Analysis and synthesis

Data from new studies published since 2009 were tabulated and discussed in a narrative review. These were integrated with data from the studies identified and analysed by Pavey et al. in 2011. Meta-analyses were used to estimate a summary measure of effect on relevant outcomes. These were based on intention-to-treat analyses.

Review Manager software was used for the meta-analysis to study fixed and random effects models. Heterogeneity was explored by considering: study populations, methods and interventions; visualisation of results; and, in statistical terms, by the $\chi 2$ test for homogeneity and the I2 statistic.

A qualitative thematic analysis of the discussion and conclusion sections of the included randomised controlled trials was undertaken (as per Pavey et al. 2011). The aim was to understand factors that predict uptake of, and adherence to, exercise referral schemes. The results are described in a narrative. A logic model explains the associations between multiple and varied barriers and facilitators to uptake and adherence.

NICE-commissioned review of context, barriers and facilitators

One review of context, barriers and facilitators was conducted using NICE methods and processes, <u>The factors that influence referral to, attendance at and successful completion of exercise schemes and longer term participation in physical activity.</u>

Identifying the evidence

Several databases and websites were searched in July 2013 for qualitative and grey literature from January 1995 to June 2013. See <u>The factors that influence referral to, attendance at and successful completion of exercise schemes and longer term participation in physical activity</u> for details

Selection criteria

Studies were included in the review if they:

- were qualitative and observational that is, they reported the views, perceptions and beliefs of those using and delivering exercise referral schemes
- mainly covered people aged 19 years and older who were potential or actual users of an exercise referral scheme
- included exercise referral schemes involving assessments and referrals by health professionals.

Systematic reviews were also identified and 'unpicked' for relevant studies meeting the inclusion criteria.

Studies were excluded if they:

- mainly focused on people under 19
- did not include an exercise referral scheme
- covered only physical activity rehabilitation programmes used to aid recovery from specific health conditions.

See <u>The factors that influence referral to, attendance at and successful</u> <u>completion of exercise schemes and longer term participation in physical</u> activity for details of the inclusion and exclusion criteria.

Quality appraisal

Included papers were assessed for methodological rigour and quality using the NICE methodology checklist, as set out in Methods for the development of NICE public health guidance. Each study was graded (++, +, -) to reflect the risk of potential bias arising from its design and execution.

Study quality

- ++ All or most of the checklist criteria have been fulfilled. Where they have not been fulfilled, the conclusions are very unlikely to alter.
- + Some of the checklist criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are unlikely to alter the conclusions.
- Few or no checklist criteria have been fulfilled. The conclusions of the study are likely or very likely to alter.

The evidence was also assessed for its applicability to the areas (populations, settings, interventions) covered by the scope of the guidance. Each evidence statement concludes with a statement of applicability (directly applicable, partially applicable, not applicable).

Summarising the evidence and making evidence statements

The review data were summarised in evidence tables (see the review).

The findings from the review were synthesised and used as the basis for a number of evidence statements relating to each key question. The evidence statements were prepared by the external contractors (see Supporting evidence). The statements reflect their judgement of the strength (quality, quantity and consistency) of evidence and its applicability to the populations and settings in the scope.

Cost effectiveness

No formal review of economic studies was conducted because a preliminary search retrieved no additional economic evidence directly related to exercise referral schemes.

Economic modelling

An existing economic model, used for NICE's guidance on <u>Physical activity</u> <u>brief advice in primary care</u>, NICE public health guidance 44 (2013), was updated. This model is a direct update of the models conducted for <u>Four commonly used methods to increase physical activity</u>, NICE public health guidance 2 (2006) and Pavey et al. 2011. See <u>A systematic review and economic evaluation of exercise referral schemes in primary care: a short report.</u>

The economic model updated 3 groups of parameters:

- estimates of the relative clinical effectiveness of exercise referral schemes versus not using them
- costs these were inflated to 2013 values using Personal Social Services
 Research Unit inflation indices
- starting age this has been changed to 50 (the mean age used in the studies to collect effectiveness data).

Additional analyses conducted before the first committee meeting

The original base case assumption that physical activity offers a 10-year protective effect related to coronary heart disease, stroke and diabetes was based on cohort studies. These studies had follow-up periods of 19 years (for coronary heart disease and stroke) and 12 years (for diabetes). Additional analyses were undertaken to test the model using these different time periods. See appendix 7 of A systematic review and economic evaluation of exercise referral schemes in primary care: a short report

The model is particularly sensitive to the feel good factor ('process utility' gain) attributable to physical activity. In the base case analysis it is assumed that this lasted for only 1 year. However, it is likely that some people who continue to be physically active at 1 year will carry on being physically active in the longer term (and so continue to benefit from the feel-good factor).

To explore the effect of a gradual fall-off in the number remaining physically active, this 'process utility' has been applied for 10 years. But the model assumes there will be a linear decrease in the number who are physically active over those 10 years and that no-one will benefit from the feel good factor after 10 years.

The additional analysis also explored the effect on the incremental costeffectiveness ratios (ICER) of combining these 2 less conservative assumptions about the longer-term benefits.

Additional analyses conducted before the second committee meeting

Following the first Public Health Advisory Committee (PHAC) meeting, further additional analyses were undertaken to inform the Committee's discussion at its second meeting. See appendix 8 of <u>A systematic review and economic evaluation of exercise referral schemes in primary care: a short report</u>

Incremental cost-effectiveness ratios (ICERs) were conducted for a 'combined scenario analysis' incorporating:

- costs for providing brief advice in the comparator arm
- efficacy estimates from the intention-to-treat analysis

 a 10-year linear fall-off in the 'feel good' factor (process utility) associated with being physically active, applied with the original base-case assumption that the protective effects of exercise are limited to 10 years.

In addition, several sensitivity analyses were undertaken. These:

- Explored the effect of using EQ-5D data from a study by Murphy et al (2012) as an alternative to the process utility gain estimated by Pavey et al. (2011). The latter was applied in the model used to inform NICE public health guidance 44.
- Explored the cost-effectiveness of less intensive exercise referral schemes.

Finally a threshold analysis was undertaken on the intervention cost for exercise referral schemes.

Fieldwork

This section will be completed in the final document.

How the PHAC formulated the recommendations

At its meetings in December 2013 and January 2014, the Public Health Advisory Committee (PHAC) considered the evidence reviews and cost effectiveness to determine:

- whether there was sufficient evidence (in terms of strength and applicability) to form a judgement
- where relevant, whether (on balance) the evidence demonstrates that the intervention or programme/activity can be effective or is inconclusive
- where relevant, the typical size of effect
- whether the evidence is applicable to the target groups and context covered by the guideline.

The PHAC developed draft recommendations through informal consensus, based on the following criteria:

Strength (type, quality, quantity and consistency) of the evidence.

- The applicability of the evidence to the populations/settings referred to in the scope.
- Effect size and potential impact on the target population's health.
- Impact on inequalities in health between different groups of the population.
- Equality and diversity legislation.
- Ethical issues and social value judgements.
- Cost effectiveness (for the NHS and other public sector organisations).
- Balance of harms and benefits.
- Ease of implementation and any anticipated changes in practice.

Where evidence was lacking, the PHAC also considered whether a recommendation should only be implemented as part of a research programme.

9 The evidence

See What evidence is the guideline based on? in 'About this guideline'.

This section will be completed in the final document.

10 Gaps in the evidence

The Public Health Advisory Committee (PHAC) identified a number of gaps in the evidence related to the programmes under examination based on an assessment of the evidence. These gaps are set out below.

- 1. High quality controlled and randomised controlled studies on exercise referral schemes.
- 2. Effectiveness and cost effectiveness evidence on the effect of exercise referral schemes on people with multiple health conditions.
- 3. Effectiveness and cost effectiveness evidence on the effect of exercise referral schemes on mental health.

- 4. Effectiveness and cost effectiveness evidence on whether physical activity levels are maintained in the long term after attendance at an exercise referral scheme.
- 5. Information about the different types or models of exercise referral scheme and for whom each type may be most effective.
- 6. Information about how practitioners identify whether or not someone should be referred for a physical activity intervention, including exercise referral.

7. Information on factors that:

- encourage participation in physical activity during and after an exercise referral scheme
- prevent or reduce the risk of drop out by those referred to such schemes.
- 8. Information about levels of participation by under-represented groups, such as people from black and minority ethnic groups and people with disabilities.
- 9. Information about all the short- and long-term benefits of exercise referral schemes. This includes the 'feel good' factor ('process utility').
- 10. Information about measures and outputs to use to establish the effectiveness of exercise referral schemes.

11 Membership of the Public Health Advisory Committee and the NICE project team

Public Health Advisory Committee A

NICE has set up several Public Health Advisory Committees (PHACs). These standing committees consider the evidence and develop public health guidance. Membership is multidisciplinary, comprising academics, public health practitioners, topic experts and members of the public. They may come from the NHS, education, social care, environmental health, local government or the voluntary sector. The following are members of PHAC A:

Chair

Susan Jebb

Professor of Diet and Population Health, Department of Primary Care Health Sciences, University of Oxford

Core members

Alison Lloyd

Community Member; Pastoral Manager, Specialist School

Amanda Sowden

Deputy Director, National Institute for Health Research Centre for Reviews and Dissemination, University of York

Chris Packham

Associate Medical Director, Nottinghamshire Healthcare NHS Trust

Joyce Rothschild JP

Independent Education Consultant

Lucy Yardley

Professor of Health Psychology, University of Southampton

Mireia Jofre Bonet

Professor of Health Economics, City University, London

Toby Prevost

Professor of Medical Statistics, King's College London

Topic members

Andy Pringle

Reader in Physical Activity, Exercise and Health, Research Institute of Sport, Physical Activity and Leisure, Leeds Metropolitan University

Elaine McNish

Physical Activity Manager, Celtic Nations

Malcolm Ward

Principal Health Promotion Specialist, Public Health Wales

Ruth Jepson

Senior Scientific Advisor, Scottish Collaboration for Public Health Research and Policy

Stephen Sutton

Professor of Behavioural Science, University of Cambridge

Jennifer Bostock

Community Member

NICE project team

Mike Kelly

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Simon Ellis

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Analyst

Hugo Crombie

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Kim Jeong

Technical Adviser Health Economics

Rukshana Begum

Project Manager

Emily Aidoo

Coordinator

Sue Jelley

Senior Editor

Susie Burlace

Editor

About this guideline

What does this guideline cover?

This guideline is a partial update of <u>Four commonly used methods to increase</u> <u>physical activity</u>, NICE public health guideline 2 (2006). It seeks to clarify the factors that influence referral to, attendance at and successful completion of an exercise referral scheme and longer term participation in physical activity.

The recommendations in the final guideline will replace <u>recommendation 5</u> in 'Four commonly used methods to increase physical activity'.

This guideline does not provide detail on pedometers and community-based exercise programmes for walking and cycling. (See Related NICE guidance for other recommendations that may be relevant to exercise referral.)

The absence of any recommendations on interventions that fall within the scope of this guideline is a result of lack of evidence. It should not be taken as a judgement on whether they are cost effective.

How was this guideline developed?

The recommendations are based on the best available evidence. They were developed by the Public Health Advisory Committee (PHAC).

Members of the PHAC are listed in <u>Membership of the Public Health Advisory</u> Committee and the NICE project team.

For information on how NICE public health guidelines are developed, see the NICE public health guideline process and methods guides.

What evidence is the guideline based on?

The evidence that the PHAC considered included:

- Evidence reviews:
 - Review 1: 'A systematic review and economic evaluation of exercise referral schemes in primary care: a short report' was commissioned by the National Institute for Health Research Health Technology Appraisal

programme (NIHR HTA). It was carried out by The University of Sheffield, School of Health and Related Research (ScHARR). The principal authors were: Fiona Campbell, Mike Holmes, Emma Everson-Hock E, Sarah Davis, Helen Buckley Woods, Nana Anokye, Paul Tappenden and Eva Kaltenthaler.

- Review 2: 'The factors that influence referral to, attendance at and successful completion of exercise schemes and longer term participation in physical activity' was carried out by the Support Unit for Research Evidence (SURE), Cardiff University. The principal authors were: Fiona Morgan, Ruth Turley, Helen Morgan, Lydia Searchfield, Alison Weightman, Eva Elliot and Simon Murphy.
- Economic modelling: review 1 contains the economic modelling.

In some cases the evidence was insufficient and the PHAC has made recommendations for future research. For the research recommendations and gaps in research, see Recommendations for research and Gaps in the evidence.

Status of this guideline

This is a draft guideline. The recommendations made in section 1 are provisional and may change after consultation with <u>stakeholders</u> and fieldwork.

This document does not include all sections that will appear in the final guideline. The stages NICE will follow after consultation (including fieldwork) are summarised below.

- The Committee will meet again to consider the comments, reports and any additional evidence that has been submitted.
- After that meeting, the Committee will produce a second draft of the quideline.
- The draft guideline will be signed off by the NICE Guidance Executive.

The key dates are:

- Closing date for comments: 2 May 2014.
- Next PHAC meeting: 23 May 2014.

The guideline will replace recommendation 5 in NICE guideline on 'Four commonly used methods to increase physical activity' (NICE public health guidance 2). (For further details, see Related NICE guidance).

The recommendations should be read in conjunction with existing NICE guidance unless explicitly stated otherwise. They should be implemented in light of duties set out in the Equality Act 2010.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

Implementation

NICE guidelines can help:

- Commissioners and providers of NHS services to meet the requirements of the NHS outcomes framework 2013–14. This includes helping them to deliver against domain 1: preventing people from dying prematurely.
- Local health and wellbeing boards to meet the requirements of the <u>Health</u> and <u>Social Care Act (2012)</u> and the <u>Public health outcomes framework for</u> <u>England 2013–16</u>.
- Local authorities, NHS services and local organisations determine how to improve health outcomes and reduce health inequalities during the joint strategic needs assessment process.

NICE will develop tools to help organisations put this guideline into practice. Details will be available on our website after the guideline has been issued.

Updating the recommendations

This section will be completed in the final document

Your responsibility

This guideline represents the views of the Institute and was arrived at after careful consideration of the evidence available. Those working in the NHS, local authorities, the wider public, voluntary and community sectors and the private sector should take it into account when carrying out their professional, managerial or voluntary duties.

Implementation of this guideline is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guideline, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guideline should be interpreted in a way which would be inconsistent with compliance with those duties.

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