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The clinical effectiveness and cost-effectiveness of exercise referral schemes to promote physical activity: A short report.

HTA 13/45/01

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Plain English Summary

Physical activity has many benefits in terms of preventing disease and ill health. These include reducing the risks of coronary heart disease, stroke, diabetes, some cancers, osteoporosis, depression and dementia. The health benefits of physical activity are so great that the Department of Health recommends that adults should take at 30 minutes of physical activity five times every week. However, it is evident from surveys of the general population in the UK that most people do not achieve these recommended levels of physical activity. Therefore, interventions that might promote levels of physical activity would have considerable benefits for public health. One such intervention is an exercise referral scheme. This is an intervention where individuals who need to increase their levels of physical activity are referred by a primary health care professional to a service designed to increase physical activity or exercise. The programme is tailored to the needs of the individual patient and its effects are monitored. At present there is considerable uncertainty as to whether these schemes represent good value for money for the NHS, with uncertain evidence that they are clinically effective. This update will review the new evidence and critically examine the cost-effectiveness of these interventions from the perspective of the NHS and Personal Social Services (PSS).

Decision problem

There is a considerable body of evidence demonstrating the benefits of physical activity both in terms of treating and preventing diseases; including coronary heart disease, stroke, type 2 diabetes mellitus, chronic back pain, osteoporosis, cancers, depression and dementia.[1,2] Current recommendations from the Department of Health suggest that adults should undertake at least 150 minutes of moderate intensity activity each week, yet according to the 2008 Health Survey for England, only 39% of men and 29% of women achieved these levels (DoH 2009[3]).

Interventions to promote increased levels of physical activity require a wide variety of approaches, with each facilitating small increments in behaviour change.[4] These may include interventions targeted at the population level, such as changes in the environment as well as interventions targeted at the individual level, such as brief advice delivered in primary care.

Primary care has been recognised as a potentially valuable setting for the promotion of physical activity in those who might benefit most. One commonly used method to increase physical activity is the use of exercise referral schemes (ERS). For the purpose of this report we will adopt the same definition of 'exercise referral schemes' as that used in the Pavey *et al* (2011[4]) review of the clinical effectiveness and cost-effectiveness of exercise referral schemes. This defines ERS as being comprised of three core components:

- Referral by a primary care health care professional to a service designed to increase physical activity or exercise.
- A physical activity or exercise programme tailored to individual needs
- Initial assessment and monitoring throughout the programme.

Five previous systematic reviews have been undertaken (Morgan 2005,[5] Sorensen et al 2006,[6] NICE 2006,[7] Williams et al 2007,[8] Pavey 2011[4]). There was a lack of consistency in the included studies in each of these reviews, revealing a different understanding and interpretation of ERS between authors. These previous systematic reviews appear to conclude that ERS have a small effect in increasing physical activity in the short-term, with little or no evidence of long-term sustainability (i.e. 12-months or longer). There was also evidence of a reduced level of depression for participants given exercise referral compared to usual care (Pavey 2011[4]). However, owing to the considerable uncertainty surrounding the clinical effectiveness and cost-effectiveness of exercise referral schemes, in 2006, the NICE Public Health Intervention programme determined that there was insufficient evidence to

recommend the use of ERS as an intervention, other than as part of research studies where their effectiveness could be evaluated.

The NICE guidance (2006[7]) for ERS drew on a review of evidence which included four randomised controlled trials (RCTs - Taylor *et al* 1998,[9] Halbert *et al* 2000,[10] Lamb *et al* 2002,[11] Harrison *et al* 2005[12]). An additional four studies have been included in a more recent review (Pavey 2011[4]), three of which have been published since 2006 (Murphy *et al* 2010,[13] Jolley *et al* 2010,[14] Issacs *et al* 2007[15]).

A model-based economic evaluation of ERS concluded that the cost-effectiveness of ERS is highly sensitive to small changes in the effectiveness and cost of ERS and is subject to significant uncertainty mainly due to limitations in the clinical effectiveness evidence base (Anokye *et al* 2011[16]). Given the considerable public health benefits of increasing levels of physical activity, it is important that any initiatives for its promotion are kept under consideration and review. Within this short report, newly available effectiveness evidence will be used to update the existing knowledge base and inform NICE guidance for ERS referred from primary care. The report will address the question: "what is the clinical effectiveness and cost-effectiveness of ERS to promote physical activity?" Key factors that will be addressed will include an analysis of effects for those referred for particular clinical conditions, and an exploration of sub-groups for whom intervention effectiveness might have a greater effect that in others, such as differences between genders, and age groups. We shall also explore where there may be differences in outcomes that relate to key elements of the intervention, such as frequency of contact with the exercise service.

Report methods for synthesis of evidence of clinical effectiveness

This report will be an update of the Pavey (2011) systematic review of the evidence; updated searches will be carried out in order to identify new evidence. Any new evidence that is identified will be reviewed systematically and the findings integrated with those of the existing review. The scope of the review will be more limited than Pavey (2011) due to the time and resource constraints of this project. We will only include RCTs and systematic reviews of RCTs to analyse effectiveness. We will use only the included RCTs to further explore issues of adherence and uptake. We will do this in two ways; we shall explore adherence and uptake in the trials, and examine explanations given within the papers by the authors. This will be done by qualitatively analysing the discussion and conclusion sections of the included trials as well as extracting data on the numbers of participants who were included in the trials and the drop out rates. In addition, using the included RCTs, we shall identify qualitative studies undertaken as part of a mixed methods analysis of exercise referral

schemes. We describe these as 'sibling studies', i.e. an evaluation of the same trial but a publication describing different aspects of the study findings.

Inclusion/Exclusion criteria:

- **Population**

  Any adult (aged 18 years or over) with or without a medical diagnosis and deemed appropriate for ERS.

Interventions

The ERS exercise/physical activity programme is required to be more intensive than simple advice and needs to include one or a combination of counselling (face-to-face or via telephone); written materials; supervised exercise training. Programmes or systems of exercise referral initiated in secondary or tertiary care, such as conventional comprehensive cardiac or pulmonary rehabilitation programmes, will be excluded. We will exclude trials of exercise programmes for which individuals will be recruited from primary care, but there was no clear statement of referral by a member of the primary care team.

- **Comparators**

  Any control, for example usual ('brief') physical activity advice, no intervention, attention control or alternative forms of ERS.

- **Outcomes**

  Physical activity (self-report or objectively monitored), physical fitness (e.g. maximal oxygen uptake (VO_{2max}), health outcomes (e.g. blood pressure), adverse events (e.g. musculoskeletal injury), and uptake and adherence to ERS. We will also explore how patient characteristics, (age, gender and diagnosis) and programme factors (e.g. length and intensity of the exercise programme) that might influence the outcome of ERS.

- **Search strategy**

The search strategy will comprise the following main elements:

- Searching of electronic databases
- Contact with experts in the field
- Scrutiny of bibliographies of retrieved papers

An example of the search strategy is shown in Appendix 1.

Electronic databases: MEDLINE and Medline in Process (via Ovid); EMBASE (via Ovid); PsycINFO (via Ovid); SPORTDiscus (via EBSCO); The Cochrane Library including the Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CENTRAL) NHS Health Technology Assessment (HTA), NHS Economic Evaluation Database (NHS EED), Database of Abstracts of Reviews of Effects (DARE); Science Citation Index and proceedings and Social Science Citation Index and proceedings (via Web of Science Thomson ISI), UKCRN portfolio database; Current Controlled Trials; Clinical Trials.gov.

- **Study design**

We will include any new RCT evidence, identified in searches of electronic databases published from October 2009 to the present. These will be subject to data extraction and the data extraction tool will be modelled on that used in the Pavey (2011) review. We will also search for any systematic reviews published from 2009 to present of exercise referral schemes. Their lists of included studies will be handsearched to identify any further relevant studies.

For any new RCTs that we identify, any qualitative data that has been reported as part of a mixed methods evaluation an ERS intervention will also be included.

Any ongoing studies that we identify will also be reported. These would offer the most relevant insights into the particular factors influencing the adherence and uptake of that particular ERS intervention.

Titles and abstracts will be examined for inclusion by two reviewers independently. Disagreement will be resolved by consensus.

- **Exclusion criteria**
- Animal models
- Preclinical and biological studies
- Narrative reviews, editorials, opinions
- Non-English language papers
- Reports published as meeting abstracts only, where insufficient methodological details are reported to allow critical appraisal of study quality

- **Quality assessment strategy**

The Cochrane risk of bias tool will be used to assess study quality (Higgins & Altman2008[17]). Consideration of study quality will include the following factors:

Trial characteristics:

1. Method of randomisation
2. Allocation concealment
3. Blinding
4. Numbers of participants randomised, excluded and lost to follow up.
5. Whether intent to treat analysis has been performed
6. Methods for handling missing data
7. Baseline comparability between groups

- **Methods of analysis/synthesis**

Data from new studies published since 2009 will be tabulated and discussed in a narrative review. The data from studies already identified and analysed by Pavey (2011) will be used as published and data from new studies will be integrated with it.

Where appropriate, meta-analysis will be employed to estimate a summary measure of effect on relevant outcomes based on intention to treat analyses. As a meta-analysis was carried out in the Pavey (2011) review, additional meta-analyses will use these data and new data from studies we identify will be added.

Meta-analysis will be carried out using fixed and random effects models, using Review Manager software. Heterogeneity will be explored through consideration of the study populations, methods and interventions, by visualisation of results and, in statistical terms, by the χ^2 test for homogeneity and the I^2 statistic.

In order to extend our understanding of the factors that predict uptake and adherence, we shall undertake a qualitative thematic analysis of the discussion and conclusion sections of the included RCTs. These may yield insights into the factors identified by the trialists that may result in variations in uptake or adherence.

Report methods for synthesising evidence of cost-effectiveness

A decision-analytic model was developed for and used in the Health Technology Assessment (HTA) report.[4,16] This model was later amended to inform the NICE Public Health appraisal of brief advice in primary care to promote physical activity (PH44). This short report will involve updating this latter existing model rather than the development of a *de novo* model.

The model operates at the cohort level and estimates the effect of ERS on the proportion of a cohort of sedentary individuals aged between 40 and 60 years who become 'active' (i.e. reach a fixed threshold of physical activity) following the intervention, compared with an otherwise identical cohort of individuals who do not receive ERS. Compared with being inactive, being active is assumed to lead to a reduced risk of conditions such as coronary heart disease, stroke and type 2 diabetes mellitus. Subgroup analyses for cohorts of patients who are either obese, hypertensive or depressive were considered separately and will also be updated in this short report. There will be extensive collaboration and consultation with the author of this model to ensure the model is being used correctly.

In order to consistently compare the health effects of each of these conditions, quality-adjusted life years (QALYs) will be derived from estimates of the prevalence of a range of conditions expected, together with existing estimates of the QALY impact of each condition.[16] The time horizon for this analysis will be the patient's remaining lifetime. The analysis will be undertaken from the perspective of the UK NHS and Personal Social Services (PSS). In accordance with the NICE Public Health Methods Guide,[18] costs and QALY will be discounted at a rate of 1.5% per annum.

The update of the economic analysis will focus only on two groups of parameters – all other parameters will be held at the values contained within the published report. Firstly, estimates of the relative clinical effectiveness of ERS versus no ERS will be updated using additional information identified within the clinical review. Evidence relating to injuries and adverse effects will be considered in the model if there is evidence suggesting a substantive impact. Secondly, costs will be inflated to 2013 values using Hospital Inflation Indices; where Reference Costs have been used to inform resource cost parameters, these will be updated to current values. No other model parameter values will be updated, nor will the model structure be amended; this is due to the limited resource and time available for this project. Deterministic univariate/multivariate sensitivity analyses will also be undertaken to examine the impact of parameter values on cost-effectiveness results. Probabilistic sensitivity analysis (PSA) will be conducted to assess the effect of parameter uncertainty on estimates of clinical and cost-effectiveness. Decision uncertainty will be represented using cost-effectiveness planes and cost-effectiveness acceptability curves (CEACs). If quantitative evidence of uptake and adherence is identified these will be included in the model where possible. Cost-consequences will be presented insofar as the existing Brunel model (PH44) already estimates these. We will explore the possibility of subgroup analyses for particular patient groups and/or types of ERS upon consideration of the findings of the clinical review.

The assessment will *not* include a review of other studies relating to the cost-effectiveness of ERS.

TAR Centre

The ScHARR Technology Assessment Group (ScHARR-TAG) undertakes reviews of the effectiveness and cost-effectiveness of healthcare interventions for the NHS R&D Health Technology Assessment Programme on behalf of a range of policy makers in a short timescale, including the National Institute for Health and Care Excellence. A list of our publications can be found at:
http://www.sheffield.ac.uk/scharr/sections/heds/collaborations/scharr-tag/reports.

Much of this work, together with our reviews for the international Cochrane Collaboration, underpins excellence in healthcare worldwide.

Competing interests of authors

The authors do not have any competing interests.

Timetable/milestones

Activity	Due date
TAR centre deliver draft protocol to NETSCC	31 May 2013
TAR centre deliver final protocol to NETSCC	12 July 2013
TAR centre deliver progress report to NETSCC	3 October 2013
TAR centre deliver final report to NETSCC	31 October 2013

Appendix 1: Draft search strategy

Search Strategy Exercise Referral HTA Update Project

Searches will be limited by English Language and publication date of October 2009 to current.

Stage One Search

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

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1 physical activity referral*.ti,ab.
2 exercise on prescription.ti,ab.
3 exercise referral*.ti,ab.
4 supervised exercise.ti.
5 1 or 2 or 3 or 4

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Stage Two Search

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

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1 "Referral and Consultation"/
2 (exercise* or physical*).ti,ab.
3 1 and 2 (2396)
4 ((physical* or exercise*) adj2 (superv* or subsid* or prescrib*)).ti,ab.
5 (exercise* adj2 (fit* or train* or activit* or promot* or program* or intervention*)).ti,ab.
6 (physical* adj2 (fit* or train* or activit* or promot* or program* or intervention*)).ti,ab.
7 ((physical* or exercise*) and referral*).ti,ab.
8 4 or 5 or 6 or 7
9 Randomized controlled trial.pt.
10 Randomized Controlled Trial/
11 (random$ or placebo$).ti,ab,sh.
12 ((singl$ or double$ or triple$ or treble$) and (blind$ or mask$)).tw,sh.
13 9 or 10 or 11 or 12
14 controlled clinical trial.pt.
15 (retraction of publication or retracted publication).pt.
16 13 or 14 or 15
17 (family medicine$ or family practice$ or general practice$ or primary care or primary health care or primary health service$ or primary healthcare or primary medical care or family medical practice$ or family doctor$ or family physician$ or family practitioner$ or general medical practitioner$ or general practitioner$ or local doctor$).ti,ab.
18 Family Practice/
19 Primary Health Care/
20 Physicians, Family/
21 Community Health Centers/
22 (community healthcare or community health care).ti,ab.
23 (GP or GPs).ti,ab.
24 general practic*.ti,ab.
25 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
26 (referral* or promot* or program* or intervent*).ti,ab.
27 25 or 26
28 Exercise/
29 Exercise Therapy/
30 28 or 29
31 27 and 30
32 3 or 8 or 31

33 (child* or adolescent* or school* or pediatric* or paediatric*).ti.
34 32 not 33
35 16 and 34
36 (animals not humans).sh.
37 35 not 36
38 ("2009 October*" or "2009 November*" or "2009 December*" or "2010*" or "2011*" or "2012*" or "2013*").dp.
39 37 and 38
40 limit 39 to english language

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Team members' contributions

Fiona Campbell, Research Fellow. FC has extensive experience in systematic review of public health interventions. FC will be the main reviewer on this project and will maintain day-to-day running of the review. She has compiled the study protocol and will carry out the study selection, data extraction and undertake the meta-analyses. It is intended that she will draft the methods, narratives for included trials, and part of the results and discussion of the final report.

Emma Everson-Hock, Research Fellow. EEH has experience in systematic reviewing of health technologies and public health interventions, including physical activity interventions for preventing diabetes. EEH will assist FC in undertaking the systematic reviewing. She will be involved in assessing abstracts for eligibility, quality assessment of trials, data extraction, data entry, data analysis and review development of background information and clinical effectiveness.

Paul Tappenden, Reader in Health Economic Modelling. PT has over 10 years' experience in designing, developing and critically appraising health economic models across a number of disease areas. PT has undertaken modelling assessments for a range of decision-making bodies including NICE, the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), the Department of Health and NHS Cancer Screening Programmes. PT will supervise the economic analysis within this short report.

Nana Anokye, Research Fellow. NA is a cost effectiveness modeller within the Health Economics Research Group (HERG) at Brunel University. NA has extensive expertise in modelling cost-effectiveness interventions. NA will provide ongoing support in updating the existing economic model.

Helen Buckley Woods, Information Specialist. HB was lead Information Specialist on both quantitative and qualitative evidence reviews in the topics of Walking and Cycling and Brief Advice on Physical Activity in Primary Care for the PHCC. She will provide specialist support and conduct all the searches in close consultation with the multi-disciplinary reviewing team.

Andrea Shippam, Programme Administrator will assist in the retrieval of papers and in preparing and formatting the report.

Dr Alistair Bradley, GP, Tramways Medical Centre, Hillsborough, Sheffield UK. AB will assist with protocol development (advisor), help interpret data, provide a methodological, policy and clinical perspective on data and review development of background information and clinical effectiveness.

Aimee Rogers, Personal Trainer, Revitalize Fitness, Sheffield UK. AR will assist with protocol development (advisor), help interpret data, provide a methodological, policy and clinical perspective on data and review development of background information and clinical effectiveness.

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