

Dadansoddi ar gyfer Polisi



Llywodraeth Cynulliad Cymru
Welsh Assembly Government

Ymchwil gymdeithasol
Social research

Number: 07/2010

www.cymru.gov.uk

The evaluation of the National Exercise Referral Scheme in Wales



The evaluation of the National Exercise Referral Scheme in Wales

**Simon Murphy¹, Larry Raisanen¹, Graham Moore¹,
Rhiannon Tudor Edwards², Pat Linck², Natalia
Hounsome², Nefyn Williams³, Nafees Ud Din³ and
Laurence Moore¹**

¹Cardiff Institute of Society and Health, School of Social Sciences, Cardiff University, Cardiff, Wales,

² Centre for Economics and Policy in Health, Institute of Medical and Social Care Research, Bangor University

³ Dept. of Primary Care and Public Health, Cardiff University, School of Medicine, North Wales Clinical School, Wrexham

Views expressed in this report are those of the researcher and not necessarily those of the Welsh Assembly Government

For further information please contact:

Name: Janine Hale

Department: Public Health Research, Social Research Division

Welsh Assembly Government

Cathays Park

Cardiff

CF10 3NQ

Tel: 029 2082 6539

Fax: 029 2082 3430

Email: janine.hale@wales.gsi.gov.uk

Welsh Assembly Government Social Research, 2010

ISBN

© Crown Copyright 2010

Table of contents

Acknowledgements	3
Background.....	4
Methods	6
Results.....	10
Conclusions and Recommendations.....	15
References.....	21
Appendix.....	24

Acknowledgements

We thank the scheme's coordinators, Elaine McNish and Jeannie Wyatt-Williams, and the research contract manager Janine Hale of the Welsh Assembly Government for providing information and on going support to facilitate this study. We are grateful to all exercise coordinators and professionals and patients that took part in the study. The research was funded by the Welsh Assembly Government.

The Thames Valley Multi-centre Research Ethics Committee (MREC) approved the evaluation of the Welsh NERS on Feb. 8, 2007 (Ref: 06/MRE12/85). Due to changes in COREC procedures, an additional Site-Specific Information (SSI) form (Ref: C/92139/137055/1) was also later submitted to the MREC. Approval from medical directors within each local health board (LHB) has also been obtained in partnership with local exercise co-ordinators.

Background

1. Physical activity and health

The benefits to health of a physically active lifestyle are well established and there is growing evidence that a sedentary lifestyle plays a significant role in the onset and progression of chronic disease (DOH, 2004). Despite a recognised need for effective public health interventions such as Exercise Referral Schemes (ERS), encouraging sedentary people with a medical condition to become more active, evidence of the effectiveness is equivocal (Williams et al, 2007) and there are few rigorous evaluations of their cost effectiveness (Munro et al, 2004). This has led the National Institute for Clinical Excellence to conclude that further research is needed in this area (NICE, 2006).

2. The National Exercise Referral Scheme in Wales

In 2005, existing good practice in local schemes across Wales was assessed and standardised Wales-wide protocols developed. The Welsh Assembly Government working in partnership with Local Authorities (LA), the then National Public Health Service and local health boards (LHBs) implemented the National Exercise Referrals Scheme (NERS) in phases from 2007. In each LA area, a dedicated Exercise Co-ordinator (EC) and a number of Exercise Professionals (EP) support a tailored subsidised 16 week activity programme typically based in a local leisure centre. Participants must be sedentary and have at least one medical condition, covering CHD risk factors, mental health, musculoskeletal, respiratory/pulmonary and neurological conditions. The 16 week scheme is outlined below in Box 1.

Box 1: Delivery of the Welsh National Exercise Referral Scheme (NERS)

16 week programme of exercise supervised by a qualified exercise professional

- Initial consultation with exercise professional on entry - lifestyle questionnaire, health check (resting heart rate, blood pressure, BMI, and waist circumference), introduction to leisure centre facilities, MI and goal setting
- Access to one to one exercise instruction and / or group exercise classes
- Discounted rate for exercise activities, £1 per session.
- Four week telephone contact with EP – review of goals and MI
- Sixteen week consultation with EP - review of goals, MI, health check, lifestyle questionnaire, service evaluation questionnaire (Cock, Adams et al. 2006) and signposted to exit routes

Post 16 week activities

- 8 months telephone contact by EP to check progress
- 12 months review including repeat of entry health check and Chester fitness step test (Sykes and Roberts, 2004)

Post 16 weeks, the range and cost of exit routes varies by area, but all patients are contacted at 8 months to check progress and offered a 12 month review. The primary goal is for participants to achieve 30 minutes of moderate physical activity on at least 5 days per week

3. The evaluation of the National Exercise Referral Scheme

The Welsh Assembly Government commissioned an independent evaluation of the scheme as it rolled out in 13 of the 22 LHB in Wales. This summary reports upon the design of the national evaluation which utilised a randomised controlled trial design with nested process and economic evaluations. Details of the full trial protocol are published elsewhere (Murphy et al, 2010). It then summarises the key results and recommendations from a series of papers which have been submitted for publication (the links for which will be provided here in due course) that not only address whether the intervention has worked, but why, for whom, under what circumstances and at what cost (Pawson and Tilley, 1997).

Methods

1. Assessing implementation

The process evaluation combined quantitative and qualitative methods and focused on a number of areas:

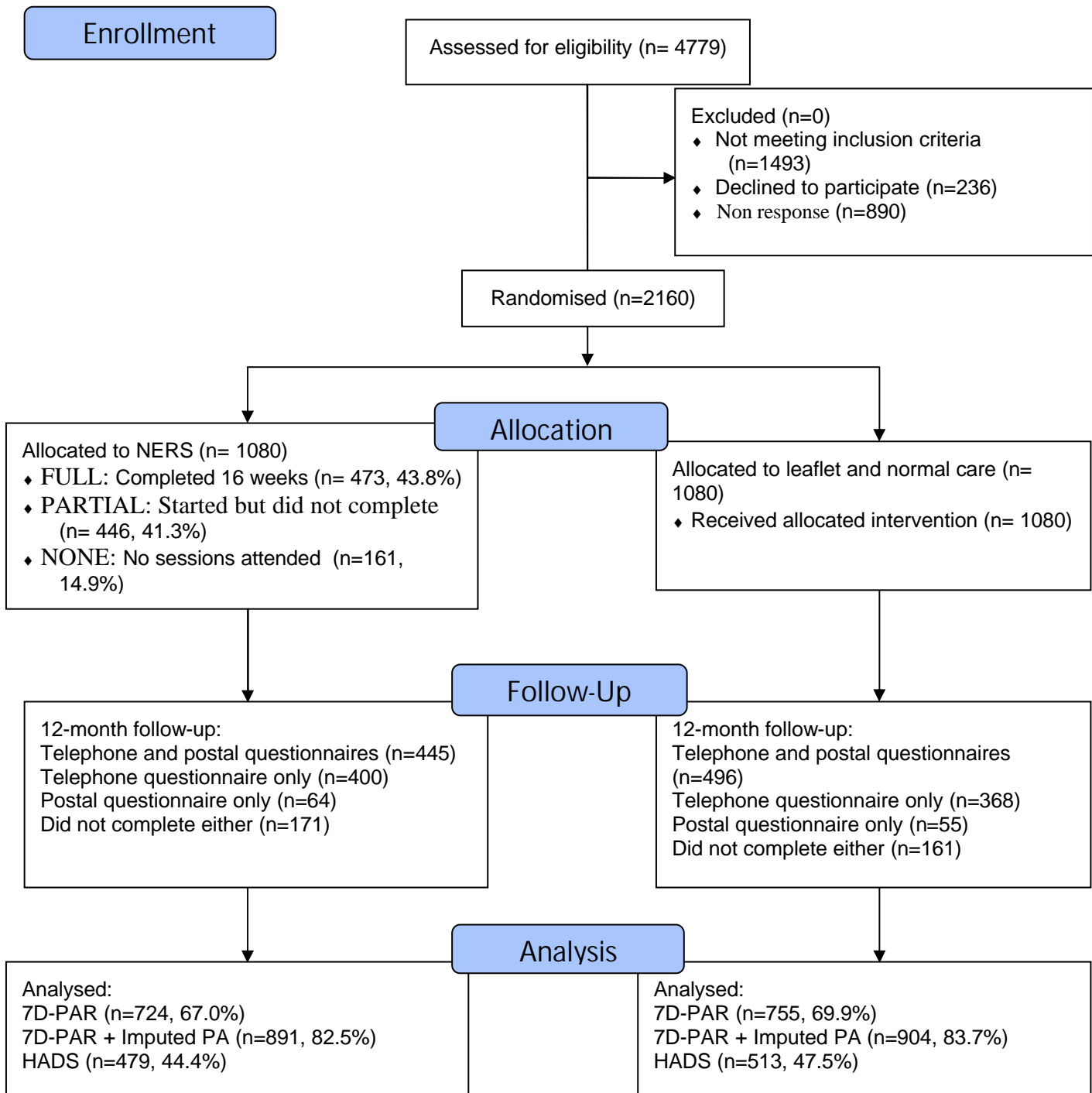
- Programme diffusion – this covered analysis of protocols and telephone and email contact with policy representatives to identify key planned programme components, causal pathways and intended outcomes. This work was followed by semi-structured interviews with policy representatives and 12 ECs and 9 focus groups with general practice staff to assess how local context shapes delivery
- Fidelity and dose delivered – to assess consistency of delivery with programme theory and quantity of intervention delivered. This included recordings of first consultations coded for MI fidelity using a validated scale, with a second round of MI fidelity checks conducted 6 months after training, to examine post-trial practice following supplementary training. This also included structured interviews with 38 EPs and 12 ECs and analysis of routine monitoring database to explore the impacts of the delivery of goal setting on patient adherence.
- Patient experience - Semi structured interviews with 38 exercise professionals and semi structured interviews with 32 patients in 6 centres to explore patient experiences and causal processes that promote change.
- Reach and adherence- Semi structured interviews with 38 exercise professionals and 32 patients and analysis of routine monitoring database to assess perceived variability in scheme reach and patterning by patient characteristics

2. Assessing effectiveness

A randomised controlled trial design was used to assess scheme effectiveness in 12 of the 13 LHBs in Wales, as the scheme failed to start in one area during the study period. Health professionals working in a range of health care settings referred to the trial with informed consent administered by the evaluation team. 2,160 inactive men and women aged 16+ with coronary heart disease (CHD) risk factors and / or mild to moderate depression, anxiety or stress were recruited. Participants were stratified by gender and LHB and randomised to the scheme (intervention), or received an information booklet on physical activity and normal GP care (control). A range of validated physical activity, mental health, psycho-social and economic measures were administered at 6 and 12 months, with the primary 12 month outcomes being weekly minutes of activity via the 7 day physical activity recall (PAR) questionnaire (Blair et al, 1985) and anxiety and depression measured by the Hospital Anxiety and Depression Scale (HADS) (Bjelland et al,

2002). For those participants without measures of 7-DAY PAR, the Baecke (Baecke et al, 1982), measured at 12 month questionnaire, and then the GPPAQ (DOH 2006), administered at 12 month telephone interview was used to impute a score for weekly activity at 12 month follow up. Participant recruitment and flow through the study is shown in figure 1 below.

CONSORT Flow Diagram



3. Assessing cost effectiveness

The aim of the integrated economic analysis was to estimate the relative cost-effectiveness of primary care referral to the National Exercise Referral Scheme as part of the management of people either at risk of CHD or with mild to moderate mental health problems as compared with usual care. Costs and benefits were viewed from a public sector, multi-agency perspective (Edwards, Hounsome, Linck et al 2008, Glick, Doshi, Sonnad et al 2007, Drummond, Sculpher Torrance et al 2005, Medical Research Council 2008). The primary outcome measure for the economic analysis was the quality adjusted life year (QALY). This is a measure of health utility calculated by 'weighting' each period of follow-up time by the value corresponding to the health-related quality of life during that period. Health related quality of life was assessed using the EQ-5D questionnaire (EuroQol 2009) which was included in the 6 and 12 month questionnaire to the full sample. The EQ-5D is a validated generic health-related preference-based measure comprising five items covering mobility, self-care, usual activity, pain, anxiety and depression, each with three levels of severity (no problems, some problems, a lot of problems).

Cost information was collected from the Welsh Assembly Government as sponsors of the scheme, local authorities administering the scheme and leisure centres delivering the scheme. In addition, study participants were asked by postal questionnaire to recall over the preceding 6 months their contacts with NHS primary care (including prescribing) and secondary care services (Knapp and Beecham 1990). The questionnaire included a question asking participants how much they were in theory willing to pay for exercise sessions through NERS. Costs were applied to service use data using nationally available sources (Curtis 2009, DoH 2009, NHS Information Centre 2009). NERS set-up and operating costs were obtained directly from WAG and additional information on costs to local authorities and WAG were obtained using semi-structured telephone interviews with WAG and across all local authorities in the trial. Costs of the Scheme were incurred in 13 local authority areas and, for completeness, these have all been included in our cost estimates even though final recruitment to the trial took place in 12 areas.

Results

1. Implementing the NERS

Programme diffusion

Initial diffusion into local practice occurred amidst resistance to national standardisation in some cases, although following implementation, NERS was widely accepted as improving past delivery. Coordinators and policy representatives both cited limited communication in initial implementation, although the appointment of a national coordinator addressed this.

Health professionals were generally seen as receptive to ERS, although promoting the trial was seen as challenging for newly employed coordinators and it was necessary to call on additional Government support to address concerns about randomisation and recruit referring GPs. General practice referral varied substantially between practices and professionals and was influenced by their perceptions of the effectiveness of ERS and the role of health professionals in promoting activity. Communications from scheme coordinators, materials and provision of feedback facilitated engagement with NERS, although some health professionals identified the evaluation as a barrier to referral due to objections to randomisation.

Leisure centres were seen as receptive to the scheme, although in some areas, the space required by the scheme conflicted with financial priorities, leading access to be limited to off-peak hours. Some also commented that centre staff often objected to accepting patients into mainstream services after the programme, as some conditions were still perceived as posing too high a risk. Coordinators discussed the need to increase the availability of low intensity exercise options for long term maintenance of activity and the value of tailoring protocols for local acceptability.

Fidelity

All areas offered a discounted exercise programme, at the rate of £1 per session, supervised by a qualified instructor. Most offered patient only group classes, with gym sessions held during general opening hours. There was large variability in protocol fidelity between areas for following up patients who stopped attending and for 8 and 12 month contacts, with some areas following up as few as 9% of patients, whilst other areas achieved follow up rates of 78%. The area achieving the highest overall fidelity also achieved the highest level of scheme completion. The area achieving the lowest fidelity achieved the lowest scheme completion rate. Whilst it is possible that these differences are exaggerated by poor record keeping, it is clear that a third of non attendees contacted at 4 weeks returned to the scheme. Attention is therefore needed to address

quality of delivery in some areas. Two areas for improvement were the non-delivery of motivational interviewing and limited goal setting quality.

Motivational interviewing delivery

There were low levels of fidelity for MI delivery during the period of the trial. Combining MI with the large amount of closed questioning in consultations was seen as challenging and professionals perceived a need for more training. The introduction of additional post trial training was well received by most and triggered increased recognition of the potential motivational role of first consultations. A minority rejected MI, seeing current practice as effective or patients as already being ready to change. Quantitative monitoring indicated that there was no aggregate change in practice and professionals suggested the need for on going training and reflection.

Goal setting and patient adherence

Many goals that were set were neither measurable nor time bound, although as the scheme developed they became more common. The majority of measurable and time-bound goals related to weight loss, with most remaining goals relating to programme attendance. There was a general trend for improved outcomes to be associated with the quality of goal setting, but differences were small and non significant.

Dose

First consultations averaged 35 minutes, although these ranged from 12 to 60 minutes. The 16 week programme typically took participants 19 weeks to complete and centres offered a median of 3 classes per week. Most professionals offered indefinite access to NERS classes after completion, with scheme discounts replaced by local discounts in most areas.

Programme reach

Participants ranged between 16 and 88 years old, with a mean age of 52 (SD 14.7), were predominately female (66%) and the vast majority classed themselves as white (96%). There was a fairly equal split between those in employment (32%) and those retired (31%), with a further 19% undertaking housework. Participants were most likely to be referred for CHD risk factors only (72%) or in combination with mental health issues (24%) and classed themselves as inactive (58.6%) or moderately inactive (15.3%), with 24% defining themselves as either active or moderately active. Table 1 shows that the intervention and control groups were similar on all baseline characteristics.

Table 1: Comparison of demographic characteristics by trial arm at baseline and for 12 month primary outcomes

	Baseline		7 Day PAR		HADS	
	Intervention % (N)	Control % (N)	Intervention % (N)	Control % (N)	Intervention % (N)	Control % (N)
Reasons for referral						
CHD only	71.3 (770)	73.1 (789)	74 (536)	75.8 (572)	75.2 (360)	76.6 (393)
Mental Health only	3.8 (41)	3.5 (38)	3.5 (25)	3.1 (23)	2.9(14)	2.9 (15)
CHD and Mental Health	24.9 (269)	23.4 (253)	22.5 (163)	21.2 (160)	21.9 (105)	20.5 (105)
Age group						
16-44	29.9 (322)	30.1 (323)	26.6 (192)	26.0 (196)	18.8 (90)	19.5 (100)
45-59	34.5 (371)	32.7 (352)	35.3 (255)	34.3 (258)	34.7 (166)	35.1 (180)
60+	35.6 (383)	37.2 (400)	38.1 (275)	39.7 (299)	46.4 (222)	45.4 (233)
Gender						
Male	34.4 (372)	34.5 (373)	34.5 (250)	33.3 (251)	35.1 (168)	33.1 (170)
Female	65.6 (708)	65.5 (707)	65.5 (474)	66.7 (504)	64.9 (311)	66.9 (343)
WIMD tertile						
Low	34.4 (361)	32.3 (340)	37.1 (262)	33.5 (246)	37.5 (173)	32.9 (165)
Middle	34.1 (358)	32.5 (342)	32.4 (232)	35.0 (257)	34.3 (158)	37.3 (187)
High	31.4 (330)	35.2 (370)	30 (212)	31.6 (232)	28.2 (130)	29.7 (149)
GPPAQ						
Inactive	59.2 (623)	60.6 (643)	58.2 (411)	61.4 (455)	59.0 (276)	60.5 (306)
Mod. inactive	16.1 (170)	15.1 (160)	15.6 (116)	15.3 (113)	14.3 (67)	14.0 (71)
Mod. Active	17.2 (181)	15.2 (161)	19.3 (136)	14.8 (110)	17.5 (82)	15.2 (77)
Active	7.5 (79)	9.2 (97)	6.4 (49)	8.5 (63)	9.2 (43)	10.3 (52)
Missing	(27)	(19)				
Employment						
Employed	32.7 (346)	28.4 (300)	32.7 (232)	29.5 (218)	27.0 (131)	27.7 (139)
Retired	30 (318)	32.9 (348)	32.7 (232)	35.1 (259)	38.8 (183)	40.2 (202)
Housework	18.8 (199)	20.3 (214)	17.0 (121)	20.6 (152)	17.0 (80)	18.5 (93)
Other	18.5 (196)	18.5 (195)	17.6 (125)	14.8 (109)	16.5 (78)	13.6 (68)
Missing	(21)	2.1 (23)				
Education						
Beyond min school leaving age	52.1 (557)	53.0 (570)	51.5 (370)	54.6 (410)	58.7 (280)	55.5 (284)
Total (n)	1080	1080	724	755	479	513

Adherence

The largest drop out occurred between scheme entry and 4 weeks, with 58% still in the scheme at 4 weeks. Overall 44% of patients completed NERS, with sizeable variation between areas (11% to 62%). Scheme completion was only slightly higher amongst men than women, although a marked increase in adherence was observed for older patients compared to younger patients. Patients in low deprivation areas were most likely to enter NERS, although there were no differences in likelihood to complete. Consistent with qualitative reports from patients suggesting that accessing the scheme was often difficult without transport, non-car owners were almost twice as likely not to enter NERS, and 6% less likely to complete. Patients referred for mental health and CHD risk factors were less likely to complete NERS than were patients referred for CHD risk factors alone.

Patient experiences

Professionals saw their role as providing education and social support to assist patients' confidence, motivation and integration into the exercise environment. Patient-only group activities were seen as creating an empathic environment, social support and modelling. Fostering social support networks emerged as a key mechanism for reducing programme dependence. Professionals reported that participants who initiated the referral decision rather than acting on GP advice, who experienced less disadvantage and were not referred for mental health issues were more likely to adhere. Older females were seen to benefit most from social aspects of the scheme.

Patients' motivations ranged from seeking medical improvements, to maintaining functional abilities, to improving occupational capacity. Patients described exercise professionals as providing education and support for confidence and motivation. Other patients were seen as providing an empathic context, reducing anxieties, and providing role models. Perceived programme limitations varied between sites; some noted poor access to transport and limited class timings in some rural centres. While some reported they had a clear action plan for activity beyond the programme, others expressed concerns that they might struggle to maintain motivation without a commitment to exercise in a set time and place and the loss of social support.

2. NERS effectiveness

Table 2 in the appendix shows the results of the regression analyses for each of the primary outcomes at 12 month follow-up. For all participants, those in the intervention group had higher levels of physical activity than those in the control, odds-ratio 1.19 (95% CI: 0.99, 1.43), but differences in activity were only statistically significant among those referred for CHD risk factors only (OR 1.29, 95% CI: 1.04, 1.60). There was no effect on physical activity among those referred wholly or partially for mental health reasons. For depression and anxiety outcomes, there were statistically significant differences among those referred wholly or

partially for mental health reasons, but the effects among all participants were of lesser magnitude and marginal statistical significance (D: -0.71, 95% CI: -1.25, -0.17; A: -0.54, 95% CI: -1.12, 0.35) due to weaker effects among those referred for CHD reasons only. In sub-group analyses, there were statistically significantly greater effects on all outcomes among those who completed the 16-week programme compared to those who attended only partially or not at all. There were significant interactions with gender for both mental health outcomes, with the beneficial effect of the intervention only apparent among females

3. NERS cost effectiveness

There were no significant differences in characteristics of study participants in intervention and control groups at baseline. Although all participants received all the measures, 55% (n=798) of all participants completed the economic sections. There were some differences between those participants included in the economic analysis from those in the effectiveness analysis, responders tended to be younger and there were more referrals for CHD risk factors. At 12 month follow-up the economic sample showed greater adherence to NERS than the effectiveness sample. The mean cost per participant in NERS used in our base case analysis was £385, (range from £289 to £579 depending on assumptions regarding number of participants in NERS). Participants who completed a willingness to pay question indicated they were willing to pay a mean sessional fee of £2.27 (SD £1.65). A conservative estimate of incremental benefit in self reported health related, quality of life was 0.03 QALYs at 12 months for the intervention group as compared with the control group, rising to 0.05 under relaxed assumptions. Our base case analysis for all study participants, assuming referral to the scheme was at a routine GP consultation and that there was no charge for exercise classes, using QALYs as our measure of effectiveness gave a cost per QALY of £12,111, (bootstrapped one-sided CI £58,881) well within the NICE threshold of £20,000-£30,000. Our results were robust to sensitivity analysis, suggesting that, as participants indicated they would be willing to pay, if a charge of £2 per exercise session was made, NERS would under £10,000 per QALY.

Conclusions and Recommendations

1. Policy diffusion

Although facing significant initial resistance to the introduction of national protocols and the roll out of the scheme within an evaluation design, the structures and systems introduced by the Assembly Government successfully facilitated diffusion of the programme and supported the evaluation. Key to this were:

- Early collaboration between government researchers, policy leads, and independent evaluators to develop and facilitate the study
- The early appointment of dedicated local coordinators to implement national policy
- The eventual appointment of a highly respected peer as national coordinator
- Regular meetings between local coordinators, evaluators and national policy makers
- Assembly and evaluator briefings for health professionals across areas to encourage study participation and support coordinators who were less experienced in this area

Recommendations:

- To adopt NERS diffusion structures and systems for best practice in future national policy implementation, particularly those within an evaluation framework
- To ensure early appointment of national and local coordinators

2. Scheme implementation

There was large variation in levels of referrals from health professionals and these were influenced by their own perceptions of scheme effectiveness and professional roles. Interestingly, professionals reported limited perceived adherence amongst patients who entered on advice of their health professional rather than through actively seeking referral, whilst patient interviews concurred that many had actively sought referral. Health professional advice may therefore not be as central an active ingredient of change within ERS as often assumed, and in many cases, may not even form part of the patients' journey through an ERS. This is particularly important as previous studies have reported that physical activity promotion was not a priority during routine consultations (Graham, Dugdill et al. 2005), primary care clinicians are inconsistent in how they perceived their role in changing patients' behaviour, and patients are frequently selected for referral to exercise schemes in an unsystematic way (Graham, Dugdill et al. 2005).

Leisure centres for their part appeared to adapt to support the scheme, with the introduction of new low intensity exercise options for activity maintenance at 16 week exit. However there were some concerns as to the financial viability of supporting the increasing referral volume. The

openness of referral criteria within NERS may therefore only be sustainable in a climate of limited adoption by referral partners. The provision of a standardised programme monitoring system was invaluable for assessing scheme implementation. Activities familiar to professionals (e.g. health checks and exercise classes) were delivered per national protocol, although new activities (e.g. motivational interviewing, goal setting and patient follow-up) were delivered with limited fidelity. Rates of follow ups for non attendees and participants at 8 and 12 months varied greatly and in some areas there is considerable room for improvement. Motivational interviewing in particular is recognised as needing significant levels of ongoing training and reflection for successful implementation. Six months after additional training, no significant change in MI fidelity was observed, which suggests a need for further support and an assessment of consultation structures. Literature is rapidly evolving to inform efforts to integrate MI into routine practice. Engagement with this growing evidence base will likely offer promise for improving delivery of MI within NERS in the future. For goal setting, the instruction to set measurable and time-bounded goals in conjunction with limited training might have led some professionals to direct patients to set unmotivating goals that could be easily measured. As with MI delivery, the impact of large volumes of closed questioning on rapport likely made it difficult to elicit motivations in order to negotiate personally meaningful goals. A longer piloting phase to establish feasibility of protocols and delivery mechanisms may have identified these issues prior to full implementation.

Recommendations:

- To consider the most effective professional and self referral routes into NERS in the light of professional views, patient perspectives, programme capacity and the need to target motivated participants.
- To review the length of first consultations and the number of tasks to be completed in that time, considering the balance between information gathering and motivational interviewing
- MI should be communicated clearly in protocol documents and should form an integral part of professionals' job description
- Provide an ongoing professional development programme to support motivational interviewing practice.
- Goal setting should identify patients' motivations for change before negotiating goals which are measurable and time-bound
- Emphasise the importance of and ensure follow ups for non attendees and contact at 8 and 12 month once participants have exited the 16 week programme
- Assess why there is such large variation in protocol fidelity across areas
- To maintain and facilitate completion of routine data monitoring systems to assess programme quality after the trial period

3. Facilitating reach and adherence

Fifteen percent of those allocated to the scheme did not attend. Those joining were most likely to be referred for CHD risk factors or in combination with mental health issues. The scheme was more popular with females and participants were most likely to fall into the 55 to 64 age group, with a fairly equal split between those in employment and those retired. For those entering the scheme, NERS achieved 44% completion. Although similar Taylor, Doust et al. (1998), it compares favourably to a number of previous evaluations of ERS which have for example resulted in completion rates of 25% (Stevens, Hillsdon et al. 1998) and 26% (Munro, Nicholl et al. 2004).

Older patients and women were seen as often exhibiting additional anxieties on entry to the scheme although were also seen as benefiting from social aspects of group classes. Group-based structures seem to have gone some way towards offsetting tendencies for lower adherence amongst female participants observed in some ERS.

Given adherence was higher amongst older patients, it is interesting that this did not manifest itself in significant differences in physical activity at 12 months. Whilst some patients nearing the end of the programme had made plans for how they would remain active, others expressed concerns regarding loss of social support, the return of external constraints, and enduring anxieties about the exercise environment, with a perceived lack of information on post scheme exercise options possibly hampering maintenance. This highlights a possible need for more intensive longer term support for the older age group to maintain activity levels.

As professionals reported, those referred with mental health issues appear to face additional barriers and were more likely to drop out. Professionals identified a need amongst mental health patients for extra support to maintain motivation and foster social interaction. Contrary to professional perspectives however, patients from lower deprivation areas were most likely to enter the programme and no more likely to drop out. Instead car ownership was associated with non entry and drop out, which highlights the need to consider access issues for this group. Limited class times were cited by working patients as a barrier to uptake, whilst access issues were seen as a barrier for patients without transport. Significantly, adherence also varied substantially between areas. Those achieving the highest overall fidelity also achieved the highest level of scheme completion. Whilst it is possible that these differences are exaggerated by poor record keeping, this issue warrants further exploration by the programme to address possible quality issues. There is some evidence that when patients who have stopped attending are invited to return, some do return to complete the scheme.

A number of key roles for professional and patients were identified to facilitate adherence. For the professional this involved fostering increases in knowledge and confidence, whilst supporting motivation. Professionals and patients also placed substantial emphasis upon roles of other patients in helping patients feel at ease in the exercise environment. However, as with professional support, creation of this

environment was seen by some as engendering dependence likely explaining the tendency in some areas to allow indefinite access to patients after the programme. Emerging strategies to lessen dependence on the programme included fostering of social support networks through filtering completers into maintenance classes or exiting patients in clusters.

Recommendations

- To explore reasons for large variations in scheme adherence by area and to share good practice adopted by high adherence areas
- To ensure accurate records for patient follow up for non attendees and 8 and 12 month post programme consultations
- To explore the adequacy of post 16 week provision for older age groups
- To examine scheme access issues for non car owners
- To address the barriers to adherence faced by those with mental health conditions
- To conduct further analysis to assess whether fidelity to protocols is associated with 12 month outcomes
- To explore the role of social support networks as an effective strategy for activity maintenance and share good practice.

4. Scheme effectiveness

Results from systematic reviews of ERS suggest they can promote exercise in the short-term but only in certain populations (Morgan 2005) and may be ineffective in sustaining long term outcomes (NICE 2006). This study provides robust evidence for the long term effectiveness of NERS for particular groups.

For participants referred with CHD risk factors only, there was a significantly increased likelihood of increases in physical activity and a statistically significant decrease in level of anxiety and depression for those in the scheme. Estimates for those referred with mental health and CHD were statistically significant for a decrease in both depression and anxiety, although there was not a statistically significant impact on physical activity for this group.

The impact of the intervention on participants adhering for the full intervention was clear. Those who completed the 16 weeks were far more likely to increase their activity compared to non completers. The impact of adhering to the full intervention also led to statistically significant improvements in mental health, with a decrease in depression and in anxiety. The impact of adherence on outcomes has been noted in previous evaluations (Williams et al. 2007) and emphasises the importance of addressing scheme uptake and drop out.

Recommendations

- To consider strategies for reducing programme drop out as outlined above
- To address the additional barriers facing mental health patients in increasing physical activity
- Exit route options should be discussed early in the scheme to allow patients to consider how they might maintain activity.
- To consider ways to improve males' social support networks within and following the 16 week programme

5. Scheme cost-effectiveness

Our conservative base case analysis is robust to a range of sensitivity analyses, leading to the conclusion that NERS is 89% likely to be cost-effective at just over £12,000 per QALY, and for those who adhere to the full programme is likely to be marginally cost saving (-£367 per QALY). The National Institute for Health and Clinical Excellence (NICE) has suggested that interventions delivering a cost per QALY of under £20,000-£30,000 are likely to be an acceptable use of NHS resources. Primary care referral to the National Exercise Referral Scheme falls well within this range or is potentially cost saving, particularly where participants pay a nominal fee per exercise class.

Recommendations

- There is a case for leisure centres continuing to charge £1 per exercise per session as part of a national exercise referral programme and to consider increasing the fee to £2 based on the willingness-to-pay findings.
- There is a need for further research i.e. studies that facilitate longer term follow up to see whether there are long term differences in costs of service use and whether exercise behaviour change is sustained and has long term impact on health related quality of life.

5. Strengths and weaknesses of the study

The evaluation of a large scale national public health intervention presents methodological challenges in terms of trial design and implementation. This study was facilitated by early collaboration with government researchers and policy colleagues to develop a rigorous design which included an innovative approach to patient referral and trial recruitment, a comprehensive process evaluation examining intervention delivery, and an integrated economic evaluation.

Collaboration was key in developing standardised programme monitoring systems with national policy leads and local practitioners. The implementation of a national rather than a number of local schemes offered the opportunity to introduce a standardized programme monitoring system for long term self evaluation. This includes dates of consultations, outcomes from consultations and demographic monitoring

data. Robust programme monitoring systems provide the opportunity for long term self evaluation once such trials are completed and provided key information to determine adherence levels.

Previous evaluations have identified significant barriers to implementing RCTs of ERS, particularly professional resistance to randomisation and a reluctance to refer when there is a perception of change or withdrawal of service, regardless of the evidence base for the effectiveness of that service. Despite this, the trial achieved high referral rates from the majority of areas. This may be in part a function of the size of the scheme being evaluated, but was inevitably facilitated by a number of strategies. This included briefing sessions for key stakeholders by the evaluation and national policy team, the provision of coordinators who were able to promote the trial at the local level, a low burden on health professionals who promoted but did not recruit to the trial and a low research burden on patients entering the trial.

The study also benefited from a high response rate to the measure of weekly activity at 12 months. This was administered by telephone which provides a more reliable measure than postal questionnaires utilised in many previous studies (Williams et al, 2007). Using other measures of physical activity (the Baecke Questionnaire of Habitual Physical Activity (Baecke) and **General Practice Physical Activity Questionnaire** (GPPAQ) to input scores for weekly activity for those without a 7 DAY PAR measure provided an enhanced response rate. It should be noted however that there was much lower response rate to the 12 month questionnaire containing the Hospital Anxiety and Depression scale and results for this group should be treated with some caution given the possibility of response bias.

6. Future analysis

Complex interventions need to be understood as leading to outcomes through the activation of mechanisms of change, with the activation of these mechanisms varying across contexts and between subgroups. Hence, it has been argued that modelling casual pathways has substantial value. This study assessed such motivation, self efficacy and social support at 6 months to be used to model casual processes amongst a number of sub groups in secondary analysis. This will further enhance our ability to link programme activity to participant responses. Whilst the variable delivery of goal setting and fidelity to protocols has been examined in relation to adherence, future analyses will focus upon variability in scheme outcomes at the area and exercise professional level according to fidelity protocols. Although the study is not powered to examine area effects, it will be possible to conduct further analysis to assess whether fidelity to protocols predicts 12 month outcomes

References

Blair SN, Haskell WL, Ho P, Paffenbarger RS Jr, Vranizan KM, Farquhar JW, Wood PD: Assessment of habitual physical activity by a seven-day recall in a community survey and controlled experiments. *American Journal of Epidemiology* 1985, **122(5)**:794-804.

Baecke, JA, Burema HJ, Frijters JE: A short questionnaire for the measurement of habitual physical activity in epidemiological studies. *American Journal of Clinical Nutrition* 1982, **36(5)**:936-942.

Bjelland I, Dahl AA, Haug TT, Necklemann D: The validity of the Hospital Anxiety and Depression Scale: An updated literature review. *Journal of Psychosomatic Research* 2002, **52(2)**:69-77.

Cock D, Adams IC, Ibbetson AB, Baugh P: REFERQUAL: a pilot study of a new service quality assessment instrument in the GP exercise referral scheme setting. *BMC Health Services Research* 2006, **6**.

Curtis L. (2009) Unit Costs of Health and Social Care, PSRRU, UK URL accessed 9th February 2010 <http://www.pssru.ac.uk/uc/uc2008contents.htm>

Department of Health: *At least five a week: Evidence on the impact of physical activity and its relationship to health*. London, Department of Health; 2004.

Department of Health: *The General Practice Physical Activity Questionnaire*. London, Department of Health; 2006.

Department of Health (2009) NHS reference Costs 2007-08, URL accessed 9th February 2010 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_098945

Drummond M, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. *Methods for the Economic Evaluation of Health Care Programmes*. 3rd Ed. Oxford: Oxford University Press; 2005

Edwards RT, Hounsome B, Linck P, Russell IT. (2008) Economic evaluation alongside pragmatic randomised trials: developing a Standard Operating Procedure for clinical trials units. *Trials* 14; 64 -65.

Euroqol (2009) User Guide version 2. URL accessed 9th June 2010 <http://www.euroqol.org/eq-5d/what-is-eq-5d/how-to-use-eq-5d.html>
Fenwick E, O'Brien B, Briggs A. (2004) Cost-effectiveness acceptability curves – facts, fallacies and frequently asked questions. *Health Econ*; 13: 405-415

- Glick HA, Doshi JA, Sonnad SS, Polsky D. *Economic Evaluation in Clinical Trials (Handbooks for Health Economic Evaluation)*. 1st Ed. Oxford: Oxford University Press; 2007
- Graham, RC, Dugdill, L, Cable, NT: Health professionals' perspectives in exercise referral: Implications for the referral process. *Ergonomics* 2005, **48(11-14)**:1411-1422.
- Knapp, M. & Beecham, J. (1990) Costing mental health services: the client service receipt inventory. *Psychological Medicine*, 20, 893-908
- Medical Research Council (MRC) (2008) Developing and evaluating complex interventions: new guidance. URL accessed 9th June 2010 <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004871>
- Morgan O. Approaches to increase physical activity: reviewing the evidence for exercise-referral schemes. *Public Health*. 2005;**119**(5):361–370.
- Munro JF, Nicholl JP, Brazier JE, Davey R, Cochrane T: Cost effectiveness of a community based exercise programme in over 65 year olds: Cluster randomised trial. *Journal of Epidemiology & Community Health* 2004, **58(12)**:1004-1010.
- Murphy S, Raisanen L, Moore G, Tudor Edwards R, Linck P, Williams N, Ud Din N, Hale J and Moore L (2010) A pragmatic randomised controlled trial of the Welsh National Exercise Referral Scheme: protocol for trial and integrated economic and process evaluation *BMC Public Health*, 2010, 10:352.
- NHS Information Centre (2009) Prescribing cost analysis 2008 England, URL accessed 9th February 2010 <http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/prescription-cost-analysis-2008>
- National Institute for Health and Clinical Excellence. Public Health Collaborating Centre for Physical Activity. *A rapid review of the effectiveness of exercise referral schemes to promote physical activity in adults*. London: National Institute for Health and Clinical Excellence; 2006.
- NICE (2008) Guide to Methods of Technology Appraisals URL accessed 25th March 2010 <http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf>
- Pawson R, Tilley N. *Realistic Evaluation*. London: Sage Publications; 1997.
- Stevens W, Hillsdon M, Thorogood M, McArdle D: Cost-effectiveness of a primary care based physical activity intervention in 45-74 year old men

and women: A randomised controlled trial. *British Journal of Sports Medicine* 1998, **32(3)**:236-241.

Sykes K, Roberts A: The Chester step test-a simple yet effective tool for the prediction of aerobic capacity. *Physiotherapy* 2004, 90(4): 183-188.

Taylor AH, Doust J, Webborn N: Randomised controlled trial to examine the effects of a GP exercise referral programme in Hailsham, East Sussex, on modifiable coronary heart disease risk factors. *Journal of Epidemiology & Community Health* 1998, **52(9)**:595-601.

Williams, N. H., M. Hendry, et al. (2007) "Effectiveness of exercise-referral schemes to promote physical activity in adults: systematic review." *British Journal of General Practice* **57**: 979-986.

Appendix

Table 2. Main effects and interaction effects - odds ratios and 95% confidence intervals from ordinal logistic regression models examining impacts of NERS on physical activity and B coefficients and 95% confidence intervals from linear regression models examining impacts of NERS on depression and anxiety.

Effect	Group	7-day PAR	7-day PAR plus imputed values	HADS Depression	HADS Anxiety		
Main effects	Whole sample All covariates included (n=1443/1749/959/956) ... Baseline GPPAQ omitted (n=1475/1788/976/973) ...	1.19 (0.99, 1.43) 1.20* (1.00, 1.45)	1.18 (0.99, 1.42) 1.19* (1.00, 1.42)	-0.71* (-1.25, -0.17) -0.74* (-1.28, -0.20)	-0.54 (-1.12, 0.35) -0.49 (-1.06, 0.08)		
	CHD only All covariates included (n=1081/1302/732/729)... Baseline GPPAQ omitted (n=1105/1329/743/740) ...	1.29* (1.04, 1.60) 1.35** (1.09, 1.67)	1.26* (1.02, 1.57) 1.30* (1.05, 1.60)	-0.60* (-1.18, -0.02) -0.64* (-1.22, -0.03)	-0.32 (-0.95, 0.31) -0.27 (-0.90, 0.35)		
	MH only or MH and CHD All covariates included (n=362/447/227/227) ... Baseline GPPAQ omitted (n=370/459/233/233) ...	1.06 (0.73, 1.55) 0.94 (0.65, 1.36)	1.04 (0.72, 1.52) 1.00 (0.69, 1.36)	-1.39* (-2.60, -0.18) -1.32* (-2.54, -0.10)	-1.56* (-2.75., -0.38) -1.52* (-2.68, -0.37)		
	Interaction effects	Deprivation (n=1405/1698/929/926) ...	Medium x intervention	1.08 (0.69 to 1.70)	0.98 (0.63 to 1.55)	0.80 (-0.50 to 2.09)	-0.24 (-1.64 to 1.15)
			High x intervention	0.83 (0.52 to 1.32)	0.80 (0.52 to 1.25)	-0.13 (-1.50 to 1.25)	-0.46 (-1.94 to 1.02)
		Adherence level (n=1443/1749/959/956) ...	Partial x Intervention	1.00 (0.78 to 1.29)	1.00 (0.79 to 1.27)	-0.12 (-0.90 to 0.65)	-0.12 (-0.84 to 0.82)
Full x intervention			1.46* (1.17 to 1.84)	1.40* (1.11 to 1.79)	-1.24* (-1.88 to -0.61)	-1.12* (-1.80 to -0.44)	
Gender (n=1443/1749/959/956) ...		Male x intervention	0.75 (0.51 to 1.10)	0.74 (0.51 to 1.07)	2.10* (0.98 to 3.23)	1.93* (0.72 to 3.14)	
Age (n=1443/1749/959/956) ...		45-59 x intervention	1.36 (0.84 to 2.21)	1.36 (0.84 to 2.18)	0.61 (-0.94 to 2.16)	2.03* (0.37 to 3.69)	
	60+ x intervention	0.99 (0.63 to 1.58)	1.04 (0.67 to 1.62)	0.65 (-0.83 to 2.13)	1.07 (-0.52 to 2.66)		

Key

* p<0.05 ** p<0.01

... n represents number of patients in 7-day PAR analyses/7-day PAR plus imputed values/HADS depression/HADS anxiety

All models include gender, LHB area, age group as covariates. Except where stated, all models also include baseline GPPAQ as a further covariate.

Links to study publications

Trial Protocol - <http://www.biomedcentral.com/1471-2458/10/352>