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Does primary care referral to an exercise programme increase physical activity 1 year later? A randomized controlled trial

Roger A. Harrison, Chris Roberts and Peter J. Elton

Abstract

Objective To assess the effectiveness of a primary care referral scheme on increasing physical activity at 1 year from referral.

Design Two-group randomized controlled trial recruiting primary care referrals to a borough-based exercise scheme.

Setting A local authority borough in the north-west of England.

Participants 545 patients defined as sedentary by a primary care practitioner.

Intervention Referral to a local-authority exercise referral scheme and written information compared with written information only.

Main outcome measures Meeting physical activity target at 12 months following referral, with a secondary outcome measured at 6 months from referral.

Results At 12 months, a non-significant increase of 5 per cent was observed in the intervention compared with control group, for participation in at least 90 minutes of moderate/vigorous activity per week (25.8 versus 20.4 per cent, OR 1.45, 0.84 to 2.50, $p=0.18$). At 6 months, a 10 per cent treatment effect was observed which was significant (22.6 versus 13.6 per cent, OR 1.67, 1.08 to 2.60, $p=0.05$). The intervention increased satisfaction with information but this did not influence adherence with physical activity.

Conclusion Community-based physical activity referral schemes have some impact on reducing sedentary behaviour in the short-term, but which is unlikely to be sustained and lead to benefits in terms of health.

Keywords: exercise referral schemes, physical activity, sedentary behaviour, randomized controlled trial, primary prevention

Introduction

Concerns remain regarding the effectiveness of primary care exercise referral schemes,[1,2] so-called *Exercise on Prescription*[3] intended to help reduce sedentary behaviour among the majority of adults failing to reach recommended levels of physical activity.[4] There are thought to be hundreds of primary care-based exercise referral schemes around the country [5] encouraged by central government[6] with national quality frameworks.[7] Typically, they involve referral from a primary care practitioner to a 10–12 week exercise programme run by local leisure services. If successful in increasing levels of physical activity, then these schemes could cost as little as £300 per-life-year-saved.[8] But a key question is just how effective are they in reducing sedentary behaviour in the longer term and how does this compare with other types of interventions or doing nothing?

Only two randomized controlled trials in primary care settings are known to have examined the effect of referral to a centre-based programme on reducing sedentary behaviour, with only small, short-term benefits observed.[9,10] The interpretation of these studies is hampered by their recruitment strategies, relying on postal invitations and employing restrictive inclusion criteria. To overcome these problems, the current study aimed to determine the effectiveness of a primary-care exercise referral scheme based on all patients initially referred by a primary care practitioner.

Methods

Study design

The study took place in a borough in the north-west of England, where a Exercise Referral Scheme had been in place since 1997, jointly funded by the Health Authority/Primary Care Trust and the Metropolitan Borough Council.

A two-group randomized controlled trial examined the effectiveness of the Exercise Referral Scheme and written information (intervention), to increase levels of physical activity at

Bolton Primary Care Trust, St Peters House, Silverwell Street, Bolton BL1 1PP

Evidence for Population Health Unit, School of Epidemiology and Health Sciences, University of Manchester, Oxford Road, Manchester M13 9PT

Roger A. Harrison, Research Development Lead, Research Scientist in Public Health

Biostatistics Group, School of Epidemiology and Health Sciences, University of Manchester, Stopford Building, Oxford Road, Manchester M13 9PT

Chris Roberts, Senior Lecturer in Medical Statistics

Bury Primary Care Trust, Silver Street, Bury BL9 0EN

Peter J. Elton, Director of Public Health

Address for correspondence to Roger A. Harrison.
E-mail: roger.harrison@bolton.nhs.uk

one year, compared with written information only (control). Individual patients were randomized by computer using minimization software and stratified by sex; age group (18–44 years, 45–59 years, ≥60 years old) and CHD risk (yes or no to: post myocardial infarction/on CHD Register). During the period of the study, all referral forms were faxed by the referring practitioner to a researcher thereby masking the exercise officers to details of patients allocated to the control group. The researcher checked the patient's eligibility for the Exercise Scheme and to the trial. The details of patients allocated to the Exercise Referral Scheme (intervention) were then forwarded to the exercise officers. All patients were posted written information packs. This included a series of leaflets on the importance of physical activity to health and well-being, information on local council-run physical activity facilities, and the telephone number of the Exercise Referral Office, for any specific queries relating to physical activity.

Patients not eligible for randomization were referred directly to the exercise officers. To prevent patients in the control group being re-referred by chance and receiving the intervention during the year of follow-up, the names of new referrals were checked against those already in the study. After follow-up, all patients could be re-referred directly to the Exercise Referral Scheme.

Intervention

After receiving a referral form, the exercise officers telephoned clients to arrange a one-hour consultation at one of three leisure centres. During the consultation, the exercise officer gave person-specific advice and information with the aim of increasing the amount of physical activity clients carried out each week. This included tailored information to meet the needs of each client, taking account of their preferences and abilities, for different types of activity. All clients were offered a subsidized 12 week leisure pass, providing reduced entrance fees to any of the council-run physical activity facilities across the Borough, and were encouraged to attend at least two centre-based sessions a week. Participants were also given information about non-leisure centre based activities available across the Borough. At the end of 12 weeks, participants attending the first consultation were invited for an exit interview. This provided an opportunity to review their progress and to identify opportunities to maintain/increase physical activity through the longer term.

Inclusion criteria

The inclusion criteria for the trial were based on existing referral criteria for the Exercise Referral Scheme. Primary care health professionals across three locality groups (including the local diabetes centre) could refer sedentary adults with additional CHD risk factors. These were obesity (as determined by the referrer); previous myocardial infarction; on the practice CHD risk-management register; or diabetes. One primary care locality also funded the Scheme to accept sedentary patients, regardless of other risk factors. Sedentary behaviour was defined as participating in less than 90 min of moderate/vigorous physical activity a week, ascertained as part of the patient consultation.

Exclusion criteria

The exclusion criteria for the trial were also based on existing criteria for the Exercise Referral Scheme. That was, patients identified by the clinician as having contraindications to physical activity; hypertension (SBP ≥200 mmHg) or aged <18 years old, not sedentary or not providing consent. Additional criteria imposed for the trial, were that more than one family member could not be knowingly recruited, to minimize contamination, and that the referring practitioner and patient had to give written informed consent.

Outcomes

The primary outcome measure was the difference between the two allocation groups in the percentage of people at one year since randomization who were participating in at least 90 min per week of moderate/vigorous physical activity. Secondary outcomes included the same measure at 6-months following randomization. Tests for interaction examined differential intervention effects by age, sex, and baseline CHD risk. Satisfaction with and demand for information was also measured at the 3 month assessment.

Data collection

Physical activity was assessed using a version of the 7-Day Physical Activity Recall (7dPAR) questionnaire.[10–13] The 7dPAR asks respondents to indicate during the past week the frequency and duration spent participating in light, moderate, or vigorous activity and to name the type of activity done. An option for 'no activity' was included and examples of types of activity by intensity were given. Additional questions were added to examine how satisfied participants were with the amount and type of information given. The 7dPAR was sent by post to participants at 3, 6, 9 and 12 months following randomization accompanied by a personalized letter explaining the purpose of the questionnaire. A reminder letter and further copy of the questionnaire was sent to non-responders ten days later at the 3, 6 and 9 month assessment. For the 12 month assessment, non-responders were sent a reminder postcard, a letter and repeat copy of the questionnaire, and a final reminder letter, at 10 day intervals. All postal questionnaires included a covering letter and a pre-paid business franked return addressed envelope.[14]

Ethical issues

Local Research Ethics approval was granted for the study. Consent was based on a Zelen design. All GPs in a single local authority borough were invited to take part in the study and could also exclude individual patients from randomization at the time of referral. For participating GPs/practices, patients were given a Patient Information Sheet at the time of referral

and signed the Referral Form with the referring practitioner, giving agreement to be sent physical activity questionnaires, while remaining unaware of group allocation.

Sample size

The minimum beneficial effect from the Exercise Referral Scheme was agreed through consultation with primary care representatives, exercise officers and the Health Authority. The Scheme was defined as effective if it led to an absolute increase of 20 per cent in the percentage defined as 'active' 12 months following referral, based on those attending at least the first consultation with the exercise officer. It was assumed that sending written information only (control) would increase the primary outcome by 10 per cent. The study was also powered to identify the effect of referral on physical activity at 12 months, regardless of attendance at the first consultation. An earlier audit found that 80 per cent of patients referred to the Scheme attended their initial assessment. Therefore, to observe an increase by 20 per cent in exercise activity at 12 months in those attending the initial assessment, the sample size was based on a increase of 16 per cent (10–26 per cent). To identify this with 90 per cent power and two-sided 5 per cent statistical significance required 264 participants. Recruitment continued until there was enough power to examine the effect of the intervention separately in participants with additional risk factors for CHD at baseline. Previous trials examining methods to increase physical activity through primary care had high drop-out rates. Therefore, to account for this, the initial sample size was inflated by 40 per cent, with a total of 440 participants needing to be recruited. Recruitment continued until this number of patients with baseline CHD risk factors had been randomized to ensure adequate power for subgroup analysis.

Analysis

The analysis was on the basis of intention-to-treat subject to the availability of follow-up data. This considered between-group changes at 12 months in the percentage participating in at least 90 minutes of moderate/vigorous physical activity (thus active vs. not active). Logistic regression adjusted for baseline stratifying variables and for predictors of non-response, with the effect represented with a common odds ratio. Interaction terms were included in the model to examine differences from the intervention by pre-specified baseline variables (CHD risk factors, sex and age). All analyses assumed that levels of physical activity in non-responders to the follow-up questionnaires would be similar in the two allocation groups. Not all participants returned questionnaires at follow-up and some responded to different assessment points. Therefore, to increase statistical power and to make use of all available data, a post-hoc analysis merged data across the 9 and 12 month assessments using robust standard errors that adjust for multiple observations. STATA (Release 8, Stata Corp., College Station, TX, USA) was used to analyse the data.

Results

Between March 2000 and December 2001, 830 patients were referred by primary care to the Exercise Referral Scheme, from 46 (88.5 per cent) of the 52 general practices in the Borough and the diabetes centre. The number of referrals not eligible for the Scheme was 110/830 (13.3 per cent). Of the remaining 720 patients, 175/720 (24.3 per cent) did not meet the criteria for the trial (13.2 per cent opted out by patient/practitioner; 5.5 per cent joint referral; 2.6 per cent no other CHD risk factor; 2.0 per cent incomplete referral form and 1.0 per cent for other reasons). Figure 1 shows the flow of participants through the study. The baseline characteristics of the 275 allocated to the intervention group and 270 to the control group were comparable (Table 1).

Response rates to the postal physical activity questionnaires in the intervention and control groups were 61.1 (168/275) versus 60.0 per cent (162/270) at 6 months and 56.4 (155/275) versus 58.1 per cent (157/270) at 12 months. Smokers defined at baseline were less likely to return the questionnaires (OR 0.57, 95 per cent CI 0.04 to 0.80) and each yearly increase in age increased the likelihood of return (OR 1.03, 95 per cent CI 1.02 to 1.05). Of the 275 participants referred to the intervention, 84.4 per cent (232/275) attended the first exercise consultation. This was not influenced by age, sex, smoking or baseline CHD risk factors.

Primary outcome

At 12 months, there was a non-significant absolute difference between the intervention and control group of 5.4 per cent in the percentage participating in at least 90 min of moderate/vigorous activity during the past week (Table 2). Adjusting for age, sex, smoking, BMI and CHD risk, the odds ratio was OR^{adj} 1.45 (95 per cent CI 0.84 to 2.50, $p=0.18$). No significant interaction was observed for baseline CHD risk ($p=0.87$), age ($p=0.54$) or sex ($p=0.48$). If this effect had been significant, then the number-needed-to-treat would be 18 (1/0.054).

After merging data across the 9 and 12 month assessments to obtain a more precise estimate, the adjusted odds ratio for participating in at least 90 min of moderate/vigorous physical activity during the past 7 days was 1.22 (95 per cent CI 0.83, 1.80, $p=0.31$). Again no interaction was observed for baseline CHD risk factors ($p=0.94$), age ($p=0.22$) or sex ($p=0.69$).

At the 6-month assessment, there was a significant absolute difference between the two groups in terms of the primary outcome measure, of 9.0 per cent (Table 2). Adjusting for the same covariates as above gave an adjusted odds of 1.67 (95 per cent CI 1.08 to 2.60), with no significant interaction for baseline CHD risk ($p=0.71$), age ($p=0.89$) or sex ($p=0.76$). The number needed to treat at 6 months was 11 people (1/0.09).

Satisfaction with information received was much higher in the intervention group compared with controls, when assessed at the 3 month assessment (Table 3). Moreover, the intervention group were more likely to feel that they knew enough about physical

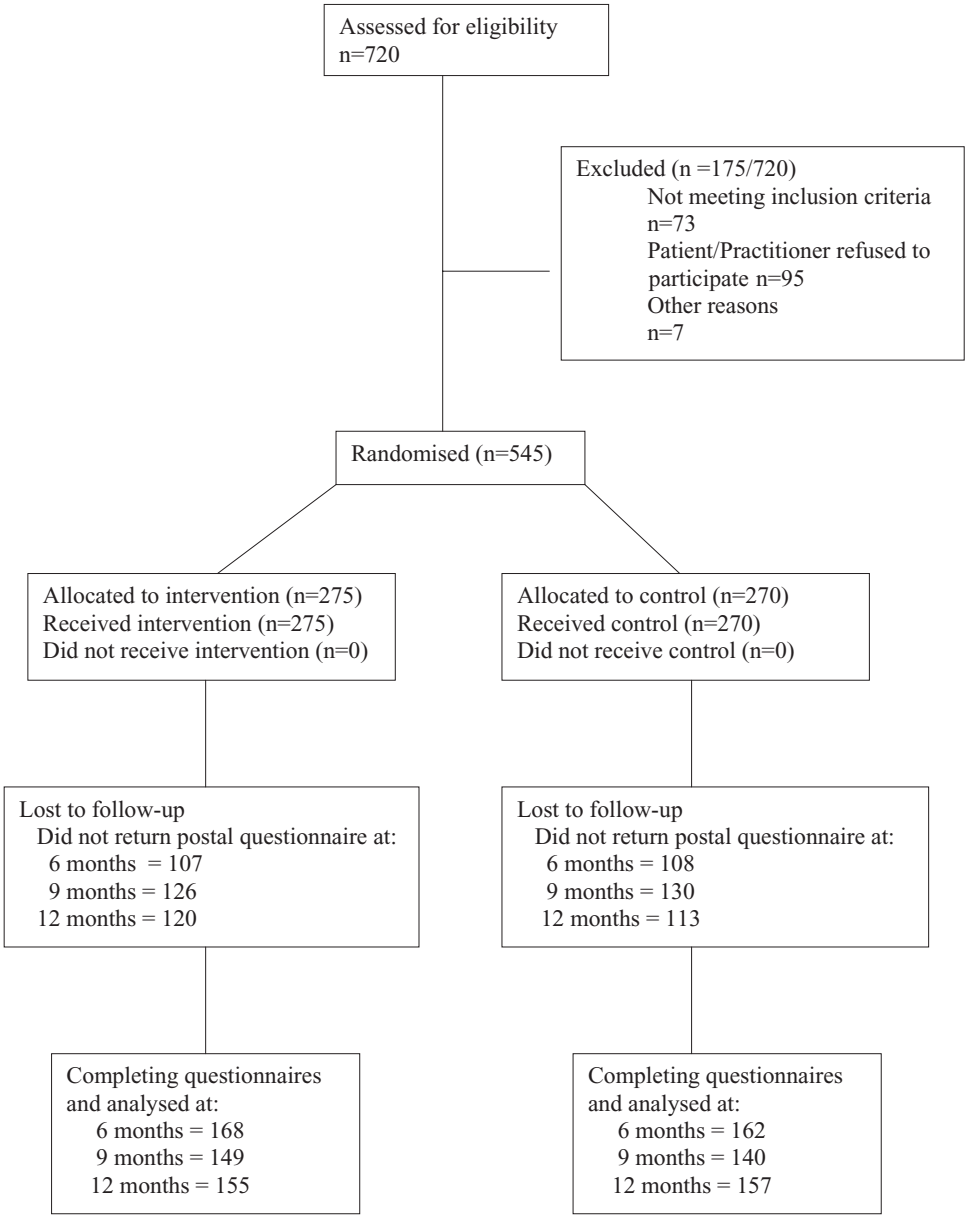

Figure 1 Flow diagram of study.

activity than the control group (Table 3). Neither of these factors influenced meeting the required physical activity levels at 12 months when included as an interaction term ($p=0.49$).

Discussion

Following referral, many patients attended a local leisure centre exercise referral scheme, suggesting a positive patient-perspective. This was reflected with increased satisfaction with information and fewer patients wanting more information on physical activity, compared with patients just sent a written information pack. At 6 months following referral, the intervention had a modest effect in increasing the number of patients participating in at least 90 min of moderate/vigorous in the week prior to assessment. At the 12 month assessment, physical activity had increased over the past 6 months for patients in the control group. This reduced the size of the benefit from the intervention observed at 6-months, which was no longer statistically significant, probably because of a lack of study power. There was no evidence that differences in terms of age, sex or baseline risk for CHD influenced the effect of the intervention at 6 or 12 months.

Anxiety amongst some of the collaborators about having a no treatment, or 'standard care' group, in the current study

Table 1 Baseline characteristics by randomization group

	Intervention group		Control group	
	***n* = 275**	**per cent**	***N* = 270**	**per cent**
Sex (male)	90	32.7 per cent	92	34.1 per cent
White*	159	71.9 per cent	163	74.1 per cent
Age group (years)				
18–44	111	40.4 per cent	107	39.6 per cent
45–59	101	36.7 per cent	98	36.3 per cent
60+	63	22.9 per cent	65	24.1 per cent
BMI mean (SD)	32.7	(6.6)	32.3	(6.8)
Current smoker	67	24.4 per cent	56	20.7 per cent
At least one CHD risk factor	207	75.3 per cent	203	75.2 per cent

*Information on ethnicity was missing for 54 patients in the intervention group and 50 in the control group.

Table 2 The effect of the intervention on physical activity at different assessment points

	Intervention group	Control group	Odds ratio^{adj} (95 per cent confidence intervals, *p*-value)
6 months	22.6 per cent (38/168)	13.6 per cent (22/162)	1.67 (1.08 to 2.60, $p=0.05$)
9 months	24.2 per cent (36/149)	22.1 per cent (31/140)	1.15 (0.66 to 2.01, $p=0.63$)
12 months	25.8 per cent (40/155)	20.4 per cent (32/157)	1.49 (0.86 to 2.57, $p=0.16$)
9–12 months			1.30 (0.84 to 2.02, $p=0.24$)

Table 3 Effect of the intervention on satisfaction with, and demand for information, at 3 months following randomization

	Intervention group *n* (per cent)	Control group *N* (per cent)
Satisfaction with information*		
Very satisfied	79/171 (46.2 per cent)	31/146 (21.2 per cent)
Quite satisfied	78/171 (45.6 per cent)	69/146 (47.3 per cent)
Not really satisfied	13/171 (7.6 per cent)	27/146 (18.5 per cent)
Not satisfied at all	1/171 (0.6 per cent)	19/146 (13.0 per cent)
Demand for information†		
Like a lot more	29/162 (17.9 per cent)	46/142 (32.4 per cent)
Like a little more	41/162 (25.3 per cent)	31/142 (21.8 per cent)
I feel I know enough	92/162 (56.8 per cent)	65/142 (45.8 per cent)

Difference between groups: *Mann–Whitney, $p=0.001$; †Mann–Whitney, $p=0.01$.

meant that the intervention was compared with sending written information only. While this was also sent to participants in the intervention group, it does mean that the effect of the intervention cannot be interpreted as compared with doing nothing. This may explain why levels of physical activity in the control group increased by 7 per cent between the 6 and 12 month assessment, suggesting a delayed affect from the written information. However, in the trial by Taylor *et al.*,[15] increases in physical activity were also observed amongst the control group given no other intervention after randomization. Thus simply taking part in a study seems to motivate a modest number of people to increase physical activity. However, statistical or biological regression to the mean could explain some of this increase. Baseline physical activity was assessed as part of a clinician consultation and it is possible that some people were recruited into the study who were in fact, already participating in at least 90 min of physical activity a week.

Few eligible patients referred by a practitioner to the exercise referral scheme were excluded from the randomized controlled trial. Consequently, our findings present a realistic effect size achievable from this type of intervention, in terms of increasing levels of moderate/vigorous physical activity. However, it is possible that the study underestimated the 'true' impact from this primary care exercise referral scheme, because the written information given to the control group may have had some impact on increasing levels of physical

activity, at least amongst a small number of motivated patients. Service members of the study team felt it would be unethical to withhold at least basic information from sedentary patients identified in primary care. Nearly all trials in this area have provided some form of additional 'intervention' or assessment in the control group over-and-above routine care.[9,15–17] The only trial in which the control group received no additional assessment or intervention used a cluster-based design.[18]

Response rates to the physical activity questionnaires were similar to previous studies.[9,15] In the analysis, we assumed that non-responders in both groups were missing at random. The fact that response rates did not differ between the intervention and control groups at the two key assessment points suggests that our assumption is unlikely to have introduced bias. To make full use of the data, we calculated a more precise estimate of the effect of the intervention by combining responses at the 9 month (interim assessment), or 12 month (primary assessment) questionnaire, or both, to increase statistical power, with allowances for multiple response. Our outcome measure was reliant on self-reported measures of physical activity and measurement error is a possibility, and may have led to an underestimate of the true effect from the intervention. The physical activity instrument has been validated and used in previous studies[10–13] and questionnaires are the only feasible way to assess habitual physical activity in studies when a large number of participants is involved.[19]

The number of patients referred to the exercise referral scheme was somewhat disappointing, and equivalent to less than one patient per GP per month. This is thought to be lower than in previous years but temporal comparisons are difficult because of changes in referral criteria. Intervention researchers are often aware of 'Lasanga's law', with study criteria appearing to reduce the number of people thought to be eligible for the study, during the recruitment period. Conscious of this, few inclusion criteria were included for the trial, and the majority of those eligible for the exercise referral scheme were randomized. Moreover, exclusion criteria for the exercise referral scheme, outwith the trial setting, meant that few sedentary patients were not capable of being referred to the scheme and the inclusion criteria were developed through consultation with local GPs. It is unlikely that high levels of physical activity amongst the source population explain the low referral rate. The borough where the study was based has above average standard mortality rates for CHD, suggesting low uptake of CHD preventive strategies such as physical activity. Moreover, a population based Health and Lifestyle Survey in this borough found the majority of adults were sedentary.[20,21]

The population impact of interventions is influenced amongst other things, by the effect size and number of 'at risk treated',[22] of which both were small in the current study. Consequently, we argue that in the current format, the exercise scheme is unlikely to make an important impact on reducing sedentary behaviour in the population. It is also possible that negative attitudes to physical activity could be being reinforced amongst those not successfully increasing physical activity levels after referral to the scheme. Given that the effect of the intervention was not influenced by age or sex, nor by existing risk factors for CHD, it appears that targeting referrals to those most at risk from CHD may not yield greater benefits in terms of participation in physical activity.

We defined the effectiveness of the physical activity referral scheme in terms of its ability to increase participation in at least 90 min of moderate/vigorous physical activity at one year following referral, with an interim outcome at 6 months. The focus for the study was underpinned by the fact that sedentary behaviour increases the risk of CHD death by 90 per cent[23] and as such, is a key potentially modifiable risk factor. Optimum levels of physical activity[24] are greater than that used to define 'physically active' in our trial. Yet, increasing levels of physical activity to at least this amount was considered to be beneficial. Clearly our study was not designed to examine other outcomes in any detail and other benefits may have been overlooked.

The Health Survey for England focusing on CHD (1998) reported that 63 per cent of men and 75 per cent of women did not meet physical activity recommendations (at least 30 min on 5 days a week of moderate intensity) and the number of sedentary people may be increasing.[4] Such trends are supported by other national surveys.[25] The UK has the 10th most inactive older population compared to 15 European member states,[26] but some countries have reversed this trend.[27,28] Hence, the national strategy to physical activity in the UK has a lot of work to do[29] but may be able to achieve success. The Health Development Agency review[30] highlights a dearth of evidence from randomized controlled trials to support interventions to reduce sedentary behaviour of our population, which is not improved when limited to primary care based interventions.[31–34] Given the complex and non-static relationships involved between individuals and their environment,[35] it is unlikely that 'one size fits all', with a range of strategies and interventions needing to be developed and tested for their effectiveness in increasing population levels of physical activity.

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Declaration

All authors declare that they have no competing interests with respect to the material presented in this paper.

Contributors

P.E. initiated the study. R.A.H. and P.E. designed the study. R.A.H. managed the study. R.A.H. and C.R. carried out statistical analysis. R.A.H. wrote the main draft of the paper. C.R. and P.E. provided a critical review of the paper. R.A.H. is the guarantor. Approval for the study was given by Bolton Local Research Ethics Committee.

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