

The clinical effectiveness and cost-effectiveness of exercise referral schemes: a systematic review and economic evaluation

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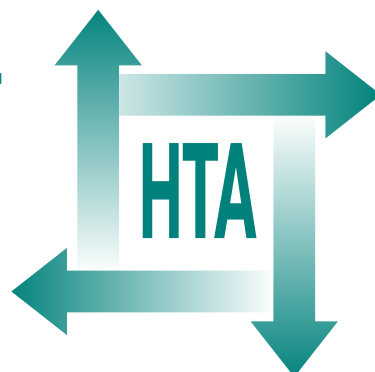


Executive summary

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Executive summary

Background

Physical activity (PA) contributes to the prevention and management of many medical conditions and diseases including coronary heart disease, type 2 diabetes mellitus, osteoporosis, cancers and mental illness, such as depression. The *Health Survey for England* in 2008 estimated that 39% of men and 29% of women met the 5 × 30 minutes per week public health target for PA, leaving the majority of the population unable to gain the known health benefits from activity. Primary care has been recognised as a potentially important setting for the promotion of PA, with over 85% of the population in the UK visiting their general practitioner (GP) at least once a year. Exercise referral schemes (ERS) aim to identify inactive adults in the primary-care setting. The GP or health-care professional refers the patient to a third-party service, with this service taking responsibility for prescribing and monitoring an exercise programme that is tailored to the individual needs of the patient. Guidance in 2006 from the National Institute for Health and Clinical Excellence (NICE) concluded that there was insufficient evidence to currently recommend the routine use of ERS to promote PA and called for further research to be undertaken.

Objectives

In people with a diagnosed medical condition known to benefit from PA:

- to assess the clinical effectiveness of ERS
- to assess the cost-effectiveness of ERS
- to identify predictors of uptake and adherence to ERS
- to explore the factors that might influence the clinical effectiveness and cost-effectiveness of ERS.

Given the extremely limited evidence base for ERS in people with a diagnosed medical condition known to benefit from PA, we extended the scope of this report to include consideration of those without a diagnosed condition, but who were sedentary.

Methods

Three systematic reviews were undertaken: (1) assessment clinical effectiveness of ERS; (2) assessment of the cost-effectiveness of ERS; and (3) identification of predictors of ERS uptake and adherence. Several electronic bibliographies (MEDLINE, EMBASE, PsycINFO, The Cochrane Library, ISI Web of Science, and SPORTDiscus) and ongoing research registers were searched from 1990 to October 2009. We also searched the references of included studies. Studies published only in languages other than English were excluded. Outcomes sought were specific to each of the three systematic reviews: clinical effectiveness – PA, physical fitness, health outcomes [e.g. blood lipids, health-related quality of life (HRQoL), and adverse events]; cost-effectiveness – costs and cost-effectiveness; predictors of uptake and adherence – quantitative reports of the level of uptake and adherence, statistical measures of the association/relationship between participant and programme factors versus uptake or adherence; and qualitative reports of factors influencing uptake and adherence.

An economic model was developed to examine the cost-effectiveness of ERS in comparison with usual care. Using a decision-analytic model, the costs of ERS and the quality-adjusted life-years (QALYs) gained were modelled over the patient lifetime. Estimates for the effectiveness of ERS were drawn from the systematic review undertaken as part of the current research. Sensitivity analyses investigated the impacts of varying ERS cost and effectiveness assumptions.

Results

Summary of exercise referral scheme effectiveness

Seven randomised controlled trials (RCTs; UK, $n = 5$; non-UK, $n = 2$) met the inclusion criteria, recruiting a total of 3030 participants (1391 randomised to ERS). Five studies compared ERS with usual care, two studies compared ERS with an alternative PA intervention (walking or motivational counselling programme) and one study compared ERS with ERS plus a self-determination theory (SDT) intervention. Studies were judged to have a moderate-to-low risk of bias. The most consistently reported outcome was self-reported PA. In an intention-to-treat analysis, compared with usual care, there was weak evidence of an increase in the number of ERS participants who achieved 90–150 minutes of at least moderate-intensity PA per week at 6–12 months' follow-up [pooled relative risk (RR) 1.11, 95% confidence interval 0.99 to 1.25]. There was no consistent evidence to support a difference between ERS and usual care in the duration of moderate/vigorous-intensity and total PA, physical fitness, blood pressure, serum lipids, glycaemic control, obesity indices (body weight, body mass index and per cent fat), respiratory function, psychological well-being (perception of self-worth, symptoms of depression or anxiety) or HRQoL. There were no differences in PA or other outcomes in ERS versus alternative PA interventions or versus ERS plus a self-determination intervention. None of the included trials separately reported outcomes in individuals with medical diagnoses.

Summary of predictors of exercise referral scheme uptake and adherence

Fourteen observational studies and five RCTs provided a numerical assessment of ERS uptake and adherence (UK, $n = 16$; non-UK, $n = 3$). There was considerable evidence of variation in levels of both ERS uptake (35–100% of people attending the first ERS induction visit) and adherence to ERS (12–82% of people taking up ERS completing the programme). ERS uptake levels were generally higher in RCTs (79%) than in observational studies (62%), with no clear difference in adherence between different study designs (37% vs 48%). Women and older people appeared to be more likely to take up ERS. Furthermore, while older people were also more likely to adhere, women were less likely to adhere than men. There was little evidence to be able to judge the influence of participant psychosocial or programme-level factors on ERS uptake or adherence. The majority of the 10 included qualitative studies highlighted participants' perception of a range of short-term physical and psychosocial benefits associated with ERS.

Summary of exercise referral scheme cost-effectiveness

Four previous economic evaluations (UK, $n = 3$; non-UK, $n = 1$) assessing the cost-effectiveness of ERS were identified – three trial-based economic evaluations and one model-based analysis. Broadly, the evidence base suggested that ERS was a cost-effective intervention in sedentary populations without a medical diagnosis.

Indicative incremental cost per QALY estimates for ERS for various scenarios were based on de novo model-based economic evaluation. Compared with usual care, the mean incremental cost for ERS was £169 and the mean incremental QALY was 0.008, with the base-case incremental cost-effectiveness ratio (ICER) for ERS at £20,876 per QALY in sedentary individuals without a diagnosed medical condition and £14,618 per QALY in sedentary obese individuals, £12,834 per QALY in sedentary hypertensive patients, and £8414 per QALY for sedentary individuals

with depression; however, findings report small incremental costs and QALYs, and ICERs were therefore highly sensitive to plausible variations in the RR for change in PA and cost of ERS.

Discussion

Strengths, limitations, uncertainties of the analysis

Our electronic database searches were restricted to controlled trials, to examine the highest level of evidence for effectiveness, with ERS studies carefully selected on the basis that there was clear evidence of referral by a primary-care health professional to a third-party exercise provider. We extended the scope of this report to undertake a review of quantitative and qualitative literature so as to better understand the potential predictors of ERS uptake and adherence. However, we did not incorporate formal methods of qualitative synthesis such as meta-ethnography. A particular strength of our cost-effectiveness analysis was the further development of the economic model originally used in the NICE evaluation of primary care-based exercise interventions. These further developments included the incorporation of epidemiological data linking PA and the future risk of clinical outcomes in specific diagnoses groups (i.e. obesity, hypertension and depression). For the purposes of generating a cost per QALY for people with a specific medical diagnosis, we assumed that the same benefit in terms of PA gains in those populations as sedentary 'at-risk' individuals.

Because of limitations and gaps in the evidence base there remain several key uncertainties regarding the effectiveness of ERS. These include (1) the certainty in the improvement in short-term PA seen in sedentary individuals without a medical diagnosis; (2) the impact of ERS in people with a medical diagnoses; (3) whether or not ERS consistently affect clinical outcomes such as blood pressure and serum lipids; and (4) whether or not the potential small gains in short-term self-reported PA with ERS are maintained over the longer term. The cost-effectiveness for ERS is uncertain because of the limitations and gaps in the clinical effectiveness evidence base. Sensitivity analyses show that the cost per QALY associated with ERS can change markedly, with plausible changes in model effectiveness and cost inputs, which means that robust evidence on whether or not ERS are likely to be cost-effective cannot currently be provided.

Conclusions

Implications for service provision

In 2006, NICE commented that there was insufficient evidence for ERS and recommended that the NHS should only make ERS available as part of a controlled trial. Although we have identified four additional trials since the NICE review, there remains very limited support for the potential role of ERS for impacting on PA and, consequently, public health. Arguably, such an uncertain impact provides a case for the disinvestment in ERS. However, little evidence was found of how the ERS intervention sought to develop a sustainable active lifestyle in participants, as recommended in the NHS National Quality Assurance Framework. Although ERS programmes in our review aimed to increase medium- to long-term PA, they were typically based on only a 10- to 12-week leisure centre-based period intervention. With the exception of one trial (Jolly K, Duda JL, Daley A, Ntoumanis N, Eves F, Rouse P, *et al.* *An evaluation of the Birmingham exercise on prescription service: standard provision and a self-determination focused arm.* Final Report; 2009), there was minimal reference to health behaviour change techniques and theories that typically underpin interventions to promote an increase in daily PA.

Research priorities

- Randomised controlled trials assessing the clinical effectiveness and cost-effectiveness of ERS in disease groups that might benefit from PA. In addition, RCTs should seek to incorporate hard to reach populations (e.g. ethnic minorities) that are traditionally not represented in trials.
- Such RCTs should be better reported, include long-term data on the clinical effectiveness of ERS and the sustainability of PA change, incorporate objective measures of PA (e.g. accelerometers) and health outcomes (e.g. blood pressure, serum lipids) and incorporate parallel-process evaluations to better understand the mediators and barriers to behaviour change.
- Exercise referral scheme programmes vary in their procedures and this may impact on uptake and adherence. Future trials should, therefore, be designed to better understand the contribution of different programme components (e.g. level of staff training) to the clinical effectiveness and cost-effectiveness of ERS.
- Head-to-head RCTs comparing the clinical effectiveness and cost-effectiveness of different models of primary-care interventions aimed at promoting PA.
- Further quantitative and qualitative studies are needed to determine the moderators of uptake and adherence to ERS.
- Theory-driven interventions should be developed to complement ERS to foster long-term change in PA, and evaluated to enhance our understanding of mediators and processes of behaviour change (e.g. SDT, motivational interviewing).
- The development of improved approaches to modelling the cost-effectiveness of ERS, capturing the potential impact on a wide range of health outcomes.

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Publication

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NIHR Health Technology Assessment programme

The Health Technology Assessment (HTA) programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 08/72/01. The contractual start date was in September 2009. The draft report began editorial review in December 2010 and was accepted for publication in March 2011. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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