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The research reported in this monograph was commissioned by the HTA Programme as project number 95/33/01. The contractual start date was in April 1998. The draft report began editorial review in January 2006 and was accepted for publication in September 2006. 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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Abstract

Exercise Evaluation Randomised Trial (EXERT): a randomised trial comparing GP referral for leisure centre-based exercise, community-based walking and advice only

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Objectives: To evaluate and compare the effectiveness and cost-effectiveness of a leisure centre-based exercise programme, an instructor-led walking programme and advice-only in patients referred for exercise by their GPs.
Design: A single-centre, parallel-group, randomised controlled trial, consisting of three arms, with the primary comparison at 6 months.
Setting: Assessments were carried out at Copthall Leisure Centre in Barnet, an outer London borough, and exercise programmes conducted there and at three other leisure centres and a variety of locations suitable for supervised walking throughout the borough.
Participants: Participants were aged between 40 and 74 years, not currently physically active and with at least one cardiovascular risk factor.
Interventions: The 943 patients who agreed to participate in the trial were assessed in cohorts and randomised to one of the following three arms: a 10-week programme of supervised exercise classes, two to three times a week in a local leisure centre; a 10-week instructor-led walking programme, two to three times a week; an advice-only control group who received tailored advice and information on physical activity including information on local exercise facilities. After 6 months the control group were rerandomised to one of the other trial arms. Assessments took place before randomisation, at 10 weeks (in a random 50% subsample of participants), 6 months and 1 year in the leisure centre and walking arms. The control participants were similarly assessed up to 6 months and then reassessed at the same intervals as those initially randomised to the leisure centre and walking groups.
Main outcome measures: The primary outcome measures were changes in self-reported exercise behaviour, blood pressure, total cholesterol and lipid subfractions. Secondary outcomes included changes in anthropometry, cardiorespiratory fitness, flexibility, strength and power, self-reported lifestyle behaviour, general and psychological health status, quality of life and health service usage. The costs of providing and making use of the service were quantified for economic evaluation.
Results: There was a net increase in the proportion of participants achieving at least 150 minutes per week of at least moderate activity in the sport/leisure and walking categories in all three study groups: at 6 months, the net increases were 13.8% in the leisure centre group, 11.1% in the walking group and 7.5% in the advice-only group. There were significant reductions in systolic and diastolic blood pressure in all groups at each assessment point compared with baseline. There were also significant and sustained improvements in cardiorespiratory fitness and leg extensor power, and small reductions in total and low-density lipoprotein cholesterol in all groups, but there were no consistent differences between the groups for

any parameter over time. All three groups showed improvement in anxiety and mental well-being scores 6 months after the beginning of the trial. Leisure centre and walking groups maintained this improvement at 1 year. There were no differences between groups. Costs to the participants amounted to £100 for the leisure centre scheme and £84 for the walking scheme, while provider costs were £186 and £92, respectively. Changes in overall Short Form 36 scores were small and advice only appeared the most cost-effective intervention.

Conclusions: The results of this trial suggest that referral for tailored advice, supported by written materials, including details of locally available facilities, supplemented by detailed assessments may be effective in increasing physical activity. The inclusion of supervised exercise classes or walks as a formal component of the scheme may not be more effective than the provision of information about their availability. On cost-effectiveness grounds, assessment and advice alone from an exercise specialist may be appropriate to initiate action in the first instance. Subsidised schemes may be best concentrated on patients at higher absolute risk, or with specific conditions for which particular programmes may be beneficial. Walking appears to be as effective as leisure centre classes and is cheaper. Efforts should be directed towards maintenance of increased activity, with proven measures such as telephone support. Further research should include an updated meta-analysis of published exercise interventions using the standardised mean difference approach.

Contents

List of abbreviations

ACSM	American College of Sports Medicine
ANCOVA	analysis of covariance
ANOVA	analysis of variance
BHA	Barnet Health Authority
BMI	body mass index
BP	blood pressure
bpm	beats per minute
BRHS	British Regional Heart Study
CHD	coronary heart disease
CI	confidence interval
CVD	cardiovascular disease
DBP	diastolic blood pressure
df	degrees of freedom
Diff%	difference in outcome between study groups expressed as percentage at 10-week, 6-month and 1-year assessment after adjusting for baseline values
EM	expectation maximisation
EXERT	Exercise Evaluation Randomised Trial
FEV_1	forced expiratory volume in 1 second
FVC	forced vital capacity
GPPAQ	General Practice Physical Activity Questionnaire
HADS	Hospital Anxiety and Depression Scale
HDL	high-density lipoprotein
ICER	incremental cost-effectiveness ratio
IKES	isometric knee extensor strength
IQR	interquartile range
ITT	intention to treat
LDL	low-density lipoprotein
LEP	leg extensor power
MANOVA	multivariate analysis of variance
MET	metabolic equivalent task
MI	myocardial infarction
NICE	National Institute for Health and Clinical Excellence
ns	not significant
NS-SEC	National Statistics Socio-economic Classification
NVQ	National Vocational Qualification
PCA	principal components analysis
PEF	peak expiratory flow
PSSRU	Personal Social Services Research Unit
QALY	quality-adjusted life-year
QOF	Quality and Outcome Framework
RCT	randomised controlled trial
RPE	rating of perceived exertion
SBP	systolic blood pressure
SD	standard deviation
SEM	standard error of the mean
SF-36	Short Form 36
SF-6D	Short Form 6 Dimensions
SOC2000	Standard Occupational Classification 2000
$VO_{2\ max}$	maximal oxygen consumption

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Background

Physical activity is known to be beneficial in reducing the risk of cardiovascular disease, but there is a high prevalence of inactivity in the UK population. Primary care is an important setting for encouraging increased physical activity, but brief advice from GPs may not be effective in increasing physical activity levels. Exercise referral schemes, also known as exercise on prescription, have been developed to address this issue and are increasingly popular, but have not been rigorously evaluated.

Objectives

Building on a large local exercise referral scheme, the objectives were to evaluate and compare the effectiveness and cost-effectiveness of a leisure centre-based exercise programme, an instructor-led walking programme and advice only in patients referred for exercise by their GPs.

Methods

Design

The study was a single-centre, parallel-group, randomised controlled trial, consisting of three arms, with the primary comparison at 6 months. The two structured exercise groups were followed for a further 6 months. Subjects in the control arm were rerandomised to one of the other trial arms and followed for a further year, although these data are not included in this report.

Setting

Assessments were carried out at Copthall Leisure Centre in Barnet, an outer London borough, and exercise programmes conducted there and at three other leisure centres and a variety of locations suitable for supervised walking throughout the borough.

Participants

Participants were aged between 40 and 74 years, not currently physically active and with at least one of the following cardiovascular risk factors: raised cholesterol, controlled moderate to mild hypertension, obesity, current smoking, diabetes and/or a family history of myocardial infarction at an early age.

Interventions

Of 1105 referrals received at the leisure centre over a 3-year period, 943 patients agreed to participate in the trial. They were assessed in cohorts and randomised to one of the following three arms: a 10-week programme of supervised exercise classes, two to three times a week in a local leisure centre; a 10-week instructor-led walking programme, two to three times a week; an advice-only control group who received tailored advice and information on physical activity including information on local exercise facilities. After 6 months the control group were rerandomised to one of the other trial arms. Assessments took place before randomisation, at 10 weeks (in a random 50% subsample of participants), 6 months and 1 year in the leisure centre and walking arms. The control participants were similarly assessed up to 6 months and then reassessed at the same intervals as those initially randomised to the leisure centre and walking groups.

Main outcome measures

The primary outcome measures were changes in self-reported exercise behaviour, blood pressure, total cholesterol and lipid subfractions. Secondary outcomes included changes in anthropometry (waist–hip ratio, body mass index and percentage body fat), cardiorespiratory fitness, flexibility, strength and power, self-reported lifestyle behaviour, general and psychological health status, quality of life and health service usage.

The costs of providing and making use of the service were quantified for economic evaluation.

Results

Follow-up rates were 66% of those eligible at the 10-week assessment, 60% at 6 months and 50% at 1 year. Primary outcomes were analysed by intention to treat.

All three study groups increased their duration of activity of at least moderate intensity by 10 weeks. By 6 months, the increase was somewhat

attenuated, but the duration of at least moderate activity remained significantly higher than at baseline, the greatest change occurring in the walking group. At 1 year, both leisure centre and walking groups maintained significant increases compared with baseline. However, there was no significant difference between the increases in duration of at least moderate activity in the three study groups at any assessment point.

There was a net increase in the proportion of participants achieving at least 150 minutes per week of at least moderate activity in the sport/leisure and walking categories in all three study groups: at 6 months, the net increases were 13.8% in the leisure centre group, 11.1% in the walking group and 7.5% in the advice-only group.

There were significant reductions in systolic and diastolic blood pressure in all groups at each assessment point compared with baseline, the largest reductions of about 6/4.5 mmHg being observed at 1 year in the leisure centre and walking groups. There were also significant and sustained improvements in cardiorespiratory fitness and leg extensor power, and small reductions in total and low-density lipoprotein cholesterol in all groups, but there were no consistent differences between the groups for any parameter over time.

All three groups showed improvement in Hospital Anxiety and Depression Scale anxiety and Short Form 36 (SF-36) mental well-being scores 6 months after the beginning of the trial. Leisure centre and walking groups maintained this improvement at 1 year. There were no differences between groups.

Costs to the participants amounted to £100 for the leisure centre scheme and £84 for the walking scheme, while provider costs were £186 and £92, respectively. Changes in overall SF-36 scores were small and advice only appeared the most cost-effective intervention.

Conclusions

Implications for healthcare

The results of this trial suggest that referral for tailored advice, supported by written materials, including details of locally available facilities, supplemented by detailed assessments may be effective in increasing physical activity. The inclusion of a 10-week programme of supervised exercise classes or walks as a formal component of the scheme may not be more effective than the provision of information about their availability. On cost-effectiveness grounds, assessment and advice alone from an exercise specialist may be appropriate to initiate action in the first instance. Subsidised schemes may be best concentrated on patients at higher absolute risk, or with specific conditions for which particular programmes may be beneficial. Walking appears to be as effective as leisure centre classes and is cheaper. Efforts should be directed towards maintenance of increased activity, with proven measures such as telephone support.

Recommendations for research

An updated meta-analysis of published exercise interventions should be undertaken using the standardised mean difference approach.

To improve future comparability of exercise intervention trials, standardised methods should be developed for measuring and presenting outcomes. This should include the development of guidelines both on the content and method of application of a standard physical activity questionnaire for trial use and on the way in which changes in duration and intensity of physical activity and in energy expenditure are best presented.

Research should identify how physical activity questionnaires might best be supplemented by objective measurements, including measures of cardiorespiratory fitness in field trials and whether simple submaximal fitness tests can be usefully incorporated into routine practice.

Research should aim to identify the components of interventions that may be beneficial for particular target groups in comparison with minimal intervention. These should include the frequency and intensity of support required to maximise exercise continuation, the value of physical assessment procedures and feedback as a stimulus to continue exercise, and the place of professional compared with lay advisers.

The effectiveness and cost-effectiveness of opportunistic referral by GPs and practice nurses versus proactive cold-calling of at-risk individuals on practice lists should be compared.

Alternative strategies for involving groups under-represented in present schemes, including men and members of deprived communities and specific minority groups, should be compared.

Studies of schemes should include qualitative research with referring clinicians and participants to determine the reasons for success or failure and should allow for long-term follow-up.

Chapter 1
Background

Benefits of physical activity

The benefits of physical activity have recently been extensively reviewed.[1] There is strong evidence that it reduces the risk of cardiovascular disease (CVD), type 2 diabetes, osteoporosis and certain cancers, as well as weaker evidence for other health benefits.[1] It may also save healthcare costs for older adults.[2] However, surveys have consistently shown a high prevalence of physical inactivity in the UK population.[3,4] Despite a 3% increase between 1997 and 2004, only 35% of men and 24% of women aged 16 years and over currently reach recommended levels of physical activity, with a progressive decline with age in both genders.[5] The previously noted secular trend towards reduced levels of physical activity has been considered of greater importance than dietary change[6] as a determinant of the dramatic increase in the prevalence of obesity,[4] which is correlated with a higher risk of coronary heart disease (CHD) in both men[7] and women.[8] Low levels of fitness are independently predictive of all-cause[9] and cardiovascular[10] mortality and may mediate the increase in cardiovascular risk.[11] Physical activity promotion is a key public health issue, and for several years advice for adults has been to undertake at least 30 minutes of moderate intensity physical activity on at least five days of the week.[12]

Physical activity promotion and evaluation

Primary care is an important setting for the encouragement of increased levels of physical activity. However, brief advice from GPs in routine consultations may not be an effective means of increasing physical activity levels;[13] hence other strategies may be required. GP exercise referral schemes (also known as exercise on prescription) are one such approach and have become increasingly popular. A survey for the Health Education Authority published in 1994 identified just under 200 schemes current or planned[14] and a 2003 report suggested that 89% of primary care trusts provide exercise on prescription.[15] A typical format involves GPs referring patients opportunistically to local leisure centres, although other types of primary care-based intervention, often involving behavioural counselling or motivational interviewing,[16–18] as well as walking schemes[19] have been developed. The variation in exercise referral models and standards of practice has led to the adoption in England of a quality framework, setting out guidelines to encourage improved standards.[20] These include measures to demonstrate the effectiveness of exercise referral schemes. However, rigorous evaluations are resource intensive and those traditionally carried out may be subject to methodological weaknesses that limit their reliability to indicate programme effectiveness or cost-effectiveness.[21]

History of exercise referral in Barnet

The Barnet 'Fitness for Life' exercise on prescription scheme was started in March 1995, jointly funded by Barnet Health Authority (BHA) and the London Borough of Barnet. The district is a large outer London suburb, with areas of both affluence and deprivation, and ranging from semi-rural to industrialised urban in character. The resident population is over 300,000, of whom over 25% are from ethnic minorities, mainly South Asian in origin (2001 Census). All GPs in the district were given the opportunity to refer suitable patients for a 10-week exercise programme at a local leisure centre by using a specially produced referral form, including relevant medical information. The suggested age range was 35–65 years, although younger and older patients were accepted. The cost of the scheme to the patient was the same as a prescription, or free to those exempt from charges. Referrals included those patients who the GP considered would improve with regular exercise, who were not already participating in regular exercise and were considered to be at risk from CHD (e.g. with mild or moderate hypertension, overweight, with raised cholesterol levels, or a family history of CHD). Contraindications included a history of heart disease [myocardial infarction (MI), angina] and uncontrolled hypertension.

Following referral the patient attended an appointment at the leisure centre with the fitness instructor. This session included a full introduction

to the scheme, a fitness assessment [including a medical questionnaire and measurement of weight, body fat, resting heart rate and blood pressure, flexibility, grip strength, cardiorespiratory fitness and peak expiratory flow (PEF)], an explanation of the content and format of the exercise programme, completion of record cards and a tour of facilities, including relevant health and safety information. Patient preference was taken into account in allocation to specific exercise groups and sessions. Each patient was offered a 10-week exercise programme, usually consisting of three exercise sessions per week, each of 1 hour's duration. These could comprise supervised gym work using cardiovascular and weight machines, aerobics, aqua-aerobics, swimming or supervised walks. Although the fitness officer monitored the participants' activity during the period to ensure safe and satisfactory progress, the clinical responsibility remained with the referring GP. Participants were responsible for reporting to the leisure centre staff if they felt unwell or were unable to comply with the programme.

After the 10-week programme, participants' fitness was again assessed by the fitness officer and they were encouraged to continue with a long-term regular exercise programme that could include using the leisure centre facility or another facility, walking or swimming. The option was offered of continuing leisure centre activities for a further 10 weeks at half the standard price.

Participants were enrolled in groups of up to 110 at approximately 3-month intervals. The scheme expanded since its initiation to involve additional leisure centres and by 1998, 50 of the 180 local GPs had referred to the scheme, with approximately 1000 patients participating and the development of a waiting list.

An initial evaluation, consisting of a number of components, was undertaken to inform an internal report to determine the future of the scheme. This showed positive responses from participants, small, but potentially significant reductions in risk factors such as body mass index (BMI) and blood pressure after 10 weeks, and 77% continuation of exercise at 3 months. However, the lack of control data or prolonged follow-up made interpretation difficult.

Previous exercise intervention studies in the UK

Randomised controlled trials (RCTs) have shown the value of exercise in the disease management of certain patients, such as for cardiac rehabilitation, but there have been few RCTs of physical activity promotion in 'healthy' populations. The majority of studies have been undertaken in the USA, are not necessarily applicable to the UK context and are not considered further here. A systematic review published in 1996, restricted to RCTs with change in physical activity as an outcome, found only 11, with none from the UK.[22] An update in 1999 added six further studies, two from the UK.[23] A Cochrane review by the same authors, covering the literature to the end of 2001, found only 18 studies sufficiently methodologically rigorous to be included, of which two were UK based and neither of these involved GP referral.[24] A systematic review in 1998 assessing the effectiveness of primary care-based physical activity promotion schemes identified 11 published and unpublished UK studies.[21] It concluded that the majority reported some form of improvement in either physical activity or related measures, but the size of the effect was generally small, with no real consistency across studies. Not all of these involved exercise referral and some were relatively small and/or with limited follow-up. Some were uncontrolled and in others, allocation to different types of intervention and control groups was not randomised. A more recent review of studies to 2002 included four RCTs from the UK.[25] It noted that exercise referral increases physical activity levels in certain populations, but that the effects may not be sustained over time. Other reviews have evaluated stages of change-based interventions, with no clear evidence for their effectiveness, particularly for maintenance of increased physical activity.[26,27] Two RCTs based in general practice from Australia[28] and New Zealand[29] showed that counselling together with ongoing support from exercise therapists was effective in increasing physical activity up to 1 year.

Key features of large, published, UK-based RCTs with adequate follow-up are shown in *Table 1*. As with studies performed elsewhere, they are characterised by heterogeneity in patient populations, interventions and outcome measures, which makes comparison of results difficult, although the Cochrane review used the standardised mean difference approach for this purpose.[24] The disparate nature of measures of change in self-reported physical activity is shown in *Table 2*.

Although short-term benefits have been described in several schemes, it is important to confirm their effectiveness in high-risk patients in the longer

TABLE 1 *Major RCTs of exercise advice or referral in the UK*

Study	Brief description of intervention type	Inclusion criteria and no. randomised (*N*)	No. (%) assessed and length of follow-up	Main results
Taylor *et al.*, 1998[30]	Mailed invitation to 345 patients on two health centre registers. 20 sessions of exercise over 10 weeks at local leisure centre vs control	Age 40–70 years. Smokers, hypertensive (BP ≥ 140/90), or overweight (BMI >25) $N = 142$	71 (50%) attended repeat assessments at 16, 26 and 37 weeks	No change in physical activity by intervention or control group at 37 weeks. Greater reduction in SBP at 26 and 37 weeks in 'high adherers' than 'low adherers', but not in comparison with controls. Significant reduction in body fat compared with controls at 16 weeks
Stevens *et al.*, 1998[31]	Mailed questionnaire to 2253 patients on two practice registers followed by either mailed invitation for consultation with an exercise specialist and personalised 10-week programme or mailed leaflet on local leisure centres (control)	Age 45–74 years. Inactive $N = 714$	415 (58%) at 8 months (questionnaire)	11.2% of intervention group vs 0.8% of control group increased physical activity ($p = 0.013$)
Harland *et al.*, 1999[16]	Opportunistic and postal approach by researcher to patients on a practice register. Brief vs intensive motivational interviewing by trained nurse, with or without financial incentives for local leisure centre, or control	Age 40–64 years. Not taking vigorous exercise $N = 523$	424 (81%) at 12 weeks (questionnaire) and 442 (85%) at 1 year (321 (61%) repeat assessment; 121 (23%) questionnaire)	Combined intervention groups increased sessions of moderate and vigorous physical activity more than controls at 12 weeks, but not at 1 year
Steptoe *et al.*, 1999[18]	Recruitment of patients from 20 practices in cluster RCT. Intervention practice patients received behavioural counselling, based on Stages of Change model, directed at risk factor	No age criterion (mean age 46.7 years). Smokers, raised cholesterol (6.5–9 mmol $l)^{-1}$, or combined overweight (BMI 25–35) and low physical activity $N = 883$, of whom 669 were in overweight/low physical activity group	626 (71%) at 4 months and 520 (59%) at 1 year	Intervention group increased episodes of moderate or vigorous physical activity more than controls at 4 months and 1 year. SBP reduced to greater extent in intervention (3.3 mmHg) than control (0.9 mmHg) group at 4 months, but not at 1 year
Hillsdon *et al.*, 2002[32]	Mailed questionnaire to 5797 patients on two practice registers followed by allocation to (i) mailed invitation to a health check for either (a) brief motivational interviewing or (b) direct advice, with telephone follow-up, or (ii) control	Age 45–64 years. Inactive $N = 1658$	1011 (61%) at 11 months, of whom 654 (41%) completed 4-week physical activity log book	No significant differences in increase in physical activity between the two intervention groups, or between the combined intervention groups and controls by ITT. Motivational interviewing completers increased energy expenditure by 24% more than controls. DBP fell by 2.5 mmHg and 0.2 mmHg in motivational interviewing and direct advice groups, respectively ($p < 0.01$ for between-group comparison)

continued

TABLE 1 *Major RCTs of exercise advice or referral in the UK (cont'd)*

Study	Brief description of intervention type	Inclusion criteria and no. randomised (*N*)	No. (%) assessed and length of follow-up	Main results
Lamb *et al.*, 2002[19]	Mailed questionnaire and invitation to random sample of 2000 patients on a practice register followed by allocation of those eligible to seminars for advice only or supplemented by information about local health walks	Age 40–70 years. <120 minutes of moderate-intensity exercise per week $N = 260$	200 (76.9%) at 6 months and 188 (72.3%) at 1 year	33% of those allocated to health walks attended them. 35.7% of health walk trial completers and 22.6% of advice-only trial completers increased moderate intensity exercise to 120 minutes per week at 1 year ($p < 0.05$). No significant difference between the two groups for completers at 6 months, or by ITT at either time-point. Median 60 minutes per week for both groups at 1 year. No change in cardiovascular risk factors
Harrison *et al.*, 2005[33]	GP referral followed by randomisation to consultation with exercise officer for tailored advice, subsidised pass for centre-based activity and mailed information packs vs mailed packs only	Age ≥18 years. Sedentary, with additional risk factors (obesity, previous MI, on practice CHD risk-management register or diabetes) $N = 545$, of whom 410 had at least one CHD risk factor	330 (61%) at 6 months, 289 at 9 months (53%) and 312 (57 %) at 1 year (all postal questionnaire)	Greater increase in participation in ≥90 minutes of moderate/vigorous physical activity per week in intervention than control group at 6 months ($p = 0.05$), but not at 9 months or 1 year

BP, blood pressure; DBP, diastolic blood pressure; ITT, intention to treat; MI, myocardial infarction; SBP, systolic blood pressure.

TABLE 2 *Measures of self-reported physical activity outcome in UK studies*

Study	Measure of physical activity	Measure of energy expenditure	Analysis of outcome
Taylor *et al.*, 1998[30]	Moderate (minutes per week) Vigorous (minutes per week)	kcal/kg^{-1} per day	Mean vs control Mean vs control Mean vs control
Stevens *et al.*, 1998[31]	Moderate (no. of occasions of ≥ 20 minutes) Vigorous (no. of occasions) Moderate/vigorous (no. of occasions) Classification as: • sedentary (<4 20-minute episodes in 4 weeks) • low intermediate (4–11 episodes in 4 weeks) • high intermediate (≥12 episodes in 4 weeks) • active (≥20 30-minute episodes of moderate or ≥12 20-minute episodes of vigorous activity in 4 weeks)	Not given	Mean vs control Mean vs control Mean vs control Change from baseline in proportion of subjects in each group, relative to control

continued

TABLE 2 *Measures of self-reported physical activity outcome in UK studies (cont'd)*

Study	Measure of physical activity	Measure of energy expenditure	Analysis of outcome
Harland *et al.*, 1999[16]	Physical activity score (over 4 weeks) • level 0 (no sessions moderate or vigorous) • level 1 (1–4 sessions moderate or vigorous) • level 2 (5–11 sessions moderate or vigorous) • level 3 (≥12 sessions moderate) • level 4 (≥12 sessions moderate or vigorous) • level 5 (≥12 sessions vigorous)	Not given	Increase of one or more levels from baseline compared with other intervention groups and for all intervention groups vs control. Increased total sessions of: • vigorous activity • moderate activity vs other groups and control
Steptoe *et al.*, 1999[18]	Moderate or vigorous (episodes in 4 weeks)	Not given	Change from baseline vs control
Hillsdon *et al.*, 2002[32]	Not given	kcal per kg per week	% change from baseline vs control
Lamb *et al.*, 2002[19]	Moderate (minutes per week) • Achieving target level of activity • Total minutes per week		Change from baseline in % participating in >120 minutes per week vs control
	Moderate (sessions per week)		Change in median compared with control Change in median compared with control
Harrison *et al.*, 2005[33]	Moderate/vigorous physical activity (minutes)	Not given	% participating in ≥90 minutes per week vs control

term and to determine whether simpler and cheaper interventions would be as effective. In particular, it has been suggested[22,23] (although with a subsequent retraction[24]), based mainly on evidence from the USA, that 'home'-based schemes involving walking may be more efficacious in achieving long-term adherence than those dependent on facilities. However, the social support provided by co-participants should also be considered, with some (although inconclusive) evidence for higher long-term participation rates in group-based than individually based activities.[34] It is also important to consider whether increases in self-reported physical activity can be translated into sustained improvements in other measures of physical and mental health, including cardiovascular risk factors.

In 1996, the NHS HTA Programme called for bids to address the question: 'Do different types of exercise prescription lead to differences in outcome (morbidity, mortality, quality of life, reduced risk of osteoporosis and coronary heart disease) in middle-aged and elderly patients?' On the basis of 'Fitness for Life', together with a recently developed 'Walking Partners' scheme, a successful bid was made for HTA funding to carry out an RCT, Exercise Evaluation Randomised Trial (EXERT), which was designed to compare the leisure centre-based scheme with community-based walks and a control 'advice-only' group, with a focus on those at increased cardiovascular risk.

The EXERT study, described in more detail in Chapter 2, was designed to evaluate the longer term success of exercise referral in a relatively large sample size. It differs from most of the previously described studies in that it relies on direct recruitment through general practice, rather than a postal invitation, and also compares the effectiveness of different types of exercise programme.

Chapter 2
Methods

Study description and aims

The EXERT study was designed to evaluate the effectiveness and cost-effectiveness of two specific types and one general type of exercise intervention in increasing physical activity and reducing cardiovascular risk factors. Participants were randomised to one of three arms:

- A leisure centre-based programme: this arm of the trial was based on the pre-existing 'Fitness for Life' programme in Barnet and is a very common format for many GP exercise referral programmes. It took place at one of four sites in the borough.
- A community-based walking programme, 'Walking Partners', with over 20 walks in different parts of Barnet.
  Both of these schemes were instructor led and progressive, and lasted for 10 weeks, with provision for continuing exercise at the end of the programme. This included advice on how to continue being active and a financial incentive (a book of 20 half-price tickets for the leisure centre). No charge was made to attend any of the exercise sessions during the 10-week period.
- A control group who were given tailored advice and information on physical activity, including local exercise facilities. Participants randomised to this group were put on a waiting list for potential rerandomisation to one of the two active intervention groups after approximately 6–9 months.

The null hypothesis was that leisure centre-based exercise was no more effective than an instructor-led walking programme or simple advice (control) in reducing cardiovascular risk factors or increasing exercise uptake and maintenance.

Follow-up was planned up to 1 year after finishing the exercise programme, with a total sample size exceeding 1100 participants (including controls reallocated to one of the two active exercise programmes).

Outcomes measured

The major outcome measures were changes in self-reported exercise behaviour and cardiovascular risk factors, including systolic and diastolic blood pressure, total cholesterol and lipid subfractions.

Secondary outcomes included changes in anthropometry (waist–hip ratio, BMI, percentage body fat), cardiorespiratory fitness, flexibility, strength and power, self-reported lifestyle behaviours including selected food intakes and smoking, general and psychological health status, quality of life and health service usage.

Economic evaluation

The study also measured the costs and cost-effectiveness of any changes, and compared these outcomes and costs with those of the walking partners exercise programme and simple advice (control group). The participants' costs and benefits of attending the exercise programme, as well as those incurred by the NHS, were measured. EXERT can therefore quantify:

- the costs of providing and making use of the service
- cost offsets (primarily those that accrue to the NHS as a result of reductions in disease and the consequent reduction in future treatment costs)
- the benefits to the patient resulting from health improvements (should they arise).

Sample size calculations

Estimates were made of the sample size required to demonstrate clinically significant differences in the major cardiovascular risk factors: blood pressure and total cholesterol. It was estimated that 273 patients would be required in each arm of the trial to detect a difference of 5 mmHg in systolic blood pressure, with 90% power and a two-sided p-value of 0.05. A similar number (n = 300) would provide over 90% power to detect a difference of 0.3 mmol l^{-1} in total cholesterol. The standard deviations for each estimate were based on those observed in the Health Survey for England, 1994.[35] The planned study size was initially four cohorts of 300 participants (i.e. 1200 in total), allowing for dropouts. A fifth cohort was

TABLE 3 *Revised power calculations to detect a clinically important difference between the intervention groups*

Primary effect (difference to be detected)	Power with projected sample size of 1200
SBP of 6 mmHg	90%
SBP of 5 mmHg	76%
DBP of 3 mmHg	88%
Total cholesterol (assuming 5% difference between groups)	81%
HDL-cholesterol (assuming difference of 0.1 mmol l^{-1})	83%
Difference in shuttle walking test of one level (1 minute)	99%
Difference in heart rate after 6 minutes (bicycle test) of 10% (10 bpm)	99%
Difference in leg power per kg body weight of 10%	80%
Difference in leg strength of 10%	78%

These figures allow for a 70% completion rate. Approximately 80% of participants provided a blood sample; the remainder either refused or blood could not be obtained, and the power calculations take this into account. Only about 85% of participants completed an aerobic test (shuttle walking or bicycle) at baseline; the rest were excluded owing to high blood pressure. The figures for the shuttle walking test and bicycle test take this into account, and allow for the fact that participants complete one or other of these tests, not both.
bpm, beats per minute.

built into the schedule in case recruitment was lower than anticipated.

An analysis of data from the first two cohorts suggested that the study population standard deviations for total cholesterol and blood pressure were greater than those observed in the Health Survey for England sample. The sample size calculations were revised at this point, and other secondary outcomes were also considered at this time (*Table 3*).

Ethical approval

Ethical approval was obtained from the Barnet Local Research Ethics Committee. The study protocol was also approved by the Barnet Local Medical Committee.

Methods of recruitment

All GPs in Barnet were contacted with details of the trial and information about the method for referring patients. Information for GPs and patients and further details of the methods used to boost recruitment are detailed in Appendices 1 and 2. Referrals to EXERT could be made by the GP or practice nurse for any patient meeting the inclusion criteria. Referrals were also accepted in some instances (with approval from the patient's GP) from other primary and secondary care professionals such as dietitians and diabetes nurses. Potential participants were given details of the programme including a leaflet explaining the study and copy of the referral form by the referring health professional. GPs and practice nurses in Barnet were sent a specially prepared 'prescription pad'. To make a referral, the professional had to complete and sign the prescription, providing contact information for the patient and information on their cardiovascular risk factors (tick boxes). They also had to verify that none of the exclusion criteria applied.

The 'prescription pad' consisted of prescription forms in triplicate. The top (white) copy was to be given to the patient, while the other copies were to be retained by the practice (pink) or returned to the study office at Barnet Copthall Stadium (green). It was the patient's responsibility to contact the study personnel for an initial assessment. However, an attempt was made to enrol patients who did not make such contact, for whom the green copy was received.

When an appointment was made, the patient was sent an appointment card and letter describing the study, and providing some guidance concerning appropriate clothing for the assessment. Participants were particularly asked not to consume any caffeinated drinks for at least 3 hours before the assessment time.

Information on 'non-starters'

A two-page questionnaire was designed and posted to patients referred who did not enter EXERT. These included both patients who did not contact Copthall Leisure Centre after referral and those who declined to take part in the study after the initial explanation. The questionnaire elicited

basic demographic information, reasons why they did not join the study and information about any types of exercise programme they would have preferred. The questionnaire was sent with a prepaid envelope for return on at least two occasions.

Study design

Inclusion criteria

GPs were invited to refer potential participants aged between 40 and 74 years, not currently physically active, and with at least one of the following cardiovascular risk factors:

- raised cholesterol
- controlled mild to moderate hypertension
- obesity
- current smoking
- diabetes
- a family history of MI at an early age.

A precise definition was given for only one of these criteria (family history of MI at an early age, close male relative <55 years or close female relative <65 years of age). After discussion with GPs, it was decided to accept current GP referral practices. Referral under each category was therefore left to individual discretion, as for the pre-existing scheme. However, the term 'obesity' was used on the referral form, rather than 'overweight', to signify that patients referred under this category should be significantly and clinically overweight, rather than patients who wished to lose weight for cosmetic reasons alone.

Exclusions

The major exclusion criterion was pre-existing overt CVD. Other exclusion criteria were uncontrolled hypertension, uncontrolled insulin-dependent diabetes, psychiatric conditions or physical disabilities that would prevent participation in an exercise class, or conditions requiring a specialist programme (e.g. uncontrolled epilepsy).

Most of the exclusions were due to the presence of overt CVD. This was partly due to safety considerations; a Phase IV community cardiac rehabilitation programme exists in Barnet to provide exercise rehabilitation for these patients. Further, the study was designed primarily to assess the effectiveness of exercise interventions in 'at-risk healthy' populations, where there was greater uncertainty about their effectiveness.

Assessment procedures

Initial assessment at leisure centre

Table 4 summarises the components of the initial assessment for the EXERT study. On arrival at the leisure centre (Barnet Copthall Stadium) for a first appointment, the patient was greeted by the research nurse or another member of the research team. Details of the study were explained and the patient was given the time and opportunity to raise any concerns or ask questions. The participant was then asked whether they wished to enter the trial and, if so, to sign an informed consent form. At this first assessment, the participant was then asked to complete a number of questionnaires, and to undertake some simple tests of health and fitness. The complete assessment took approximately 2 hours; appointments before work (07.00 h) were made available and many GPs certified attendance for the assessment.

Questionnaires

These included:

- a general questionnaire which asked for basic demographic information including age, gender, employment and educational status, reasons for referral to the study and health professional who initiated the referral
- a medical questionnaire, which was reviewed before the fitness assessment was undertaken to ensure that there were no contraindications for exercise
- a brief 'Food Choices' questionnaire, adapted from British Regional Heart Study (BRHS) questionnaires[36] with assistance from local dietitians
- a smoking questionnaire adapted from the BRHS[37] with assistance from the former Health Education Authority
- a physical activity questionnaire which attempts to measure leisure-time activities, walking, occupational activity and work in the home over the previous 7 days; adapted from a questionnaire used in a randomised trial of physical activity in West London[32] (Hillsdon M, London School of Hygiene and Tropical Medicine: personal communication, 1998)
- a number of psychological predictors of exercise behaviour, including elements of the transtheoretical model[38] (stages of change for exercise, decisional balance, barriers to taking up exercise, self-efficacy for exercise), and 'implementation-intention' theory.
- measurements of general health status [Short Form 36 (SF-36)[39] and EuroQol[40]] and anxiety and depression [Hospital Anxiety and Depression Scale (HADS)[41,42]].

TABLE 4 *Components of the baseline examination in the EXERT study*

Procedure	Description
Reception	Greet participant, check signed prescription form, verify that participant is eligible for EXERT, determine fasting status
Informed consent	Explain study again, obtain informed consent
Questionnaires	Explain questionnaires, provide assistance if necessary
Medical data review	Review prescription form and completed medical questionnaire. Amend physical assessment if appropriate
Blood pressure	Obtain resting blood pressure pulse rate, average of two measurements
Anthropometry	Measure height, weight, waist and hip measurements, percentage body fat
Pulmonary function	Obtain digitised spirometric measurements of pulmonary function (FVC, FEV_1) and PEF
Venepuncture	If participant agrees, obtain blood sample
Snack	If fasting, provide snack which contains no caffeine or stimulants
Muscle strength and power	Measured using the 'strength chair' (isometric dynamometry) and Nottingham power rig respectively
Cardiorespiratory function	Shuttle walking or bicycle ergometer test
Flexibility	'Sit and reach' test (lower back and hamstring flexibility), shoulder abduction
Review of data collected	Check for any omissions in questionnaire. Highlight any abnormal results (e.g. BP) and refer to GP if appropriate
Obtain allocation and organise exercise programmes	Telephone Barnet Health Authority to obtain next allocation. Feed result back to participant and note any preferences they may have had. Offer participant appropriate exercise sessions starting on next 10-week programme
Exit	Thank participant

FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity.

The questionnaires took approximately 45 minutes to complete. All were designed to be self-completed, but some participants took considerably longer and required help, usually because their first language was not English, they had forgotten their reading glasses or they had some degree of learning difficulty. In these cases, one of the research team provided assistance to complete the questionnaires. The physical activity questionnaire is shown in Appendix 3. Other questionnaires are available on request. The dietary and smoking questionnaire responses are not analysed in this report.

Physical fitness assessment

A physical fitness assessment was then carried out, divided into two sections.

Blood pressure, anthropometry, pulmonary function and blood sampling

Blood pressure and heart rate

On entering the field laboratory, participants were allowed at least 5 minutes to rest on a couch in a quiet room before the initial blood pressure measurement was taken by the research nurse. Systolic and diastolic blood pressure (mmHg) and resting pulse rate (bpm) were measured twice in a semi-recumbent position using an oscillatory device, the OMRON-HEM.[43] An average of the two values was taken for analysis.

Anthropometry

Following the blood pressure recording, the participant's height (m) (without shoes) was measured using a stadiometer, and weight (kg) (without shoes or heavy clothing) using Salter scales. Waist and hip measurements (cm) were then taken with a tape-measure. Four electrodes were placed on the dorsum of the left hand and wrist and on the dorsum of the left foot and ankle, and body fat (%) was estimated by bioimpedance.[44] BMI was calculated as weight (kg)/height (m^2).

Lung function

Subjects were instructed to exhale as forcefully as possible into a spirometer (Micro Medical, Microplus) for measurement of PEF (l $minute^{-1}$), FEV_1 (l $minute^{-1}$) and FVC (litres), with the best of three attempts used for analysis.

Blood sampling
If the subjects consented, blood samples were taken by venepuncture. The samples were separated immediately by cold centrifuge and aliquots were refrigerated and frozen as appropriate. These were taken once a week to the Royal Free Hospital Clinical Biochemistry Laboratory for analysis. Routine biochemistry was undertaken and measurements (mmol l^{-1}) were made of total cholesterol,[45] high-density lipoprotein (HDL)-cholesterol[46] and triglycerides,[47] for calculation of low-density lipoprotein (LDL)-cholesterol.[48] Sera were stored at –70°C for subsequent analysis. Fasting status was noted, but the majority of samples were obtained in the non-fasting state. Participants were given the option of making an early appointment (e.g. before approximately 11.00 h) and providing a fasting sample. In this case, staff provided a simple snack before completing the rest of the assessment.

This first section of the assessment took about 20–30 minutes to complete for each participant. Including preparation of blood samples, the research nurse required about 1 hour to complete each assessment.

Muscular function, flexibility and cardiorespiratory fitness
This part of the assessment was carried out by an exercise specialist.

Muscular power and strength
Isometric strength (N kg^{-1}) of the knee extensor muscles was determined using a purpose-built isometric dynamometer where the subjects were seated upright with the knee of the preferred leg flexed to 90 degrees.[49] Subjects were instructed to try to extend their knee as 'fast and as forcibly as possible'. Contractions lasted between 2 and 4 seconds and verbal encouragement was given throughout. Muscle power (W kg^{-1}) of the lower limb muscles was determined while the subjects were seated in a separate apparatus (Nottingham power rig[50]). Average power during a single thrust of the leg extensor muscles (hip and knee extensors) was determined from the acceleration of a heavy flywheel connected to a foot pedal. The best of six attempts using the subject's preferred leg was taken for analysis.

Cardiorespiratory fitness
Two separate estimates of cardiovascular fitness were undertaken, which were based on the heart rate response to increased exercise intensity. Subjects were allocated alternately to either a submaximal bicycle ergometer exercise test [modified American College of Sports Medicine (ACSM) protocol], or a submaximal shuttle walking test (modified Singh test),[51] and completed the same tests at each follow-up after the exercise intervention. It was not considered appropriate to use only one test of cardiorespiratory fitness, since participants on the 'Walking Partners' programme may have had an advantage in completing the shuttle walking test, whereas participants attending the leisure centre may have been accustomed to exercising on a stationary bicycle, hence finding the bicycle ergometer test easier. Analyses were undertaken both of all subjects and to exclude patients on medication likely to affect this measure (e.g. β-blockers).

Modified ACSM cycle test For this test the subjects sat on an electronically braked cycle ergometer with a telemetric heart rate monitoring system (Polar) attached to their chest. Following a 5-minute rest (during which resting heart rate was recorded) the subjects began cycling. The power output at which the subjects were required to work was dependent on their age and gender. Heart rate was noted at the end of each minute, as was a rating of the patient's perceived exertion using the Borg scale.[52] After 3 minutes the power output was increased. The subjects exercised at three power outputs (levels 1–3), according to the protocol shown in *Table 5*, with heart rate being recorded during the last minute of each workload.

The test was terminated if the subject's heart rate exceeded 75% of the age predicted maximum (220 – age), the subject's rating of perceived exertion on the Borg scale reached 17 or the tester observed that the subject was distressed. By contrast, the patient was allowed to cycle for an additional 3 minutes at a further (fourth) power output if at the end of the third power output stage heart rate was considerably lower than 70% of the age-predicted maximum. The criteria for terminating the test, during this final workload, were the same as before. Measurements were compared of heart rate and Borg scale recorded at the highest comparable power output between repeated tests.

Shuttle walking test The subjects were required to walk backwards and forwards between two cones spaced 20 m apart on a level, non-slippery floor. The speed of walking was determined by a series of timed bleeps emanating from a calibrated tape-recorder. Starting at a very slow walking pace (level 1), speed was increased (decreasing interval

TABLE 5 *Cycling protocol according to age and gender*

		Power output (W)			
	Age (years)	**Level 1**	**Level 2**	**Level 3**	**Level 4**
Men	35–44	40	80	120	160
	45–54	35	70	105	140
	55–64	30	60	90	120
	≥65	25	50	70	100
Women	35–44	25	55	80	105
	45–54	25	45	65	75
	55–64	25	40	55	70
	≥65	25	35	45	55

TABLE 6 *Shuttle walking protocol*

Level	No. of shuttles
1	3
2	7
3	12
4	18
5	25
6	33
7	42
8	52
9	63
10	75
11	88
12	102

of beeps) every minute (up to a maximum of level 12). Each level consisted of a maximum number of shuttles to be completed before moving to the next level, as shown in *Table 6*. Subjects again wore a telemetric heart rate system, so that heart rate could be monitored at the end of every stage, as could a rating of perceived exertion. The test was terminated when the subject's heart rate reached 75% of the age-predicted maximum. Comparison was made of the number of stages completed before termination of the test and of heart rate at maximum comparable stage between repeated tests.

Flexibility

Two tests of flexibility (sit and reach, and shoulder abduction) were carried out, although the sit and reach test was discontinued during the trial and the available results were not analysed. For measurement of shoulder flexion the participants were asked to stand with their heels, lower back and back of the head against the side of an open door. A clinical goniometer (MIE Medical Research, UK) was placed and held in position by the instructor on the triceps of their preferred arm, equidistant between the shoulder and elbow. They were asked to turn their thumb outwards to 45 degrees and, keeping a straight arm, raise it towards the back of the ear. Care was taken to ensure that the lower back remained against the door and the arm remained straight. The angle of elevation was measured and the best of three attempts was recorded.

In a number of cases one or more of these tests was not completed. For example, participants with raised blood pressure (>160 mmHg SBP or >102 mmHg DBP) did not undertake the test of strength, the aerobic fitness test or the sit and reach test. This section took approximately 40 minutes to complete.

Feedback of results of assessment to GPs and participants

A copy of the blood test results was routinely sent to the referring GP, with any significant abnormalities highlighted in a covering letter. If blood pressure was elevated (>160 mmHg SBP or 102 mmHg DBP), the referring GP was also informed. Similarly, GPs were informed if their patients scored 11 or above (out of a possible maximum of 21) on either scale of the HADs questionnaire, since this was a clinically validated scale for depression and anxiety.

Many participants requested feedback of results of their tests. Wherever possible, the research team avoided giving results verbally or in writing until the final 1-year follow-up assessment, since it was felt that providing detailed feedback could influence their behaviour in future assessments. However, participants were provided with written feedback after 1 year. This consisted of a graphical summary of their results over each assessment,

with brief explanations of the meaning of each test.

Training

Training of the research nurse and fitness instructors on all aspects of the physical fitness assessment was carried out before the trial commenced (August 1998), under the guidance of the Royal Free Hospital Muscle Function Laboratory, over 1 week. Training updates were also carried out at regular intervals subsequently to ensure that new members of staff were competent in delivering the assessment and using the standardised protocols. These sessions were designed to ensure that all of the instructors were delivering the same exercise prescription. All the instructors were qualified to National Vocational Qualification (NVQ) Level 3 standard, consistent with the recommendations of the National Quality Assurance Framework. First aid and cardiopulmonary resuscitation (CPR) training was also provided for the instructors carrying out the assessments at regular 6-monthly intervals.

Planning of exercise cohorts

After a certain number of patients had been randomised, a 10-week exercise programme was started. This organisational method had the advantage that participants began their programme at the same time, facilitating social support and providing exercise partners at the end of the 10-week period. There was a gap of 4–10 weeks between each cohort to allow time to randomise new participants, and to complete postexercise assessments and later, at 6 months and 1 year, assessments for previous cohorts. After 6 months, controls were reassessed and randomly allocated to one of the other two interventions.

The timing of cohorts required ongoing planning. Initially it was thought possible to recruit about 300 for each cohort (i.e. 100 in each arm) and run four cohorts per year. In practice, only about three cohorts could be accommodated per year, with an average of about 130–140 per cohort at the peak, mainly because assessments took longer than originally anticipated, but also because of variations in referral rate.

Assignment

The progress of participants through the study is illustrated in *Figure 1*.

Randomisation schedules

The unit of randomisation was the individual patient. The schedule was designed using the statistical package STATA. Block randomisation was used to keep the numbers randomised to each arm of the trial relatively constant at all times. Variable block sizes of three, six and nine were used to ensure that the sequence did not become predictable.

Around 50% of participants were invited for a full assessment at 10 weeks. These participants were selected at random, using the statistical package CLINSTAT or SPSS. Reassignment to one of the exercise programmes for participants allocated initially to the control group was carried out in the same manner.

Allocation concealment

The randomisation schedule was concealed from staff carrying out the assessments at all times. The schedule was kept on computer at BHA, some 4 km from the assessment site. The computer was secure, requiring two passwords to access any network files. Paper copies of the schedule were also held by the research officer and certain other staff members in the Public Health Department at BHA. At the end of the assessment, the exercise staff telephoned BHA to obtain the next allocation. Brief details of each participant (e.g. name and date of birth), were noted for each allocation so that these could be verified at a later date if necessary.

Blinding

Ideally, assessors carrying out the postexercise assessments should be blinded to the patient's allocation. However, this was not practicable for a number of reasons. To minimise inter-rater error, the same fitness assessor carried out the preprogramme and postprogramme exercise assessment wherever possible. Assessors could therefore have recalled some participants' allocations from their initial assessment. In any event, since only one full-time equivalent research nurse was employed on the project, it would not have been possible for a different nurse to carry out preintervention and postintervention assessments.

The fitness assessors employed by the study also carried out some of the classes for both the leisure centre and Walking Partners programme; some participants would therefore have been known to the assessors from attending these classes. Participants frequently revealed their assignment to the assessors.

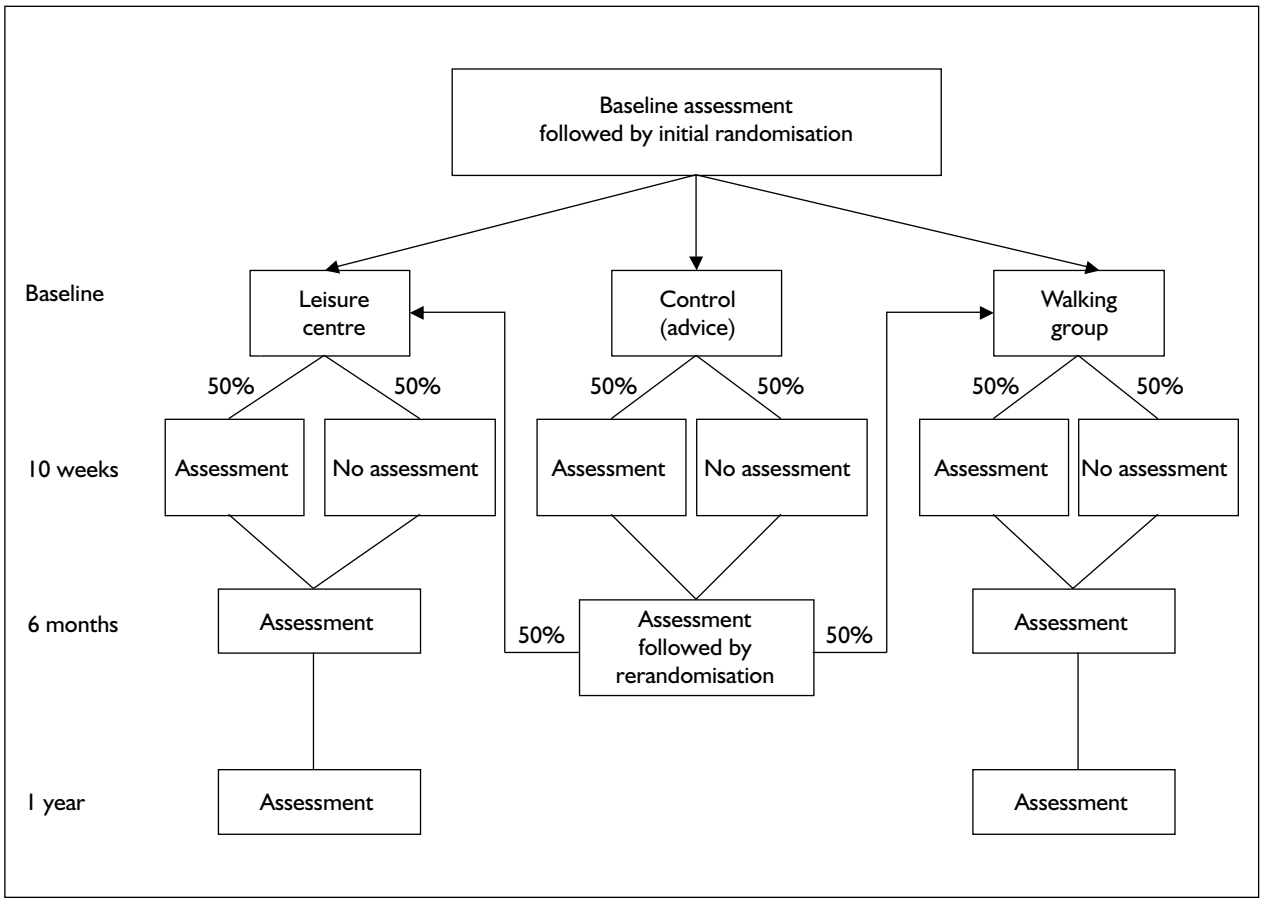

FIGURE 1 *Flowchart to illustrate progress through the EXERT study*

Description of exercise programmes

The exercise programmes consisted of instructor-led exercise classes in a leisure centre setting and instructor-led walks. In both instances the classes were designed to increase the participants' general fitness, taking them through a range of exercises and routines. Every class consisted of at least 45 minutes of exercises aimed to increase stamina, strength and flexibility, preceded and followed by a warm-up and warm-down period. Classes were taken by appropriately qualified staff; walking instructors had the YMCA Instructor-led Walks module and the leisure centre instructors had the YMCA Exercising the Older Person Module. Each instructor also took part in a pretrial training and assessment week, ensuring consistent exercise delivery.

Classes took place at a variety of locations and times to ensure that participants had the flexibility to fit the sessions into their weekly routine.

Walking classes

There were 12 different locations around the borough parks and open spaces and a total of 20 classes for people to choose from, running 7 days a week. Classes started at 09.30 h and ran throughout the day until 19.30 h. During the winter months the evening classes took place under floodlights.

Although the walks were graded by difficulty (1, easy to 5, hard), these were recommendations and not enforced, so participants still had the flexibility to choose from all of the classes.

Leisure centre-based exercise classes

These classes took place in a choice of four different leisure centres at different sites in the district, on Monday to Friday, between the hours of 07.00 and 16.00 h.

The types of class available were aerobics, body conditioning, aqua-aerobics, gymnasium and an optional swimming class.

Appendix 4 shows the detailed content of the classes.

Follow-up assessments

Schedule of assessments

These were planned to take place at 10 weeks (for around 50% of participants, because of time and space constraints), at 6 months, and at 1 year after completing the exercise programme. The same fitness assessments were carried out at each assessment. Wherever possible the repeat assessment was carried out at the same time of day, by the same research nurse and exercise specialist. Fasting status was also kept constant. The same set of questionnaires was also completed (except for demographic details, which were assumed to remain the same unless the participant informed the researchers otherwise). An additional economic evaluation questionnaire was completed at 10 weeks' follow-up to enable information on patient costs to be collected. These included the cost of time spent travelling (either as loss of work or leisure), the cost of time spent in the leisure centre (either as loss of work or leisure), travel costs of attending the leisure centre (fares, costs of private transport, etc.), equipment purchased specifically to comply with the exercise prescription scheme (e.g. sports wear) and costs for the treatment of injuries arising as a result of the exercise programmes. Further questions were asked at 6 and 12 months to help to assess whether participants had continued any form of exercise.

Efforts to boost attendance for follow-up assessments

Appointments for follow-up assessments were made by letter. These suggested a suitable time, and asked the patient to telephone to confirm attendance or make another appointment at a different time. Previous research suggests that a higher response rate may be achieved when a set appointment time is given. The recipient was asked to cancel or rearrange the appointment if not convenient. Participants who did not respond were also telephoned on at least two occasions at different times of day in an attempt to boost response.

While it was normal practice for patients undergoing the previous Fitness for Life exercise referral scheme to attend for fitness assessments at baseline and after 10 weeks, there may be less incentive for reattendance at 6 months and 1 year, particularly for those randomised to the Walking Partners scheme or simple advice. To maximise attendance for testing, participants were offered an *ex gratia* payment of £10 as compensation for the time spent and inconvenience incurred when they attended for their 1-year follow-up appointment. It was not considered that this small payment would constitute a sufficient inducement to alter exercise behaviour throughout the follow-up period.

Efforts to contact non-attenders

A telephone survey was developed in an effort to contact those participants who did not attend their final 1-year assessment. This essentially covered continuation of exercise and lifestyle changes, but was briefer than the 1-year follow-up questionnaire filled in by those attending the appointment, and took about 5–10 minutes to complete. Two additional questions concerning medication for cholesterol or blood pressure lowering were included. Attempts were made to telephone at various times of day, including the evening.

GP record reviews

Permission for examination of GP medical records was sought from participants when they attended for follow-up assessment. Those who did not attend were contacted by letter for their consent. As not all participants responded, during the course of the trial the initial consent form was modified to include permission to examine medical records.

A form was devised to collect information on attendance at the GP surgery, presenting conditions and any medication prescribed. Information was collected for periods commencing 1 year before entry into the trial until 1 year after the due date for the final assessment.

A research nurse made contact with the GP practices to arrange access to the records, although not all GPs agreed to facilitate this. Because of time constraints, the nurse concentrated on retrieval of information from the practices that had referred at least eight patients. Information was extracted from both paper and electronic records where available.

Data handling and analysis

An access database was designed to store and manipulate questionnaire, fitness assessment and biochemical data. Copies of the database were stored in three separate, secure locations, the main 'master' version being held at BHA (subsequently moved to Middlesex University). Data entry for some of the basic demographic data and the physical fitness assessments was carried out by the

study team or by data-entry clerks at any of the three locations and then merged to the main database. Paper versions of questionnaires were also stored and locked in filing cabinets. Most other questionnaires were entered using an optical reader and scanner (FORMIC system).

Each data file was checked for missing and inconsistent data. Logic and range checks were carried out where appropriate. Open questions were coded. Where necessary the original copies of paper questionnaires were checked, and in the case of errors either in manual data entry or produced by the optical scanning system, data were re-entered by hand.

Data analysis was undertaken using SPSS and STATA for the economic evaluation. Analytical techniques varied according to the specific data and are described separately for the key results chapters.

Chapter 3

Recruitment and follow-up

Referral

Patients were referred to the trial from 77 of the 89 Barnet practices and 11 practices from neighbouring areas with Barnet residents on their lists. Patients were referred by GPs and practice nurses, and in a few cases by other health professionals. Referral sources are shown in *Table 7*.

Numbers referred

The number of patients who may have been advised by their GPs to take part in the trial, but did not wish to do so, is unknown. There may also have been a number of cases where referral was intended, but the referral form was not sent in by the GP and the patient did not make an appointment at the leisure centre. Estimates based on the proportion of patients making appointments, where no referral form was received from the GP, suggest that there may have been about 200 patients referred who never attended for an assessment. In total, 1105 referrals were received at the leisure centre. Of these, 158 patients did not take part in the programme, because either they did not make an appointment at the leisure centre or they did not wish to take part in the trial. Altogether 949 patients were initially assessed and randomised to one of the three trial arms. Six patients were subsequently excluded, on the basis of pre-existing vascular disease which was not disclosed prior to randomisation or, in one case, because of withdrawal of consent.

TABLE 7 *Sources of referral to EXERT*

Referral source	No. of patients
GP	796
Practice nurse	293
Psychiatrist	1
Community psychiatric nurse	1
Rheumatologist	2
Physiotherapist	1
Not stated	8

Non-participants

Limited information was available from the GP referral forms of the 158 patients who had not taken part in the trial. Questionnaires were sent to these 158 patients to ascertain the reasons for non-participation. Replies were received from 59 (37%). Of these respondents, four were aged under 40 years and therefore would have been ineligible for the trial. A further two subsequently joined the trial. Gender, ethnicity and referral criteria in comparison with trial participants are shown in *Table 8*, and age groups, available only in survey respondents, in *Table 9*.

TABLE 8 *Characteristics of trial participants and non-participants*

Characteristic	% trial non-participants (n = 151[a])	% trial participants (n = 943)	p
Female	65.4	67.3	ns
Asian[b]	16.8	14.3	ns
Referral criteria			
Raised cholesterol	20.1	20.9	ns
Hypertension	44.2	44.8	ns
Obesity	71.0	62.7	<0.05
Smoking	11.7	10.3	ns
Diabetes	16.9	13.0	ns
Family history of MI	14.3	14.3	ns

[a] Excluding three cases with missing data and four aged under 40 years.
[b] Ethnicity estimated by surname for trial non-participants.
ns, not significant.

TABLE 9 *Age of trial participants and non-participant survey responders*

Age band (years)	% non-participant survey (n = 49[a])	% trial participants (n = 943)	p
40–49	16.3	23.9	ns
50–59	38.8	38.4	ns
60–69	30.6	30.1	ns
>70	14.3	7.3	ns

[a] Excluding four subjects under 40 years and four where an age was not recorded.

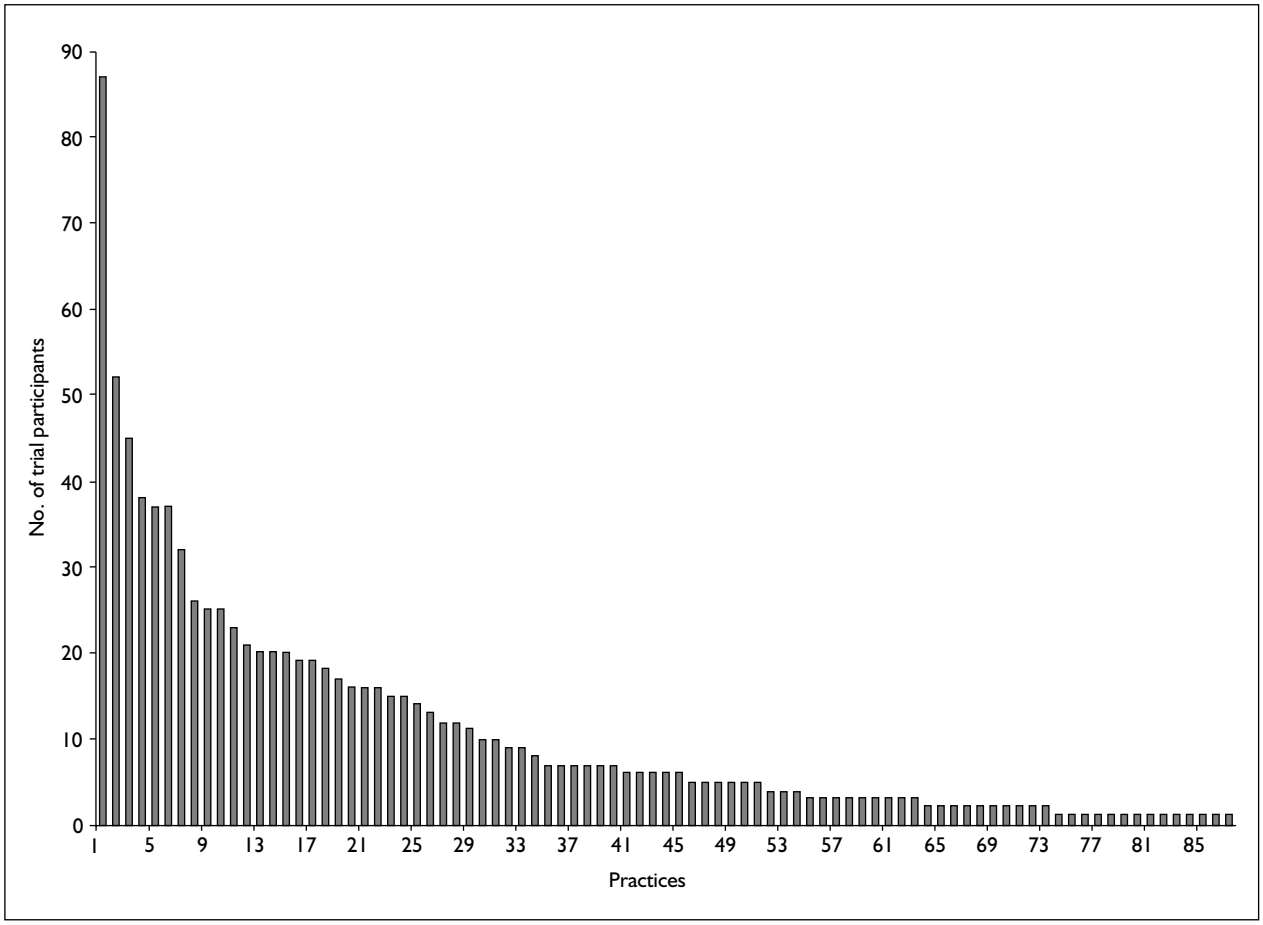

FIGURE 2 *Distribution of trial participants by practice*

There were no significant differences between trial participants and non-participants regarding referral criteria apart from obesity, which was more common in non-participants. Gender and ethnicity did not appear to be associated with trial participation. However, subjects aged 40–49 years were more likely to participate and those aged 70 years or over less so.

The principal reasons for non-participation are shown in *Table 10*. More than one reason could be stated.

Participant flow

The distribution of trial participants by referring practice is shown in *Figure 2* and participant flow through the trial in *Figure 3*.

Cohorts

Participants were recruited in nine cohorts from October 1998 to August 2001. The first eight cohorts were followed up for 1 year as planned, or in the case of the advice-only group for 18 months (including 1 year after rerandomisation). The ninth cohort consisted of 47 participants who were

TABLE 10 *Reasons for non-participation*

Reason	% (*n* = 59)
Time commitments at work	37.3
Difficulty getting transport to classes	25.4
Deciding to start own exercise programme	25.4
Disliked being asked to attend classes at set times/location	23.7
Personal ill-health/injury	20.3
Dependants at home	13.6
Not enjoying exercise	11.9
Disliked being allocated to one of three groups	11.9
Didn't think could keep up with exercise programme	10.2
Difficulty contacting sports centre for initial appointment	10.2

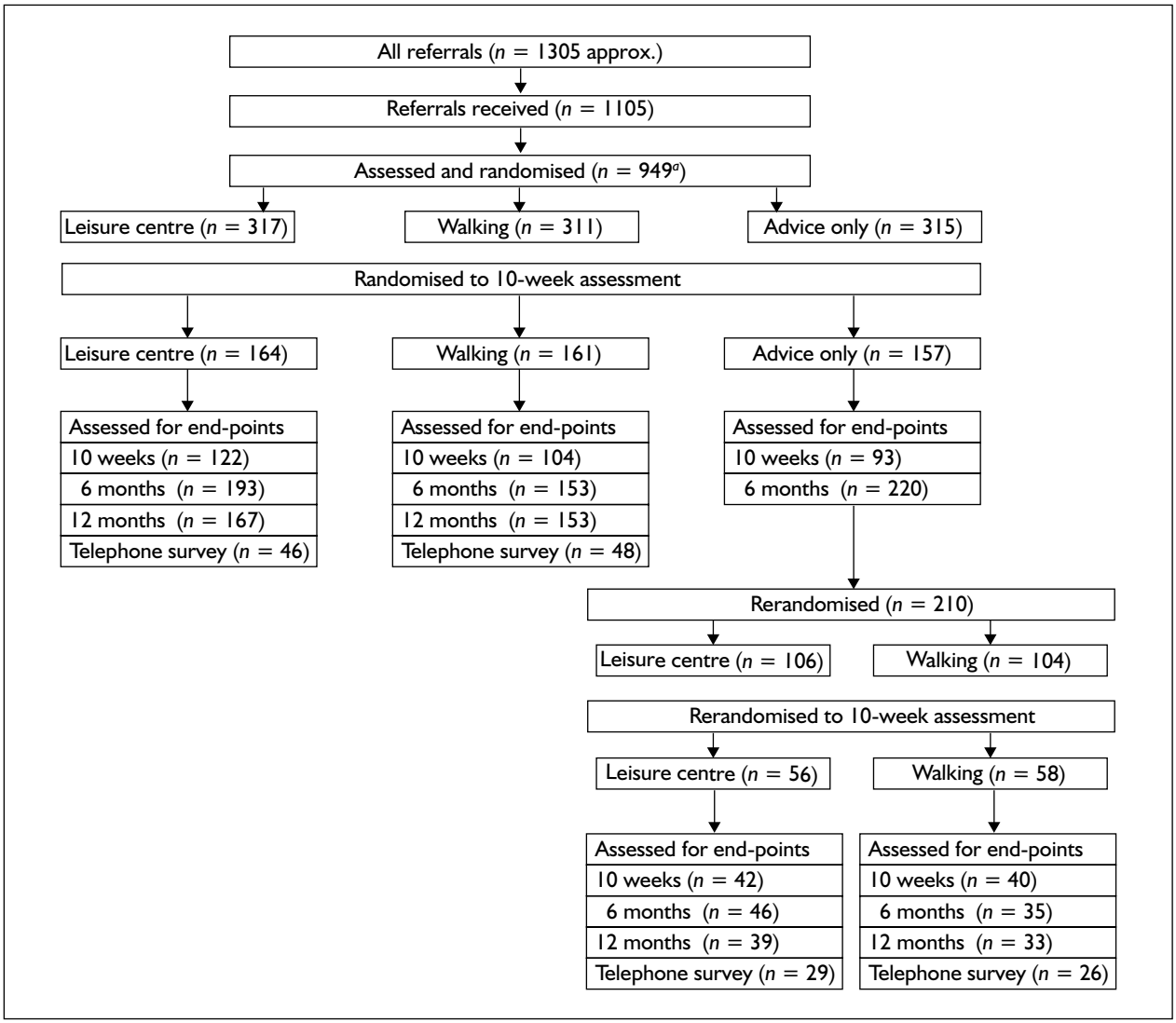

FIGURE 3 *Participant flow through the trial.* [a] *Six excluded postrandomisation.*

recruited near the end of the trial and therefore were followed up only to the 6-month assessment point. After that, the control subjects in the ninth cohort were allowed to access the leisure centre facilities and walks, but were no longer assessed as part of the trial. Final assessments were completed in April 2002.

Chapter 4

Baseline characteristics, adherence and follow-up

Baseline characteristics of participants

The mean age of the 943 trial participants was 57.04 years (SD 8.73). 635 (67.3%) were female and 308 (32.7%) male. Baseline socio-demographic characteristics are shown in *Table 11*.

Current or most recent post was coded for each participant using the Standard Occupational Classification 2000 (SOC2000) four-digit unit group code.[53] The code was then located on the simplified National Statistics Socio-economic Classification (NS-SEC) derivation table matrix[54] to assign the appropriate NS-SEC category. In comparison with data available from the 2001 Census,[55] the ethnic and socio-demographic mix broadly reflected the composition of the borough. However, owner occupation at 82.4% exceeded the borough figure of 65.7%.

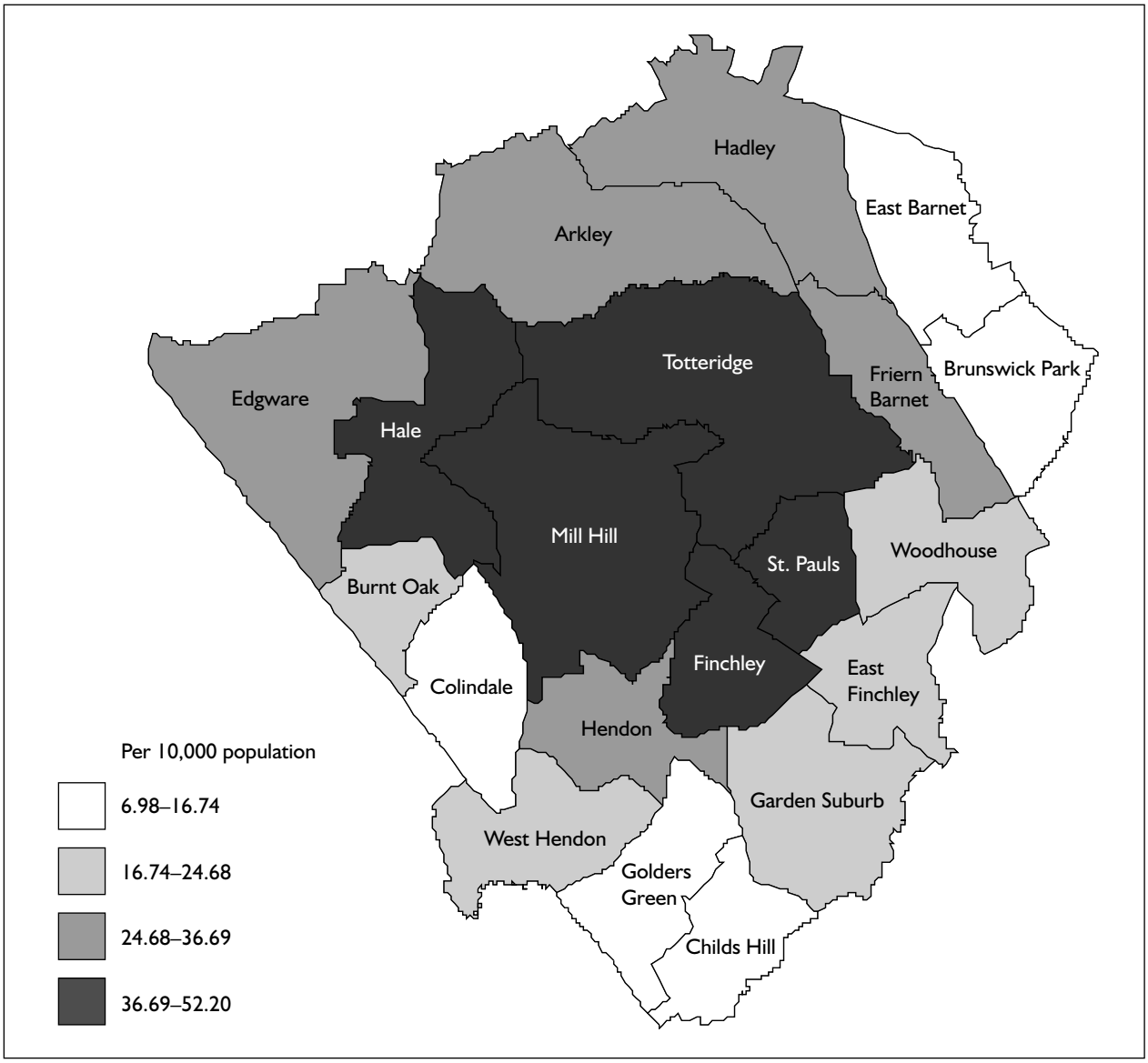

FIGURE 4 *Map of Barnet showing referral pattern by ward*

TABLE 11 *Baseline demography by age and gender*

Characteristic	Total	Women					Men				
		All	40–49	50–59	60–69	≥70	All	40–49	50–59	60–69	≥70
Single	275 (29.2)	227 (35.9)	50 (32.7)	88 (35.9)	66 (35.1)	23 (50.0)	48 (15.6)	16 (22.5)	18 (15.5)	10 (10.6)	4 (15.4)
Ethnicity											
White	717 (76.0)	476 (75.0)	95 (61.7)	182 (74.3)	158 (83.2)	41 (89.1)	241 (78.2)	43 (60.6)	100 (85.5)	77 (81.9)	21 (80.8)
Asian	135 (14.3)	92 (14.5)	34 (22.1)	43 (17.6)	15 (7.9)	0 (0.0)	43 (14.0)	20 (28.2)	9 (7.7)	11 (11.7)	3 (11.5)
Educational level											
Degree or above	220 (23.3)	119 (18.7)	50 (32.5)	35 (14.3)	28 (14.7)	6 (13.0)	101 (32.8)	32 (45.1)	36 (30.8)	29 (30.9)	4 (15.4)
Technical qualification	59 (6.2)	28 (4.4)	7 (4.5)	12 (4.9)	6 (3.2)	3 (6.5)	31 (10.1)	6 (8.5)	14 (12.0)	7 (7.4)	4 (15.4)
Diploma	121 (12.8)	99 (15.6)	24 (15.6)	38 (15.5)	32 (16.8)	5 (10.9)	22 (7.1)	5 (7.0)	9 (7.7)	5 (5.3)	3 (11.5)
'A' level	99 (10.5)	62 (9.8)	18 (11.7)	25 (10.2)	15 (7.9)	4 (8.7)	37 (12.0)	11 (15.5)	15 (12.8)	10 (10.6)	1 (3.8)
'O' level or GCSE	187 (19.8)	143 (22.5)	28 (18.2)	63 (25.7)	45 (23.7)	7 (15.2)	44 (14.3)	9 (12.7)	17 (14.5)	14 (14.9)	4 (15.4)
None	203 (21.5)	140 (22.0)	18 (11.7)	56 (22.9)	53 (27.9)	13 (28.3)	63 (20.5)	8 (11.3)	22 (18.8)	25 (26.6)	8 (30.8)
Employment status											
Employed full time	223 (23.6)	131 (20.6)	47 (30.5)	71 (29.0)	13 (6.8)	0(.0)	92 (29.9)	41 (57.7)	39 (33.3)	11 (11.7)	1 (3.8)
Employed part time	124 (13.1)	110 (15.7)	36 (23.4)	49 (20.0)	22(11.6)	3 (6.5)	14 (4.5)	1 (1.4)	2 (1.7)	9 (9.6)	2 (7.7)
Self-employed	108 (11.5)	53 (8.3)	11 (7.1)	28 (11.4)	14 (7.4)	0 (.0)	89 (28.9)	20 (28.2)	45 (38.4)	22 (23.4)	2 (7.7)
Not in paid employment	170 (18.0)	136 (21.4)	48 (31.2)	65 (42.2)	16 (8.4)	7 (15.2)	34 (11.0)	8 (11.3)	14 (12.0)	11 (11.7)	1 (3.8)
Receipt of means-tested benefits	287 (30.4)	195 (30.7)	55 (35.7)	86 (35.1)	48 (25.3)	6 (13.0)	84 (27.3)	18 (25.4)	29 (24.8)	31 (33.0)	6 (23.1)
Retired	288 (30.5)	198 (31.2)	3 (1.9)	30 (12.2)	127 (66.9)	38 (82.6)	90(29.2)	3 (4.2)	14 (12.0)	51 (54.3)	22 (84.6)
Main income:											
State pension	139 (14.7)	107(16.9)	3 (1.9)	14 (5.7)	70 (36.8)	20 (43.5)	32 (10.4)	3 (4.2)	2 (1.7)	20 (21.3)	7 (26.9)
Other sources	154 (16.3)	92 (14.5)	9(5.8)	25 (10.2)	41 (21.6)	17 (37.0)	62 (20.1)	4 (5.6)	16 (13.7)	32 (34.0)	10 (38.5)
Socio-economic classification[a]:											
1.1	46 (4.9)	14 (2.2)	6 (3.9)	4 (1.6)	3 (1.6)	1 (2.2)	32 (10.4)	6 (8.5)	15 (12.8)	7 (7.4)	4 (15.4)
1.2	85 (9.0)	36 (5.7)	16 (10.4)	11 (4.5)	7 (3.7)	2 (4.3)	49 (15.9)	10 (14.1)	18 (15.4)	17 (18.1)	4 (15.4)
2	216 (22.9)	145 (22.8)	35 (22.7)	56 (22.9)	46 (24.2)	8 (17.4)	71 (23.1)	20 (28.2)	26 (22.2)	20 (21.3)	5 (19.2)
3	172 (18.2)	134 (21.1)	26 (16.9)	47 (19.2)	47 (24.7)	14 (30.4)	38 (12.3)	10 (14.1)	18 (15.4)	9 (9.6)	1 (3.8)
4	65 (6.9)	25 (3.9)	4 (2.6)	8 (3.3)	10 (5.3)	3 (6.5)	40 (13.0)	8 (11.3)	17 (14.5)	14 (14.9)	1 (3.8)
5	17 (1.8)	5 (0.8)	1 (0.6)	4 (1.6)	0 (0.0)	0 (0.0)	12 (3.9)	2 (2.8)	4 (3.4)	3 (3.2)	3 (11.5)
6	135 (14.3)	107 (16.9)	24 (15.6)	54 (22.0)	26 (13.7)	3 (6.5)	28 (9.1)	6 (8.5)	8 (6.8)	11 (11.7)	3 (11.5)
7	43 (4.6)	28 (4.4)	4 (2.6)	12 (4.9)	11 (5.8)	1 (2.2)	15 (4.9)	4 (5.6)	5 (4.3)	6 (6.4)	0 (0.0)
8	164 (17.4)	141 (22.2)	38 (24.7)	49 (20.0)	40 (21.1)	14 (30.4)	23 (7.5)	5 (7.0)	6 (5.1)	7 (7.4)	5 (19.2)

continued

TABLE 11 *Baseline demography by age and gender (cont'd)*

Characteristic	Total	Women					Men				
		All	40–49	50–59	60–69	≥70	All	40–49	50–59	60–69	≥70
Housing tenure											
Council tenant	60 (6.8)	47 (14.0)	19 (8.1)	19 (5.0)	9 (5.0)	0 (0.0)	13 (4.5)	6 (9.0)	4 (3.6)	3 (3.3)	0 (0.0)
Private tenant	61 (6.9)	36 (6.1)	10 (7.4)	13 (5.6)	11 (6.1)	2 (4.8)	25 (8.6)	6 (9.0)	12 (10.8)	6 (6.6)	1 (4.5)
Owner occupier	727 (82.4)	483 (81.7)	98 (72.1)	199 (85.0)	147 (82.1)	39 (92.9)	244 (83.8)	52 (77.6)	92 (82.9)	80 (87.9)	20 (90.9)
Access to private transport	776 (85.2)	496 (81.4)	118 (81.4)	201 (84.8)	143 (78.1)	34 (77.3)	280 (92.7)	64 (92.8)	105 (92.1)	86 (92.5)	25 (96.2)

Data are numbers (%) within age groups.

[a] 1.1, large employers and higher managerial occupations; 1.2, higher professional occupations; 2, lower managerial and professional occupations; 3, intermediate occupations; 4, small employers and own account workers; 5, lower supervisory and technical occupations; 6, semi-routine occupations; 7, routine occupations; 8/not classified, never worked and long-term unemployed/full-time students/occupation not stated or inadequately described/not classifiable for other reasons.

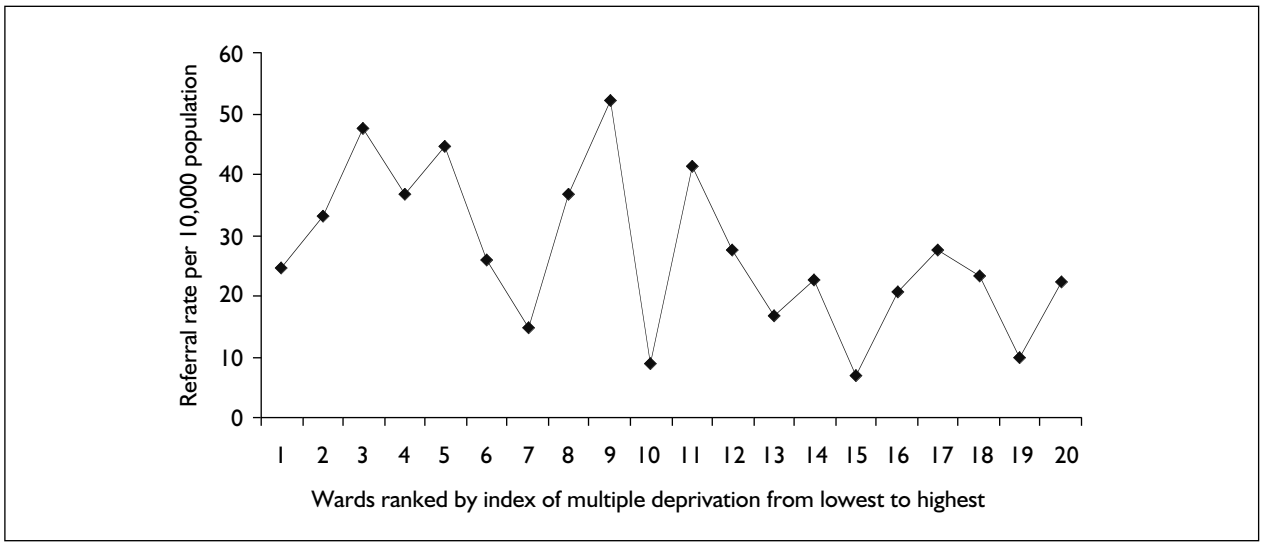

FIGURE 5 *Referral rates by ward ranked by deprivation score*

Figure 4 shows the referral pattern by ward and *Figure 5* the relationship of referral rate to deprivation at ward level[56] (Barnet was ranked 193 out of 354 local authorities in England for deprivation, based on 2001/02 data[57]). Referral rates varied considerably by ward, in part related to their proximity to Copthall Leisure Centre, where the assessments were undertaken. However, referral rates tended to be higher in the least deprived wards and lower in the most deprived.

The main referral categories were obesity and hypertension. In many cases, more than one referral criterion was indicated. Referral criteria by age and gender are shown in *Table 12*. The three trial arms were well matched in terms of referral criteria and socio-demographic characteristics, as shown in *Tables 13* and *14*. The groups were also well matched by clinical characteristics (*Table 15*).

Adherence

The adherence of subjects to the active intervention arms was assessed by the use of handheld diaries and class registers. Neither of these information sources was complete. Adherence was calculated as the proportion of sessions undertaken of those prescribed for each subject (generally 20 or 30). For the purposes of analysis, adherence was divided into five grades:

- grade 1: 0% adherence (i.e. no record of attendance at any session; non-adherers)
- grade 2: 1–24% adherence
- grade 3: 25–49% adherence
- grade 4: 50–74% adherence
- grade 5: 75–100% adherence (high adherers, as defined elsewhere[31]).

Where there was a discrepancy between the number of sessions recorded in the handheld diary and the class register, the higher figure was taken.

In total, 200 participants originally randomised to the leisure centre and walking groups completed at least 75% of their allocated sessions (*Table 16*). Adherence was significantly higher in the leisure centre group than in the walking group ($\chi^2 = 63.9$, 4 df, $p < 0.001$). A similar pattern was shown for control subjects after rerandomisation. However, adherence was generally lower in the rerandomised controls than in those initially randomised to the leisure centre and walking groups.

Referral criteria together with a number of key sociodemographic variables were explored for associations with adherence in subjects initially randomised to the leisure centre and walking groups. Of the three major referral categories, raised cholesterol and hypertension were associated with better adherence to both the leisure centre and walking programmes than was obesity (*Table 17*). The same pattern was apparent in rerandomised controls.

There were no significant differences in adherence between men and women, single people and those living with a partner, or by employment status, educational level, socio-economic classification or ethnicity: 52.8% of Asian subjects and 40% of whites were high adherers to the leisure centre

TABLE 12 *Referral criteria by age and gender*

Criterion	Total	Women					Men				
		All	40–49	50–59	60–69	≥70	All	40–49	50–59	60–69	≥70
Raised cholesterol	197 (20.9)	125 (19.7)	15 (9.7)	41 (16.7)	51 (26.8)	18 (39.1)	72 (23.4)	15 (21.1)	34 (29.1)	20 (21.3)	3 (11.5)
Hypertension	422 (44.8)	268 (42.2)	45 (29.2)	100 (40.8)	99 (52.1)	24 (52.2)	154 (50.0)	26 (36.6)	58 (49.6)	56 (59.6)	14 (53.8)
Obesity	591 (62.7)	408 (64.3)	119 (77.3)	165 (67.3)	105 (55.3)	19 (41.3)	183 (59.4)	43 (60.6)	79 (67.5)	49 (52.1)	12 (46.2)
Smoking	97 (10.3)	67 (10.6)	15 (9.7)	32 (13.1)	15 (7.9)	5 (10.9)	30 (9.7)	9 (12.7)	12 (10.3)	9 (9.6)	0 (0)
Diabetes	123 (13.0)	55 (8.7)	17 (11.0)	15 (6.1)	20 (10.5)	3 (6.5)	68 (22.1)	12 (16.9)	20 (17.1)	24 (25.5)	12 (46.2)
Family history of MI	135 (14.3)	98 (15.4)	30 (19.5)	39 (15.9)	26 (13.7)	3 (6.5)	37 (12.0)	14 (19.7)	14 (12.0)	5 (5.3)	4 (15.4)

Data are numbers (%) within age groups.

TABLE 13 *Study groups: referral criteria*

Criterion	Leisure centre (*n* = 317)	Walking (*n* = 311)	Advice (*n* = 315)
Raised cholesterol	76 (24.0)	67 (21.5)	54 (17.1)
Hypertension	141 (44.5)	144 (46.3)	137 (43.5)
Obesity	209 (65.9)	182 (58.5)	200 (63.5)
Smoking	33 (10.4)	38 (12.2)	26 (8.3)
Diabetes	39 (12.3)	35 (11.3)	49 (15.6)
Family history of MI	44 (13.9)	40 (12.9)	51 (16.2)

Data are numbers (%).

TABLE 14 *Study groups: sociodemographic characteristics*

Characteristic	Leisure centre (*n* = 317)	Walking (*n* = 311)	Advice (*n* = 315)
Mean age (SD)	57.1 (8.7)	56.9 (8.5)	57.0 (9.0)
Gender			
Male	111 (35.0)	97 (31.2)	100 (31.7)
Female	206 (65.0)	214 (68.8)	215 (68.3)
Single	93 (29.3)	90 (29.0)	92 (29.5)
Ethnicity			
White	240 (75.7)	236 (75.9)	241 (76.5)
Asian	53 (16.7)	38 (12.2)	44 (14.0)
Educational level			
Degree or above	77 (24.3)	71 (22.8)	72 (22.9)
Technical qualification	19 (6.0)	19 (6.1)	21 (6.7)
Diploma	38 (12.0)	45 (14.5)	38 (12.2)
'A' level	32 (10.1)	29 (9.3)	38 (12.1)
'O' level or GCSE	62 (19.6)	61 (19.6)	64 (20.3)
None	72 (22.7)	69 (22.2)	62 (19.7)
Employment status			
Employed full time	64 (20.2)	76 (24.4)	83 (26.3)
Employed part time	33 (10.4)	48 (15.4)	43 (13.7)
Self-employed	37 (12.2)	34 (11.4)	37 (12.1)
Not in paid employment	65 (20.5)	59 (19.0)	46 (14.6)
Receipt of means tested benefits	97 (30.8)	97 (31.3)	93 (29.6)
Retired	104 (32.8)	88 (28.3)	96 (30.5)
Retirement income			
Main income state pension	46 (41.8)	46 (50.5)	47 (51.1)
Main income other sources	64 (58.2)	45 (49.5)	45 (48.9)
Socio-economic classification			
1.1	19 (6.0)	12 (3.9)	15 (4.8)
1.2	35 (11.0)	25 (8.0)	25 (7.9)
2	74 (23.3)	69 (22.2)	73 (23.2)
3	57 (18.0)	53 (17.0)	62 (19.7)
4	14 (4.4)	26 (8.4)	25 (7.9)
5	3 (0.9)	10 (3.2)	4 (1.3)
6	41 (12.9)	42 (13.5)	52 (16.5)
7	13 (4.1)	16 (5.1)	14 (4.4)
8/not classified	61 (19.2)	58 (18.6)	45 (14.3)
Housing tenure			
Council tenant	19 (6.5)	20 (6.8)	21 (7.0)
Private tenant	12 (4.1)	27 (9.2)	22 (7.4)
Owner occupier	249 (85.6)	235 (80.5)	243 (81.3)
Access to private transport	252 (83.7)	258 (85.4)	266 (86.4)

Data are numbers (%) unless stated otherwise.

TABLE 15 *Study groups: clinical characteristics at baseline*

Characteristic	Leisure centre (*n* = 317)	Walking (*n* = 311)	Advice (*n* = 315)
No of smokers (%)	40 (12.6)	52 (16.7)	46 (14.6)
Weight (kg)	83.0 (18.2)	82.4 (16.9)	81.8 (18.4)
BMI (kg m^{-2})	30.7 (6.0)	30.6 (5.9)	30.3 (5.5)
SBP (mmHg)	136.0 (19.9)	135.7 (21.4)	134.0 (23.0)
DBP (mmHg)	84.0 (9.8)	84.1 (10.2)	83.5 (12.6)
Total cholesterol (mmol l^{-1})	5.8 (1.1)	5.7 (1.1)	5.7 (1.0)
HDL-cholesterol (mmol l^{-1})	1.3 (0.3)	1.4 (0.4)	1.4 (0.4)
LDL-cholesterol (mmol l^{-1})	3.5 (0. 9)	3.4 (0.9)	3.5 (0.8)
HADs score			
Anxiety	7.7 (4.2)	7.9 (4.0)	7.5 (3.8)
Depression	5.4 (3.4)	5.1 (3.2)	4.9 (3.3)

Data are mean (SD) unless stated otherwise.

TABLE 16 *Adherence by study group*

Adherence grade	Leisure centre (*n* = 317)	Walking (*n* = 311)
1	24 (7.6)	73 (23.5)
2	33 (10.4)	63 (20.3)
3	47 (14.8)	58 (18.6)
4	80 (25.2)	50 (16.1)
5	133 (42.0)	67 (21.5)

Data are numbers (%) within study groups.

TABLE 17 *Adherence by referral criterion*

Study group	Referral criterion	Adherence grade				
		1	2	3	4	5
Leisure centre	Raised cholesterol	3 (3.9)	9 (11.8)	12 (15.8)	16 (21.1)	36 (47.4)
	Hypertension	9 (6.4)	18 (12.8)	18 (12.8)	31 (22.0)	65 (46.1)
	Obesity	17 (8.1)	21 (10.0)	35 (16.7)	55 (26.3)	81 (38.8)
	Smoking	2 (6.1)	0 (0.0)	6 (18.2)	10 (30.3)	15 (45.5)
	Diabetes	2 (5.1)	7 (17.9)	8 (20.5)	8 (20.5)	14 (35.9)
	Family history of MI	4 (9.1)	2 (4.5)	5 (11.4)	10 (22.7)	23 (52.3)
Walking	Raised cholesterol	15 (22.4)	7 (10.4)	15 (22.4)	8 (11.9)	22 (32.8)
	Hypertension	32 (22.2)	31 (21.5)	22 (15.3)	26 (18.1)	33 (22.9)
	Obesity	41 (22.5)	40 (22.0)	35 (19.2)	32 (17.6)	34 (18.7)
	Smoking	11 (28.9)	8 (21.1)	6 (15.8)	3 (7.9)	10 (26.3)
	Diabetes	12 (34.3)	10 (28.6)	4 (11.4)	3 (8.6)	6 (17.1)
	Family history of MI	9 (22.5)	8 (20.0)	9 (22.5)	6 (15.0)	8 (20.0)

Data are numbers (%) within criteria.

TABLE 18 *Adherence by age*

Study group	Age group (years)	Adherence grade				
		1	2	3	4	5
Leisure centre	40–49	6 (8.2)	14 (19.2)	9 (12.3)	17 (23.3)	27 (37.0)
	50–59	12 (9.6)	6 (4.8)	22 (17.6)	39 (31.2)	46 (36.8)
	60–69	3 (3.3)	10 (11.1)	13 (14.4)	16 (17.8)	48 (53.3)
	70–74	3 (10.3)	3 (10.3)	3 (10.3)	8 (27.6)	12 (41.4)
Walking	40–49	21 (28.8)	15 (20.5)	12 (16.4)	11 (15.1)	14 (19.2))
	50–59	32 (25.4)	24 (19.0)	20 (15.9)	24 (19.0)	26 (20.6)
	60–69	13 (14.3)	24 (26.4)	21 (23.1)	11 (12.1)	22 (24.2)
	70–74	7 (33.3)	0 (0.0)	5 (23.8)	4 (19.0)	5 (23.8)

Data are numbers (%) within age groups.

programme, and 18.4% and 22.9%, respectively, to the walking programme. Adherence was lower in both trial arms for subjects without access to private transport, 28.6% of whom were high adherers to the leisure centre programme, compared with 45.6% of those with access to private transport. For the walking programme the differences were even more striking, with 2.3% and 25.2% high adherers, respectively. Adherence was highest in the age group 60–69 years (*Table 18*).

Attendance at follow-up assessments

Overall attendance was 67% among those randomised to the 10-week assessment, 60% at 6 months and 50% at 1 year.

Attendance was slightly higher for men than women and was generally highest in the 60–69-year-old age group.

A comparison of referral criteria and baseline characteristics for the whole sample and those attending at 6 months, the assessment point for the three group comparison of primary end-points, is shown in *Table 19*. There were no significant differences between attenders at 6 months and the whole group.

Effect of adherence on attendance

There was a strong and graded relationship between adherence grade and subsequent attendance at each assessment point. Thus, attendance by high adherers at the immediate postprogramme 10-week assessment point was over 90% in both the leisure centre and walking groups. However, even at 1 year about 75% of high adherers attended for assessment, compared with 50% overall (*Table 20*).

Effect of 10-week assessment on attendance at 6 months

Of those subjects randomised to the 10-week assessment, 75.5% of those who attended at 10 weeks also attended the 6-month assessment, compared with 30.1% of those who failed to attend at 10 weeks ($p < 0.001$). However, this was not attributable to the intervention at 10 weeks itself, as there was no difference in the 6-month attendance rate between those randomised and not randomised to assessment at 10 weeks (*Table 21*).

TABLE 19 *Baseline demography and referral criteria for all participants and those attending at 6 months*

	All participants (*n* = 943)	**Attenders at 6 months (*n* = 566)**
Referral criterion		
Raised cholesterol	197 (20.9)	128 (22.6)
Hypertension	422 (44.8)	261 (46.1)
Obesity	591 (62.7)	343 (60.6)
Smoking	97 (10.3)	54 (9.5)
Diabetes	123 (13.0)	68 (12.0)
Family history of MI	135 (14.3)	90 (15.9)
Baseline characteristic		
Age (years), mean (SD)	57.04 (8.73)	57.73 (8.50)
Female	635 (67.3)	379 (67.0)
Single	275 (29.2)	159 (28.1)
Ethnicity		
White	717 (76.0)	429 (75.8)
Asian	135 (14.3)	90 (15.9)
Educational level		
Degree or above	220 (23.3)	151 (26.7)
Technical qualification	59 (6.2)	35 (6.2)
Diploma	121 (12.8)	70 (12.4)
'A' level	99 (10.5)	62 (11.0)
'O' level or GCSE	187 (19.8)	114 (20.1)
None	203 (21.5)	105 (18.6)
Employment status		
Employed full time	223 (23.6)	135 (23.9)
Employed part time	124 (13.1)	69 (12.2)
Self-employed	108 (11.5)	66 (12.1)
Not in paid employment	170 (18.0)	89 (15.7)
Receipt of means-tested benefits	287 (30.4)	144 (25.4)
Retired	288 (30.5)	139 (14.7)
Main income: state pension	154 (16.3)	196 (34.6)
other sources	90 (15.9)	108 (19.1)
Socio-economic classification		
1.1	46 (4.9)	32 (5.7)
1.2	85 (9.0)	58 (10.2)
2	216 (22.9)	138 (24.4)
3	172 (18.2)	105 (18.6)
4	65 (6.9)	34 (6.0)
5	17 (1.8)	11 (1.9)
6	135 (14.3)	74 (13.1)
7	43 (4.6)	26 (4.6)
8	164 (17.4)	88 (15.5)
Housing tenure		
Council tenant	60 (6.8)	26 (4.8)
Private tenant	61 (6.9)	24 (4.5)
Owner occupier	727 (82.4)	470 (87.5)
Access to private transport	776 (85.2)	488 (88.4)

Data are numbers (%) except where stated otherwise.

TABLE 20 *Attendance for assessment by adherence grade*

Study group	Adherence grade	Attendance for assessment		
		10 weeks	6 months	1 year
Leisure centre	1	1 (6.7)	2 (8.3)	1 (4.8)
	2	4 (22.2)	10 (30.3)	8 (25.0)
	3	11 (55.0)	21 (44.7)	20 (42.6)
	4	36 (90.0)	60 (75.0)	47 (62.7)
	5	70 (98.6)	100 (76.3)	91 (74.6)
Walking	1	13 (37.1)	15 (20.5)	20 (29.4)
	2	9 (31.0)	23 (36.5)	24 (40.0)
	3	19 (73.1)	34 (58.6)	31 (55.3)
	4	20 (83.3)	33 (66.0)	27 (57.4)
	5	43 (91.5)	48 (71.6)	48 (76.2)

Data are numbers (%) of those eligible to attend at each point.

TABLE 21 *Attendance at 6-month follow-up by randomisation to 10-week assessment*

	Leisure centre		Walking		Advice	
	Randomised to 10-week assessment					
	Yes	No	Yes	No	Yes	No
Attendance at 6 months	98 (59.8)	95 (62.1)	82 (50.9)	71 (47.3)	110 (70.1)	110 (69.6)

Data are numbers (%).

Chapter 5

Results: physical activity

Measures of physical activity and exercise continuation

The measures of physical activity were self-reported. The primary outcome was based on the comparison between changes in the time spent on moderate or vigorous physical activity from baseline to 6 months in the three groups initially randomised to the leisure centre programme, walking programme and advice only (control), as determined from the 7-day recall questionnaires. Comparisons were also made at 10 weeks for all groups and at 1 year for the leisure centre and walking groups. Secondary outcomes included the proportions of participants achieving the recommended national weekly target in terms of duration of moderate and/or vigorous activity, and the proportions who increased their moderate and/or vigorous physical activity by a minimum of 60 minutes per week ('improvers'). Changes in exercise behaviour were also determined from the Stages of Change questionnaire, from evaluation questionnaires and from telephone interviews with participants who did not attend the 1-year assessment.

The design of the study required rerandomising the subjects in the advice-only control group to either the leisure centre or walking group after 6 months, with the intention of combining their results with those of the initially randomised subjects. In fact, as indicated below, these subjects showed significant increases in physical activity between baseline and the 10-week and 6-month assessments. These advice-only subjects could thus no longer be considered identical to those entering the study at the outset. Hence, it was not considered appropriate to aggregate their results with those from the initially randomised subjects as originally planned, and data recorded following their entry into the exercise programmes after rerandomisation are not included in this report.

Seven-day recall of physical activity

Participants were asked to recall and record the frequency and duration of activities in the previous week at each assessment point. The categories of activity included:

- sport and leisure
- walking (including walking in everyday life as well as fitness walking)
- gardening
- DIY
- work inside the home
- work outside the home.

Each activity item recorded was assigned a metabolic equivalent task (MET) value[58] and a categorisation as light (energy cost at least 2 kcal minute^{-1} but less than 5 kcal minute^{-1}), moderate (at least 5 kcal minute^{-1} but less than 7.5 kcal minute^{-1}) or vigorous (at least 7.5 kcal minute^{-1}).[4] Data were calculated as minutes of each activity within each of the light, moderate and vigorous categories. To determine approximate levels of activity in accordance with guidelines for recommended amounts of physical activity, minutes of moderate and vigorous activity were combined to define a level of 'at least moderate' activity.

Participants were also asked whether their record of activity in the previous week was 'typical' or not. Data are presented for all participants, as well for those for whom the week was typical.

The ways in which participants completed the 7-day recall questionnaire varied. Participants may have overstated some of the frequencies and durations for work in the home and outside the home (e.g. by recording total time for the week rather than for the occasion) and some double-counting across activities cannot be excluded, although this was consistent across assessments. Definite outliers (implausible times) were excluded.

Recommended level of physical activity

A summary of activity levels from the 1998 Health Survey for England,[4] classified informants according to the (then recently revised) physical activity guidelines, stating that adults should take part in five or more occasions a week of activity of

at least moderate intensity of 30 minutes or more in duration.

The summary activity level classification is as follows:

- group 1 – low activity: up to three occasions of moderate or vigorous activity of at least 30 minutes' duration in the past 4 weeks (less than once a week)
- group 2 – medium activity: four to 19 occasions of moderate or vigorous activity of at least 30 minutes' duration in the past 4 weeks (at least once, less than 5 days a week)
- group 3 – high activity: 20 or more occasions of moderate or vigorous activity of at least 30 minutes' duration in the past 4 weeks (at least 5 days a week).

In terms of 'minutes of activity', there is some overlap between these three groups. For example, a person's activity may be classified in group 2 if they are doing four 1-hour sessions per week of moderate activity giving a total of 240 minutes, thus potentially underestimating the total duration of moderate activity.

Data were approximately categorised according to these groups as follows, where group 1 also contains those who only recorded doing light activity.

- group 1: less than 30 minutes of moderate or vigorous activity per week
- group 2: 30–149 minutes of moderate or vigorous activity per week
- group 3: at least 150 minutes of moderate or vigorous activity per week.

Here, the activity of the person in the example above would be placed in group 3, and therefore the proportion of subjects achieving the 'recommended amount' will be overstated in comparison with the above summary classifications. However, in this study this will be consistent across the assessment points.

It is unclear whether five sessions of 30 minutes in one week equate to 150 minutes in one week. However, there is evidence to indicate that both fitness and health benefits can be derived from the accumulation of equivalent volumes of activity achieved through shorter (10–15 minutes' duration) and longer (30 minutes' duration) bouts.[1] The classifications chosen for this study, based on total accumulated moderate or vigorous activity, therefore seem appropriate. Another issue is the reliability of the recording of everyday activities as distinct from targeted activity such as sport and leisure. Inconsistencies were found in the recording of time spent on everyday activities, suggesting that this was overestimated. Furthermore, there is evidence that such activities may be ineffective in reducing cardiovascular risk.[59] To address this in the study, grouped data are presented based on minutes of moderate/vigorous activity for all activities recorded and separately, restricted to minutes of sport/leisure and walking, on which greater reliance has been placed.

Statistical analysis

Data were categorised as minutes of moderate and/or vigorous activity; total minutes of activity; and energy expenditure in terms of kcal kg^{-1} per week (MET value for activity × duration of activity in hours) for each participant at each assessment point.

The distributions of all physical activity data were very skewed, so the data were transformed by taking (natural) logarithms. The back-transform or antilog of the mean of log (transformed) data produces the geometric mean (similar to the median and less than the mean). Analysis of the difference in means of log-transformed data provides the most accurate estimate of the percentage change or difference.

Non-parametric statistical techniques (Mann–Whitney and Kruskal–Wallis) were used to investigate potential differences between study groups and subgroups (e.g. gender) at baseline. Within study group changes from baseline to each assessment point (and for rerandomised controls, from the 6-month assessment, which constitutes a second baseline for this group) were analysed using paired *t*-tests on the log-transformed data. Taking antilogs of the observed differences represented the mean percentage change from baseline for each group.

Minutes of moderate and/or vigorous activity were calculated by aggregating all minutes of activity assigned a moderate or vigorous categorisation. Participants who only reported 'light activity' were assigned a value of zero. For this reason a value of '1' was added to each person's minutes of moderate or vigorous activity before performing a log transformation. Total minutes of activity included all minutes of light activity.

Analysis of covariance (ANCOVA) adjusted for baseline values was used on the log-transformed

data to analyse the changes from baseline and to determine any potentially significant differences between the study groups by using a post hoc Bonferroni correction. The adjusted mean data were antilogged to the original scale. Data were analysed both for trial completers (where data were available both at baseline and at one or more subsequent assessments) and on an ITT basis. As there was a consistent trend towards an increase in the level of physical activity at subsequent assessments in all groups, it was not appropriate to use the baseline or last observation carried forward for missing data. Therefore, the median of available data at each assessment point for the control group grouped by gender within each age group was used for imputation of missing data. Age was grouped into four categories: 40–44, 45–54, 55–64 and 65 years and over.

Changes in the proportions of participants in different activity groups over time were assessed on a trial completers basis, with comparisons between baseline and subsequent assessment points for those who had available data at the relevant time-points.

Changes in physical activity over time were assessed in relation to adherence to the exercise programmes, as defined in Chapter 4. High adherers, who attended at least 75% of allocated sessions, were compared with those who attended less than 75% of allocated sessions.

Subgroup analyses were also performed for those who reported that the previous week was 'typical' and for sport and leisure and walking activities only.

Subjects in the control (advice-only) arm were asked at their 6-month assessment whether they had attended health walks and/or the leisure centre or gym since their baseline assessment. In total, 162 participants answered this question, of whom 72 had done so. Some analyses were performed excluding these subjects for comparison with the complete sample.

For ease of presentation, some outcome data tables, including all subgroup analyses, are shown in Appendix 5 (*Tables 75–92*).

Results

Completion of the questionnaires was high, with 92.4–96.1% of the potential sample at each time-point recording at least one activity.

Assessment at baseline

There were no significant differences in minutes of light, moderate or vigorous activity or in energy expenditure in kcal kg^{-1} per week between the groups at baseline (*Table 22*), or between high adherers and others.

Women reported significantly more minutes of light activity than men at baseline (men, $n = 290$: median 374.0 minutes per week; women, $n = 603$: median 758.0 minutes per week; Mann–Whitney $p < 0.001$) and showed higher energy expenditure (men, $n = 299$: median 27.4 kcal kg^{-1} per week; women, $n = 607$: median 41.1 kcal kg^{-1} per week; Mann–Whitney $p < 0.001$). No participants aged 70 years or above participated in any vigorous activity at baseline. The only vigorous activities reported were sport and leisure.

There were no significant differences in proportions in activity groups 1, 2 and 3 (see above) between trial arms using χ^2 tests for total activity or for sport and walking. Recorded activities for those participants who said that the previous week was typical did not differ from the whole group. The proportions in activity groups 1, 2 and 3 in the leisure centre and walking groups who subsequently completed at least 75% of their allocated programme (high adherers) were also similar to the groups as a whole at baseline.

For activities related to sport and walking in particular, the proportion of subjects overall who were achieving 150 or more minutes per week of at least moderate activity was 16.5%, with roughly similar proportions by study group (*Table 23*).

Assessment at 10 weeks

There were significant increases in the time spent on moderate/vigorous activity, to about three times the baseline level (ITT analysis) in all three study groups (see Appendix 5, *Tables 75* and *76*). For example, participants in the leisure centre group increased their 'at least moderate' activity from about 23 to 93 minutes from baseline to 10 weeks. Participants' report of 'total minutes of activity' was marginally less for leisure centre and control than for walking group subjects, which was reflected in their overall energy expenditure. Only the walking group significantly increased total activity and energy expenditure, with a (geometric) mean increase of 46% (ITT).

The walking group reported the most activity and had the highest energy expenditure across the three groups, after adjusting for baseline values,

TABLE 22 *Activity and energy expenditure at baseline (minutes per week)*

Measurement	Leisure centre	Walking	Advice
Minutes of light activity			
	n = 298	*n* = 295	*n* = 300
Median (IQR)	637.5 (780.0)	585.0 (824.0)	664.0 (787.3)
Geometric mean	549.96	495.03	606.32
Minutes of moderate and/or vigorous activity			
	n = 301	*n* = 300	*n* = 305
Median (IQR)	46.00 (153.0)	61.00 (184.0)	46.00 (178.0)
Geometric mean	22.44	28.73	23.83
Energy expenditure (kcal kg^{-1} per week)[a]			
	n = 301	*n* = 300	*n* = 305
Median (IQR)	35.9 (42.8)	36.6 (52.8)	39.7 (45.7)
Geometric mean	33.6	31.1	35.9
Total energy (kcal)			
	n = 301	*n* = 300	*n* = 305
Median (IQR)	2863 (3401)	2914 (4136)	2968 (3943)
Geometric mean	2723	2506	2857

IQR, interquartile range.
Geometric means are calculated on the non-transformed scale.
Minutes of vigorous activity only included sport and leisure.
[a] MET value for activity × duration of activity in hours.

on both ITT and completers analysis. The leisure centre group reported more 'at least moderate' activity than the control group, but the controls reported more overall activity and consequently had slightly higher energy expenditure (*Table 24*).

Table 25 shows the net increase in each measure of physical activity compared between the study groups. The net increase in activity was higher in the walking group than in the leisure centre and control groups and was significantly higher than the leisure centre group, by a mean of 36% for total minutes of activity (ITT analysis). The increase in at least moderate activity for the walking group was 31% higher than for the controls, and for the leisure centre group was about 18% higher, but neither reached statistical significance (ITT analysis).

There was a noticeable shift in the proportions of participants in the three grouped levels of duration of activity from baseline to 10 weeks, particularly for the leisure centre and walking groups, with a marked reduction in the proportions of participants in group 1 and an increase in groups 2 and 3 (*Table 26*). Thus, the proportions recording 150 minutes or more of at least moderate sport/leisure and walking activity per week were approximately 18% higher in the leisure centre and walking groups, reaching about 36%, and 11% higher in the advice-only control group, reaching 27%. As this assessment was made after completion of the exercise programmes, these results would be anticipated.

A similar pattern overall was shown by those participants who described their week as typical, although with a slightly lower increment for the walking group (Appendix 5, *Table 77*). High adherers also showed a similar pattern, although the proportion of those in the walking group recording 150 minutes or more of at least moderate sport/leisure and walking activity per week was 26% higher at 38% (Appendix 5, *Table 78*).

Exclusion of the 72 control subjects who reported joining exercise programmes since their baseline assessment (see Chapter 10) had no marked effect on the results, the remaining controls in fact showing slightly higher proportions achieving 150 minutes or more of all activities and of sport/leisure and walking (Appendix 5, *Table 79*).

Assessment at 6 months

At 6 months, all groups had maintained a significant increase in duration of 'at least moderate' activity compared with baseline (*Table 27*, and *Table 80* in Appendix 5).

TABLE 23 *Durations of activity of at least moderate intensity at baseline*

	Group 1 (<30 minutes) *n* (%)	Group 2 (30–149 minutes) *n* (%)	Group 3 (≥150 minutes) *n* (%)
All activities ($n = 906$)			
Leisure centre	129 (42.9)	96 (31.9)	76 (25.2)
Walking	115 (38.3)	94 (31.3)	91 (30.3)
Advice	124 (40.7)	90 (29.5)	91 (29.8)
Totals	368 (40.6)	280 (30.9)	258 (28.5)
Sport and walking ($n = 782$)			
Leisure centre	137 (52.3)	87 (33.2)	38 (14.5)
Walking	116 (45.3)	95 (37.1)	45 (17.6)
Advice	129 (48.9)	89 (33.7)	46 (17.4)
Totals	382 (48.8)	271 (34.7)	129 (16.5)
'Typical week' ($n = 610$)			
All activities			
Leisure centre	84 (11.6)	67 (33.8)	47 (23.7)
Walking	90 (14.2)	62 (29.4)	59 (28.0)
Advice	77 (13.3)	66 (32.8)	58 (28.9)
Totals	251 (41.1)	195 (32.0)	164 (26.9)
'Typical week' ($n = 520$)			
Sport and walking			
Leisure centre	88 (51.2)	61 (35.5)	23 (13.4)
Walking	84 (48.8)	58 (33.7)	30 (17.4)
Advice	85 (48.3)	63 (35.8)	28 (15.9)
Totals	257 (49.4)	182 (35.0)	81 (15.6)
'High adherers' ($n = 199$)			
All activities			
Leisure centre	53 (40.2)	45 (34.1)	34 (25.8)
Walking	24 (35.8)	20 (29.9)	23 (34.3)
Totals	77 (38.7)	65 (32.7)	57 (28.6)
'High adherers' ($n = 180$)			
Sport and walking			
Leisure centre	62 (50.4)	42 (34.1)	19 (15.4)
Walking	27 (47.4)	22 (38.6)	8 (14.0)
Totals	89 (49.4)	64 (35.6)	27 (15.0)

TABLE 24 *Adjusted geometric mean activity durations and energy expenditure at 10 weeks*

Measurement	Leisure centre	Walking	Advice
Completers	$n = 113$	$n = 92$	$n = 86$
Minutes of moderate and/or vigorous activity	92 (68 to 124)	113 (81 to 159)	70 (49 to 99)
Total minutes of activity	533 (456 to 621)	863 (726 to 1025)	644 (539 to 769)
Energy expenditure (kcal kg^{-1} per week)	31 (27 to 37)	49 (41 to 58)	36 (30 to 43)
ITT	$n = 157$	$n = 154$	$n = 153$
Minutes of moderate and/or vigorous activity	93 (75 to 15)	103 (83 to 127)	79 (63 to 97)
Total minutes of activity	584 (517 to 659)	796 (704 to 901)	668 (590 to 756)
Energy expenditure (kcal kg^{-1} per week)	34 (30 to 38)	43 (38 to 49)	36 (32 to 41)

Data are geometric means adjusted for baseline values and 95% confidence intervals (CIs) (antilogged from transformed scale).

TABLE 25 *Mean percentage differences between study groups at 10 weeks*

Measurement	Walking vs Leisure centre	Walking vs Advice	Leisure centre vs Advice
Completers	*n* = 113	*n* = 92	*n* = 86
Minutes of moderate and/or vigorous activity	23% (–29 to 115%)	62% (–11 to 194%)	31% (–26 to 132%)
Total minutes of activity	62% (22 to 115%)**	34% (–1 to 82%)	17% (–38 to 10%)
Energy expenditure (kcal kg^{-1} per week)	56% (18 to 106%)**	36% (1 to 83%)*	–13% (–34 to 16%)
ITT	*n* = 157	*n* = 154	*n* = 153
Minutes of moderate and/or vigorous activity	11% (–24 to 60%)	31% (–10 to 90%)	18% (–18 to 71%)
Total minutes of activity	36% (10 to 68%)**	19% (–4 to 48%)	–13% (–29 to 8%)
Energy expenditure (kcal kg^{-1} per week)	27% (3 to 56%)*	18% (–4 to 45%)	–7% (–24 to 14%)

Data are Diff % (95% CI). Diff % is the difference in outcome between table groups expressed as a percentage at the 10-week assessment after adjusting for baseline values.
** $p < 0.01$, * $p < 0.05$.

TABLE 26 *Changes in levels of activity from baseline to 10 weeks by study group*

	Group 1 (<30 minutes) *n* (%)	Group 2 (30–149 minutes) *n* (%)	Group 3 (≥150 minutes) *n* (%)
All activities (*n* = 291)			
Baseline			
Leisure centre	46 (40.7)	37 (32.7)	30 (26.5)
Walking	31 (33.7)	33 (35.9)	28 (30.4)
Advice	39 (45.3)	23 (26.7)	24 (27.9)
All activities			
10 weeks			
Leisure centre	10 (8.8)	55 (48.7)	48 (42.5)
Walking	13 (14.1)	26 (28.3)	53 (57.6)
Advice	16 (18.6)	41 (47.7)	29 (33.7)
Sport and walking (*n* = 247)			
Baseline			
Leisure centre	54 (51.9)	31 (29.8)	19 (18.3)
Walking	29 (39.7)	32 (43.8)	12 (16.4)
Advice	34 (48.6)	25 (35.7)	11 (15.7)
Sport and walking			
10 weeks			
Leisure centre	9 (8.7)	57 (54.8)	38 (36.5)
Walking	11 (15.1)	36 (49.3)	26 (35.6)
Advice	16 (22.9)	35 (50.0)	19 (27.1)

The greatest change was again seen in the walking group, followed by the leisure centre and control groups. The duration of at least moderate activity was less than at 10 weeks, but reported overall activity and subsequently energy expenditure were comparable.

As at 10 weeks, activity levels were significantly higher in the walking group than in the leisure centre group and controls (Appendix 5, *Table 81*). The net increase in minutes of moderate activity in the walking group was 38% higher than in the leisure centre group and 53% higher than in the controls after adjusting for baseline values (*Table 28*).

There was an increase in the proportions of participants in activity groups 2 and 3 from

TABLE 27 *Adjusted geometric mean activity durations and energy expenditure at 6 months*

Measurement	Leisure centre	Walking	Advice
Completers	*n* = 179	*n* = 141	*n* = 200
Minutes of moderate and/or vigorous activity	52 (39 to 69)	89 (65 to 121)	48 (37 to 63)
Total minutes of activity	688 (609 to 777)	833 (726 to 956)	653 (582 to 733)
Energy expenditure (kcal kg^{-1} per week)	37 (33 to 42)	46 (40 to 53)	35 (32 to 40)
ITT	*n* = 301	*n* = 300	*n* = 305
Minutes of moderate and/or vigorous activity	65 (55 to 77)	89 (75 to 106)	58 (49 to 69)
Total minutes of activity	692 (641 to 748)	759 (703 to 820)	647 (600 to 699)
Energy expenditure (kcal kg^{-1} per week)	38 (35 to 41)	42 (39 to 45)	35 (33 to 38)

Data are mean adjusted for baseline values and 95% CIs (antilogged from transformed scale).

TABLE 28 *Mean percentage differences between study groups at 6 months*

Measurement	Walking vs Leisure centre	Walking vs Advice	Leisure centre vs Advice
Completers	*n* = 179	*n* = 141	*n* = 200
Minutes of moderate and/or vigorous activity	70% (2 to 184%)*	84% (11 to 204%)*	8% (–32 to 73%)
Total minutes of activity	21% (–3 to 52%)	28% (2 to 59%)*	5% (–14 to 29%)
Energy expenditure (kcal kg^{-1} per week)	23% (–2 to 55%)	30% (4 to 62%)*	5% (–14 to 30%)
ITT	*n* = 301	*n* = 300	*n* = 305
Minutes of moderate and/or vigorous activity	38% (3 to 86%)*	53% (14 to 106%)**	11% (–17 to 49%)
Total minutes of activity	10% (–4 to 25%)	17% (3 to 34%)*	7% (–6 to 22%)
Energy expenditure (kcal kg^{-1} per week)	11% (–3 to 27%)	19% (4 to 36%)**	7% (–6 to 23%)

Data are Diff % (95% CI). Diff % is the difference in outcome between table groups expressed as a percentage at the 6-month assessment after adjusting for baseline values.
** $p < 0.01$, * $p < 0.05$.

baseline to 6 months (*Table 29*), although generally less marked than at 10 weeks. There was a marked reduction in the proportions in group 1 in all three study groups. As before, the increases in the proportions recording 150 minutes or more of at least moderate sport/leisure and walking activity per week (group 3) were greater in the leisure centre (increase of 13.8% to reach 30.1%) and walking (increase of 11.1% to reach 28%) groups than in the control group (increase of 7.5% to reach 22.1%).

Exclusion of participants whose week was not typical increased the difference between the leisure centre and walking groups and the control group (Appendix 5, *Table 82*), with the walking group displaying the biggest change, an increase of 26.3% in group 3 to reach 52.6%. High adherers showed greater increments in the proportions in group 3, particularly for the walking group, although the numbers were relatively small (Appendix 5, *Table 83*).

Exclusion of the 72 control subjects who exercised since their baseline assessment reduced the increment in the proportion in group 3 at 6 months (increase of 2.7% to reach 19.5%) (Appendix 5, *Table 84*).

A subgroup analysis was undertaken at 6 months of the 465 participants who were obese at the baseline assessment (BMI ≥30). These showed similar proportionate changes in physical activity to the whole study population.

Assessment at 1 year

At 1 year, both intervention groups still maintained substantial and statistically significant increases in the duration of at least moderate activity compared with baseline (Appendix 5, *Tables 85* and *86*).

On ITT analysis, the duration of total and at least moderate activity, as well as energy expenditure, was significantly higher in the

TABLE 29 *Changes in levels of activity from baseline to 6 months by study group*

	Group 1 (<30 minutes) *n* (%)	Group 2 (30–149 minutes) *n* (%)	Group 3 (≥150 minutes) *n* (%)
All activities ($n = 520$)			
Baseline			
Leisure centre	73 (40.8)	58 (32.4)	48 (26.8)
Walking	45 (31.9)	53 (37.6)	43 (30.5)
Advice	84 (42.0)	64 (32.0)	52 (26.0)
All activities			
6 months			
Leisure centre	50 (27.9)	59 (33.0)	70 (39.1)
Walking	24 (17.0)	55 (39.0)	62 (44.0)
Advice	51 (25.5)	83 (41.5)	66 (33.0)
Sport and walking ($n = 434$)			
Baseline			
Leisure centre	77 (50.3)	51 (33.3)	25 (16.3)
Walking	43 (36.4)	55 (46.6)	20 (16.9)
Advice	89 (54.6)	50 (30.7)	24 (14.7)
Sport and walking			
6 months			
Leisure centre	48 (31.4)	59 (38.6)	46 (30.1)
Walking	27 (22.9)	58 (49.2)	33 (28.0)
Advice	52 (31.9)	75 (46.0)	36 (22.1)

TABLE 30 *Adjusted geometric mean activity and energy expenditure at 1 year*

Measurement	Leisure centre	Walking
Completers	$n = 153$	$n = 132$
Minutes of moderate and/or vigorous activity	50 (36 to 68)	101 (72 to 142)
Total minutes of activity	736 (642 to 842)	822 (711 to 951)
Energy expenditure (kcal kg^{-1} per week)	40 (35 to 46)	47 (40 to 54)
ITT	$n = 301$	$n = 300$
Minutes of moderate and/or vigorous activity	65 (55 to 76)	128 (109 to 151)
Total minutes of activity	709 (658 to 764)	907 (841 to 977)
Energy expenditure (kcal kg^{-1} per week)	38 (36 to 41)	49 (45 to 52)

Data are mean adjusted for baseline values and 95% CIs (antilogged from transformed scale).

walking group than in the leisure centre group (*Tables 30* and *31*).

The same trend towards a decrease in the proportions of participants in group 1 duration of activity and an increase in those in group 3 that had been shown at earlier assessment points was apparent at 1 year, for both the leisure centre and walking groups. The increases from baseline in the proportions recording 150 minutes or more of at least moderate sport/leisure and walking activity per week (group 3) were 13.4% in the leisure centre group (to reach 27.6%) and 17.9% in the walking group (to reach 37.5%) (*Table 32*), suggestive of a more sustained effect in the latter compared with 6 months.

Exclusion of participants whose week was not typical augmented the increase in leisure centre participants in group 3, although not the absolute proportion (Appendix 5, *Table 87*). High adherers showed similar proportionate changes to the whole group (Appendix 5, *Table 88*).

TABLE 31 *Mean percentage differences between study groups at 1 year*

Measurement	Walking vs Leisure centre	
	Completers	**ITT**
Minutes of moderate and/or vigorous activity	103% (28 to 222%)**	99% (58 to 150%)**
Total minutes of activity	12% (–8 to 36%)	28% (15 to 42%)**
Energy expenditure (kcal kg^{-1} per week)	17% (–4 to 43%)	26% (14 to 40%)**

Data are Diff % (95% CI). Diff % is the difference in outcome between table groups expressed as a percentage at the 1-year assessment after adjusting for baseline values.
** $p < 0.01$.

TABLE 32 *Changes in levels of activity from baseline to 1 year: leisure centre and walking groups only*

	Group 1 (<30 minutes) *n* (%)	**Group 2 (30–149 minutes) *n* (%)**	**Group 3 (≥150 minutes) *n* (%)**
All activities ($n = 285$)			
Baseline			
Leisure centre	65 (42.5)	49 (32.0)	39 (25.5)
Walking	42 (31.8)	46 (34.8)	44 (33.3)
All activities			
One year			
Leisure centre	45 (29.4)	52 (34.0)	56 (36.6)
Walking	18 (13.6)	49 (37.1)	65 (49.2)
Sport and walking			
Baseline			
Leisure centre	68 (53.5)	41 (32.3)	18 (14.2)
Walking	40 (35.7)	50 (44.6)	22 (19.6)
Sport and walking			
One year			
Leisure centre	42 (33.1)	50 (39.4)	35 (27.6)
Walking	24 (21.4)	46 (41.1)	42 (37.5)

Improvers

Improvers were arbitrarily defined as those participants whose recall questionnaires at 6 months showed a minimum increase in moderate and/or vigorous physical activity of 60 minutes per week compared with baseline. A total of 208 participants (22.1%) were improvers. The proportion of improvers was marginally but not significantly higher in the advice-only group (Appendix 5, *Table 89*). To exclude the effect of distortions due to unusual activity in the week under review, a subsample of these participants who said that their report of physical activity at baseline and 6 months was typical was examined (Appendix 5, *Table 90*). Proportions were significantly different (χ^2 test, 2 df, $p = 0.042$), with about 20% more participants in the walking group than in the leisure centre and advice-only groups reporting at least 60 minutes more moderate or vigorous activity.

Restriction of the analysis of improvers to the subsample of the above participants who reported no moderate or vigorous activity at all baseline (only light activity) (282/943, 30%) showed similar results, both for the whole subsample (Appendix 5, *Table 91*) and for those who reported the weeks as typical (Appendix 5, *Table 92*). There was a higher proportion of improvers in the advice-only group in the whole subsample, while in the 'typical weeks' group (72/282, 26%) a significantly higher proportion of the walking group increased their moderate/vigorous activity from none to at least 60 minutes (χ^2 test, 2 df, $p = 0.003$), although the numbers were small. These findings are consistent with the reported increase in the amount of

TABLE 33 *Stages of change during trial*

Study group	Stage	Assessment point			
		Baseline	10 weeks	6 months	12 months
Leisure centre	1	7 (2.4)	4 (3.9)	4 (2.3)	3 (2.0)
	2	172 (58.1)	9 (8.7)	51 (29.1)	39 (25.7)
	3	61 (20.6)	20 (19.4)	59 (33.7)	50 (32.9)
	4	18 (6.1)	55 (53.4)	26 (14.9)	12 (7.9)
	5	38 (12.8)	15 (14.6)	35 (20.0)	48 (31.6)
Walking	1	4 (1.4)	1 (1.1)	2 (1.5)	6 (4.4)
	2	161 (55.7)	18 (20.0)	21 (15.6)	23 (16.9)
	3	81 (28.0)	20 (22.2)	46 (34.1)	39 (28.7)
	4	18 (6.2)	37 (41.1)	23 (17.0)	15 (11.0)
	5	25 (8.7)	14 (15.6)	43 (31.9)	53 (39.0)
Advice	1	9 (3.1)	0 (0.0)	4 (2.0)	
	2	167 (57.0)	36 (42.4)	70 (35.2)	
	3	72 (24.6)	23 (27.1)	63 (31.7)	
	4	18 (6.1)	21 (24.7)	23 (11.6)	
	5	27 (9.2)	5 (5.9)	39 (19.6)	

Data are numbers (%) within study groups.

activity by walking group participants seen at the 6-month assessment detailed in the previous sections.

Stages of change

Trial participants were asked to specify one of the following five stages at each assessment point:

1. precontemplation: 'I do not exercise and do not intend to start exercising in the next 6 months'
2. contemplation: 'I do not exercise but I am thinking about starting to exercise in the next 6 months'
3. preparation: 'I currently exercise, but not regularly'
4. action: 'I exercise regularly, but have only started doing so in the last 6 months'
5. maintenance: 'I exercise regularly and have done so for more than 6 months'.

The majority of participants (56.9%) were in the contemplation stage at baseline, while for those attending at 6 months, the figures were 35.2% in the control advice-only group, 29.1% in the leisure centre group and 15.6% in the walking group. At baseline, 16.4% of participants were in the action and maintenance groups. For those attending at 6 months, the figures were 31.2% in the advice group, 34.9% in the leisure centre group and 48.9% in the walking group.

These figures in part reflect differential dropout, and a truer picture of individual change is obtained from trial completers.

Stages of change for each study group for those attending each assessment point are shown in *Table 33* and for trial completers only in *Table 34*.

Tables 35–37 show the shift in stages of change for individual participants in the three trial groups between baseline and 6 months. Of those at the contemplation stage, the proportions moving to a higher stage were 59.1% in the leisure centre group, 73.4% in the walking group and 42.7% in the advice group. These results are considered further in Chapter 7.

Evaluation questionnaires

At the 6-month assessment, trial participants in the leisure centre and walking groups were asked whether they had carried on any regular exercise since finishing the 10-week programme. Of those responding to this question ($n = 293$), 98 (57.3%) of the leisure centre group said they had done so, compared with 98 (80.3%) of the walking group, a significant difference in favour of the latter ($\chi^2 = 17.03$, $p < 0.001$).

At the 1-year assessment, trial participants in the leisure centre and walking groups were again asked whether they had carried on any regular

TABLE 34 *Stages of change during trial: completers only*

Study group	Stage	Assessment point			
		Baseline[a]	6 months	Baseline[b]	12 months
Leisure centre	1	2 (1.2)	3 (1.8)	3 (2.1)	3 (2.1)
	2	93 (56)	49 (29.5)	78 (54.9)	34 (23.9)
	3	31 (18.7)	57 (34.3)	24 (16.9)	48 (33.8)
	4	10 (6.0)	24 (14.5)	8 (5.6)	11 (7.7)
	5	30 (18.1)	33 (19.9)	29 (20.4)	46 (32.4)
Walking	1	2 (1.5)	2 (1.5)	3 (2.3)	5 (3.8)
	2	64 (49.2)	21 (16.2)	67 (51.1)	23 (17.6)
	3	40 (30.8)	44 (33.8)	39 (29.8)	37 (28.2)
	4	9 (6.9)	23 (17.7)	8 (6.1)	15 (11.5)
	5	15 (11.5)	40 (30.8)	14 (10.7)	51 (38.9)
Advice	1	4 (2.1)	4 (2.1)		
	2	103 (54.2)	68 (35.8)		
	3	50 (26.3)	60 (31.6)		
	4	10 (5.3)	22 (11.6)		
	5	23 (12.1)	36 (18.9)		

Data are numbers (%) within study groups.
[a] Baseline for attenders at 6 months.
[b] Baseline for attenders at 12 months.

TABLE 35 *Stages of change at baseline and 6 months: leisure centre group completers*

		Stage at 6 months				
		1	2	3	4	5
Stage at baseline	1	**0**	2	0	0	0
	2	2	**36**	32	14	9
	3	1	4	**16**	6	4
	4	0	2	2	**1**	5
	5	0	5	7	3	**15**

Data are numbers.
No change line is shown in bold.

TABLE 36 *Stages of change at baseline and 6 months: walking group completers*

		Stage at 6 months				
		1	2	3	4	5
Stage at baseline	1	**0**	1	0	1	0
	2	2	**15**	21	13	13
	3	0	5	**15**	7	13
	4	0	0	3	**1**	5
	5	0	0	5	1	**9**

Data are numbers.
No change line is shown in bold.

TABLE 37 *Stages of change at baseline and 6 months: advice group completers*

		Stage at 6 months				
		1	2	3	4	5
Stage at baseline	1	**0**	3	0	0	1
	2	2	**57**	25	14	5
	3	1	6	**26**	6	11
	4	0	2	3	**0**	5
	5	1	0	6	2	**14**

Data are numbers.
No change line is shown in bold.

exercise since finishing the 10-week programme, specified as at least once a week. Of those responding (n = 283), 115 (74.2%) of the leisure centre group had done so, compared with 106 of the walking group (82.8%), a non-significant difference.

Telephone interview

Trial participants who did not attend the 1-year assessment in the leisure centre were contacted by telephone. Several were unobtainable and some refused to take part in the interview. Of 89 respondents, 16 (36.4%) of the leisure centre group had continued to exercise, compared with

22 (48.9%) of the walking group, a non-significant difference.

Summary

All three study groups increased their duration of at least moderate activity by 10 weeks. By 6 months, the increase was somewhat attenuated, but the duration of at least moderate activity remained significantly higher than at baseline, the greatest change occurring in the walking group. At 1 year, both leisure centre and walking groups maintained significant increases compared with baseline.

There was no significant difference between the increases in duration of at least moderate activity in the three study groups at any assessment point.

There was an increase in the proportion of participants achieving at least 150 minutes per week of at least moderate activity in the sport/leisure and walking categories in all three study groups. At 6 months, there was a net increase in the proportions achieving this duration and intensity of activity of 13.8% in the leisure centre group, 11.1% in the walking group and 7.5% in the advice-only group. At 1 year, the net increases were 13.4% in the leisure centre group and 17.9% in the walking group.

A similar proportion increased the time spent on at least moderate activity by a minimum of 60 minutes per week compared with baseline in each study group. When those whose recorded weeks were not typical were excluded, a significantly higher percentage in the walking group achieved this degree of improvement at 6 months.

All groups showed progression through the stages of change during the trial. The majority were in the contemplation stage at baseline. At 6 months, 73.4% of the walking group, 59.1% of the leisure centre group and 42.7% of the advice-only group had moved to a higher stage.

A higher proportion of walking group than leisure centre participants said they had continued regular exercise since finishing the exercise programme at the 6-month assessment, but this difference was no longer apparent at the 1-year assessment.

Smaller proportions of non-attenders at the 1-year assessment continued to exercise than those who attended for assessment.

Chapter 6

Results: anthropometry, physiology and biochemistry

Introduction

The results of the physical assessments are divided into anthropometry, cardiorespiratory function including exercise performance, muscle function/flexibility and biochemical measures, as set out in Chapter 2. The design of the study required rerandomising the subjects in the advice-only control group to either the leisure or walking groups after 6 months. This meant that no data were available at the 1-year assessment for these subjects. Furthermore, these subjects showed significant changes in both exercise behaviour (see Chapter 5) and a number of physiological variables between baseline and the 10-week and 6-month assessments. As explained in Chapter 5, their results after rerandomisation could not be aggregated with those of the participants originally randomised to the leisure centre and walking groups, and have not been presented in this report.

Statistical analysis

The main analyses involved investigation of differences between study groups at each assessment (10 weeks, 6 months and 1 year) ANCOVA adjusted for baseline values, age and gender, with post-hoc tests with corrections for multiple testing for potential differences between groups. Within study group, changes in outcomes were also analysed using paired *t*-tests. As the 10-week assessment included only a 50% random sample of those who presented at baseline, analysis of only those subjects who presented at all four time-points would have resulted in a much reduced sample. Comparisons were therefore made between baseline and each time-point for subjects available at the two time-points being analysed (completers), and on an ITT basis.

The ITT analysis used observations from the preceding assessment as this was considered to be the most conservative approach. That is, for missing data at the 10-week assessment, baseline observations were used for imputation. At 6 months, 10-week data were used and when 10-week data were unavailable, baseline data were used for imputation of missing data. This method was chosen owing to the reduced sample randomised to the 10-week assessment. At 1 year (for leisure centre and walking subjects), 6-month data were used for imputation of missing data.

Data were also analysed excluding the following:

- those taking β-blockers for all exercise performance outcomes, for example heart rate (resting and exercise)
- those taking blood pressure-lowering medication for analysis of blood pressure measurements
- those taking lipid-lowering medication for analysis of cholesterol and triglycerides.

Results are presented for all available subjects (completers) and on ITT, and excluding those taking medication where applicable. For ease of presentation, only baseline measurements of the primary outcomes (blood pressure and lipids) and tables for ITT analyses of all outcomes in the whole study population are shown in this chapter. Tables for other baseline measurements, completers analyses and exploratory subgroup analyses are shown in Appendix 6 (*Tables 93–136*).

Anthropometry

Baseline measurements for weight, BMI, percentage body fat and waist–hip ratio are shown in *Table 93* (Appendix 6). There were no significant differences between groups for any of the physical characteristics at baseline.

Although women had a significantly lower waist–hip ratio than men at baseline, there was no difference in the waist–hip ratio between study groups or age groups either at baseline or at subsequent assessment points. Men were significantly heavier than women, by almost 13 kg (*t*-test, $p < 0.01$), while women's percentage body fat was significantly greater (*t*-test, $p < 0.01$). Weight, BMI and body composition varied significantly by age group [analysis of variance (ANOVA), $p < 0.01$], with weight decreasing and percentage body fat increasing with age.

Weight and BMI were reduced slightly in all three groups immediately after the exercise programme,

TABLE 38 *Changes in physical characteristics: ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 164)					
Weight (kg)	82.2	81.8	–0.5 (–0.85 to –0.10)	–0.6%	*
BMI	30.1	30.0	–0.1 (–0.31 to –0.03)	–0.1%	*
% Body fat	36.7	36.7	0.0 (–0.23 to 0.31)	0.0%	
Waist–hip ratio	0.88	0.88	0.0 (–0.005 to 0.004)	0.0%	
Walking (*n* = 104)					
Weight (kg)	83.2	82.9	–0.3 (–0.55 to 0.04)	–0.4%	
BMI	30.7	30.6	–0.1 (–0.20 to 0.02)	–0.3%	
% Body fat	38.0	37.6	–0.4 (–0.62 to –0.13)	–1.1%	**
Waist–hip ratio	0.87	0.87	0.0 (–0.004 to 0.004)	0.0%	
Advice (*n* = 156)					
Weight (kg)	82.2	82.0	–0.2 (–0.58 to 0.15)	–0.2%	
BMI	30.4	30.3	–0.1 (–0.20 to 0.06)	–0.3%	
% Body fat	37.6	37.8	0.2 (–0.14 to 0.48)	0.5%	
Waist–hip ratio	0.88	0.89	0.01 (–0.002 to 0.01)	1.1%	
6 months					
Leisure centre (*n* = 317)					
Weight (kg)	83.0	82.8	–0.1 (–0.48 to 0.19)	–0.1%	
BMI	30.7	30.7	0.0 (–0.17 to 0.08)	0.0%	
% Body fat	37.6	37.8	0.2 (–0.03 to 0.39)	0.5%	
Waist–hip ratio	0.88	0.88	0.0 (–0.01 to 0.001)	0.0%	
Walking (*n* = 311)					
Weight (kg)	82.4	82.3	–0.1 (–0.37 to 0.11)	–0.1%	
BMI	30.6	30.5	–0.1 (–0.13 to 0.05)	–0.3%	
% Body fat	37.7	37.9	0.2 (0.03 to 0.40)	0.1%	
Waist–hip ratio	0.87	0.87	0.0 (–0.003 to 0.004)	0.0%	
Advice (*n* = 315)					
Weight (kg)	81.8	81.6	–0.2 (–0.57 to 0.13)	–0.2%	
BMI	30.3	30.2	–0.1 (–0.20 to 0.05)	–0.3%	
% Body fat	37.8	38.1	0.3 (–0.01 to 0.55)	0.8%	
Waist–hip ratio	0.87	0.88	0.01 (–0.003 to 0.005)	1.1%	
1 year					
Leisure centre (*n* = 220)					
Weight (kg)	82.6	82.5	–0.1 (–0.67 to 0.42)	–0.1%	
BMI	30.4	30.3	–0.05 (–0.26 to 0.16)	–0.2%	
% Body fat	37.1	37.6	0.5 (0.23 to 0.90)	1.3%	**
Waist–hip ratio	0.88	0.88	0.0 (–0.001 to 0.001)	0.0%	
Walking (*n* = 193)					
Weight (kg)	80.8	80.9	0.1 (–0.48 to 0.54)	0.2%	
BMI	30.0	30.0	0.0 (–0.17 to 0.21)	0.0%	
% Body fat	37.4	38.1	0.7 (0.29 to 1.11)	1.9%	**
Waist–hip ratio	0.86	0.86	0.0 (–0.001 to 0.01)	0.0%	

** $p < 0.01$, * $p < 0.05$.

but these reductions were significant only in the leisure centre group (paired *t*-test; $p = 0.017$) (*Table 38*, ITT; see *Table 94* in Appendix 6 for completers). The reduction was accounted for by a weight loss of one kg by the men. However, by 6 months, weight loss was attenuated and non-significant in all groups. After adjusting for age, gender and baseline values there were no significant differences between groups in weight or BMI at any assessment.

There was a small but significant decrease in percentage body fat after the exercise programme in walking group participants (*Table 38*;

TABLE 39 *Physical characteristics – comparison of values between groups at each assessment: ITT*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 164	*n* = 160	*n* = 156
Weight (kg)	80.53 (80.04 to 81.03)	80.93 (80.38 to 81.49)	80.73 (80.13 to 81.32)
BMI	30.22 (30.09 to 30.35)	30.33 (30.20 to 30.47)	30.11 (30.18 to 30.45)
% Body fat	37.41 (37.12 to 37.70)	37.06 (36.76 to 37.36)	37.58 (37.28 to 37.88)
Waist–hip ratio	0.88 (0.88 to 0.89)	0.88 (0.88 to 0.89)	0.89 (0.88 to 0.89)
6 months	*n* = 317	*n* = 311	*n* = 315
Weight (kg)	82.28 (81.95 to 82.61)	82.29 (81.95 to 82.63)	82.17 (81.84 to 82.51)
BMI	30.47 (30.35 to 30.59)	30.48 (30.36 to 30.60)	30.44 (30.31 to 30.56)
% Body fat	37.78 (37.53 to 38.04)	37.79 (37.53 to 38.05)	37.83 (37.57 to 38.09)
Waist–hip ratio	0.88 (0.87 to 0.88)	0.88 (0.87 to 0.88)	0.88 (0.87 to 0.88)
1 Year	*n* = 220	*n* = 193	
Weight (kg)	81.72 (81.18 to 82.26)	81.87 (81.26 to 82.48)	
BMI	30.17 (29.96 to 30.37)	30.23 (30.00 to 30.46)	
% Body fat	37.60 (37.22 to 37.97)	37.65 (37.22 to 38.08)	
Waist–hip ratio	0.88 (0.87 to 0.89)	0.88 (0.87 to 0.88)	

Appendix 6, *Table 94*). This was mainly attributable to the women in the group, who showed an absolute decrease in percentage body fat of about 0.7%. After adjustment for age, gender and baseline values at 10 weeks, participants in the walking group had a significantly lower percentage of body fat (36.2%) than participants in the advice-only group (37.1%) (post hoc test $p = 0.03$). By 6 months, percentage body fat was increased in all groups, and significantly for men in the walking group by about 0.6%. Body fat percentage continued to rise significantly for both men and women in the leisure centre and walking groups by 1 year. The initial benefits for the leisure centre and walking groups after completing the exercise programmes were not sustained at 6 months and 1 year, and all groups showed gains in weight, BMI and percentage body fat. *Tables 39* and *95* (Appendix 6) show the physical characteristics for each study group after adjustment for age, gender and baseline values, where there were no significant differences between groups for any physical characteristics at each assessment point.

Physiology

Cardiorespiratory function

Resting heart rate

Heart rate was measured electronically after 5 minutes' rest before the measurement of blood pressure (resting pulse rate). Resting pulse rate was significantly higher at baseline (Appendix 6, *Table 96*) in the age groups 40–44, 45–54 and 65–74 years (ANOVA; post hoc tests, $p = 0.05$ and $p = 0.009$), respectively. Although there were small decreases in resting pulse rate in the leisure centre and walking groups after completing the exercise programmes (*Table 40*; Appendix 6, *Tables 97–99*), no significant differences were observed between groups at any of the time points after adjusting for age, gender and baseline values (*Table 41*; Appendix 6, *Tables 100* and *101*), irrespective of the use of β-blockers.

Blood pressure

At baseline, blood pressure increased progressively with age and was significantly higher in men than women (*t*-tests, $p < 0.001$ both for all subjects and excluding those known to be taking blood pressure-lowering medication, reflecting the difference in referral criteria (*Table 42*). Significant reductions in systolic and diastolic blood pressure were seen in all groups at each assessment point compared with baseline (*Table 43*; Appendix 6, *Table 102*), except for those not taking blood pressure-lowering medication in the walking group at the 10-week assessment (Appendix 6, *Tables 103* and *104*). For the leisure centre and walking groups these reductions were larger over time. After adjusting for age, gender and baseline values there were no significant differences between groups at any assessment point (*Table 44*; Appendix 6, *Tables 105* and *106*).

At entry to the study, 424 participants had hypertension, as defined by baseline systolic blood pressure of at least 140 mmHg and/or diastolic blood pressure of at least 90 mmHg. Of these, just

TABLE 40 *Changes in resting pulse: ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 164)					
Resting pulse	65.8	64.9	–0.9 (–1.92 to 0.21)	–1.4%	
Walking (*n* = 160)					
Resting pulse	65.2	65.1	–0.1 (–0.88 to 0.69)	–0.2%	
Advice (*n* = 156)					
Resting pulse	65.3	65.4	0.1 (–0.75 to 0.97)	0.2%	
6 months					
Leisure centre (*n* = 316)					
Resting pulse	65.7	65.6	–0.1 (–0.95 to 0.68)	–0.2%	
Walking (*n* = 311)					
Resting pulse	64.7	64.9	0.2 (–0.44 to 0.85)	0.3%	
Advice (*n* = 314)					
Resting pulse	65.8	66.0	0.2 (–0.52 to 0.96)	0.3%	
1 year					
Leisure centre (*n* = 218)					
Resting pulse	65.5	64.9	–0.6 (–1.86 to 0.68)	–0.9%	
Walking (*n* = 191)					
Resting pulse	64.0	65.3	1.3 (0.19 to 2.43)	2.0%	*

* $p < 0.05$.

TABLE 41 *Resting pulse: comparison of values between groups at each assessment: ITT*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 164	*n* = 160	*n* = 156
Resting pulse	64.7 (63.8 to 65.5)	65.0 (64.1 to 65.9)	65.7 (64.7 to 66.6)
6 months	*n* = 316	*n* = 311	*n* = 314
Resting pulse	65.3 (64.5 to 66.0)	65.2 (64.4 to 65.9)	65.7 (65.0 to 66.4)
1 year	*n* = 218	*n* = 191	
Resting pulse	64.5 (63.4 to 65.6)	65.5 (64.3 to 66.8)	

TABLE 42 *Baseline measurements for blood pressure*

	SBP (all cases)	DBP (all cases)	SBP (cases not known to be taking any BP-lowering medication)	DBP (cases not known to be taking any BP-lowering medication)
	Mean (SEM) (*n*)	Mean (SEM) (*n*)	Mean (SEM) (*n*)	Mean (SEM) (*n*)
Leisure centre	136.3 (1.12) (317)	84.2 (0.55) (317)	132.9 (1.46) (194)	83.0 (0.73) (194)
Walking	136.1 (1.22) (311)	84.3 (0.57) (311)	131.3 (1.51) (192)	82.2 (0.69 (192)
Advice	135.4 (1.19) (314)	84.4 (0.62) (314)	130.2 (1.48) (209)	82.4 (0.79) (209)
Female	132.8 (0.84) (635)	82.1 (0.38) (635)	128.1 (1.01) (413)	80.6 (0.48) (413)
Male	142.5 (1.08) (307)	88.7 (0.60) (307	138.9 (1.46) (182)	86.9 (0.79) (182)
Age (years)				
40–44	124.9 (2.20) (81)	82.4 (1.22) (81)	121.3 (2.13) (64)	80.9 (1.34) (64)
45–54	129.1 (0.98) (338)	83.3 (0.56) (338)	125.8 (1.19) (234)	81.6 (0.68) (234)
55–64	138.9 (1.11) (316)	85.0 (0.57) (316)	134.8 (1.42) (195)	83.4 (0.72) (195)
65–74	146.9 (1.47) (207)	85.4 (0.71) (207)	144.2 (2.32) (102)	84.4 (1.08) (102)

TABLE 43 *Changes in blood pressure: ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 164)					
SBP	136.0	132.9	–3.1 (–4.90 to –1.35)	–2.3%	**
DBP	83.9	81.6	–2.4 (–3.34 to –1.46)	–2.9%	**
Walking (*n* = 160)					
SBP	135.8	133.5	–2.3 (–3.92 to –0.75)	–1.7%	**
DBP	84.4	83.4	–1.0 (–1.96 to 0.04)	–1.2%	^
Advice (*n* = 156)					
SBP	135.7	131.9	–3.9 (–5.50 to –2.22)	–2.9%	**
DBP	85.0	82.9	–2.2 (–3.23 to –1.11)	–2.6%	**
6 months					
Leisure centre (*n* = 317)					
SBP	136.3	132.8	–3.5 (–4.87 to –2.18)	–2.6%	**
DBP	84.2	81.5	–2.7 (–3.40 to –1.94)	–3.2%	**
Walking (*n* = 311)					
SBP	136.1	133.4	–2.7 (–3.92 to –1.48)	–2.0%	**
DBP	84.3	82.3	–2.0 (–2.72 to –1.26)	–2.4%	**
Advice (*n* = 314)					
SBP	136.4	132.6	–2.9 (–4.24 to –1.56)	–2.1%	**
DBP	84.4	82.2	–2.1 (–2.88 to –1.39)	–2.5%	**
1 year					
Leisure centre (*n* = 220)					
SBP	137.1	130.8	–6.2 (–8.27 to –4.20)	–4.5%	**
DBP	84.5	80.0	–4.5 (–5.54 to –3.44)	–5.3%	**
Walking (*n* = 192)					
SBP	134.6	128.8	–5.8 (–7.78 to –3.73)	–4.3%	**
DBP	83.9	79.4	–4.5 (–5.57 to –3.39)	–5.4%	**

** $p < 0.01$, ^ $p = 0.06$.

TABLE 44 *Blood pressure: comparison of values between groups at each assessment: ITT*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 164	*n* = 160	*n* = 156
SBP	132.9 (131.3 to 134.4)	134.4 (132.7 to 136.0)	132.0 (130.3 to 133.6)
DBP	82.0 (81.1 to 82.9)	84.0 (83.0 to 85.0)	82.5 (81.5 to 83.5)
6 months	*n* = 317	*n* = 311	*n* = 314
SBP	132.5 (131.3 to 133.8)	134.1 (132.8 to 135.4)	133.3 (132.0 to 134.6)
DBP	81.6 (80.8 to 82.3)	82.7 (81.9 to 83.4)	82.3 (81.6 to 83.1)
1 Year	*n* = 220	*n* = 192	
SBP	130.7 (128.9 to 132.5)	130.7 (128.7 to 132.7)	
DBP	80.2 (79.2 to 81.1)	80.3 (79.2 to 81.4)	

over half were taking blood pressure-lowering medication. Subgroup analysis was undertaken of the blood pressure changes in the hypertensive group at 6 months. These were somewhat larger than, but parallel to, the changes in the whole population by study group, irrespective of the use of medication. Although there were numerically greater changes in the leisure centre and walking groups than the advice group, there were no significant between-group differences after

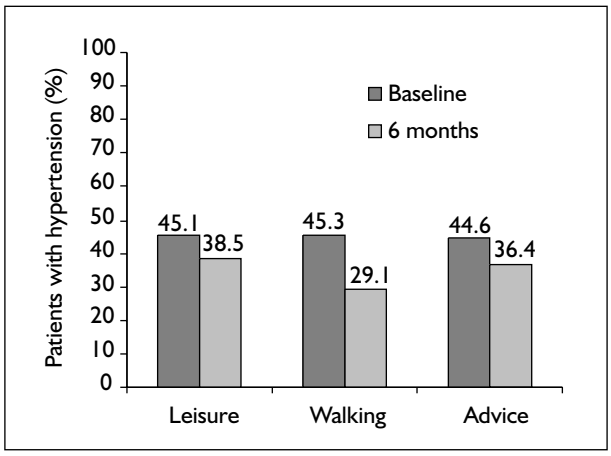

FIGURE 6 *Percentage of participants with hypertension at baseline and 6 months*

adjusting for age, gender and baseline values. There were reductions in the proportions with hypertension in each study group at 6 months, as shown in *Figure 6*, but no significant between-group differences in the change from baseline by χ^2 tests.

Lung function

FEV_1, FVC and PEF were not significantly different between groups at baseline (Appendix 6, *Table 107*). All measures of lung function decreased significantly with age (ANOVA; post hoc tests with Bonferroni correction, $p < 0.001$) and all measurements except for the FEV_1/FVC ratio differed significantly between men and women (*t*-tests, $p < 0.001$). The advice group had a slight but significant increase in FEV_1/FVC ratio at 10 weeks and both the advice and leisure centre groups at 6 months, owing to a greater decline in FVC than in FEV_1, but there was no significant change in PEF (*Table 45*; and Appendix 6, *Table 108*). Between-group analysis showed no differences between study groups for each measurement at any time-point (*Table 46*; and Appendix 6, *Table 109*).

Exercise performance

Two tests were used to allow for any bias due to the specific training effects of either walking or cycling (see Chapter 2). Eligible subjects were allocated alternately to undertake one or other of these tests. In total, 447/943 (47.4%) were allocated to the cycle test and 412/943 (43.7%) to the walking test.

Cycle ergometer

The outcomes measured were:

- heart rate measured at highest workload and minute completed (end heart rate)
- rating of perceived exertion (RPE), (Borg scale, 6 = rest to 20 = exhausted)
- number of minutes cycled (approximately).

The heart rate comparison was based on the average rates attained at the highest identical workloads across two assessment periods. Thus, if a participant completed 3 minutes for a particular workload, the average of the heart rates at minute 2 and minute 3 was calculated. However, if a participant completed 2 minutes at workload 2 at baseline, and 3 minutes at workload 2 at the 10-week assessment, the heart rates recorded after 2 minutes at workload 2 at each assessment were compared. If the participant did not complete all 3 minutes of a workload, the heart rate recorded for the highest minute achieved was used.

At baseline there were no significant differences between study groups for end heart rate, perceived exertion or number of minutes cycled (Appendix 6, *Tables 110* and *111*). End heart rate was significantly higher for men than for women, including all subjects (men: 120.3; women: 115.5; *t*-test $p = 0.004$) and excluding cases taking β-blockers (men: 122.5, women: 117.8; *t*-test, $p = 0.004$). Heart rate also varied significantly by age both for all subjects and excluding those on β-blockers (ANOVA with post hoc Bonferroni correction for multiple comparisons between groups, $p < 0.001$).

The highest level achieved was on average between workload 3, minutes 2 and 3 for the leisure group and between workload 3, minute 3 and workload 4, minute 1 for the walking and advice-only groups. There were no significant differences between men and women either for the highest level achieved or for perceived exertion.

When tested on the cycle ergometer following the intervention period, participants in the leisure centre group were able to cycle for significantly longer than at baseline before the test had to be terminated (*Table 47*; Appendix 6, *Tables 112* and *113*). ANCOVA showed that at 10 weeks, subjects in the leisure centre group cycled for significantly longer than those in the advice-only group after adjusting for age, gender and baseline values (*Tables 47* and *48*; Appendix 6, *Tables 114* and *115*), although significance was lost when subjects taking β-blockers were excluded from the analysis.

An improvement in exercise performance was supported by a significantly lower heart rate measured at the highest comparable workload at

TABLE 45 *Changes in measures of lung function: ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (n = 163)					
FEV_1	2.42	2.43	0.01 (–0.005 to 0.04)	0.4%	
FVC	2.85	2.84	0.01 (–0.04 to 0.02)	0.4%	
FEV_1/FVC	0.85	0.85	0.00 (–0.007 to 0.02)	0.0%	
PEF (n = 148)	425.2	429.2	3.91 (–4.49 to 12.31)	0.92%	
Walking (n = 156)					
FEV_1	2.32	2.33	0.01 (–0.01 to 0.03)	0.4%	
FVC	2.74	2.75	0.01 (–0.01 to 0.04)	0.4%	
FEV_1/FVC	0.85	0.85	0.00 (–0.01 to 0.01)	0.0%	
PEF (n = 144)	407.6	404.2	–3.45 (13.52 to 6.62)	0.8%	
Advice (n = 152)					
FEV_1	2.32	2.33	0.01 (–0.02 to 0.03)	0.4%	
FVC	2.75	2.72	–0.03 (–0.05 to –0.01)	–1.1%	**
FEV_1/FVC	0.85	0.86	0.01 (0.002 to 0.01)	1.2%	*
PEF (n = 76)	396.9	395.4	–1.55 (–10.67 to 7.57)	–0.4%	
6 months					
Leisure centre (n = 313)					
FEV_1	2.37	2.37	0.00 (–0.02 to 0.01)	0.0%	
FVC	2.80	2.77	–0.03 (–0.06 to –0.005)	–1.1%	*
FEV_1/ FVC	0.85	0.86	0.01 (0.0004 to 0.01)	1.2%	*
PEF (n = 285)	410.8	408.1	–2.68 (–8.67 to 3.30)	–0.7%	
Walking (n = 306)					
FEV_1	2.33	2.33	0.00 (–0.02 to 0.01)	0.0%	
FVC	2.76	2.74	–0.02 (–0.04 to 0.01)	0.7%	
FEV_1/FVC	0.85	0.85	0.00 (–0.01 to 0.01)	0.0%	
PEF (n = 278)	399.9	409.9	10.01 (–10.35 to 30.31)	2.5%	
Advice (n = 310)					
FEV_1	2.33	2.31	–0.02 (–0.04 to –0.001)	–0.9%	*
FVC	2.74	2.69	–0.05 (–0.08 to –0.03)	–1.8%	**
FEV_1/FVC	0.86	0.87	0.01 (0.01 to 0.02)	1.2%	**
PEF (n = 280)	402.7	404.7	2.00 (–4.30 to 8.29)	0.5%	
1 year					
Leisure centre (n = 215)					
FEV_1	2.41	2.37	0.04 (–0.07 to –0.01)	1.7%	**
FVC	2.85	2.76	0.09 (–0.12 to –0.05)	3.2%	**
FEV_1/FVC	0.85	0.86	0.01 (0.002 to 0.02)	1.2%	*
PEF (n = 192)	412.3	405.6	6.73 (–17.80 to 4.34)	1.6%	
Walking (n = 183)					
FEV_1	2.35	2.30	0.05 (–0.07 to –0.02)	2.1%	**
FVC	2.76	2.69	–0.07 (–0.11 to –0.04)	–2.5%	**
FEV_1/FVC	0.85	0.86	0.01 (0.001 to –0.02)	1.2%	
PEF (n = 192)	400.5	403.0	2.56 (–7.61 to 12.72)	0.6%	

** $p < 0.01$, * $p < 0.05$.

the 10-week and 6-month time-points compared with baseline in all three groups. At the 1-year time-point, heart rate was still about 3–4 bpm lower than at baseline (*Table 49*; Appendix 6, *Tables 116–118*). The highest workload used for comparative purposes was that obtained on the baseline test. In other words, subjects were able to cycle for longer at the same workloads after the training intervention than before. The Borg scale indicated that subjects in the leisure centre group reported a significantly lower RPE at a comparable power output after 10 weeks. At 6 months and 1 year, perceived exertion was similar to baseline. Heart rate and perceived exertion were similar between groups at each time-

TABLE 46 *Lung function – comparison of values between groups at each assessment: ITT*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 163	*n* = 156	*n* = 152
FEV_1	2.38 (2.36 to 2.40)	2.38 (2.36 to 2.40)	2.36 (2.34 to 2.39)
FVC	2.78 (2.75 to 2.81)	2.81 (2.78 to 2.84)	2.76 (2.73 to 2.79)
FEV_1/FVC	0.86 (0.85 to 0.86)	0.85 (0.84 to 0.86)	0.86 (0.85 to 0.87)
PEF	417.6 (408.3 to 426.9) (*n* = 148)	407.2 (397.4 to 417.1) (*n* = 144)	409.1 (399.4 to 418.7) (*n* = 138)
6 months	*n* = 313	*n* = 306	*n* = 310
FEV_1	2.35 (2.33 to 2.37)	2.35 (2.33 to 2.37)	2.33 (2.31 to 2.35)
FVC	2.74 (2.71 to 2.77)	2.76 (2.73 to 2.78)	2.72 (2.69 to 2.74)
FEV_1/FVC	0.86 (0.85 to 0.87)	0.85 (0.84 to 0.86)	0.86 (0.86 to 0.87)
PEF	407.3 (394.0 to 420.7) (*n* = 285)	415.6 (402.0 to 429.3) (*n* = 278)	410.6 (396.9 to 424.3) (*n* = 280)
1 year	*n* = 215	*n* = 183	
FEV_1	2.34 (2.31 to 2.37)	2.35 (2.32 to 2.38)	
FVC	2.73 (2.69 to 2.77)	2.75 (2.71 to 2.79)	
FEV_1/FVC	0.86 (0.85 to 0.87)	0.86 (0.85 to 0.87)	
PEF	407.3 (396.7 to 418.0) (*n* = 192)	415.6 (403.7 to 427.5) (*n* = 162)	

TABLE 47 *Cycle ergometer – number of minutes cycled: ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 77)	8.19	9.09	0.90 (0.48 to 1.31)	11.0%	**
Walking (*n* =69)	9.30	9.32	0.01 (–0.36 to 0.39)	0.1%	
Advice (*n* =63)	9.10	9.03	–0.06 (–0.36 to 0.24)	–0.7%	
6 months					
Leisure centre (*n* =142)	8.55	8.69	0.14 (–0.19 to 0.47)	1.6%	
Walking (*n* =125)	9.01	9.10	0.10 (–0.19 to 0.38)	1.1%	
Advice (*n* =130)	8.92	9.10	0.18 (–0.07 to 0.44)	2.0%	
1 year					
Leisure centre (*n* =91)	8.86	9.08	0.22 (–0.28 to 0.72)	2.5%	
Walking (*n* =72)	9.35	9.32	–0.03 (–0.49 to 0.44)	0.3%	

** $p < 0.01$.

TABLE 48 *Cycle ergometer – number of minutes cycled; comparison of values between groups at each assessment: ITT*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 77	*n* = 69	*n* = 63
Minutes cycled	9.65 (9.31 to 9.99)[a]	8.92 (8.52 to 9.31)	8.87 (8.49 to 9.25)[a]
6 months	*n* = 142	*n* = 125	*n* = 130
Minutes cycled	8.86 (8.59 to 9.14)	8.97 (8.65 to 9.29)	9.08 (8.78 to 9.38)
1 year	*n* = 91	*n* = 72	
Minutes cycled	9.20 (8.79 to 9.61)	9.40 (8.86 to 9.94)	

[a] Significant difference between leisure centre and advice groups ($p = 0.024$) after adjusting for age, gender and baseline values and multiple testing (Bonferroni correction).

TABLE 49 *Cycle ergometer – heart rate at highest comparable workload and perceived exertion: ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 81)					
Heart rate	115.1	111.2	–3.9 (–6.97 to –0.78)	–3.4%	*
Borg	(14.8)	(14.2)	–0.6 (–0.96 to –0.18)	–4.1%	**
Walking (*n* = 72)					
Heart rate	115.1	112.3	–2.8 (–4.96 to –0.72)	–2.4%	**
Borg	(14.8)	(14.6)	–0.2 (–0.47 to 0.24)	–1.4%	
Advice (*n* = 69)					
Heart rate	114.2	112.1	–2.1 (–3.83 to –0.44)	–1.8%	*
Borg	(14.8)	(14.5)	–0.3 (–0.60 to 0.04)	–2.0%	
6 months					
Leisure centre (*n* = 152)					
Heart rate	114.2	111.2	–3.0 (–4.87 to –1.09)	–2.6%	**
Borg	(14.7)	(14.5)	–0.2 (–0.51 to 0.06)	–1.4%	
Walking (*n* = 133)					
Heart rate	116.1	114.0	–2.1 (–3.54 to –0.67)	–1.8%	**
Borg	(14.8)	(14.8)	0.0 (–0.30 to 0.28)	0.0%	
Advice (*n* = 139)					
Heart rate	115.2	111.9	–3.3 (–5.28 to –1.28)	–2.9%	**
Borg	(14.9)	(14.7)	–0.2 (–0.51 to 0.10)	–1.3%	
1 year					
Leisure centre (*n* = 106)					
Heart rate	113.3	108.9	–4.4 (–7.20 to –1.62)	–3.9%	**
Borg	(14.5)	(14.3)	–0.2 (–0.68 to 0.10)	–1.4%	
Walking (*n* = 82)					
Heart rate	114.3	111.5	–2.8 (–5.42 to –0.22)	–2.4%	*
Borg	(14.5)	(14.3)	–0.2 (–0.74 to 0.13)	–1.4%	

** $p < 0.01$, * $p < 0.05$.

point after adjustments (*Table 50*; Appendix 6, *Tables 119* and *120*).

Shuttle walking test

Outcomes measured were:

- heart rate measured at highest workload and minute completed (end heart rate)
- RPE (Borg scale, 6 = rest to 20 = exhausted)
- total distance covered.

As for the cycle ergometer test, to compare the outcomes of the walking test at different assessments, the heart rate was compared at the highest identical completed level across two assessment periods. For example, if a person achieved level 8 at baseline and level 10 at the 10-week assessment, the heart rates recorded at level 8 for each assessment were compared. If a participant attained level 8 at two time-points, but completed 50 shuttles at baseline and 52 at the second time-point, then the heart rates for the previous level were compared.

At baseline, patients in the walking group were able to walk the farthest before the test had to be terminated, but there were no significant differences in distance covered, end heart rate or perceived exertion between groups. Men, however, were able to walk at least 86 metres more than women, whether they were taking β-blockers or not (*t*-test, $p < 0.001$) (Appendix 6, *Tables 121* and *122*). End heart rate and the distance walked decreased significantly with age (ANOVA, $p < 0.001$).

Participants in all groups showed an improvement in exercise performance, as indicated by an increase in the distance walked before the test had to be terminated (*Table 51*; Appendix 6, *Tables 123–124*). This involved the completion both of more shuttles (same intensity) and of more

TABLE 50 *Cycle ergometer – heart rate at highest comparable workload and perceived exertion; comparison of values between groups at each assessment: ITT*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 81	*n* = 72	*n* = 69
Heart rate	110.7 (108.6 to 112.8)	110.7 (108.2 to 113.2)	113.0 (110.6 to 115.4)
Borg	14.2 (13.87 to 14.5)	14.4 (14.03 to 14.81)	14.6 (14.2 to 14.9)
6 months	*n* = 152	*n* = 133	*n* = 139
Heart rate	111.8 (110.2 to 113.5)	112.7 (110.8 to 114.6)	111.7 (109.9 to 113.5)
Borg	14.5 (14.23 to 14.78)	14.7 (14.40 to 15.02)	14.7 (14.4 to 15.0)
1 year	*n* = 106	*n* = 82	
Heart rate	106.4 (107.2 to 111.6)	109.9 (107.0 to 112.8)	
Borg	14.3 (13.8 to 14.8)	14.3 (13.8 to 14.8)	

TABLE 51 *Shuttle walking test – total distance covered (m): ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 62)	425.2	455.2	30.00 (9.36 to 50.64)	7.1%	**
Walking (*n* = 74)	416.5	430.0	13.51 (–14.43 to 41.45)	3.2%	
Advice (*n* = 68)	414.6	425.0	10.44 (–8.41 to 29.30)	2.5%	
6 months					
Leisure centre (*n* = 124)	416.4	439.6	23.23 (8.19 to 38.26)	5.6%	**
Walking (*n* = 141)	422.4	443.5	21.06 (4.87 to 37.26)	5.0%	*
Advice (*n* = 138)	411.6	420.7	9.13 (–5.74 to 24.00)	2.2%	
1 year					
Leisure centre (*n* = 77)	429.0	444.0	15.07 (–16.15 to 62.10)	3.5%	
Walking (*n* = 81)	427.9	462.8	34.94 (–5.69 to 64.19)	8.2%	

** $p < 0.01$, * $p < 0.05$.

TABLE 52 *Shuttle walking test – total distance covered (m); comparison of values between groups at each assessment: ITT*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 62	*n* = 74	*n* = 68
Total distance	456.7 (431.3 to 482.1)	436.6 (413.9 to 459.3)	434.2 (409.5 to 459.0)
6 months	*n* = 124	*n* = 141	*n* = 138
Total distance	445.8 (428.8 to 462.7)	448.4 (432.8 to 464.1)	434.1 (417.8 to 450.3)
1 year	*n* = 77	*n* = 81	
Total distance	455.2 (425.4 to 485.0)	486.6 (456.2 to 517.0)	

levels (increased intensity). The leisure centre group covered significantly more distance (at least 30 m farther) when tested after 10 weeks compared with baseline, and both the walking and leisure centre groups covered significantly more distance (between 20 and 59 m farther) at 6 months. At 1 year, the two groups walked at least 15 m farther than at baseline. No measures were significantly different between groups at each time-point after adjusting for age, gender and baseline values (*Table 52*; Appendix 6, *Tables 125* and *126*).

TABLE 53 *Shuttle walking test – heart rate at highest comparable level and perceived exertion: ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 62)					
Heart rate	116.8	113.6	–3.2 (–5.48 to –0.91)	–2.7%	**
Borg	(13.0)	(12.7)	–0.3 (–0.73 to 0.12)	–2.3%	
Walking (*n* = 74)					
Heart rate	116.8	115.3	–1.4 (–3.35 to 0.49)	–1.2%	
Borg	(12.4)	(12.4)	0.0 (–0.26 to 0.42)	0.0%	
Advice (*n* = 68)					
Heart rate	119.1	117.1	–2.0 (–3.43 to –0.66)	–1.7%	**
Borg	(13.0)	(12.6)	–0.4 (–0.71 to –0.09)	–3.1%	*
6 months					
Leisure centre (*n* = 124)					
Heart rate	116.1	113.8	–2.3 (–3.76 to –0.76)	–2.0%	**
Borg	(12.9)	(12.4)	–0.5 (–0.73 to –0.25)	–3.4%	**
Walking (*n* = 141)					
Heart rate	117.8	116.0	–1.8 (–3.32 to –0.33)	–1.5%	*
Borg	(12.5)	(12.5)	0.0 (–0.27 to 0.22)	0.0%	
Advice (*n* = 138)					
Heart rate	114.7	113.7	–1.0 (–3.34 to 1.31)	–0.9%	
Borg	(12.6)	(12.4)	–0.2 (–0.54 to 0.19)	–1.6%	
1 year					
Leisure centre (*n* = 77)					
Heart rate	112.7	110.1	–2.6 (–6.67 to 0.48)	–2.3%	
Borg	(12.6)	(12.4)	–0.2 (–0.72 to 0.28)	–1.6%	
Walking (*n* = 81)					
Heart rate	116.3	113.8	–2.5 (–5.21 to 0.20)	–2.1%	
Borg	(12.2)	(11.8)	–0.4 (–0.87 to 0.08)	–3.3%	

** $p < 0.01$, * $p < 0.05$.

Again, an improvement in exercise performance was confirmed by significantly lower heart rates measured at the highest comparable part of the walking test compared with baseline in all three groups. There were significant decreases in end heart rates in the leisure centre and advice-only participants at 10 weeks, and leisure centre and walking participants at 6 months, irrespective of β-blocker use (*Table 53*; Appendix 6, *Tables 127–129*). Again, there were no significant differences between the groups after adjustments (*Table 54*; Appendix 6, *Tables 130* and *131*).

Muscle function and flexibility

Baseline measurements for isometric knee extensor strength (IKES), leg extensor power (LEP), power relative to weight and shoulder abduction are shown in *Table 132* (Appendix 6).

Isometric knee extensor strength

IKES declined significantly with increasing age at baseline and men were significantly stronger than women ($p < 0.0001$) (Appendix 6, *Table 132*). Leisure centre and walking group participants had significant increases in IKES after the exercise programme, which were not sustained over time (*Table 55*; Appendix 6, *Table 133*). After adjustments for age, gender and baseline values, there were no significant differences in IKES between groups at each assessment point (*Table 56*; Appendix 6, *Table 134*).

Leg extensor power

As for strength, both absolute LEP and power relative to weight declined significantly with increasing age and were significantly greater in men than women (Appendix 6, *Table 132*). Significant increases in power over time were seen in all groups, although to a consistently greater extent in leisure centre group than walking group participants (*Table 55*; Appendix 6, *Table 133*). At 10 weeks, after adjusting for age, gender and baseline values, LEP and relative power in the leisure centre group (177.6 W; 2.19 W kg^{-1}) were

TABLE 54 *Shuttle walking test – heart rate at highest comparable level and perceived exertion; comparison of values between groups at each assessment: ITT*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 62	*n* = 74	*n* = 68
Heart rate	114.0 (112.0 to 116.0)	116.0 (114.2 to 117.8)	115.8 (113.8 to 117.7)
Borg	12.5 (12.09 to 12.85)	12.8 (12.47 to 13.16)	12.5 (12.10 to 12.85)
6 months	*n* = 124	*n* = 141	*n* = 138
Heart rate	113.9 (112.0 to 115.8)	114.6 (112.8 to 116.3)	114.3 (112.5 to 116.1)
Borg	12.2 (11.86 to 12.47)	12.6 (12.32 to 12.88)	12.3 (12.04 to 12.62)
1 year	*n* = 77	*n* = 81	
Heart rate	111.0 (108.1 to 113.9)	111.6 (108.6 to 114.6)	
Borg	12.4 (11.90 to 12.80)	11.9 (11.43 to 12.35)	

significantly greater than in the advice-only group (165.1 W; 2.04 W kg^{-1}) (*Table 56*; Appendix 6, *Table 134*). By 6 months and 1 year, there were no differences between groups after adjustments, but at 1 year LEP was about 21 W more for the leisure centre group and 15 W more for the walking group compared with baseline.

Flexibility: shoulder abduction

At baseline, shoulder abduction varied significantly by age, but not by gender or study group (Appendix 6. *Table 132*). Modest but significant improvements were seen in the walking group after the exercise programme (*Table 55*; Appendix 6, *Table 133*). Measurements in all groups were similar over time (*Tables 55* and *56*; Appendix 6, *Tables 133* and *134*).

Biochemistry

As noted in Chapter 2, only a minority of blood samples were taken fasting, although an attempt was made to carry out subsequent assessments and hence blood tests at the same time of day as for the first assessment. Baseline measurements for total cholesterol, HDL-cholesterol, total cholesterol/HDL-cholesterol ratio, LDL-cholesterol and triglycerides are shown in *Table 57*. At baseline, HDL-cholesterol was significantly higher for walking group participants than for those in the leisure centre group (ANOVA; post hoc tests with Bonferroni correction, $p = 0.006$) (*Table 57*). All measures varied significantly between age groups (*Table 57*) (ANOVA; post hoc tests with Bonferroni correction, $p < 0.05$ to $p < 0.001$). Women had significantly higher values for total cholesterol and HDL-cholesterol (*t*-test, $p < 0.001$), and men had significantly higher triglycerides (*t*-test, $p < 0.001$). Measurements of triglycerides for each group were lower at subsequent time-points, although not significantly so, but significant, albeit small, reductions in total cholesterol and LDL-cholesterol immediately after the exercise programme were maintained over time. Thus, at the 10-week assessment, participants in the leisure centre and advice-only group had significant 2.8% (by ITT) reductions in their levels of LDL-cholesterol (*Table 58*; Appendix 6, *Table 135*), but there were no differences between groups after adjustments. At 6 months, total cholesterol and LDL-cholesterol and cholesterol/HDL ratios were reduced from baseline in all groups. After adjustment for age, gender and baseline values, cholesterol was significantly lower in walking group participants (5.42 mmol l^{-1}) than in leisure centre group participants (5.68 mmol l^{-1}) ($p = 0.007$ after post hoc Bonferroni correction for multiple comparisons), by completers analysis, but the significance was lost on ITT analysis (*Table 59*; Appendix 6, *Table 136*). By 1 year, there was a further improvement in cholesterol levels for both study groups, apart from a reduction in HDL-cholesterol in the walking group. Triglyceride levels had decreased to lower than baseline in both groups. Completers analysis at 1 year, after adjustments, showed a significantly higher total cholesterol/HDL-cholesterol ratio in the walking group (4.37) than in the leisure centre group (4.11) ($p = 0.023$ after Bonferroni correction for multiple comparisons), although this was not confirmed on ITT analysis (*Table 59*; Appendix 6, *Table 136*). Subanalysis excluding 18 cases who were taking lipid-lowering medication showed no differences in results and therefore these are not presented.

TABLE 55 *Changes in muscle function and flexibility: ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 162)					
IKES (N) (*n* = 140)	258.3	268.9	10.6 (0.71 to 20.47)	4.1%	*
LEP (W)	155.1	168.6	13.4 (7.78 to 19.10)	8.6%	**
LEP (W kg^{-1})	1.9	2.0	0.2 (0.12 to 0.25)	10.5%	**
Shoulder abduction	143.6	144.4	0.8 (–1.10 to 2.73)	0.1%	
Walking (*n* = 160)					
IKES (N) (*n* = 142)	268.0	271.3	3.3 (–5.84 to 12.44)	1.2%	
LEP (W)	156.4	162.4	6.1 (1.22 to 10.92)	3.9%	*
LEP (W kg^{-1})	1.9	2.0	0.1 (0.03 to 0.14)	5.3%	**
Shoulder abduction	143.2	145.8	2.6 (0.58 to 4.59)	1.8%	*
Advice (*n* = 154)					
IKES (N) (*n* = 134)	262.5	261.3	–1.2 (–9.35 to 6.99)	0.5%	
LEP (W)	161.9	166.5	4.6 (1.32 to 7.78)	2.8%	**
LEP (W kg^{-1})	1.9	2.0	0.1 (0.03 to 0.11)	5.3%	**
Shoulder abduction	144.4	143.9	–0.4 (–2.05 to 1.16)	–0.3%	
6 months					
Leisure centre (*n* = 315)					
IKES (N) (*n* = 272)	252.7	253.2	0.5 (–7.49 to 8.49)	0.2%	
LEP (W)	153.2	166.2	13.4 (9.68 to 17.10)	8.7%	**
LEP (W kg^{-1})	1.8	2.0	0.2 (0.13 to 0.21)	11.1%	**
Shoulder abduction	143.9	145.1	1.2 (–0.30 to 2.71)	0.8%	
Walking (*n* = 311)					
IKES (N) (*n* = 265)	263.6	260.6	–2.9 (–9.97 to 4.14)	–1.1%	
LEP (W)	157.7	162.8	5.1 (1.91 to 8.28)	3.2%	*
LEP (W kg^{-1})	1.9	2.0	0.1 (0.03 to 0.11)	5.3%	**
Shoulder abduction	144.2	145.2	1.0 (–0.47 to 2.55)	0.7%	
Advice (*n* = 312)					
IKES (N) (*n* = 267)	263.8	261.4	–2.5 (–10.48 to 5.55)	–0.9%	
LEP (W)	157.8	168.0	10.1 (–1.03 to 21.19)	6.4%	
LEP (W kg^{-1})	1.9	2.0	0.1 (–0.01 to 0.30)	5.3%	
Shoulder abduction	143.3	143.4	0.1 (–1.65 to 1.89)	0.1%	
1 year					
Leisure centre (*n* = 220)					
IKES (N) (*n* = 186)	258.6	253.7	–4.9 (–16.22 to 6.38)	–1.9%	
LEP (W)	156.9	177.4	20.5 (15.34 to 25.64)	13.1%	**
LEP (W kg^{-1})	1.9	2.2	0.3 (0.19 to 0.31)	15.8%	**
Shoulder abduction	144.3	143.8	–0.5 (–3.01 to 2.09)	–0.3%	
Walking (*n* = 193)					
IKES (N) (*n* = 156)	254.8	246.8	–8.0 (–21.27 to 5.22)	–3.1%	
LEP (W)	158.1	169.8	11.7 (5.81 to 17.57)	7.4%	**
LEP (W kg^{-1})	2.0	2.1	0.2 (0.09 to 0.23)	10.0%	**
Shoulder abduction	143.4	142.8	–0.6 (–3.39 to 2.11)	–0.4%	

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** $p < 0.01$. * $p < 0.05$.

Summary

There were slight reductions in weight in all three study groups at 10 weeks and in percentage body fat in the walking group, but these changes were not sustained at subsequent assessments.

There were significant reductions in systolic and diastolic blood pressure in all groups at each assessment point compared with baseline. Reductions were largest at 1 year in the leisure centre and walking groups.

TABLE 56 *Muscle function and flexibility – comparison of values between groups at each assessment: ITT*

	Leisure centre Mean (95% CI) (*n*)	Walking Mean (95% CI) (*n*)	Advice Mean (95% CI) (*n*)
10 weeks	*n* = 162	*n* = 160	*n* = 154
IKES (N)	277.9 (268.9 to 286.8) (140)	275.0 (265.5 to 284.6) (142)	265.1 (255.7 to 274.6) (134)
LEP (W)	173.6 (168.9 to 178.3)	165.6 (160.6 to 170.5)	164.6 (159.7 to 169.5)
LEP (W kg^{-1})	2.10 (2.04 to 2.16)	1.99 (1.93 to 2.05)	1.98 (1.92 to 2.04)
Shoulder abduction	144.7 (143.0 to 146.5)	146.2 (144.4 to 148.1)	143.6 (141.7 to 145.4)
6 months	*n* = 315	*n* = 311	*n* = 312
IKES (N)	264.5 (257.1 to 271.9) (274)	263.8 (256.0 to 271.7) (265)	267.1 (259.2 to 275.0) (267)
LEP (W)	172.7 (165.4 to 180.0)	163.8 (156.2 to 171.4)	167.3 (159.8 to 174.9)
LEP (W kg^{-1})	2.08 (1.98 to 2.18)	1.98 (1.87 to 2.08)	2.03 (1.93 to 2.13)
Shoulder abduction	145.5 (144.0 to 147.1)	145.4 (143.7 to 147.0)	143.4 (141.8 to 145.0)
1 year	*n* = 220	*n* = 193	
IKES (N)	260.7 (249.7 to 271.7) (186)	256.1 (243.1 to 269.1) (156)	
LEP (W)	182.2 (176.8 to 187.5)	174.3 (168.1 to 180.5)	
LEP (W kg^{-1})	2.20 (2.14 to 2.26)	2.13 (2.06 to 2.21)	
Shoulder abduction	144.1 (141.7 to 146.4)	143.0 (140.4 to 145.7)	

TABLE 57 *Baseline measurements of biochemical markers*

	Total cholesterol Mean (SEM) (*n*)	HDL Mean (SEM) (*n*)	Cholesterol/HDL Mean (SEM) (*n*)	LDL Mean (SEM) (*n*)	Triglycerides Mean (SEM) (*n*)
Leisure centre	5.76 (0.06) (262)	1.32 (0.02) (258)	4.56 (0.07) (258)	3.52 (0.06) (251)	2.17 (0.08) (263)
Walking	5.76 (0.07) (258)	1.41 (0.03) (256)	4.37 (0.09) (256)	3.44 (0.06) (250)	2.04 (0.08) (258)
Advice	5.65 (0.06) (272)	1.37 (0.02) (272)	4.37 (0.07) (271)	3.47 (0.05) (264)	1.90 (0.06) (272)
Female	5.82 (0.04) (528)	1.45 (0.02) (524)	4.22 (0.06) (524)	3.53 (0.04) (517)	1.90 (0.05) (529)
Male	5.54 (0.06) (264)	1.19 (0.02) (262)	4.85 (0.08) (261)	3.36 (0.05) (248)	2.30 (0.08) (264)
(Age (years)					
40–44	5.50 (0.11) (67)	1.19 (0.03) (67)	4.89 (0.17) (67)	3.38 (0.10) (66)	2.09 (0.13) (67)
45–54	5.56 (0.06) (274)	1.33 (0.02) (271)	4.41 (0.09) (270)	3.32 (0.05) (261)	2.08 (0.08) (275)
55–64	5.81 (0.06) (275)	1.39 (0.02) (272)	4.38 (0.07) (272)	3.54 (0.05) (264)	2.02 (0.08) (276)
65–74	5.93 (0.08) (176)	1.44 (0.03) (176)	4.37 (0.09) (176)	3.64 (0.07) (174)	1.93 (0.07) (175)

Tests of cardiorespiratory fitness showed improvements in exercise performance in all three groups, with some attenuation over time, but maintenance of improvement over baseline at 1 year in the leisure centre and walking groups.

IKES increased significantly in the leisure centre and walking group participants at 10 weeks, but this improvement was not sustained. LEP increased in all groups, with maintenance of improvement over baseline at 1 year in the leisure centre and walking groups.

Small reductions were observed in total cholesterol and LDL-cholesterol in all groups, which were sustained over time. No improvement was seen in HDL-cholesterol.

Although there were minor differences in the improvements in certain parameters between the three study groups at some individual time-points, there were no consistent differences between the groups for any parameter over time.

TABLE 58 *Changes in biochemical markers: ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure					
Cholesterol (*n* = 133)	5.79	5.70	–0.09 (–0.18 to –0.01)	–1.6%	*
HDL (*n* = 131)	1.29	1.30	0.01 (–0.2 to 0.04)	0.8%	
Cholesterol/HDL (*n* = 131)	4.65	4.59	–0.06 (–0.16 to 0.05)	–1.3%	
LDL (*n* = 127)	3.52	3.42	–0.10 (–0.18 to –0.02)	–2.8%	*
Triglycerides (*n* = 134)	2.27	2.23	–0.03 (–0.18 to 0.11)	–1.3%	
Walking					
Cholesterol (*n* = 131)	5.83	5.74	–0.09 (–0.19 to 0.003)	–1.5%	^
HDL (*n* = 129)	1.39	1.38	–0.01 (–0.03 to 0.01)	–0.7%	
Cholesterol/HDL (*n* = 129)	4.49	4.45	–0.04 (–0.14 to 0.06)	–0.9%	
LDL (*n* = 126)	3.51	3.46	–0.05 (–0.14 to 0.03)	–1.4%	
Triglycerides (*n* = 131)	2.09	1.01	–0.08 (–0.21 to 0.04)	–3.8%	
Advice					
Cholesterol (*n* = 136)	5.72	5.64	–0.08 (–0.17 to 0.01)	–1.4%	
HDL (*n* = 135)	1.34	1.35	0.01 (–0.01 to 0.04)	0.7%	
Cholesterol/HDL (*n* = 135)	4.46	4.38	–0.08 (–0.17 to 0.004)	–1.8%	
LDL (*n* = 133)	3.51	3.41	–0.10 (–0.18 to –0.02)	–2.8%	*
Triglycerides (*n* = 136)	1.99	2.03	0.05 (–0.08 to 0.17)	2.5%	
6 months					
Leisure centre					
Cholesterol (*n* = 262)	5.76	5.68	–0.09 (–0.15 to –0.02)	–1.6%	*
HDL (*n* = 258)	1.32	1.33	0.01 (–0.01 to –0.04)	0.8%	
Cholesterol/HDL (*n* = 258)	4.56	4.45	–0.11 (0.19 to 0.03)	–2.4%	**
LDL (*n* = 251)	3.52	3.42	–0.10 (–0.15 to –0.04)	–2.8%	**
Triglycerides (*n* = 263)	2.17	2.14	–0.02 (–0.12 to 0.07)	–0.9%	
Walking					
Cholesterol (*n* = 258)	5.76	5.60	–0.16 (–0.23 to –0.09)	–2.8%	**
HDL (*n* = 256)	1.41	1.42	0.01 (–0.02 to –0.03)	0.8%	
Cholesterol/HDL (*n* = 256)	4.37	4.24	–0.13 (0.21 to 0.06)	–3.0%	**
LDL (*n* = 250)	3.44	3.33	–0.10 (–0.16 to –0.05)	–2.9%	**
Triglycerides (*n* = 258)	2.04	1.93	–0.11 (–0.20 to 0.01)	–5.4%	*
Advice					
Cholesterol (*n* = 272)	5.65	5.55	–0.10 (–0.16 to –0.04)	–1.8%	**
HDL (*n* = 272)	1.37	1.39	0.02 (–0.001 to –0.04)	1.5%	*
Cholesterol/HDL (*n* = 271)	4.37	4.25	–0.13 (0.20 to 0.05)	–3.0%	**
LDL (*n* = 264)	3.47	3.37	–0.11 (–0.17 to –0.05)	–3.2%	**
Triglycerides (*n* = 272)	1.90	1.88	–0.02 (–0.11 to 0.07)	–1.1%	*
1 year					
Leisure centre					
Cholesterol (*n* = 159)	5.83	5.49	–0.33 (–0.46 to –0.21)	–5.7%	**
HDL (*n* = 158)	1.33	1.35	0.01 (–0.02 to –0.05)	0.8%	
Cholesterol/HDL (*n* = 158)	4.54	4.25	–0.29 (0.42 to 0.15)	–6.4%	**
LDL (*n* = 148)	3.61	3.27	–0.34 (–0.45 to –0.22)	–9.4%	**
Triglycerides (*n* = 159)	2.10	2.03	–0.07 (–0.23 to 0.09)	–3.3%	
Walking					
Cholesterol (*n* = 132)	5.89	5.45	–0.36 (–0.49 to –0.22)	–6.1%	**
HDL (*n* = 129)	1.45	1.40	–0.05 (–0.08 to –0.01)	3.4%	*
Cholesterol/HDL (*n* = 129)	4.35	4.21	–0.14 (–0.30 to 0.02)	–3.2%	
LDL (*n* = 125)	3.53	3.31	–0.22 (–0.34 to –0.10)	–6.2%	**
Triglycerides (*n* = 132)	2.05	1.87	–0.18 (–0.36 to –0.01)	–8.8%	*

** $p < 0.01$, * $p < 0.05$, ^ $p = 0.057$.

TABLE 59 *Biochemical markers – comparison of values between groups at each assessment: ITT*

	Leisure centre Mean (95% CI) (*n*)	Walking Mean (95% CI) (*n*)	Advice Mean (95% CI) (*n*)
10 weeks			
Cholesterol	5.68 (5.60 to 5.77) (133)	5.69 (5.60 to 5.78) (131)	5.71 (5.60 to 5.78) (136)
HDL	1.35 (1.32 to 1.38) (131)	1.33 (1.30 to 1.36) (129)	1.35 (1.33 to 1.38) (135)
Cholesterol/HDL	4.48 (4.38 to 4.58) (131)	4.52 (4.41 to 4.62) (129)	4.46 (4.36 to 4.56) (135)
LDL	3.41 (3.34 to 3.49) (127)	3.45 (3.37 to 3.53) (126)	3.44 (3.36 to 3.52) (133)
Triglycerides	2.12 (2.00 to 2.24) (134)	2.05 (1.92 to 2.18) (131)	2.14 (2.01 to 2.26) (136)
6 months			
Cholesterol	5.65 (5.58 to 5.71) (262)	5.56 (5.50 to 5.63) (258)	5.60 (5.53 to 5.66) (272)
HDL	1.37 (1.35 to 1.40) (258)	1.37 (1.35 to 1.39) (256)	1.38 (1.36 to 1.40) (272)
Cholesterol/HDL	4.36 (4.28 to 4.43) (258)	4.31 (4.23 to 4.39) (256)	4.33 (4.25 to 4.40) (271)
LDL	3.40 (3.34 to 3.46) (251)	3.36 (3.30 to 3.42) (250)	3.37 (3.31 to 3.43) (264)
Triglycerides	2.04 (1.95 to 2.13) (263)	1.95 (1.85 to 2.04) (258)	2.00 (1.91 to 2.10) (272)
1 year			
Cholesterol	5.50 (5.39 to 5.62) (159)	5.49 (5.35 to 5.62) (132)	
HDL	1.38 (1.35 to 1.41) (158)	1.35 (1.31 to 1.38) (129)	
Cholesterol/HDL	4.24 (4.12 to 4.37) (158)	4.32 (4.18 to 4.47) (129)	
LDL	3.25 (3.15 to 3.36) (148)	3.32 (3.21 to 3.44) (125)	
Triglycerides	2.05 (1.91 to 2.18) (159)	1.93 (1.77 to 2.09) (132)	

Chapter 7

Results: psychological outcomes

Introduction

There is an emerging consensus within the literature based on results of both cross-sectional and longitudinal studies that moderate aerobic exercise training has antidepressant and anxiolytic effects, and protects against harmful consequences of stress in both clinical and non-clinical populations.[60–62]

This chapter examines a number of measures that were collected as part of the EXERT study. These include two measures of mental well-being: the Hospital Anxiety and Depression Scale (HADS) and the SF-36 Medical Outcomes Scale; and two measures of readiness to engage in behavioural change: Stages of Change and a Barriers to Exercise scale (both of these measures were developed on the basis of the transtheoretical model of behavioural change.[63]). Several measures, including a Health Locus of Control scale[64] (taken at baseline only), the EuroQol (EQ-5D) measure of well-being, and self-efficacy[65] and decisional balance[66] scales for exercise, are not discussed here because statistical analysis revealed no differences between treatment groups or over the period of the trial and follow-up.

Measures of mental well-being

HADS measures

The HADS is a 14-item five-point Likert scale questionnaire in which half of the questions are designed to measure anxiety and the other half to measure depression. Responses are scored on a scale from 3 to 0 and therefore the maximum score is 21 for depression and 21 for anxiety. A score of 11 or higher is taken to indicate the probable presence of the mood disorder, with a score of 8–10 being suggestive of the presence of the respective state. The two subscales, anxiety and depression, have been found to be independent measures. [A rotated principal component analysis (PCA) on the sample data supports a two-factor model (anxiety and depression accounting for 47% of the variance) of the HADs. Cronbach's reliability coefficients for the anxiety and depression scales were 0.82 and 0.77, respectively.] In its current form, the HADS is divided into four ranges: normal (0–7), mild (8–10), moderate (11–15) and severe (16–21).[67,68]

Mahalanobis distance analyses[69] were performed on HADS scores to remove multivariate outliers before the data set was analysed. Participants who had not completed the HADS questionnaire at 6-month and 1-year follow-up were also removed from the analyses. Participants who partially completed the questionnaire were included provided no more than three scale items had a missing response. Missing responses for these participants were replaced using an expectation maximisation (EM) analysis.[70]

Tables 60 and *61* show the distribution of participants among the four ranges of HADS scores (normal, mild, moderate, severe) for both anxiety and depression scales at baseline, 10 weeks, 6 months and 1 year. For anxiety scores, the narrow majority in all treatment groups falls into the normal range at baseline, but there are large proportions that fall into the mild and moderately anxious categories. There is a general trend towards improvement in anxiety scores over the period of the trial, which is reviewed in the next section on inferential analysis, but large proportions remain within the mild and moderately anxious categories throughout. High levels of anxiety at baseline and in subsequent measures may be related to the nature of the trial and the health state of the participants.

The majority of depression scores are distributed in the normal range for all three treatment groups throughout the period of the trial. The most notable improvement in depression scores is for the leisure centre group and this is examined in the next section on inferential statistics.

HADS analysis: inferential statistics

To maximise the sample that could be included in repeated measures analyses, and hence the power of the statistical analysis, data collected at the 10-week stage were excluded from the following analyses. The type I error rate for statistical comparison was set at 5% unless noted otherwise.

A mixed-model multivariate analysis of variance (MANOVA) was carried out on HADS scores using

TABLE 60 *Percentage distribution of EXERT participants in each range of anxiety scoring on HADS*

	Normal	Mild	Moderate	Severe	*n*
Leisure centre					
Baseline	55.5%	22.9%	21.6%	4%	301
10 weeks	63.3%	19.3%	15.6%	1.8%	109
6 months	66.1%	15.3%	16.9%	1.7%	177
1 year	65.4%	16.3%	15.7%	2.6%	153
Walking					
Baseline	50.5%	22.6%	22.6%	4.4%	297
10 weeks	63.7%	19.8%	15.4%	1.1%	91
6 months	62.6%	16.5%	18%	2.9%	139
1 year	65.4%	15.0%	12.8%	6.8%	133
Advice					
Baseline	50.8%	30.5%	15.9%	2.7%	295
10 weeks	70.1%	21.8%	5.7%	2.3%	87
6 months	60.6%	25.3%	12.1%	2%	198

TABLE 61 *Percentage distribution of EXERT participants in each range of depression scoring on HADS*

	Normal	Mild	Moderate	Severe	*n*
Leisure centre					
Baseline	77.3%	14.1%	6.9%	1.6%	301
10 weeks	86.1%	12.0%	1.9%	0.0%	108
6 months	85.9%	9.6%	4.5%	0.0%	177
1 year	81.9%	14.8%	2.7%	0.7%	151
Walking					
Baseline	76.8%	15.4%	7.7%	0.0%	297
10 weeks	83.0%	11.7%	5.3%	0.0%	93
6 months	78.4%	14.4%	7.2%	0.0%	139
1 year	80.5%	12.0%	6.8%	0.8%	133
Advice					
Baseline	80.7%	14.3%	4.0%	1.0%	295
10 weeks	83.0%	12.5%	5.4%	0.0%	88
6 months	82.3%	11.1%	6.1%	0.5%	198

treatment group (leisure centre, $n = 177$; walking, $n = 139$; and control, $n = 198$), and time (baseline, 6 months) as independent variables. This analysis revealed no significant overall effect of treatment group on HADS scores and no significant interactions between any of the independent variables. There was, however, a significant overall main effect of time whereby HADS scores improved for all groups between baseline and 6-month follow-up ($F_{2,511} = 3.74$, $p < 0.05$). Follow-up univariate analyses explored anxiety and depression subscales separately.

The univariate test on anxiety scores revealed no main effect of treatment group but a significant main effect of time ($F_{1,512} = 7.40$, $p < 0.05$). There was no interaction between these independent variables. Post hoc *t*-tests (with Bonferroni adjustment to the type I error rate; family-wise $\alpha = 0.167$) confirmed that there was a significant reduction in anxiety scores between baseline and 6 months for all treatment groups (*Figure 7*).

Univariate tests of depression scores revealed no overall main effect of treatment group or time. There was, however, a significant interaction between these two independent variables ($F_{1,512} = 5.08$, $p < 0.05$). This interaction is illustrated in *Figure 8*.

A simple main effects analysis of the interaction term revealed no significant differences in

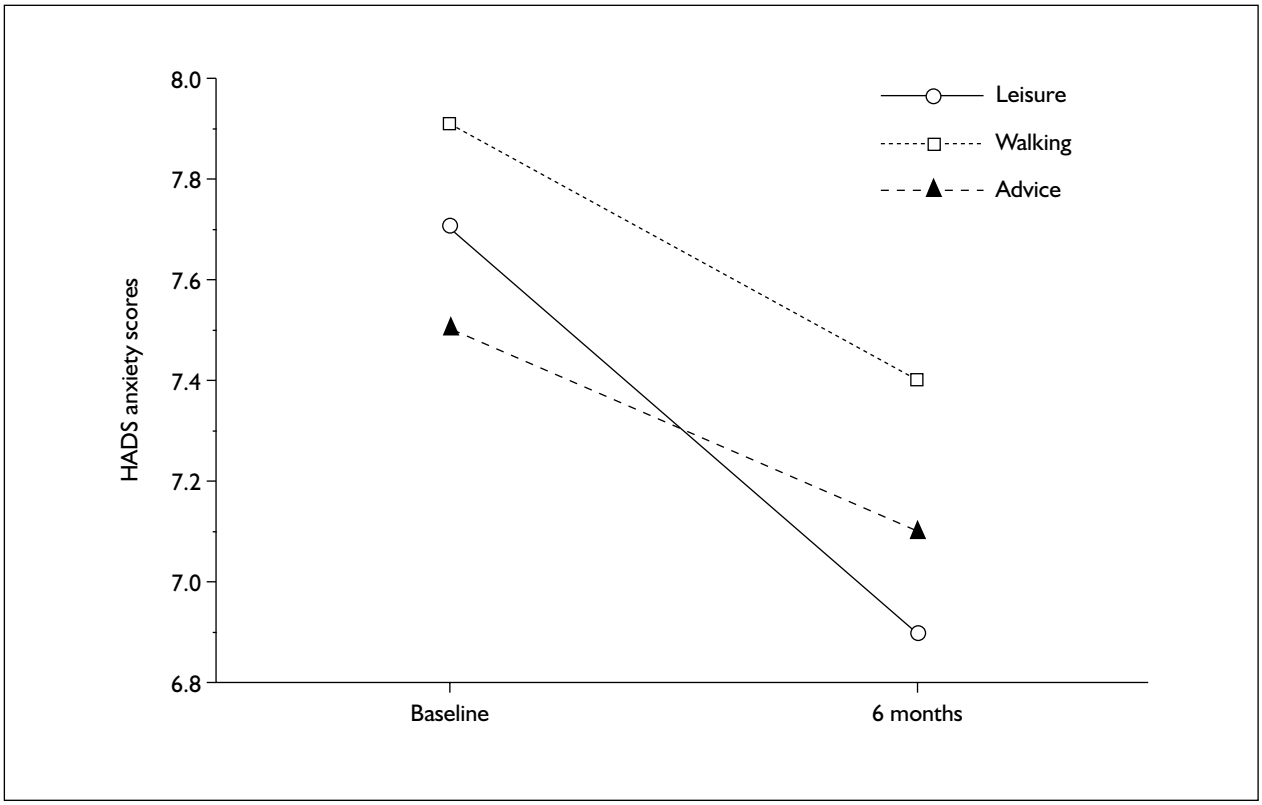

FIGURE 7 *Leisure centre, walking and advice group anxiety scores measured by HADS at baseline and 6-month follow-up*

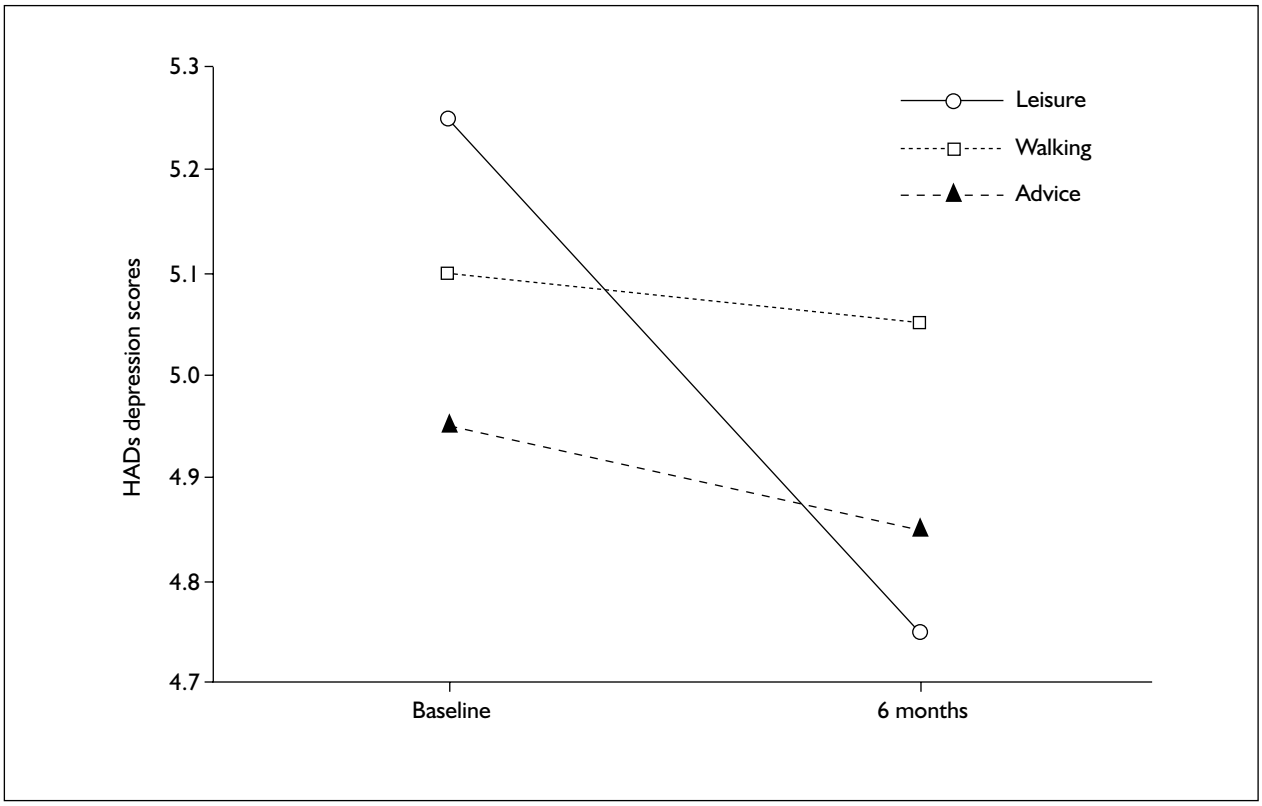

FIGURE 8 *Interaction between treatment group and time, for depression scores measured by HADS at baseline and 6-month follow-up*

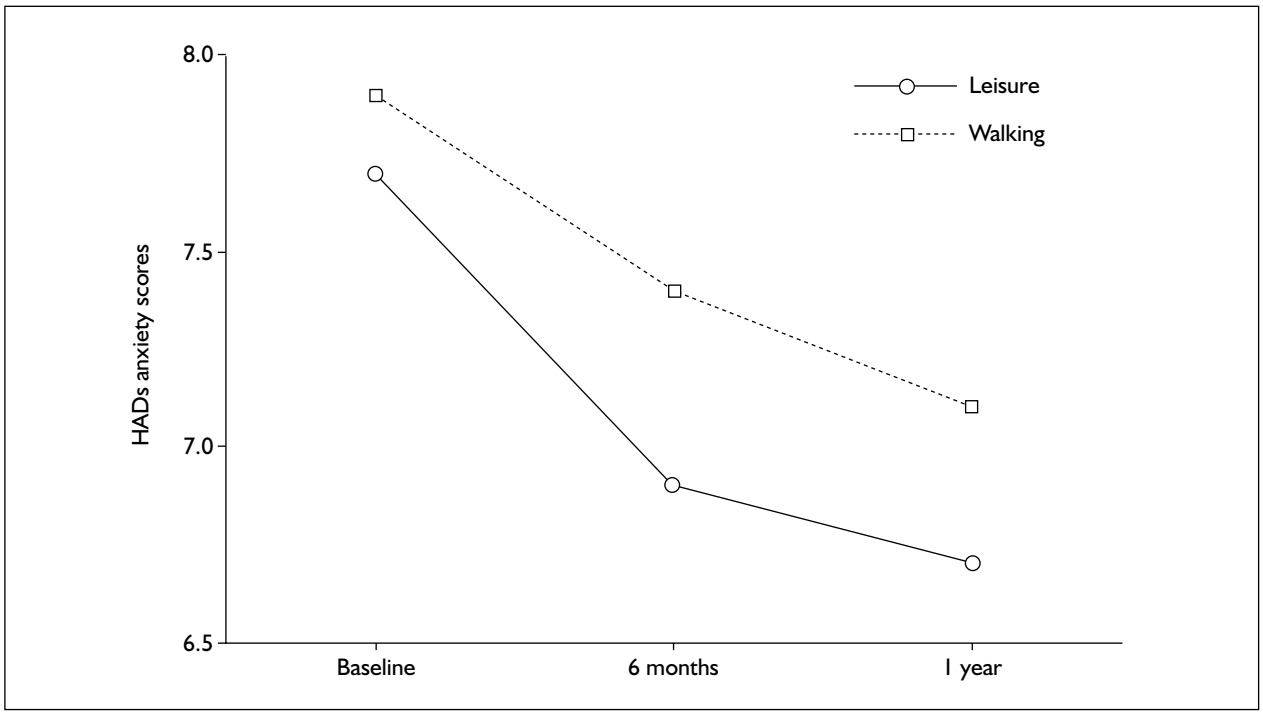

FIGURE 9 *Leisure centre and walking group anxiety scores measured by HADS at baseline, 6 months and 1-year follow-up*

depression scores between treatment groups at either baseline or 6-month follow-up. There was, however, a significant improvement in depression scores for the leisure centre group between baseline and 6-months ($F_{1,176} = 16.98$, $p < 0.05$). No significant differences in depression scores over time for the control and walking group were found.

To examine HADS scores at 1-year follow-up for the leisure centre and walking groups a mixed-model MANOVA was carried out using treatment group (leisure centre, $n = 144$; walking, $n = 128$), and time (baseline, 6 months, 1 year) as independent variables. Once again, this analysis found no overall significant difference of treatment group, but a significant main effect of time on HADS scores ($F_{4,269} = 26.62$, $p < 0.05$). There was no significant interaction between the two independent variables. Univariate analyses on anxiety scores showed a main effect over time ($F_{2,270} = 56.68$, $p < 0.05$) and no main effect of treatment group. Post hoc Bonferroni *t*-tests demonstrated that there was a significant reduction in anxiety between baseline and 6 months, and also baseline and 1 year for both treatment groups. There was no significant difference between 6 months and 1 year (*Figure 9*).

Univariate analysis of depression scores revealed a main effect of time, but not treatment condition. However, this main effect of time was subsumed by a significant interaction between time and treatment group ($F_{2,540} = 3.77$, $p < 0.05$). The interaction between these two variables is illustrated in *Figure 10*. A simple main effects analysis of the interaction term revealed no significant differences in depression scores between treatment groups at baseline, 6-month or 1-year follow-up. There was, however, a significant improvement in depression scores for the leisure centre group between baseline and 6 months ($F_{1,270} = 55.81$, $p < 0.05$) and baseline and 1 year ($F_{1,270} = 38.82$, $p < 0.05$). No significant differences in depression scores over time were found for the walking group.

SF-36 Medical Outcomes Scale

Analysis of HADS measures of mental health were followed up with analysis of the SF-36 Medical Outcomes Scale. The SF-36 comprises one multi-item scale that assesses eight health concepts: (1) limitations in physical activities because of health problems; (2) limitations in social activities because of physical or emotional problems; (3) limitations in usual role activities because of physical health problems; (4) bodily pain; (5) mental health (psychological distress and well-being); (6) limitations in usual role activities because of emotional problems; (7) vitality (energy and fatigue); and (8) general health perceptions. Each of these dimensions is claimed to be

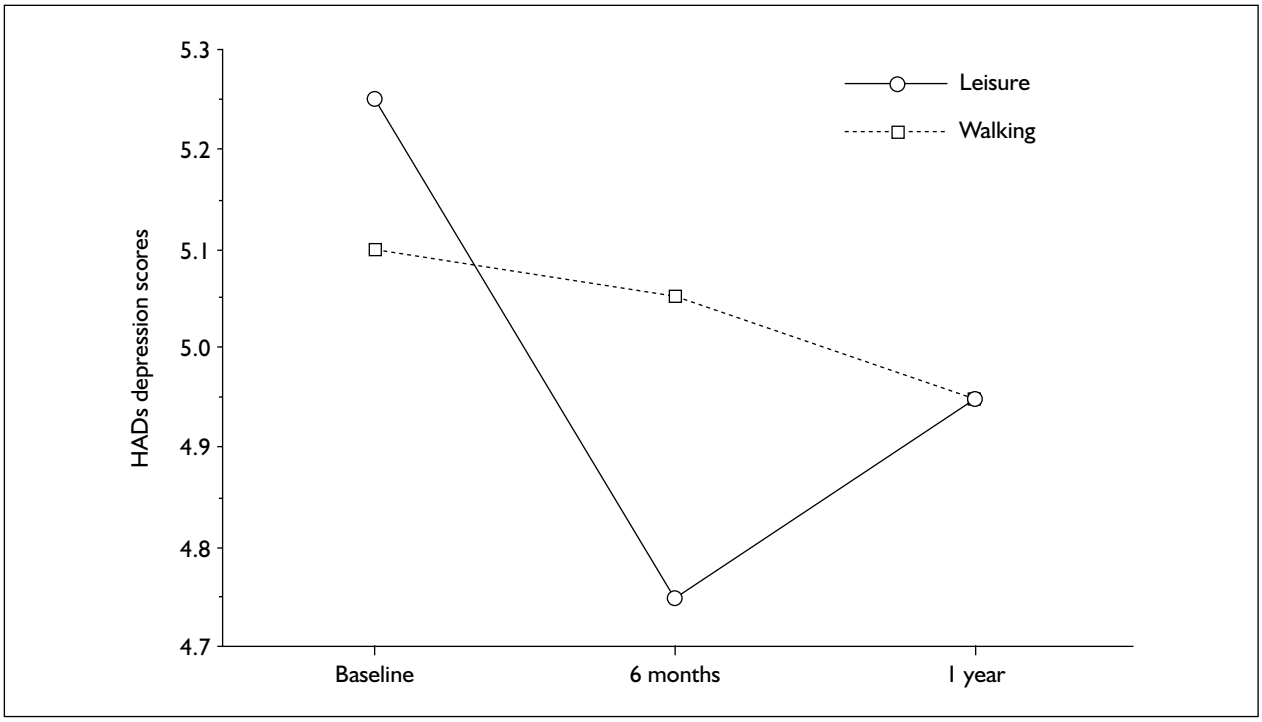

FIGURE 10 *Leisure centre and walking group depression scores measured by HADS at baseline, 6 months and 1-year follow-up*

independent of the others.[39] These health dimensions are said to be further grouped into two higher order clusters: physical health (comprising concepts 1, 3, 4 and 8 above) and mental health (comprising concepts 2, 5, 6 and 7).[39] [A rotated PCA on the sample data found that two factors (physical and mental health) accounted for 67% of the reliable variance in the eight scales of the SF-36. Cronbach's reliability coefficients were 0.68 for the physical health scales and 0.80 for the mental health scale.]

The full SF-36 measurement model is considered in Chapter 8. This section only considers measures within the SF-36 that relate to the mental health cluster of scales. A mixed model ANOVA was carried out on the overall measure of mental health using assessment time (baseline, 6 months) and treatment group (leisure, $n = 113$; walking, $n = 96$; control, $n = 109$) as independent variables. As with the HADS analyses, data at 10 weeks were excluded to maximise the number of participants in the repeated measure analysis.

Mahalanobis distance analyses[69] were performed on scores to remove multivariate outliers before the data set was analysed. Participants who had not completed the SF-36 questionnaire at 6 months were also removed from the analyses. Participants who partially completed the questionnaire were included provided no more than two general mental health scale items had a missing response. Missing responses for these participants were replaced using an EM analysis.[70]

The ANOVA showed a significant improvement in mental health scores between baseline and 6 months for all three treatment groups ($F_{1,315} = 23.02$, $p < 0.05$), and no interaction between assessment period and group (*Figure 11*).

In general, mental health measures in this study are consistent with previous research that low to moderate intensity exercise reduces anxiety and depression and improves general mental well-being. The lack of difference between treatment groups in all cases except for depression scores (where the leisure centre participants were the only group to show significant improvement) is perhaps not surprising since several previous studies suggest ceiling effects in psychosocial response to exercise.[71] Thus, it is likely that even moderate change in exercise behaviour was sufficient to create a maximal change in overall mental well-being. However, HADS depression scores are differentiated among the treatment groups, with a significant improvement shown by the leisure centre participants between baseline and 6 months, but no improvement shown by other groups over the same period. It is possible that, in this case, exercise intensity may have been more important in differentiating antidepressant

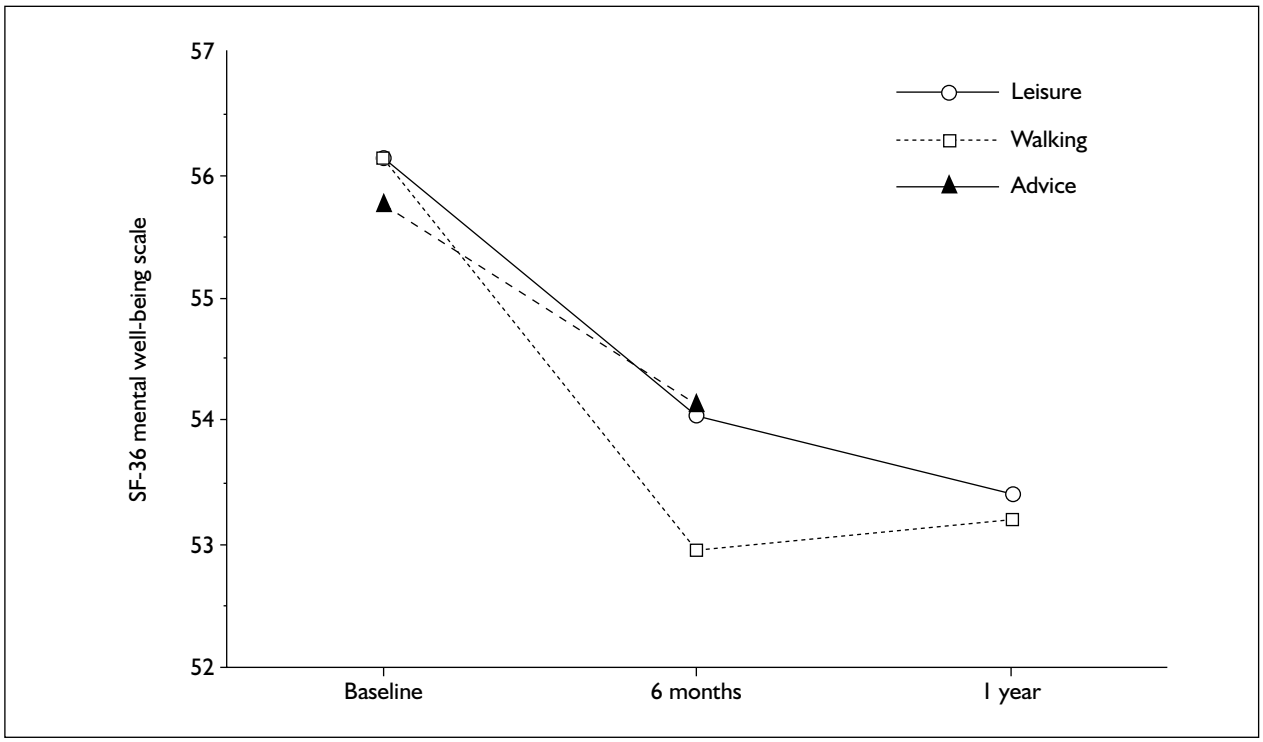

FIGURE 11 *Leisure centre, walking and advice group SF-36 mental well-being scores at baseline, 6 months and 1-year follow-up. Lower scores indicate increased mental well-being.*

effects among the groups; however, the range of physical exercise being undertaken is too diverse to examine this through statistical analysis.

Behavioural change measures

The measures of attitudes to exercise and behavioural change used in EXERT are based on constructs taken from the transtheoretical model[63,72] of intentional change, which focuses on individuals' decision-making with respect to health behaviours. The core construct is stages of change, which represent ordered categories along a continuum of behavioural change. The model also incorporates intervening variables such as decisional balance (the pros and cons of change), self-efficacy (confidence in the ability to change behaviour across problem situations) and beliefs that are specific to the problem area (barriers to exercise in the context of this study). Measures of stage of change and barriers to exercise are reviewed in the sections that follow. Measures of decisional balance and self-efficacy are discussed only briefly since they show no significant differences among the treatment groups or change over the period of the trial and are not correlated with or predictive of either stage of change or barriers-to-exercise.

Stages of change

The stages of change construct[73] incorporate five steps: precontemplation, contemplation, preparation, action and maintenance. Precontemplation is the stage at which there is no intention to change behaviour in the foreseeable future. Individuals in this stage may be unaware or have little awareness that behavioural change would be beneficial. Contemplation is the stage in which people are aware that a problem exists and are seriously thinking about addressing it, but have not yet made a commitment to take action. Preparation is a stage that combines intention and initiation of behavioural change. Individuals in this stage are intending to take action in the next month and have unsuccessfully taken action in the past year. Action is the stage in which individuals modify their behaviour or environment to address their problems. Action involves overt behavioural changes and requires considerable commitment of time and energy. Maintenance is the stage in which people work to consolidate the gains attained during action and prevent reversion to earlier behaviour patterns.

Stages of change were measured in this study by a single item, whereby participants were asked to specify one of the following five stages at each assessment point:

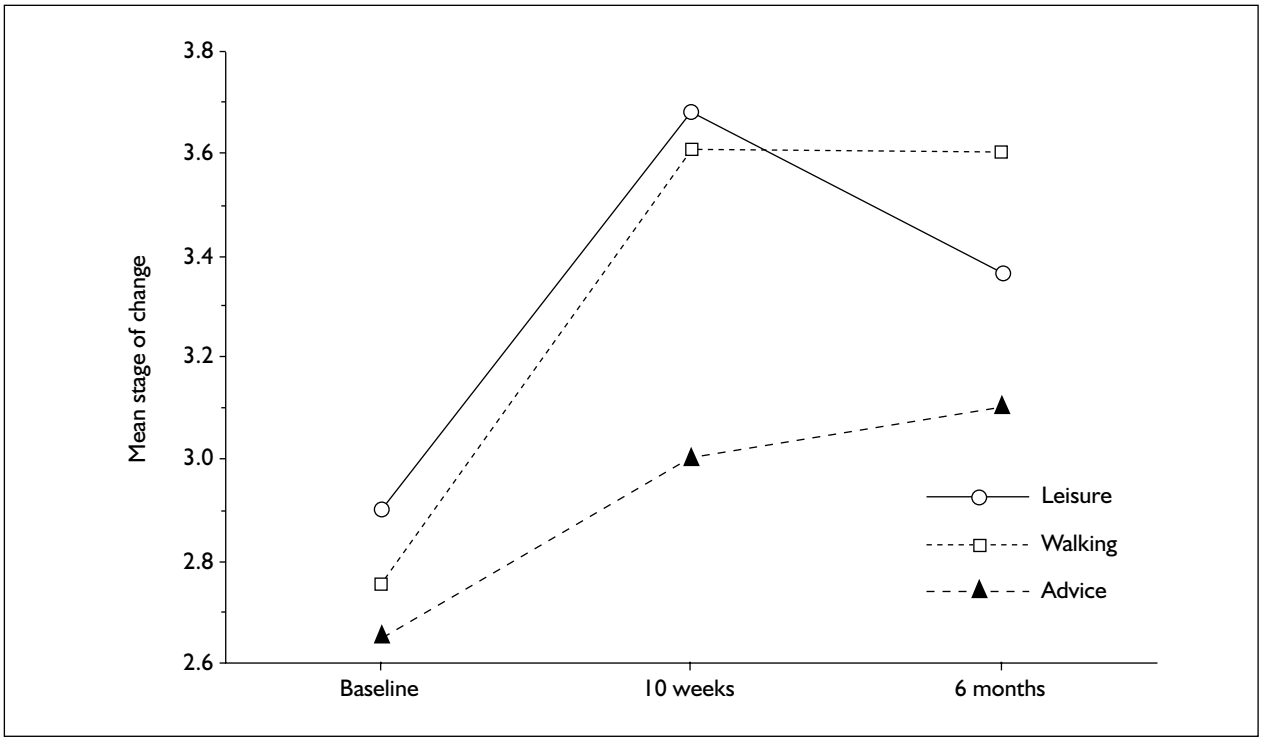

FIGURE 12 *Mean stage of change for leisure centre, walking and advice groups*

1. precontemplation: 'I do not exercise and do not intend to start exercising in the next 6 months'
2. contemplation: 'I do not exercise but I am thinking about starting to exercise in the next 6 months'
3. preparation: 'I currently exercise, but not regularly'
4. action: 'I exercise regularly, but have only started doing so in the last 6 months'
5. maintenance: 'I exercise regularly and have done so for more than 6 months'.

In Chapter 5 it was noted that mean stage of change progressively improves across the periods of assessment, but that some of this change can be attributed to participant withdrawal from the study. A mixed model ANOVA using assessment period (baseline, 10 weeks, 6 months) and treatment group (leisure, $n = 62$; walking, $n = 68$; control, $n = 52$) as independent variables revealed a significant main effect of time on stages of change ($F_{2,178} = 33.13$, $p < 0.05$; stage of change for this analysis is coded on a five-point scale, where 1 = precontemplation stage and 5 = maintenance stage). This main effect was modified by a significant interaction between the two independent variables ($F_{4,358} = 2.48$, $p < 0.05$), which is illustrated in *Figure 12*.

Further analysis using Bonferroni- adjusted *t*-tests showed no difference between groups at baseline. At 10 weeks the leisure centre and walking groups were at a significantly higher mean stage of change than the advice-only control group, but did not differ from each other. Mean stage of change was also significantly higher for these groups compared with the baseline measures. At 6 months, mean stage of change remained significantly higher for both leisure and walking groups compared with controls. However, at this assessment point walkers also had a significantly higher stage of change than the leisure centre group. On extending this analysis to 1 year for the leisure centre and walking groups, both retained a significant improvement in mean stage of change compared with baseline. The mean stage of change remained higher for the walking group than for the leisure centre group at the 1-year follow-up stage (*Figure 13*).

Barriers to exercise

The perceived barriers to exercise scale comprises 18 items accounting for three separate factors: intrinsic barriers, external barriers and time barriers to exercise. (A rotated PCA on the sample data revealed a three-factor solution accounting

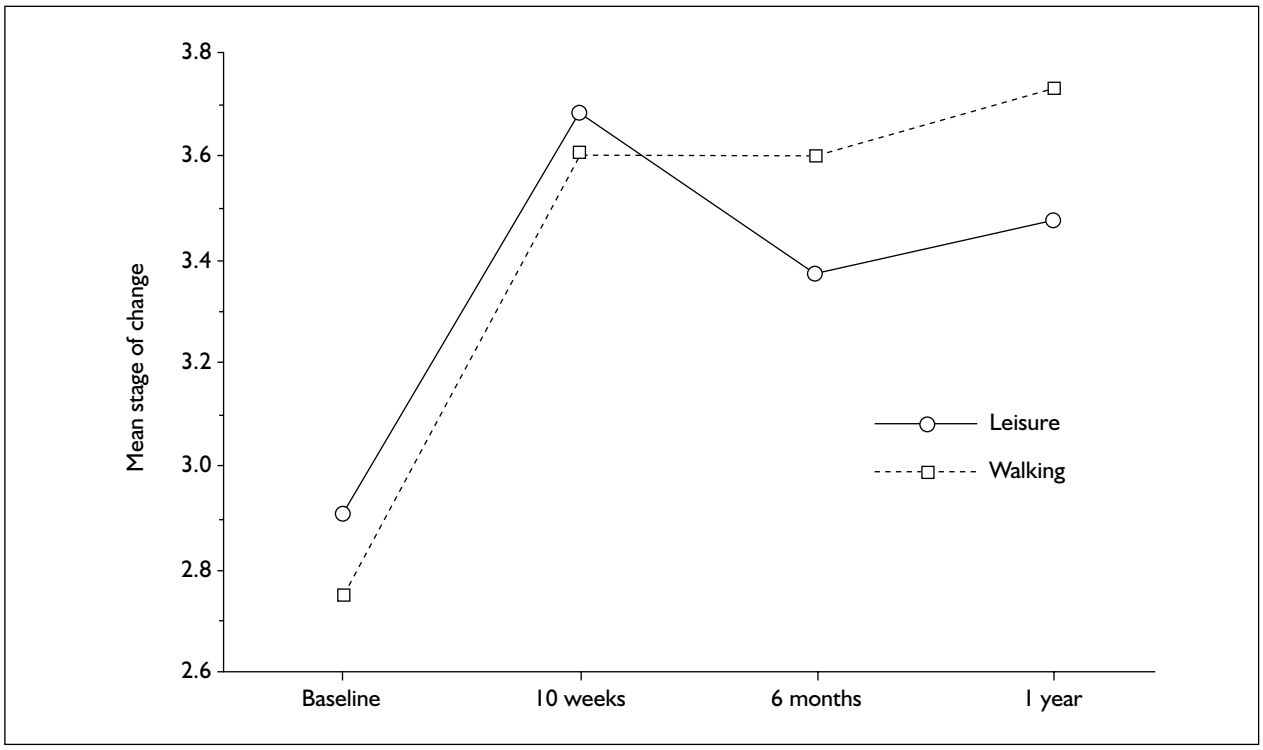

FIGURE 13 *Mean stage of change for leisure centre and walking groups*

for 51% of the unique variance. Cronbach's reliability coefficients for intrinsic barriers, extrinsic barriers and time barriers were 0.83, 0.71 and 0.77, respectively.) The intrinsic barriers comprise answers from ten items in the scale and relate to issues of self-efficacy, such as not feeling competent to exercise or finding exercise boring. External barriers comprise answers from four scale items and relate to issues such as support from others and guidance from fitness instructors. Finally, time barriers comprise answers from four scale items that relate to the amount of time that the participant feels that they have for exercise.

A mixed model MANOVA was carried out on perceived barriers to exercise scores using treatment group (leisure centre, $n = 64$; walking, $n = 67$; control, $n = 56$), time (baseline, 10 weeks and 6-month follow-up) and gender of participant as independent variables. Gender is included as a variable here because previous research has suggested differences between men and women in perceived barriers to exercise.[74] The analysis revealed no significant effects of study group or gender on perceived barriers to exercise and no significant interactions between any of the independent variables. There was a significant main effect of time ($F_{3,174} = 5.59$, $p < 0.05$) on perceived barriers to exercise, which was further explored using univariate ANOVAs. These analyses revealed significant main effects of time on intrinsic and extrinsic barriers to exercise, but no univariate effect on time barriers (*Figures 14–16*). Post hoc *t*-tests (with Bonferroni adjustment to the type I error rate; family-wise $\alpha = 0.167$) demonstrated that there was a significant reduction in perception of both intrinsic and extrinsic barriers to exercise between baseline and 6 months, and also baseline and 1 year for all study groups. The finding of a reduction in self-reported intrinsic barriers, which relate to self-efficacy for exercise, contrasts with the results from the self-efficacy for exercise scale.[65] Measurements using this scale did not significantly differ among treatment groups or over the period of the trial. It is possible that, since the self-efficacy scale comprises fewer items than the intrinsic barriers scale, the former was not as sensitive to change as the latter.

There was no significant difference between 6 months and 1 year for either intrinsic or extrinsic barriers.

Summary

All three study groups showed improvement in HADS anxiety and SF-36 mental well-being scores 6 months after the beginning of the trial. Leisure

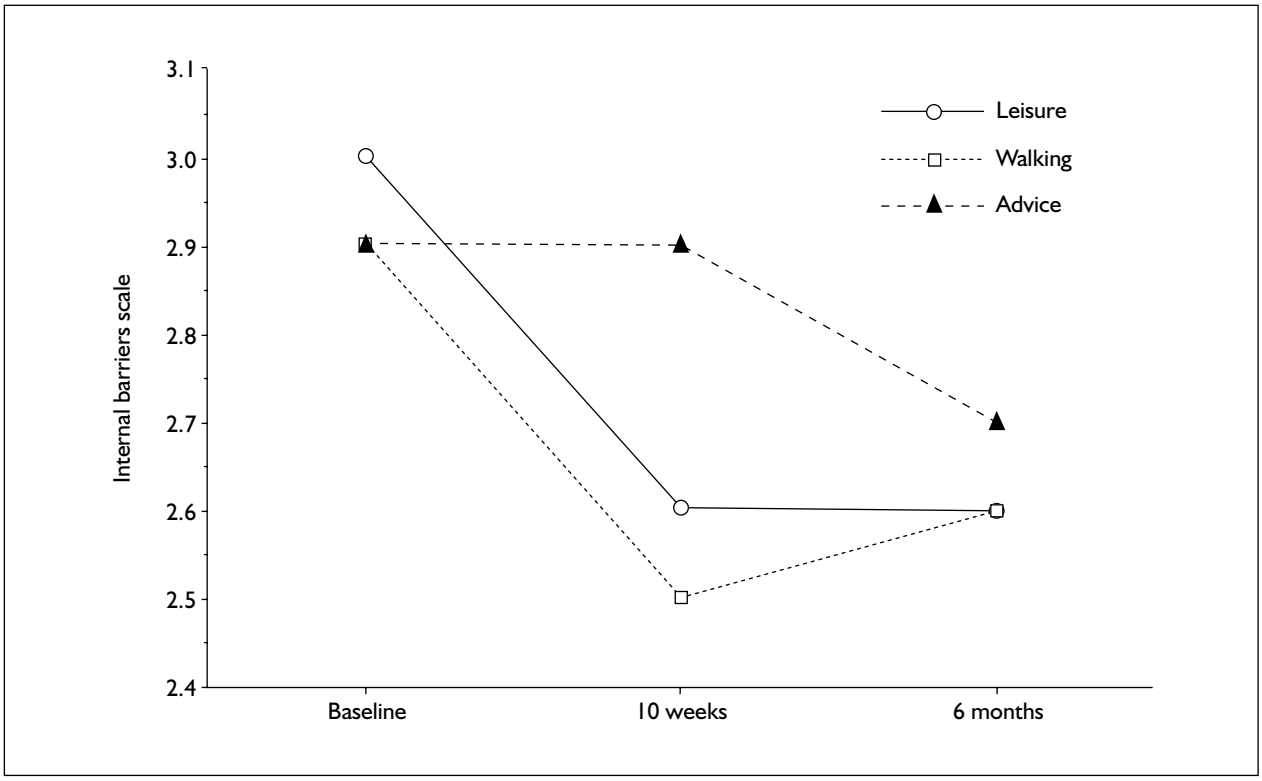

FIGURE 14 *Perceived intrinsic barriers to exercise scores at baseline, 10 weeks and 6-month follow-up*

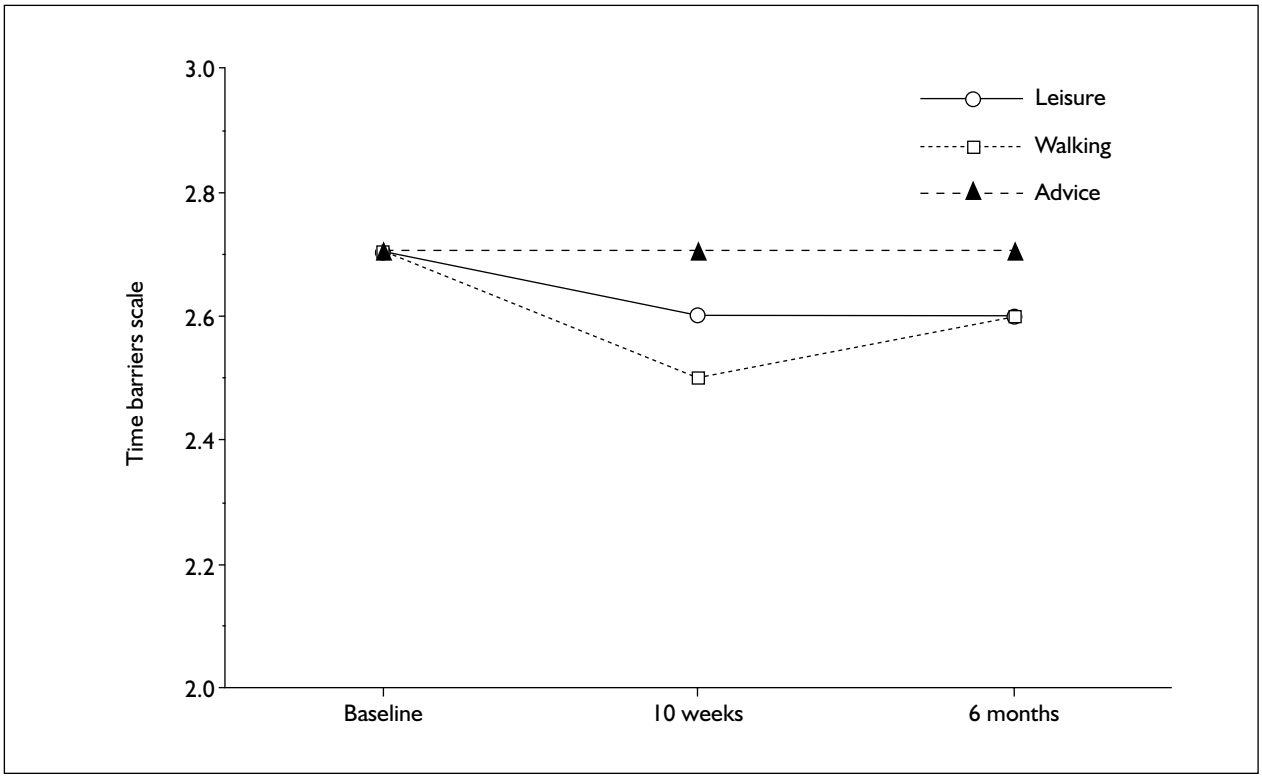

FIGURE 15 *Perceived time barriers to exercise scores at baseline, 10 weeks and 6-month follow-up*

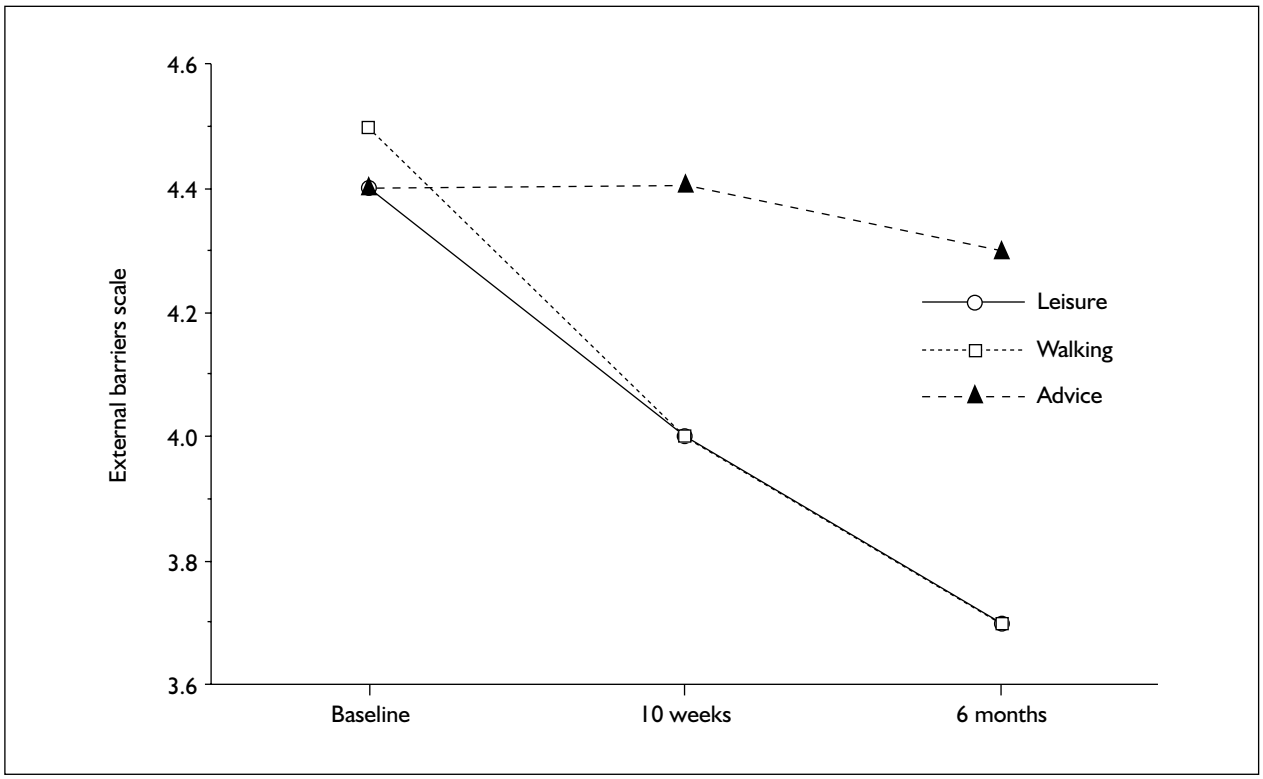

FIGURE 16 *Perceived external barriers to exercise scores at baseline, 10 weeks and 6-month follow-up*

centre and walking groups maintained this improvement at 1 year.

HADS depression scores improved significantly between baseline and 6 months for the leisure centre group only. At 12 months, however, there was no difference in depression scores between the leisure centre and walking groups.

Mean stage of change improved in the direction of stronger commitment to exercise for all treatment groups. However, this improvement was more marked in the leisure centre and walking groups at 10 weeks. By 6 months, this improvement was significantly higher for walkers compared with the leisure centre group, principally because the latter group showed a small decline in mean stage of change. This advantage for walkers over the leisure centre group was maintained at 1 year, although both groups improved in mean stage of change.

Barriers to exercise relating to self-efficacy and external factors showed a reduction in the leisure centre and walking groups, but not the advice group, that persisted at 1-year follow-up.

In general, the findings from the psychological measures in this study are consistent with two broad conclusions. The first is that most interventions that promote physical activity will have positive effects on mental well-being. The second is that interventions that offer tangible opportunities for exercise (as with the leisure centre and walking referral groups) may be more effective than psychosocial support and advice for promoting change in levels of physical activity.[27]

Chapter 8

Economic evaluation

Introduction

The economic analysis was conducted using cost-effectiveness analysis. It has been undertaken from a societal viewpoint and includes costs borne by the NHS, local government and participants. Since the cost and effects are limited to those occurring over a period of 12 months, discounting was not necessary.

Methods

Outcomes

The SF-36 was used to measure health outcomes.[75] This instrument measures eight dimensions of health: health perceptions, physical health, mental health, the effect that physical health has upon role functioning, the effect that mental health has upon role functioning, social health, pain and energy. Brazier and colleagues used a population sample to scale preferences over a reduced set of the SF-36 questions, which is referred to as the SF-6D.[76] Values are measured on a scale in which 1 represents full health and 0 represents being dead. The algorithm suggested by Brazier was used to convert the SF-36 responses into health state valuations.

Costs

Intervention costs to the public sector

The interventions incurred costs that were borne by the health service and the local authority, comprising those of providing facilities, exercise trainers and administrative support. The cost per session was calculated as the fixed cost (facilities and administration) divided by the total number of sessions, plus the cost per session of the exercise trainer's time. The cost per session so calculated was then divided by the average number of participants per session to obtain a mean cost per participant per session. The number of sessions that participants were to receive was decided at their initial assessment. To arrive at a total cost per person, the mean cost per participant per session was multiplied by the number of sessions planned for each individual.

Participants who attended fewer sessions than planned were nevertheless attributed with all the costs for those sessions. However, in determining the costs to the participant, costs were only attributed according to the actual number of sessions attended. Thus, the providers incurred costs by planning for non-attenders, while the participants were assumed not to incur costs if they did not attend.

All participants underwent an initial assessment, which took approximately 2 hours and was considerably longer than would be required under normal operating conditions because of the need to collect additional information for the trial. The cost estimates allow for this, by reducing the staff costs by 60%.

Intervention costs to the participants

Data relating to participant costs for the leisure centre and walking arms of the study were collected using a self-completed questionnaire filled in by those of the 50% of participants randomised to undergo follow-up at 10 weeks who attended for the assessment. Respondents provided information about both their attendance at the assessment and the previous exercise session that they attended.

The costs to the participant included both the time costs and the travel costs. Information was also collected about any additional expenditure, for example, the need to pay for childcare and to purchase equipment.

Time was costed as either working time or non-working time, depending on whether the respondent had to take time off work to attend. The time costs reported by the Department of Transport[77] were used. Working time was costed at the average perceived cost for all workers (£11–57 per hour). Non-working time was costed at the perceived cost of non-working time (£4–52 per hour). The 1998 prices reported by the Department of Transport were inflated by 4.7% to 2002 prices using the Retail Price Index.

Where participants used public transport, the travel costs comprised the fares that they paid. For people travelling by private vehicles (including participants using local 'dial-a-ride' and 'good neighbours' schemes), travel was costed using the

AA cost per mile for cars of 1100–1549 cc.[78] People who walked or cycled were costed at zero pence per mile. Where data were only available for a single leg of the journey (either to or from their appointment), this figure was doubled to estimate the return journey. The cost per journey, including incidental costs specific to that attendance, was multiplied by the actual number of exercise sessions recorded to determine the cost to the participant. The cost of equipment purchased was added to the estimated cost of attending exercise sessions.

Similar procedures were used to determine the cost of attending the initial assessment, using data collected relating to the postintervention assessment. This was deemed reasonable, since both assessments took place in the same leisure centre and hence would have cost a similar amount for the participant to attend.

Costs averted

Since any changes in health resulting from the intervention might have resulted in a reduced (or increased) use of health services, data were obtained on primary care contacts, the use of pharmaceuticals prescribed by GPs and hospital admissions (both day case and inpatient). Information on primary care contacts and pharmaceuticals was obtained by a case-note review covering the period 1997–2002. Where access to GP records was granted, information was collected on visits to the GP for both the 12 months before and the 12 months after the intervention. All patients would have had at least one visit, at which they were referred to the scheme. Information on hospital admissions was obtained from the local District Health Authority. Data were not available for the 50 participants living outside the District Health Authority catchment area.

Primary care contacts were classified as occurring during the 12 months before the participant's active start date, during the 6 months after the active start date or allocation to the control group, or during the 12 months after the active start date. Pharmaceutical costs were similarly classified according to the time at which they were assumed to be used. The costs of hospital admissions were attributed to the period in which the admission occurred; thus, if an admission occurred during the 12 months before the active start date of the participant in the study, all the costs of that admission were attributed to that period. A similar procedure was used in determining the inpatient costs arising in the 6 months and the 12 months following the active start date.

Primary healthcare costs were costed using the Personal Social Services Research Unit (PSSRU) unit cost calculations for 2002.[79] Pharmaceuticals were costed using the British National Formulary for 2002.[80] Hospital admissions were costed using the NHS reference costs for 2002.[81]

Data analysis

The primary outcome comparisons are between the control and each of the intervention groups (walking and leisure centre) at 6 months. [Although the intention was to use the information from the SF-36 and the clinical outcomes to model patient outcomes in terms of quality-adjusted life-years (QALYs), the results were judged to be insufficiently stable to enable such estimates to be made. Accordingly, the SF-36 scores are simply reported.] The primary cost comparisons are between the same groups, but with costs cumulated over the period. The costs comprise both the costs of the intervention and the cost of healthcare provided during the 6 months.

An ANCOVA procedure was used to control for differences in health and the use of health services before the intervention.[82] Health was controlled for using the baseline SF-36 score. Health service costs were controlled for using the cumulated costs during the 12 months before the intervention start date. Because the hospital cost data are highly skewed (*Figure 17*), normal parametric confidence intervals calculated from the untransformed data would be unreliable. To mitigate this effect, bootstrapped robust regression procedures[83] (from STATA version 8) were used to estimate confidence intervals for the ANCOVA estimates of differences between groups.

Results are presented as cost-effectiveness ratios (the additional cost of the intervention groups compared with the costs of the control group, divided by the additional health benefits of the intervention groups compared with the control groups). Uncertainty about these estimates was examined using an ANCOVA approach to adjust for baseline values. Again, bootstrapping was used, but in the examination of uncertainty, parallel samples were used; that is, each bootstrap-replicated data set included both health and cost variables, so that matching estimates of the incremental health effects and incremental costs were obtained from the same resampled data. These matching estimates thus retain any correlations between costs and effects that exist in the original data. A more detailed discussion of the analysis of cost-effectiveness and the treatment

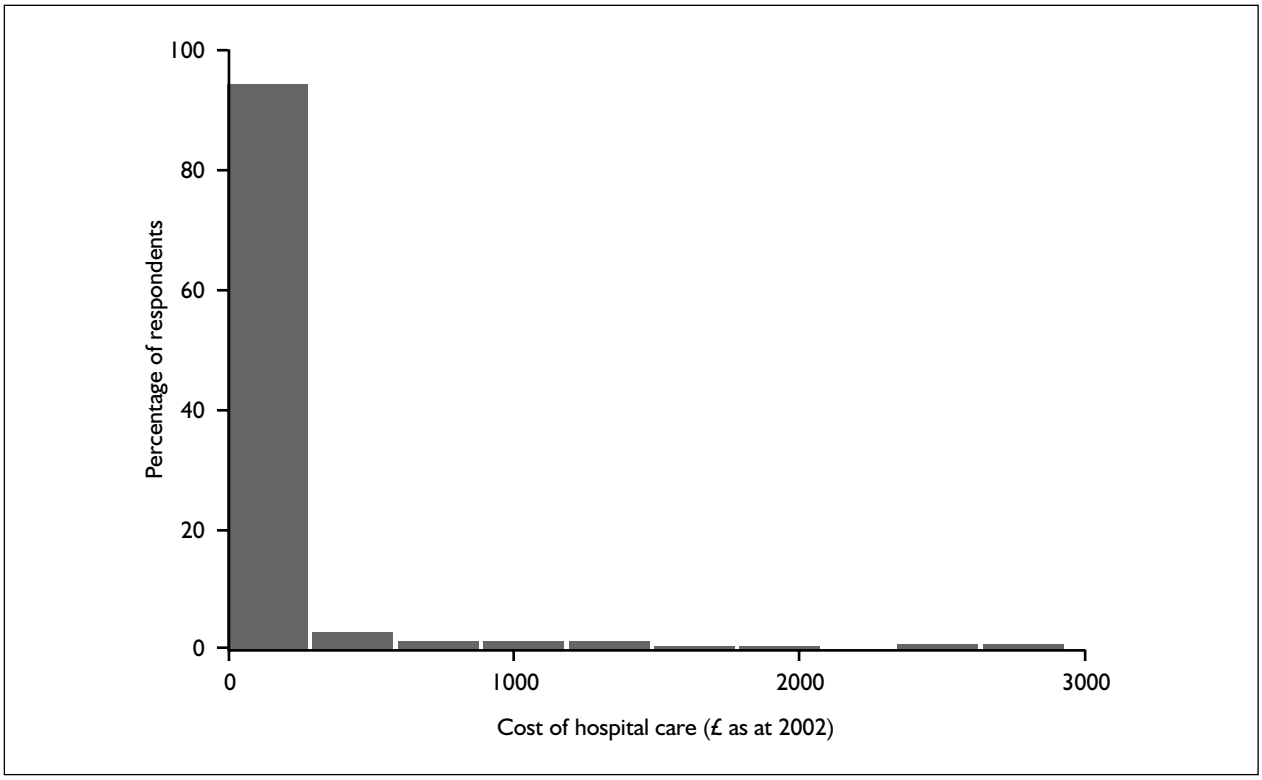

FIGURE 17 *Cost of hospital care*

of uncertainty is included in the Annex to this chapter (p. 78).

Results

Estimated costs and effects

Drummond and colleagues[84] advocate that quantities as well as costs be reported to enable readers to apply local price vectors to quantity information and thereby determine the costs as they would apply within their own local jurisdictions. However, with respect to averted health service costs, given the very large number of pharmaceutical preparations (1196 different preparations) and inpatient admissions, this would have been impractical and probably unhelpful. Readers are advised to consider whether prices in their own jurisdiction are likely to approximate to the sources used in this study (see References).

With respect to the intervention, the unit cost per attendance at the leisure centre was estimated to be £8.02, and per walking group attendance to be £4.03. The cost of the assessment that each patient received before the initiation of their course of treatment was estimated to be £8.56. This figure was the same for both interventions. The mean number of planned leisure centre attendances was 22.08 and the mean number of planned walking group attendances was 20.71.

Table 62 shows summary statistics for the key variables used in the economic analysis at baseline, 6 months after randomisation and 12 months after the start of active intervention for the leisure centre and walking groups.

In general, the major components of healthcare costs (general practice costs, pharmaceuticals and hospital costs) were of a similar order of magnitude to each other. The mean cost of each of these components was usually between about £45 per person and about £95 per person for the 6 months following the intervention. Against this background, the costs of the intervention were quite high, in terms of both the provision of exercise facilities and in the participation costs borne by the participant of attending and purchasing equipment. The mean cost to the providers of the leisure centre intervention was estimated at £186 per person. The mean cost to the providers of the walking intervention was estimated to be £92 per person. The participation costs amounted to £101 per person for the leisure centre intervention and £84 for the walking group. *Figures 18* and *19* show the skewed distribution of these costs.

TABLE 62 *Summary statistics of key economic variables*

	Observations	Mean	SD	Median	Min.	Max.
Control group[a]						
SF-36 baseline[b]	260	0.75	0.13	0.76	0.30	1.00
SF-36 6 months[b]	161	0.75	0.14	0.79	0.44	1.00
GP costs 12 months prerandomisation	123	£118.86	£77.68	£109	£0	£411.00
GP costs 6 months postrandomisation	123	£46.57	£46.17	£34.00	£0	£284.00
Pharmaceutical costs 12 months prerandomisation	123	£81.85	£136.18	£10.95	£0	£697.15
Pharmaceutical costs 6 months postrandomisation	123	£53.76	£89.80	£12.98	£0	£541.07
Hospital costs 12 months prerandomisation	310	£119.13	£479.95	£0	£0	£4356.42
Hospital costs 6 months postrandomisation	310	£46.58	£206.98	£0	£0	£1995.73
Cost of the intervention to the providers	316	£0	£0	£0	£0	£0
Cost of the intervention to the participants[c]	316	£0	£0	£0	£0	£0
Equipment costs (a component of participant costs)[c]	316	£0	£0	£0	£0	£0
Leisure centre group						
SF-36 baseline[b]	272	0.74	0.13	0.75	0.35	1.00
SF-36 6 months[b]	143	0.78	0.13	0.81	0.47	1.00
SF-36 12 months[b]	122	0.75	0.13	0.75	0.45	1.00
GP costs preintervention	149	£125.49	£93.99	£110.00	£0	£714.00
GP costs 6 months postintervention	149	£57.60	£49.88	£51.00	£0	£255.00
GP costs 12 months postintervention	149	£107.28	£82.47	£85.00	£0	£476.00
Pharmaceutical costs 12 months preintervention	149	£109.08	£293.01	£16.7	£0	£2764.15
Pharmaceutical costs 6 months postintervention	149	£74.25	£168.91	£23.73	£0	£1585.92
Pharmaceutical costs 12 months postintervention	149	£136.82	£329.55	£47.45	£0	£3184.25
Hospital costs 12 months preintervention	312	£134.32	£662.31	£0	£0	£7901.25
Hospital costs 6 months postintervention	312	£61.64	£283.83	£0	£0	£2938.36
Hospital costs 12 months postintervention	312	£127.02	£441.40	£0	£0	£3360.43
Cost of the intervention to the providers	317	£185.66	£33.23	£168.96	£88.76	£249.16
Cost of the intervention to the participants	88	£100.60	£103.50	£70.45	£4.73	£771.89
Equipment costs (a component of participant costs)	88	£6.68	£15.16	£0	£0	£60.00
Walking group						
SF-36 baseline[b]	259	0.74	0.14	0.76	0.37	1.00
SF-36 6 months[b]	107	0.75	0.14	0.79	0.40	1.00
SF-36 12 months[b]	92	0.77	0.15	0.81	0.41	1.00
GP costs preintervention	134	£125.36	£82.45	£110	£0	£374.00
GP costs 6 months postintervention	134	£52.30	£43.10	£42	£0	£187.00
GP costs 12 months postintervention	134	£103.49	£71.14	£84.5	£0	£323.00
Pharmaceutical costs 12 months preintervention	134	£148.51	£294.78	£25.18	£0	£1788.50
Pharmaceutical costs 6 months postintervention	134	£94.38	£161.01	£24.26	£0	£894.25
Pharmaceutical costs 12 months postintervention	134	£169.25	£295.62	£37.59	£0	£1609.65
Hospital costs 12 months preintervention	308	£178.79	£761.96	£0	£0	£7610.88
Hospital costs 6 months postintervention	308	£46.16	£219.54	£0	£0	£1682.59
Hospital costs 12 months postintervention	308	£162.07	£590.17	£0	£0	£4530.51
Cost of the intervention to the providers	310	£92.02	£11.33	£89.16	£48.86	£129.46
Cost of the intervention to the participants	75	£84.40	£170.54	£35.55	£0.76	£1460.01
Equipment costs (a component of participant costs)	75	£7.78	£26.56	£0	£0	£155.00

[a] Information on the control group is restricted to the 12 months before the intervention and the 6 months following the intervention. After that period patients in the control group were assigned to one of the active interventions.
[b] Numbers of SF-36 respondents attenuated as a result of incomplete responses.
[c] Participant costs for the control group are defined as zero.

The occasional very high costs appear to have been incurred on those few occasions when people reported having to travel a great distance to attend. This might have arisen for people whose other commitments had meant that they were away from home before or after their attendance.

The lower cost of the walking scheme arises because, on average, slightly less travel was required. Equipment costs comprised only a small element within the total compliance cost to the participant and differed little between the interventions, with estimated mean values of £6.70

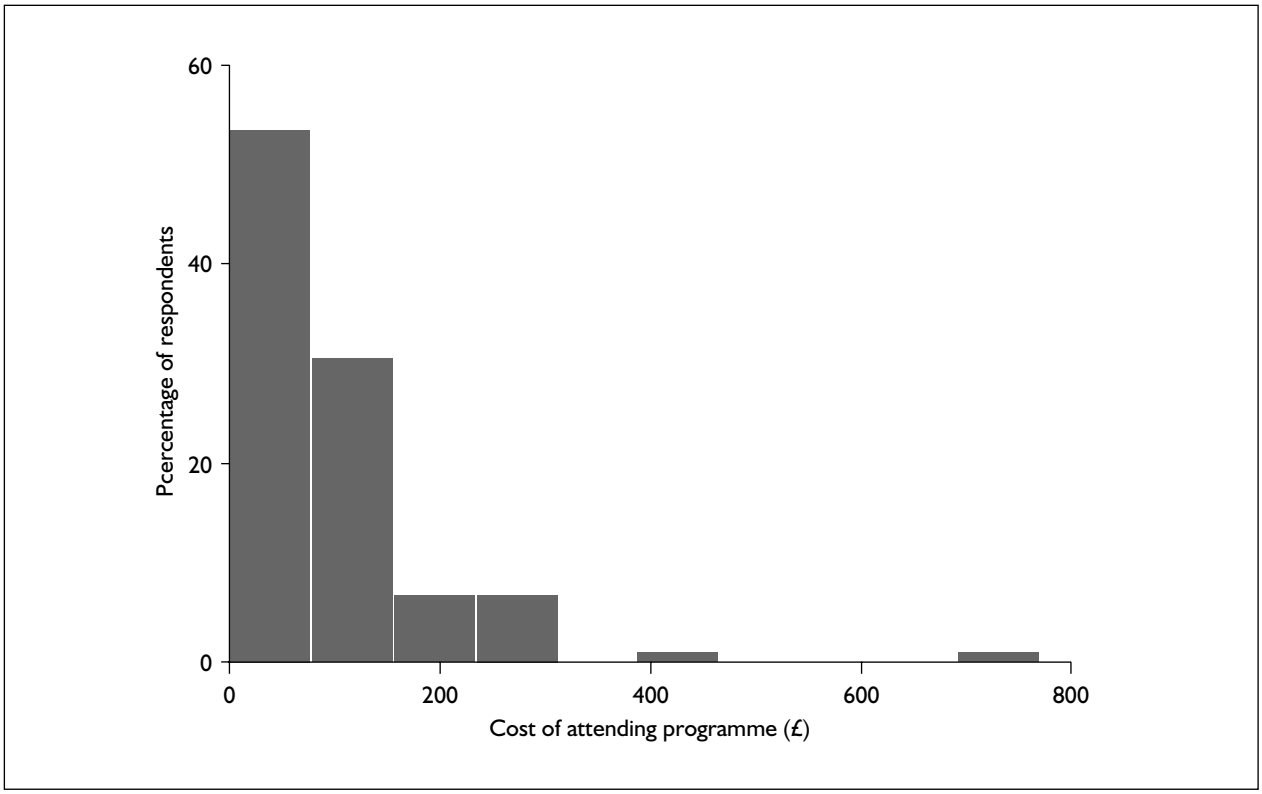

FIGURE 18 *Attendance costs for the leisure centre intervention*

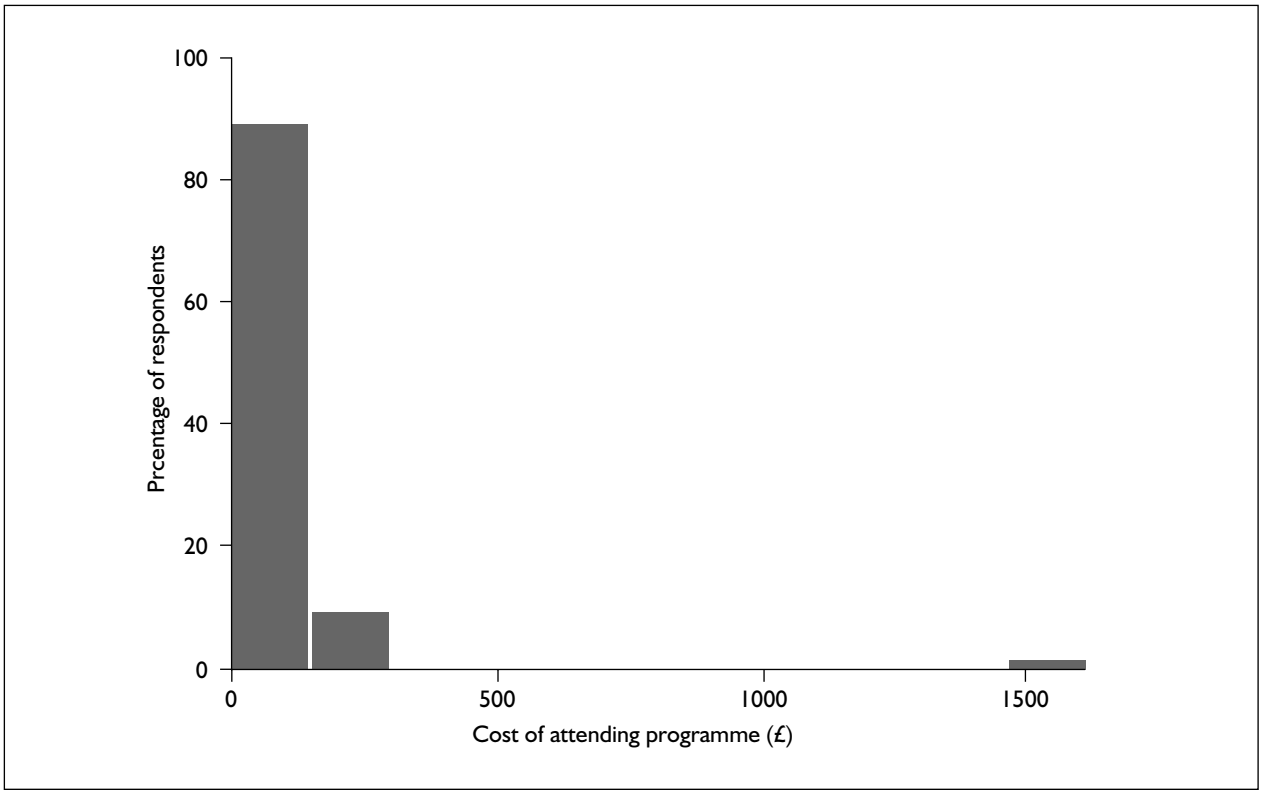

FIGURE 19 *Attendance costs for the walking intervention*

and £7.80 for the leisure centre and the walking group intervention, respectively.

Comparison of costs and effects

The following sections take a societal view of costs, such that total costs comprise the sum of healthcare costs, intervention costs and patient participation costs. The analyses examined whether health effects and the total costs so defined differed between groups.

Differences between the control group and the leisure centre group at 6 months

The controls were compared with the intervention groups at 6 months using an ANCOVA procedure to adjust for differences at baseline. (Whereas 12 months of follow-up information was obtained for the leisure centre and walking groups, the control groups were only followed up as controls for 6 months. After that time, they were randomised to one of the active interventions.)

After adjusting for differences in baseline SF-36 scores, the incremental effect of the leisure centre intervention on SF-36 score at 6 months amounted to a (just) statistically significant increase (improvement) of +0.0161 on the scale from 0 to 1. The bias-corrected bootstrapped 95% confidence interval spanned the range from +0.0024 to +0.0299.

After adjusting for differences in baseline, the total incremental cost (i.e. the costs of the intervention, plus any subsequent healthcare during the succeeding 6 months, plus the costs to participants) of the leisure centre intervention in comparison with the control group was estimated to be £312, the bias-corrected bootstrapped 95% confidence interval ranging from £272 to £357. As seen from *Table 62*, most of this difference was accounted for by the cost of the intervention itself (£186) and the costs to the participants (£101). The bootstrapped incremental effect of the leisure centre intervention on healthcare costs alone amounted to a non-significant £25, with 95% bias-corrected confidence limits ranging from –£14 to £70.

Because the cost data were highly skewed, the effect was examined of excluding the three potentially influential observations which, when excluded, changed the standard errors by more than 0.3. The estimated incremental cost attributable to the leisure centre intervention fell slightly, to £301. It therefore appears that the outliers have little influence on the conclusions that may be drawn from this study.

Differences between the control group and the walking group at 6 months

An ANOVA procedure was used to quantify differences in SF-36 score and total cost for participants who were randomised to the walking group intervention. The incremental effectiveness proved not to be significant. The estimated improvement after adjusting for baseline differences was estimated to be +0.0042 on a scale of 0 (being dead) to 1 (perfect health), with the bias-corrected bootstrap confidence limits ranging from –0.009 to +0.018. The estimated difference in total costs (again including the costs of the intervention, any subsequent healthcare during the succeeding 6 months and the costs to participants) was estimated to be £190, within a 95% bias-corrected bootstrapped confidence interval ranging from £153 to £231.

The cost of the intervention was £92 and the cost to the participants £84.40 (*Table 62*). As with the leisure centre intervention, most of the difference in cost arose from the intervention rather than any subsequent change in healthcare. The bootstrapped incremental effect of the walking intervention, on healthcare costs alone, amounted to a non-significant £9.48, with 95% bias-corrected confidence limits ranging from –£26.53 to £45.64.

To examine the possibility of the estimates being strongly influenced by outliers, the effect was examined of excluding observations that changed the standard errors by more than 0.3. Eliminating a single outlier resulted in a small increase in the estimated influence of the walking group intervention on total costs from £190 to £197.

Differences between the leisure centre group and the walking group at 6 months and 12 months

As noted, participants in the control group were reallocated to an active intervention after 6 months, making a direct comparison with the active intervention groups impossible beyond that time. However, data on the latter groups were collected for 12 months following randomisation, enabling comparison of costs and outcomes for the two intervention groups at both 6 months and 12 months.

At 6 months, the difference in SF-36 scores (after adjusting for baseline values) between the leisure centre group and the walking group was –0.012 (on a scale from 0 to 1), implying that the mean health state valuations for the sample in the walking group were somewhat worse. However, as an estimate of the population differences in SF-36 score, this difference is not statistically significant,

having a bootstrapped 95% confidence interval ranging from –0.025 to +0.001.

By 12 months the situation within the sample had been reversed. The baseline adjusted health state valuations given by the walking group were higher than those in the leisure centre group by 0.008 on a scale of 0 to 1, ranging from –0.004 to +0.020. However, if one estimates the difference between the leisure centre and walking groups while adjusting for health state at 6 months, the difference between the leisure centre group and the walking group shows a relative improvement for the walking group of 0.013. This difference is just statistically significant at the 5% level, with bootstrapped 95% confidence limits from 0.002 to +0.024. Thus, there is some suggestion that the walking group shows a late improvement in comparison with the leisure centre group. *Table 62* shows that the mean SF-36 score for the leisure centre intervention declines between months 6 and 12, while the mean score of the walking group appears to improve.

The difference in total costs at 6 months shows a relative reduction of –£124 in favour of the walking group after controlling for baseline costs. This difference is statistically significant, with bootstrapped confidence limits ranging from –£171 to –£81. The difference is largely accounted for by the lower cost of the walking intervention. Again controlling for differences in baseline costs, the difference in total costs after 12 months is lower, at –£70, with confidence limits ranging from –£152 to £25. This relative increase in total costs is partly explained by the relative increase in healthcare costs in the walking group of £32.

Cost-effectiveness ratios

These are expressed as cost per unit change in SF-36 score and depicted graphically in relation to the four quadrants shown in *Figure 20* [see Annex (p. 78) for detailed explanation].

Leisure centre versus controls

The estimated incremental cost-effectiveness ratio (ICER) for the leisure centre group compared with the control group, at 6 months, implied by the figures given above, was £312/0.016, equivalent to a cost of approximately £19,500 per unit increase in SF-36 score. (To illustrate the interpretation of these ratios of costs to SF-36 scores, the implication of sustaining such a change for a single year while incurring no further costs, then reverting to pre-existing health, would be a cost per QALY of £19,500.)

More costly Less effective	More costly More effective
Less costly Less effective	Less costly More effective

FIGURE 20 *Cost-effectiveness ratios by quadrant*

Figure 21 shows the results derived from the bootstrapped regression analysis using data that include imputed values. The solid line in the figure shows the cost-effectiveness ratio. The hatched lines show the angular 95% confidence interval. This falls entirely within the north-east quadrant (the region in which an intervention has positive health effects, but results in higher costs). The scatterplot shows that there is a small possibility that health effects might be negative, but no possibility that costs would be negative. Had it been the case that savings, from a reduced need for treatment within the intervention group, exceeded the cost of the intervention, estimates would have been observed below the horizontal axis in *Figure 20*. The figure implies that there is virtually no possibility that this would occur. Converting the angular confidence interval to one expressed as cost-effectiveness ratios, the equivalent cost of a unit increase in SF-36 (i.e. from a score of 0 to a score of 1) would lie within the range from £10,074 (as shown by the hatched confidence interval line that is 'clockwise' to the solid cost-effectiveness line) to £144,180 (as shown by the hatched confidence interval line that is anticlockwise to the solid cost-effectiveness line).

Walking versus controls

The estimated ICER for the walking group compared with the control group at 6 months, implied by the figures given above, was £190/0.004, equivalent to a cost of approximately £47,500 per unit increase in SF-36 score. *Figure 22* shows the results derived from the bootstrapped regression analysis using data that include imputed values. The scatterplot shows that there is a reasonably large probability that health effects might be negative, but no possibility that costs would be negative. Again, the solid line in the figure shows the estimated cost-effectiveness ratio. The hatched lines show the angular 95% confidence interval. Note that the anticlockwise confidence limit is in an area in which there are both costs and detrimental health effects. There is no meaningful interpretation to be placed on the

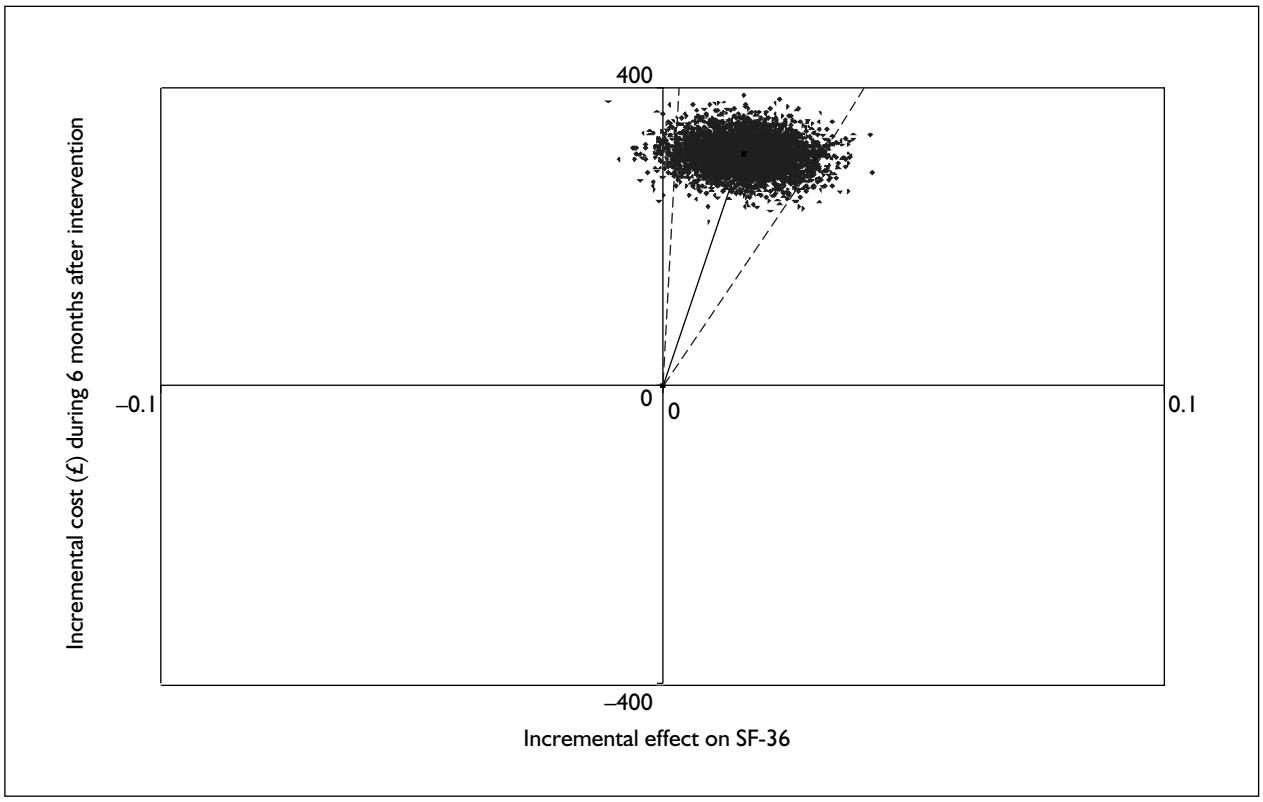

FIGURE 21 *Bootstrapped cost-effectiveness estimates with 95% angular CIs: incremental effect of leisure centre compared with controls at 6 months*

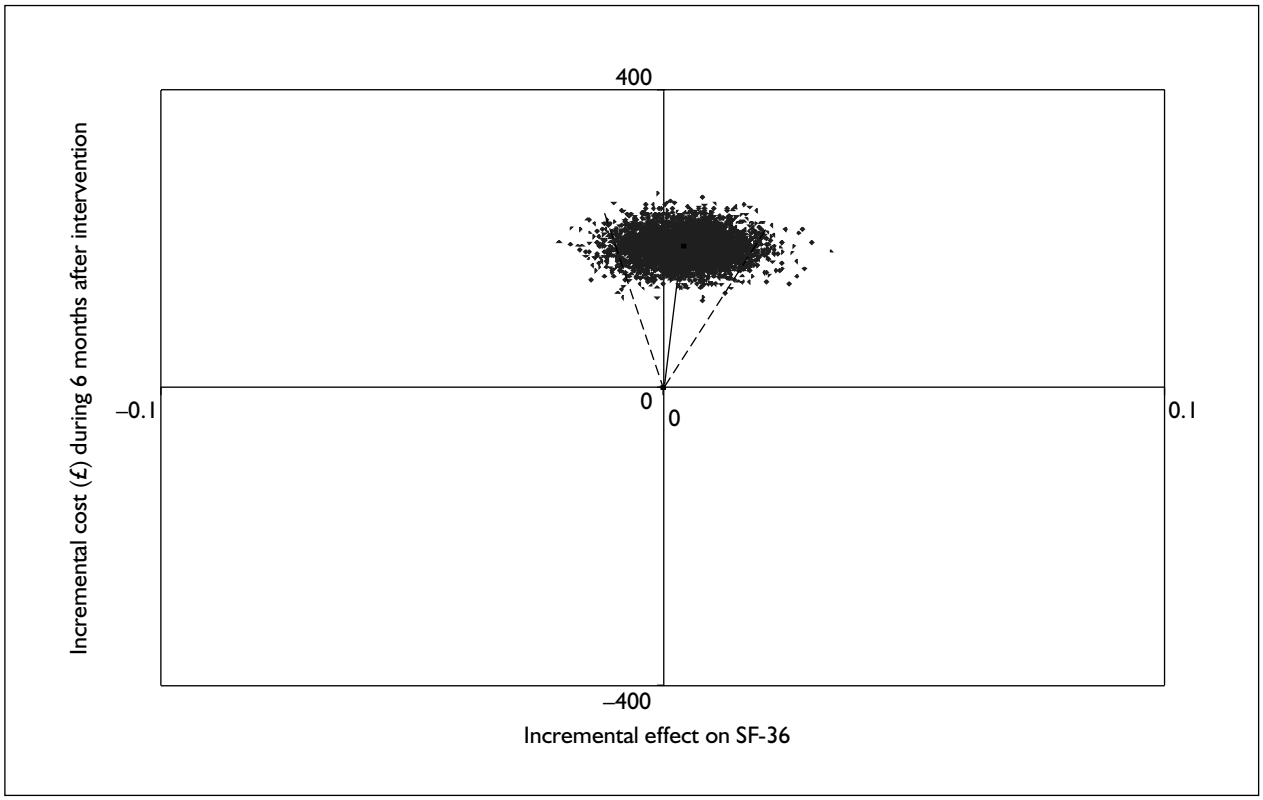

FIGURE 22 *Bootstrapped cost-effectiveness estimates with 95% angular CIs: incremental effect of walking compared with controls at 6 months*

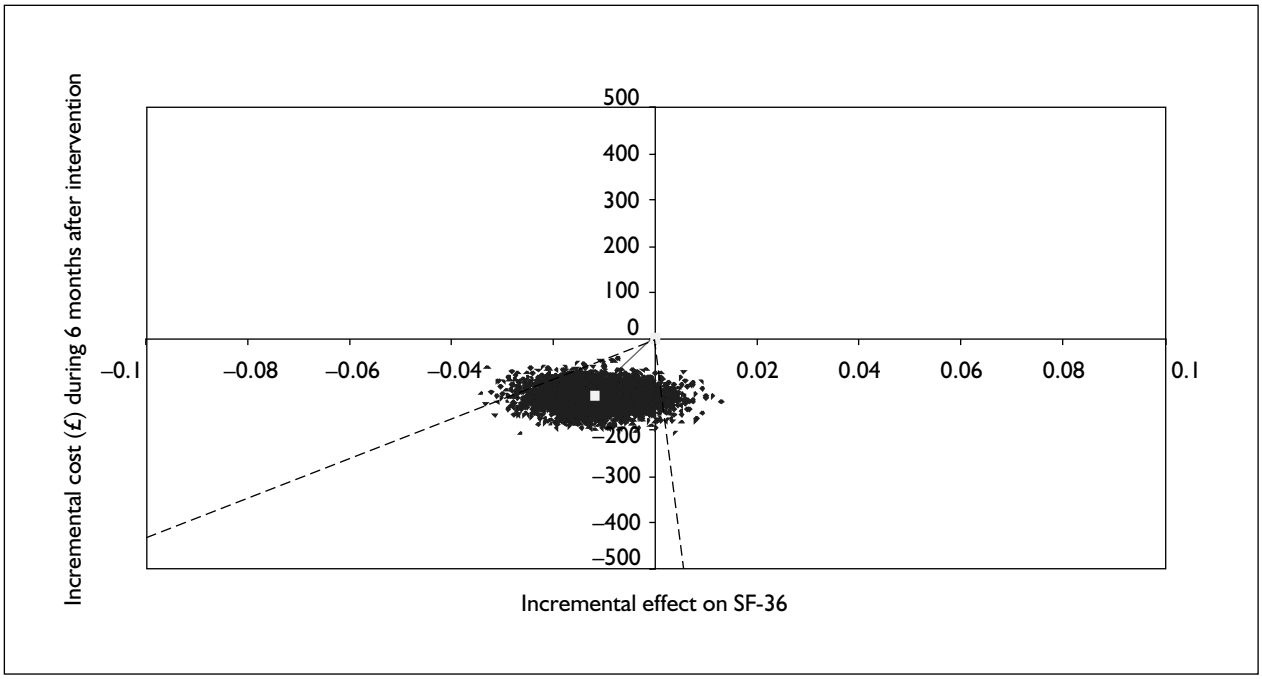

FIGURE 23 *Bootstrapped cost-effectiveness estimates with 95% angular CIs: incremental effect of walking compared with leisure centre at 6 months*

ratios of costs to disbenefits which arise in this quadrant. (To take a more prosaic analogy, it might be meaningful to ask how much one would pay to avoid a 'poke in the eye', but not how much one would pay to obtain one.) Numerically, the anticlockwise confidence limit implies a cost of £19,890 to achieve a unit reduction in SF-36 score. The clockwise confidence limit implies a cost of £10,623 for a unit improvement in SF-36 score.

Leisure centre versus walking at 6 months

The estimated ICER for the walking group compared with the leisure centre group at 6 months, implied by the figures given above, was –£124/–0.012, equivalent to a cost saving from the walking intervention of approximately £10,333 per unit decrease in SF-36 score. *Figure 23* shows the results derived from the bootstrapped regression analysis using data that include imputed values. The solid line in the figure shows the cost-effectiveness ratio. The hatched lines show the angular 95% confidence interval.

The scatterplot shows that there is a small possibility that health effects from the walking group might be better than the leisure centre group, but virtually no possibility that costs would be more; that is, the walking group appears to be cheaper, but possibly less beneficial to the health of participants at 6 months. Converting the angular confidence interval to one expressed as cost-effectiveness ratios, the interval ranges from a saving in cost per unit reduction in SF-36 score of £4289 to a saving in cost per unit increase in SF-36 of £96,376.

Leisure centre versus walking at 12 months

The estimated ICER for the walking group compared with the leisure centre group at 12 months, implied by the figures given above, was –£70/0.008, equivalent to a cost saving of approximately £8750 per unit improvement in SF-36 score. *Figure 24* shows the results derived from the bootstrapped regression analysis using data that include imputed values. The solid line in the figure shows the cost-effectiveness ratio. The hatched lines show the angular 95% confidence interval.

The scatterplot shows that there is a fairly strong possibility that the walking intervention might be preferable to the leisure centre intervention after 12 months, in both reducing costs and improving outcomes. Converting the angular confidence interval to one expressed as cost-effectiveness ratios, the interval ranges from a saving in cost per unit reduction in SF-36 score of £17,699 to a cost per unit increase in SF-36 of £2645. Thus, at 12 months, it seems probable that the walking intervention is both cheaper and more effective than the leisure centre intervention.

These results can only be suggestive, as there is no 12-month follow-up information on the control

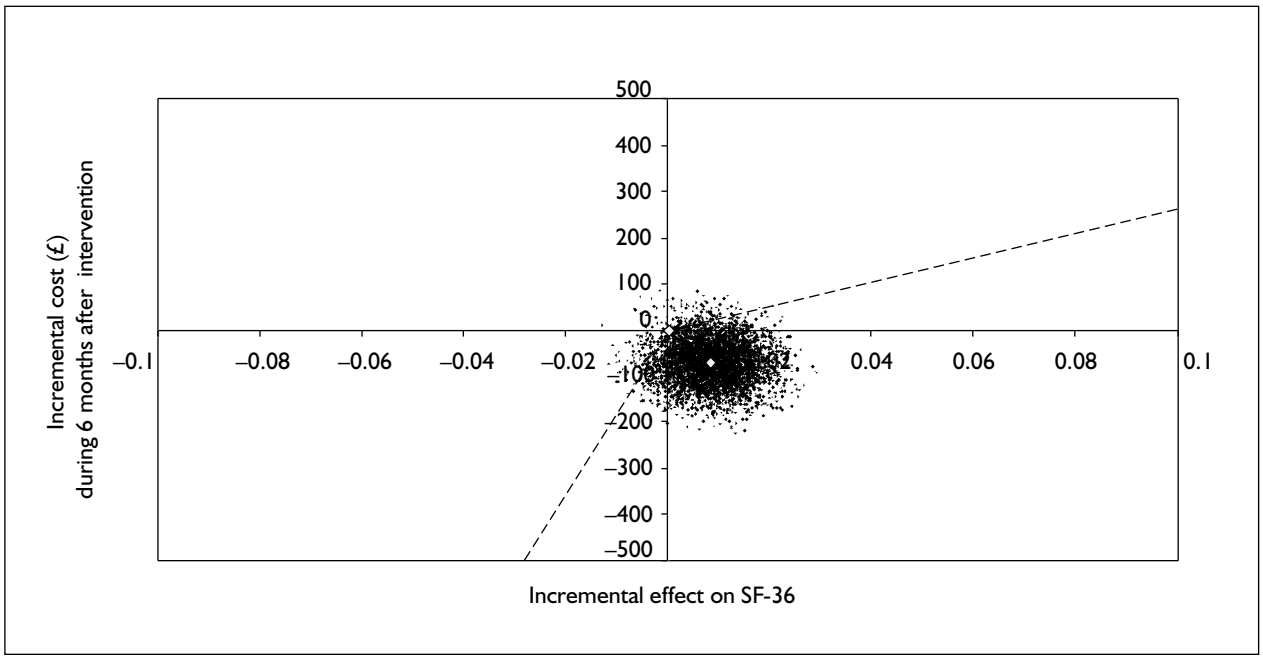

FIGURE 24 *Bootstrapped cost-effectiveness estimates with 95% angular CIs: incremental effect of walking compared with leisure centre at 12 months*

group. The difference between the leisure centre and the walking intervention at 12 months would appear to result from a more gradual and continued improvement in the people undergoing the walking intervention, together with a relapse to previous levels of health among the people attending the leisure centre.

Annex: cost-effectiveness and the treatment of uncertainty

Economists commonly advocate a more symmetrical approach to new, in comparison with existing, technologies, than that applied by other medical researchers. The latter are concerned to establish, with a high degree of certainty, whether a new intervention is superior to an existing one. Economists are more likely to consider the balance of probabilities; is it likely that we will do more good by adopting a new technology than by persisting with an existing one? In making such judgements, both costs and effects are important. All costs (those of the intervention, those of the subsequent healthcare of the participants and intervention costs borne by the participant) are added together for the purposes of this analysis. There is debate about precisely how cost and effectiveness data should be reported. In this report, results are presented in the commonly used form of ICERs (the additional cost of the intervention groups compared with the costs of the control group, divided by the additional health benefits of the intervention groups compared with the control group).

Estimates of incremental cost-effectiveness can fall into one of four areas (*Figure 20*) depending on whether an intervention is more or less effective than existing practice and whether it is more or less costly than existing practice. Ideally, a new intervention would be less costly and more effective. If it is more effective, but also more costly (the area in the north-east quadrant), then the additional health effects must be sufficient to justify the additional costs. If it is less effective, but also less costly (the area in the south-west quadrant), then the savings must be sufficient to justify the loss in health. If it were both less effective and more costly (the area in the north-west quadrant), then one would not wish to undertake the intervention.

Although an estimate of the mean costs and mean effects was presented, the fact that sample data were used, and that there was some variability within the sample, implies that the estimate might have been incorrect. Recent debate has stressed the importance of representing uncertainty about cost-effectiveness estimates and doing so in a way that recognises that there may be simultaneous uncertainty about several aspects of an intervention. Developments in statistics through the use of bootstrapping techniques allow

information to be sampled from a study and those samples to be used to understand better the distributions of complex statistics, such as cost-effectiveness ratios.

In the analysis of uncertainty, paired cost and effect data from individual participants were selected at random and placed in a temporary data set. The selection was repeated on the full data set (i.e. there was sampling with replacement), until an 'artificial' data set with as many observations as the original data had been constructed. This artificial resampled data set was entered into a regression procedure that enabled the effect of the intervention, both on costs and on effects, to be determined. This entire procedure was repeated 5000 times to produce 5000 estimates of the effect of the intervention. These estimates differed according to the particular sample drawn and reflect the variability in the sample.

Since missing information on an individual's costs might result in the wasting of data obtained on other variables used in the analysis, an imputation procedure from STATA version 8,[83] was used to substitute imputed values for missing data. These imputations are based on the age and gender of the subject. For the imputation of missing general practice and pharmaceutical cost data, the hospital cost data (where these were available) were also used in the imputations. Similarly, for those 50 participants living outside the local District Health Authority boundary for whom no inpatient records were obtained, inpatient costs were imputed using information on age, gender, the use of pharmaceuticals and GP costs (where available). A similar imputation procedure was used to infer the costs to the participant of attending either the leisure centre or the walking scheme. The variables used in this imputation were the group to which the participant belonged, their age at baseline and their gender.

It is well recognised that there are difficulties in determining confidence intervals for cost-effectiveness ratios.[85,86] Difficulties arise because the ratio can take very high values, and even infinity as the measure of effect approaches or reaches zero, and also because ratios arising from different areas in the cost-effectiveness plane (as shown in *Figures 21–24*), and with very different policy implications, can assume the same value. Thus, when measuring cost-effectiveness in terms of the incremental cost per life-year, an additional £1 spent in increasing a life by 1 year would have a cost-effectiveness ratio of +1, which might be regarded as good value for money, while a saving of £1 (i.e. an expenditure of –£1) achieved at the expense of a life-year lost (i.e. –1 life-year) would result in an identical cost-effectiveness ratio of +1, but the saving would be regarded as a very poor recompense for the life-year lost.

One way of overcoming this difficulty is to use angles rather than ratios. Each bootstrapped pair of cost-effectiveness replicates occupies a point in the cost-effectiveness plane. Cost-effectiveness ratios are simply the tangent of the angle between the horizontal axis and the radial. Rather than operate with the tangents (which, as noted, can take values from zero to infinity and are not uniquely defined) it is possible to operate with the angles themselves. A procedure was used in which the angular displacements of each bootstrap replicate from the horizontal axis are recalculated as angular displacements from the radial line representing mean incremental costs and mean incremental effects. This enabled the identification of radials that form upper and lower boundaries to a region that encompasses 95% of bootstrap replicate cost-effectiveness pairs (47.5% clockwise and 47.5% anticlockwise). The angles can be converted into cost-effectiveness ratios if desired.

Chapter 9

Results: adverse effects

GP record reviews

Information was abstracted from a pragmatic sample of 406 GP patient records. This sample largely reflected the whole study population. Referral criteria and baseline characteristics of the sample by treatment group are shown in *Tables 63* and *64*. The data were used for the economic analysis. In this chapter, the total number of GP visits and attendances for potential cardiovascular and musculoskeletal symptoms before and during the trial are considered.

GP visits

The total number of visits to primary care is shown in *Table 65*. Total visits were somewhat lower in all three groups after entering the trial.

There were no deaths recorded in the GP records and no episodes of MI, stroke or admission for cardiac interventional procedures during the trial. One episode of heart failure was recorded in a control subject during the initial 6 months after randomisation. Consultations for chest pain are shown in *Table 66*. Although there are fluctuations in the leisure centre and walking groups after starting the trial, the numbers are small and on average similar to the background rate in the control group.

A much larger number of consultations was for 'aches and pains'. These remained broadly at the pretrial level in all three groups (*Table 67*).

Sprains appeared somewhat more common in the control group, both before and during the trial. Falls and fractures were slightly more common in the leisure centre and walking groups after commencing the trial, although the numbers are small (*Tables 68–70*).

Other sources of information

Participants were not asked to report directly about adverse events, although some informed trial staff if they were unable to attend assessments, or in some cases did not wish to continue with the trial or asked to defer entry into a later cohort. Of the falls identified in the GP records, only one was reported to the trial staff. No fractures were reported directly.

Trial staff were informed about deaths during the trial of three participants, two in the walking group and one control who died after rerandomisation. No further information was available about these deaths and confirmation could not be obtained from death records.

TABLE 63 *Study groups: referral criteria. Values are numbers (percentages)*

Criterion	Leisure centre (*n* = 149)	Walking (*n* = 134)	Advice (*n* = 123)
Raised cholesterol	29 (19.5)	35 (26.1)	22 (17.9)
Hypertension	66 (44.3)	67 (50.0)	59 (48.0)
Obesity	97 (65.1)	81 (60.4)	83 (67.5)
Smoking	15 (10.1)	13 (9.7)	10 (8.1)
Diabetes	14 (9.4)	18 (13.4)	23 (18.7)
Family history of MI	25 (16.8)	22 (16.4)	15 (12.2)
Data are numbers (%).			

TABLE 64 *Study groups: sociodemographic characteristics*

Characteristic	Leisure centre (*n* = 149)	Walking (*n* = 134)	Advice (*n* = 123)
Age (years), mean (SD)	57.0 (9.0)	56.9 (8.1)	57.4 (8.5)
Gender			
Male	53 (35.6)	40 (29.9)	44 (35.8)
Female	96 (64.4)	94 (70.1)	79 (64.2)
Single	42 (28.2)	33 (24.6)	35 (28.9)
Ethnicity			
White	114 (76.5)	107 (79.9)	96 (78.0)
Asian	21 (14.1)	13 (9.7)	17 (13.8)
Educational level			
Degree or above	33 (22.1)	32 (23.9)	35 (28.5)
Technical qualification	8 (5.4)	9 (6.7)	8 (6.5)
Diploma	19 (5.4)	20 (14.9)	18 (14.6)
A level	18 (12.1)	14 (10.4)	10 (8.1)
O level or GCSE	29 (19.5)	27 (20.1)	24 (19.5)
None	34 (22.8)	27 (20.1)	20 (16.3)
Employment status			
Employed full time	36 (24.2)	33 (24.6)	34 (27.6)
Employed part time	11 (7.4)	20 (14.9)	21 (17.1)
Self-employed	16 (11.3)	12 (9.3)	15 (12.6)
Not in paid employment	25 (16.8)	24 (17.9)	9 (7.3)
Receipt of means tested benefits	41 (27.5)	40 (29.9)	29 (23.6)
Retired	54 (36.2)	42 (31.3)	36 (29.3)
Retirement income			
Main income state pension	25 (16.8)	20 (14.9)	10 (8.1)
Main income other sources	34 (22.8)	23 (17.2)	26 (21.1)
Socio-economic classification			
1.1	9 (6.0)	6 (4.5)	9 (7.3)
1.2	12 (8.1)	12 (9.0)	10 (8.1)
2	40 (26.8)	34 (25.4)	29 (23.6)
3	27 (18.1)	18 (13.4)	24 (19.5)
4	6 (4.0)	10 (7.5)	5 (4.1)
5	0 (.0)	6 (4.5)	3 (2.4)
6	19 (12.8)	20 (14.9)	20 (16.3)
7	6 (4.0)	5 (3.7)	6 (4.9)
8/not classified	30 (20.1)	23 (17.2)	17 (13.8)
Housing tenure			
Council tenant	7 (5.1)	6 (4.7)	9 (7.5)
Private tenant	7 (5.1)	10 (7.8)	9 (7.5)
Owner occupier	118 (85.5)	110 (85.9)	97 (80.8)
Access to private transport	121 (85.8)	112 (86.2)	106 (87.6)

Data are numbers (%) unless stated otherwise.

TABLE 65 *Visits to GP*

Time of visit in relation to start of study	Group		
	Leisure centre	Walking	Advice
1 year to 6 months before start	590	579	577
6 months before to start	785	653	611
Start to 6 months	632	539	480
6 months to 1 year	524	532	–

TABLE 66 *Visits for chest pain*

Time of visit in relation to start of study	Group		
	Leisure centre	Walking	Advice
1 year to 6 months before start	1	3	7
6 months before to start	3	4	7
Start to 6 months	2	9	7
6 months to 1 year	10	4	–

TABLE 67 *Visits for aches and pains*

Time of visit in relation to start of study	Group		
	Leisure centre	Walking	Advice
1 year to 6 months before start	54	48	56
6 months before to start	62	53	55
Start to 6 months	52	42	44
6 months to 1 year	63	44	–

TABLE 68 *Visits for sprains*

Time of visit in relation to start of study	Group		
	Leisure centre	Walking	Advice
1 year to 6 months before start	2	2	7
6 months before to start	3	6	2
Start to 6 months	1	4	6
6 months to 1 year	2	0	–

TABLE 69 *Visits for falls*

Time of visit in relation to start of study	Group		
	Leisure centre	Walking	Advice
1 year to 6 months before start	1	1	0
6 months before to start	1	1	2
Start to 6 months	9	2	0
6 months to 1 year	3	6	–

TABLE 70 *Visits for fractures*

Time of visit in relation to start of study	Group		
	Leisure centre	Walking	Advice
1 year to 6 months before start	0	1	1
6 months before to start	0	0	0
Start to 6 months	1	0	0
6 months to 1 year	0	4	–

Chapter 10

Evaluation by participants

Evaluation of 10-week programme

Participants allocated to the leisure centre and walking groups, who were randomised to attend the 10-week assessment, were asked to evaluate their exercise programmes. Responses were received from 164 participants; 27.4% of the leisure centre group and 29.7% of the walking group said that they had attended all the sessions as prescribed. The main reasons given for not attending all sessions were personal illness (26.2% of the 164 respondents), holiday (20.7%), work commitments (16.5%) and personal problems/commitments (10.9%). However, 66.7% of the leisure centre group and 70.3% of the walking group said that they undertook additional exercise during the 10-week period. The main additional activities were walking (46.9% of the leisure centre group and 47.8% of the walking group) and swimming (21.9% and 17.4%, respectively). Satisfaction with both programmes was extremely high, with 97.8% of the leisure centre group and 93.8% of the walking group stating that they felt better for taking part, while 97.8% and 95.2%, respectively, enjoyed participating. Eighty-six leisure centre participants and 55 walkers responded to the open question asking what aspects they particularly enjoyed. 21.8% of the walkers mentioned the instructors, compared with 4.7% of the leisure centre group; 16.3% of the latter identified group activities and 12.8% meeting people, compared with 10.9% and 18.2% for the walkers.

Only five of the leisure centre group and seven of the walking group indicated aspects that they had not enjoyed, but there were no consistent findings. Of the participants in the leisure centre group and the walking group, 80.7% and 85.2%, respectively, said that the programme had had the effect they expected, although seven leisure centre participants commented that they had not lost weight. When asked whether participating in a regular exercise programme had changed other aspects of their lives, such as eating, sleeping, smoking and stress, 57.3% of the leisure centre group and 50% of the walking group responded positively. The administrative procedures were found to be satisfactory by 93.3% of leisure centre participants and 91.2% of walkers. Further, 96.6% of the leisure centre group and 96.4% of the walking group said that they were given all the information they needed; however, 15.2% and 16.7%, respectively, had further questions about the programme, most significantly about how to continue exercise. There was no significant difference between the groups for responses to any of these questions.

Evaluation at 6 months

Participants randomised to the leisure centre and walking groups completed a short evaluation questionnaire at the 6-month assessment relating to continuation of exercise (n = 315): 98 participants in each of the two groups said that they had carried on regular exercise since finishing the 10-week programme, representing 57.3% of the leisure centre group and 80.3% of the walking group ($p < 0.001$ for between-group difference).

Exercise was carried out at the locations shown in *Table 71*. Those randomised to the leisure centre group were significantly more likely to have

TABLE 71 *Location of continued exercise at 6 months*

Location	Group		
	Leisure centre (%)	Walking (%)	*p*
At home	23.6	15.3	ns
At Barnet leisure centre	29.8	18.2	<0.05
Barnet health walks	7.3	48.2	<0.001
Elsewhere	18.5	19	ns

TABLE 72 *Location of continued exercise at 1 year*

Location	Group		
	Leisure centre (%)	Walking (%)	*p*
At home	20.9	24.5	ns
At Barnet leisure centre	32.5	21.6	<0.05
Barnet health walks	8.6	33.8	<0.001
Elsewhere	15.3	23.7	ns

continued to exercise at a leisure centre, while those randomised to walking were significantly more likely to have continued to participate in Barnet health walks.

Following the 10-week exercise programme, participants in both the leisure centre and walking groups were offered the option of buying a half-price book of tickets for further sessions. This option was taken up by 32.1% of the leisure centre group and 32.3% of the walking group. Only two-thirds of both groups stated how many tickets they had used. In each case, about one-fifth had used no tickets at all and only one-quarter had used more than half.

Participants who had stopped exercising were asked to give the main reasons, and 57 leisure centre participants and 24 walkers listed reasons. The most common were ill-health/injury, representing 21.9% of the total leisure centre participants and 13.1% of the walkers ($p < 0.05$ for between-group difference), and laziness/lack of determination representing 14% of the total leisure centre participants and 3.6% of the total walkers ($p < 0.01$ for between-group difference). The only other reasons cited by more than 3% of each group were family commitments, followed by work commitments.

Participants originally randomised to the control advice-only group were asked about their participation in structured exercise programmes since their initial assessment, to gauge the degree of contamination by the other two trial arms. 24.4% had taken part in the instructor-led Barnet health walks programme and 31.6% had attended leisure centres or gymnasiums. Those responding positively were asked whether their attendance had been regular, defined as at least once a week for at least 2 months: 14.4% of total respondents had attended health walks regularly, with 8.7% still doing so, while the respective figures for leisure centres were 15.8% and 14.6%.

Evaluation at 1 year

Participants randomised to the leisure centre and walking groups completed a short evaluation questionnaire at the 1-year assessment, similar to the 6-month questionnaire, with some additional questions ($n = 302$). The responses showed that 115 participants in the leisure centre group (74.2%) and 106 (82.8%) in the walking group had carried on regular exercise since finishing the 10-week programme (difference not significant).

Participants were asked whether their current regular exercise had been started as a result of the initial 10-week programme. Three-quarters of those continuing regular exercise answered this question, of whom 86.4% of the leisure centre group and 73.1% of the walking group said that it had.

Exercise was carried out at the locations shown in *Table 72*. As at 6 months, those randomised to the leisure centre group were significantly more likely to have continued to exercise at a leisure centre, while those randomised to walking were significantly more likely to have continued to participate in Barnet health walks.

The option of half-price tickets had now been taken up by 44.7 % of the leisure centre group and 33.9 % of the walking group. About three-quarters of both groups stated how many tickets they had used. About one-tenth had used no tickets at all and over one-third had used more than half.

Participants were asked, if they had not continued to exercise, how long it had been since they last did so regularly. There was a tendency for those discontinuing exercise in the leisure centre group to have done so earlier than the walkers (*Table 73*).

As at 6 months, participants who had stopped exercising were asked to give the main reasons with similar results; ill-health/injury being most commonly cited by both groups.

TABLE 73 *Time since discontinuing exercise*

When exercise was discontinued	Group		
	Leisure centre (%)	Walking (%)	*p*
In past month	11	15.1	ns
1–3 months previously	9.8	7.2	ns
>3 months previously	16	6.5	0.01
None since exercise programme	21.5	13.7	ns

TABLE 74 *Location of continued exercise at 1 year (telephone interview)*

Location	Group		
	Leisure centre (%)	Walking (%)	*p*
At home	10.9	6.3	ns
At Barnet leisure centre	10.9	4.2	ns
Barnet health walks	2.2	16.7	<0.05
Elsewhere	19.6	31.3	ns

Of the participants in the leisure centre group and the walking group, 17.8% and 28.3%, respectively, had kept in touch with other participants they met during the exercise programme ($p < 0.05$). Further, 37.8% of the leisure centre group and 45.5% of the walking group said they had made other changes to their lifestyle since starting the exercise programme. In answer to an open question on the changes they had made, 28.2% of the leisure centre group and 27.3 % of the walking group said that they were eating more healthily, 3.1% and 2.9%, respectively, mentioned weight loss and 3.1% and 4.3%, respectively, reducing and stopping smoking. As a result of participating in the EXERT study, 15.9% of the leisure centre group and 22.8% of the walking group said that family and friends had made changes to their lifestyle.

Telephone interview at 1 year

Trial participants who did not attend the 1-year assessment in the leisure centre were contacted by telephone. Several were unobtainable and some refused to take part in the interview. Of the 89 respondents to the question, 16 (36.4%) of the leisure centre group had continued to exercise, compared with 22 (48.9%) of the walking group, a non-significant difference. Eight leisure centre participants and 20 walkers said that this had resulted from the programme.

Continuation of exercise in any location was less than in those attending the 1-year assessment (apart from walkers exercising elsewhere), but even in this group the number of walkers continuing to attend Barnet health walks was significantly greater than those from the leisure centre group (*Table 74*).

Uptake of half-price tickets was low among the telephone interviewees (leisure centre participants 13.6%, walkers 2.2%), and usage even less. Since the end of the 10-week programme, 47.8% of leisure centre participants and 29.2% of walkers had not taken part in regular exercise, 26.1% and 20.8% respectively citing ill-health/injury.

Of the participants in the leisure centre group and the walking group, 13.6% and 11.4%, respectively, had kept in touch with other participants they had met during the exercise programme. Further, 47.7% and 51.2%, respectively, said that they had made other changes to their lifestyle, with 45.7% and 39.6% mentioning a healthier diet, and 17.4% and 20.8%, respectively, saying their family and friends had made lifestyle changes.

Comments by participants

At each assessment point participants were asked whether there were any comments they wished to make about the programme. A selection of these is shown below.

10 weeks

"I understand the course was partly intended for people like me who do not want to exercise, although I was shown to have physically benefited, I'm afraid I need even more motivation if I am to continue." (Leisure centre group)

"I feel much better in mind and health wise for doing the programme and just as important it has got me out of the house." (Walking group)

"I want to say thanks for the chance to participate because it has given me the push I needed and it is my intention to make these walks part of fitness activity for life." (Walking group)

"Making the time for the programme a bit more liberal will encourage a lot of people who are committed either with official or domestic engagements in the morning." (Leisure centre group)

Six months

"I was disappointed that after the 10 weeks I was just 'dropped'. There was no discussion or suggestions or information about what was available to do. Only through my own initiative did I continue." (Leisure centre group)

"If it hadn't been for the pain which was exacerbated by walking I would have carried on." (Walking group)

"I would like to find a 'trainer' who could supervise and formulate exercises I could do at home, and would be prepared to pay for this. I would like to buy more pink tickets as I find these encourage me." (Leisure centre group)

"In order for me to continue religiously I would need to be on a continuous assessment programme – would go out of guilt." (Walking group)

One year

"Exercise programme was excellent – follow on was nonexistent. No real help to keep it up, left to own devices. Borough facilities are far too expensive – especially for those on low incomes." (Leisure centre group)

"I wanted to lose weight, but gained it; should have addressed this more – might have encouraged to continue regularly. Enjoyed programme and follow-ups. All staff concerned were friendly and supportive." (Leisure centre group)

"I would have liked advice from a dietician about planning better eating habits, not just general advice, and the study to allow for more personal help to achieve goals, not just a baseline study for the borough on the role of exercise." (Leisure centre group)

"I feel that I would like to have time to exercise but because of work and family commitment I do not have time and am sometimes restricted to brisk walking." (Leisure centre group)

"Since my last exercise programme I have been made redundant, my mother of 88 has been living with me, been in hospital, and is now in a nursing home. This has put a lot of pressure on me mentally and subsequently physically." (Walking group)

"Going to exercise program every week very helpful, made me feel good in myself as well as fitter. I will start again right now. I mean to really make a good start today." (Leisure centre group)

"I have thoroughly enjoyed taking part in the exercise programme. I regret not being able to continue on the walks because of a problem with my foot. However it has encouraged me to lose my excess weight and to try to keep more active." (Walking group)

Chapter 11

Discussion

This study was a single-centre RCT to compare the effectiveness and cost-effectiveness of referral to two types of structured exercise programme and advice only in promoting physical activity in a sedentary primary care population at risk of CVD. Primary outcome measures included changes in self-reported physical activity and in blood lipids and blood pressure, which are well-established cardiovascular risk factors and have been shown to be influenced by exercise.[87,88] Additional outcomes included a variety of psychological and physical measures, as well as ratings of satisfaction.

The trial was based on a large pre-existing exercise on prescription scheme, which had been running in the London Borough of Barnet for 3 years. This was well used by a significant number of local GPs, who valued it highly. In designing the trial, it was felt important to reflect reality by adhering as closely as possible to the previous referral and organisational arrangements. GPs were to select patients with specified cardiovascular risk factors, who would benefit from increasing their physical activity. In practice, patients who attended for initial assessment were randomised into the trial irrespective of baseline physical activity. In retrospect, trial participants were not all sedentary, about 16% reporting physical activity levels in the sport and walking categories broadly equivalent to current recommendations of at least 30 minutes of moderate physical activity on at least 5 days of the week. Sensitivity analyses excluding these subjects had no impact on the main findings.

To persuade local GPs that it was reasonable to include a control group in the trial, it was proposed that patients randomised to this group would in effect be placed on a waiting list, for randomisation into the trial at a later stage. It was also hoped that this would boost the numbers going through the active intervention arms of the trial. In fact, the control group demonstrated a significant change in self-reported physical activity, as well as in other outcomes, over the 6 months before rerandomisation. It was therefore inappropriate to include their results after reallocation in the comparative analyses of the intervention groups. In addition, recruitment to the trial slowed during the later stages. The final numbers available for analysis were thus lower than planned.

Clinical outcomes

In terms of the primary outcome, the comparison of changes in physical activity, blood pressure and lipids in the leisure centre, walking and advice-only groups between baseline and 6 months, the results were consistent with the null hypothesis of no significant difference between the three groups. Nor were there between-group differences in other important end-points, including measures of cardiorespiratory fitness, although for some measures of exercise behaviour, including stages of change and likelihood of continuing exercise, there were differences in favour of the walking group at this time-point.

There were, however, changes in all groups at the immediate postprogramme assessment point compared with baseline, in exercise behaviour, psychological parameters and several physiological and biochemical measurements, including blood pressure, cardiorespiratory fitness, power, total cholesterol and LDL-cholesterol. Improvements in these measures were sustained until at least the 6-month assessment and to a year in some cases.

In laboratory-based studies, exercise has been shown to induce a positive effect on a number of different bodily functions, including parameters that are important for CVD prevention. The present study demonstrated that when evaluated on a larger scale in a population-based study, increased physical activity was indeed associated with improvements in a number of cardiovascular risk factors, as well as those that may impair mobility.

The ability to perform a given amount of exercise is determined by the successful interaction of the musculoskeletal, respiratory and cardiovascular systems which, even in health, show a functional decline as a result of the ageing process. The data presented here show an age-related decline in physical performance, as indicated by muscle power and ability to cycle and walk. However, the results show that explosive power of the lower limb

extensor muscles significantly improved and was maintained in concert with the increased levels of physical activity. Exercise capacity as measured by heart rate recordings at a fixed exercise intensity improved (i.e. the heart rate was lower), such that the challenge of walking at a given pace or cycling at a particular power output represented less of a physiological challenge to the body. These improvements in physical fitness, if maintained, should result in corresponding improvements in cardiovascular morbidity and mortality.

In respect of specific risk factors for CVD, the changes in total cholesterol and LDL-cholesterol were relatively small, although even a reduction of 2% would have an impact at a population level. The reductions in blood pressure, if wholly attributable to the study, were of greater biological significance. At one year, systolic blood pressure was 6 mmHg and diastolic blood pressure 4.5 mmHg lower than at baseline in the combined leisure centre and walking groups, by ITT analysis. By analogy with clinical trials of blood pressure-lowering medication, reductions of this order would be expected to have an important public health impact, with an approximate reduction in cardiovascular morbidity and mortality of at least 20%.[89]

Economic considerations

The SF-36, a commonly used measure of health status in economic studies, was chosen to determine health outcomes for the economic analysis. The results appeared to show a small improvement for the leisure centre intervention compared with advice only at 6 months. However, the improvement to people in the leisure centre group was not sustained at 12 months. At 12 months there was some suggestion that the walking intervention was more effective than the leisure centre intervention; however, direct comparison with the advice-only group at 12 months was not possible.

An alternative approach derives from the demonstration of an inverse linear dose–response relation between volume of physical activity and all-cause mortality rates in both men and women, and in younger and older people.[90] The increased understanding of the efficacy of moderate exercise on health supports the approach taken in the analysis of the Green Prescription programme in New Zealand,[91] where changes to physical activity were used to infer an impact on health. This approach can greatly simplify the study design in comparison with the approach taken here, quantifying changes in quality of life and biometric measures of patient health, although this depends critically on the accuracy of measures of change in physical activity.

With respect to costs, exercise programmes are not cheap. Costs to the participants amounted to £100 for the leisure centre scheme and not much less (£84) for the walking scheme. Provider costs were even higher, at £186 for the leisure centre scheme and £92 for the walking scheme. These costs compare favourably with the intervention reported by Stevens and colleagues,[31], in which an exercise development officer advised patients during a 10-week programme of home and leisure centre activity. That study reported provider costs of £279 per programme completer, a figure that includes the cost of proactive recruitment of patients.

Given the generally high levels of GP consultation, it seems unlikely that active recruitment would achieve a substantially higher participation rate among inactive people in the population at large. Even if it did, the incremental cost of reaching the additional people would need to be determined, to assess whether such a strategy is cost-effective. It may be that proactive 'cold calling' recruits fewer people at higher cost than offering exercise schemes to those who are visiting their GP and hence may be more amenable to the recommended treatment. This question needs to be addressed by further research.

Limitations of the study

Difficulties in maintaining a 'control' group

This study used two distinct exercise schemes, walking and leisure centre based, to initiate a lifestyle change in respect of physical activity, and compared these with each other and with an advice-only arm, which was intended to approximate to advice received in primary care and to serve as a control group. Overall, the results showed no clear or consistent differences in the efficacy of the two structured interventions when assessed at the end of the 10-week programme or after the subsequent follow-up periods, and similar changes were recorded in the advice-only group up to the 6 months of observation. Analysis of their physical activity questionnaires, however, revealed that this 'control' group had heeded the advice and increased their levels of physical activity to three times the baseline level at 10 weeks and double at

6 months. Some specific aspects of the difficulties in maintaining a 'no change' group for comparison with the active interventions are considered further below.

Ethical considerations

Two issues compromised the researchers' ability to establish an appropriate control group. The first was that it was considered unethical locally to withhold active treatment (i.e. an exercise programme) from patients deemed by their GPs to be suitable, as the previous programme was considered successful and its availability was well known. For this reason, 'controls' were informed that they would be eligible for randomisation to one of the two exercise programmes at a later date.

It was further considered unreasonable to expect these participants to wait for a year; advice from the local research ethics committee and local GPs indicated that a 6-month wait would be acceptable. Those assigned to the control group were therefore given advice and information only, but were rerandomised to one of the two active intervention arms of the trial after completing the 6-month assessment. This in itself could have affected their behaviour, but may also have had the advantages of reducing both contamination on the one hand (i.e. participants randomised to the control group taking up leisure facility-based or walking programmes of their own accord) and of dropouts on the other, which would affect the validity of measurements on those remaining within this group.

Potential for contamination of the control group

Another problem, common to this type of trial, is that people in the 'control' group are in effect given quite a detailed initial intervention, consisting of a 2-hour health and fitness assessment with individually tailored advice. This included information on exercise programmes available locally in Barnet.

Although the leisure centre-based classes could only be accessed via the EXERT study over the course of the randomisation period, the Walking Partners programmes were available separately to any Barnet resident. Until December 1999 these were offered free of charge (subsequently a charge of approximately £1.00 was made per walk). Furthermore, it was possible that some participants would elect to attend a leisure centre or gym in anticipation of starting on the programme later. Hence, it was anticipated that some 'controls' would in effect start following one of the intervention arms before they were rerandomised to an exercise programme. This could only be expected to dilute the apparent effectiveness of the exercise interventions, but was difficult to avoid, while maintaining the ethical considerations of offering advice and information to the control group.

Controls returning for their 6-month assessments before reallocation into one of the intervention arms were asked about attendance at any of the Walking Partners walks, or any other exercise programme they may have commenced, so that this potential effect could at least be measured. Seventy-six of 160 control subjects responding to the question said they had participated in organised health walks or attended the leisure centre since their initial assessment, representing a minimum of 34.5% of the 220 controls undergoing reassessment.

Hawthorne effect

A change in exercise behaviour that may be directly attributable to taking part in a trial has been observed in several studies.[25] Apart from awareness that they would be returning to join one of the two supervised exercise programmes, the control subjects' involvement in the fitness assessments may itself have caused a change in exercise behaviour.[92] This, however, was unavoidable if a key aim of the project was to compare changes in physiological variables between the three groups. To attempt to measure the possible effect of an assessment on subsequent exercise behaviour, the researchers randomly selected only half of each arm of the trial to return for a full assessment at the end of the exercise programme. Subgroup analysis showed that randomisation to the 10-week assessment made no difference to the proportions of participants undertaking 150 minutes or more per week of at least moderate intensity physical activity. This could not establish whether an initial assessment itself acts as a motivating factor.

Patient preferences

The EXERT study was designed for patients who are not physically active, and was unsuitable for patients with strong preferences for any particular exercise programme. Inevitably, some patients expressed a preference for one or other arm of the study. The authors considered whether to include a patient preference arm in the trial, but decided against this, as local knowledge of the leisure centre-based scheme would have resulted in a majority of participants selecting this option, thus substantially reducing the numbers eligible for randomisation.

Since there is good evidence of a relationship between prior preferences and treatment efficacy,[93] the fitness assessor was asked to note any preferences the patients expressed for either one intervention arm or another, or for one specific class within an intervention, and to record whether or not the study was able to meet that preference. Unfortunately, however, the recording of this information was too patchy for analysis.

Choice of outcome measures

Surrogate markers of cardiovascular risk

The trial was designed to answer questions relating to the impact of different exercise prescriptions on the risk of CHD. Therefore, blood pressure and cholesterol and its subfractions were measured as primary outcome measures, as these are well-established risk factors, with a substantial evidence base linking changes in their levels to changes in cardiovascular outcome. Cardiovascular fitness was also measured as another surrogate. These are clearly intermediate end-points; ideally, cardiovascular events should also be measured, but in a primary prevention study the sample size required would be prohibitive, if such events were to be the primary outcome measures. The validity of the blood pressure measurements was limited by the absence of a run-in period. The authors considered obtaining more than one baseline measurement both for blood pressure and for heart rate response to exercise, as anxiety and unfamiliarity with the surroundings could affect both of these measures. This option was rejected, however, on logistical grounds, because the attendance rate for a second baseline assessment was likely to be low, while the throughput would have been significantly reduced by the need to book additional appointments.

While the reductions in blood pressure observed in the study may in part have related to increased familiarity with the procedure and environment, it is noteworthy that there were no parallel changes in resting pulse rate, which might have been expected to reflect reduced anxiety. Furthermore, the assessments were carried out after quite prolonged intervals. This might have attenuated the effect of familiarisation expected with more regular monitoring, as in drug trials, while still inducing a degree of stress associated with the knowledge that the measurements were subject to scrutiny by the research staff.

A pragmatic approach was used in designing the fitness assessments. Tests were included only if they were thought likely to be acceptable to the study participants, omitting those considered too complex or arduous. For example, on strictly scientific grounds, maximal exercise tests may be preferred to submaximal ones.[94,95] However, given the potentially high-risk patient population and ethical concerns (assessments were not medically supervised), submaximal tests were considered more appropriate.[96] Similarly, direct measurement of oxygen consumption was considered impractical in this large field trial and assessment of cardiorespiratory fitness was based instead on heart rate response to exercise.

As in the case of blood pressure, increased familiarity with the testing procedure could have contributed to the improvement seen in some parameters, although it is noteworthy that although there was, for example, a sustained increase in muscular power, this was not the case for strength. Similarly, heart rate responses are likely to be susceptible to the effects of anxiety in the initial phases of an exercise protocol, but should be overridden by the effects of the exercise itself as higher work rates are achieved.

Finally, ideally lipid measurements should have been undertaken under fasting conditions, but again this would have been impractical other than for those participants who made early-morning appointments for assessment. Although studies have shown no significant diurnal or postprandial variation in total cholesterol,[97,98] the results, particularly for triglycerides, should nevertheless be treated with caution.

Indicators of exercise behaviour

Evaluations were made of both adherence to the supervised exercise programme and continuation of physical activity. The former was assessed mainly from exercise class registers, supplemented by diary records. Ideally, both sources of information should have been available and consistent for each participant, but relatively few participants brought their diary records to the assessments. Class registers were not kept consistently by all exercise instructors and may have underestimated adherence, particularly in the walking group. In the case of discrepancies, the classification of adherence was based on the higher of the two recordings, where available. Despite the likelihood of some misclassification, the adherence categories showed a graded relationship to baseline indicators of socio-economic status, such as access to transport, as well as to subsequent attendance for assessment, suggesting reasonable face validity. For analyses

relating adherence to outcome measures, differences were sought between high adherers, about whom there was reasonable certainty, and the other participants.

Continuation of physical activity was assessed in three ways. Participants were asked whether they were exercising currently as part of the stages of change questionnaire. In the programme evaluation questionnaire, they were asked in more detail about continuing participation in either leisure centre activities or the walking programme. Finally, participants completed a detailed 7-day recall questionnaire, aimed at capturing all domestic-, work- and leisure-related physical activity. The gold standard for physical activity measurement is considered to be an objective method using, for example, motion sensors or heart rate monitors, although these also have their limitations. The possibility of using an objective measurement method was considered by the steering group, but rejected on pragmatic grounds. Seven-day recall diaries and questionnaires have been extensively used and validated in large-scale field trials. Although the recall questionnaire was designed to be administered by a researcher, it has been shown to be valid as a self-administered instrument, with a good correlation ($r = 0.79$) with accelerometry.[99] However, in general, comparisons between questionnaires and with objective measurements have shown variable validity and reliability, albeit better for vigorous exercise.[100] Furthermore, although the researchers adapted a version of the questionnaire in use in another UK trial,[31] they did not validate it in their own trial population. In view of the uncertain validity of the results, the changes in activity in the 'walking' and 'sport/leisure' categories were emphasised; these should be recalled more accurately than overall activity. To allow for the possible effect of unusual patterns of activity during the week in question, an additional question was asked as to whether the week was typical, and sensitivity analyses were carried out excluding those for whom it was not typical.

Dropouts

Subjects referred who never attended for a first assessment, or decided not to enter the study, may differ in certain ways from those who agreed to be randomised. An attempt was made to evaluate this by comparing the limited data available on referral criteria, age, gender and ethnicity. It appeared that referral for obesity and age below 50 years were associated with a reduced likelihood of participation in the trial.

Trials of this type have in general suffered from high dropout rates. To try to reduce the figures for non-attendance for assessment, several attempts were made to contact non-attenders and to offer mutually convenient time slots, but there were constraints imposed by the requirements for processing participants in successive cohorts. Dropouts during the trial were similar in respect of referral criteria and socio-demography to continued attenders, but may differ critically in exercise behaviour. Thus, high adherence to the exercise programme was associated with high levels of attendance for follow-up assessments. It would further be expected that those who had increased their amount of physical activity would be more likely to reattend than those who had not. Corroboration for this assumption was obtained from the telephone interviews with non-attenders at 1 year, who were less likely than attenders to have continued exercise and more likely to have given up immediately after the initial 10-week programme.

Analyses based on available data at each time-point or on results restricted to subjects with data at baseline and a subsequent time-point ('completers' analysis) may pick out the more enthusiastic participants. Most trials of physical activity promotion have not been analysed on an ITT basis and may thus exaggerate the changes which occur, as a result of this non-response bias. They may still provide useful comparative information (assuming a similar level of bias across study groups) and may help to define a minimum effect, for example, for the proportion reaching a higher activity level. In addition to a completers analysis for all variables, an ITT analysis was used as the primary approach for the key outcomes of physical activity and physical and biochemical data. Different techniques were used for the handling of missing data, with imputation of median age- and gender-adjusted control group data in relation to physical activity, where the changes were large and the more conservative last observation carried forward approach for the harder end-points. Alternative imputation and modelling methods have recently been examined specifically in relation to a physical activity trial with a 40% 1-year dropout rate, with the conclusion that standard multiple imputation and longitudinal modelling methods are preferable to ad hoc imputation, the choice depending on contextual knowledge.[101]

Deferrals

Another issue arose in relation to those participants who completed their initial assessment, but did not

start the exercise programme as planned, for example as a result of ill-health. These were allowed to defer to a later cohort and thus their subsequent assessments were undertaken with the cohort with whom they exercised, rather than the cohort to which they were originally assigned. Inevitably, such considerations could not be applied to the control group, who were not assigned to an exercise programme and thus were all recalled for assessment with their original cohort.

Generalisability

This study should be generalisable to the extent that it was broadly representative of the local patient population seen in primary care with cardiovascular risk factors, as identified by GPs. Patients were eligible if GPs considered that they would benefit from increased physical activity, even though, in retrospect, a proportion were already active at the nationally recommended level. Furthermore, the scheme was fairly typical of the generality of exercise referral programmes, although it was initiated before the codification of best practice in the National Quality Assurance Framework.[20]

The behaviour change in the control group was influenced by the availability of borough-wide schemes to facilitate increased physical activity and, to that extent, the results of the study may not necessarily apply to areas where no leisure centre or walking schemes currently exist. However, the provision of exercise referral has now become widespread,[15] increasing the generalisability of the findings.

In terms of representativeness, there was one striking difference from the at-risk population, in that women outnumbered men by 2 to 1, despite the higher cardiovascular risk in men. This may reflect a higher consultation rate by women, a greater concern to lose weight and a higher proportion not in full-time work and therefore more easily able to take advantage of the programmes on offer.

There was less uptake at the younger end of the prescribed age range and by those referred with obesity, but no particular bias against members of ethnic minorities. Analysis of referrals by ward suggested lower referral rates from the more deprived wards, again contrary to the known gradient for cardiovascular risk.

The EXERT study was carried out in one north London borough and may not be applicable to other areas in the UK with differing levels of economic deprivation. Furthermore, Barnet is well supplied with parks and green spaces, which may make walking a more attractive option than in more urban environments. Finally, although the local Asian population made proportionate use of the scheme, they are mainly of Gujarati origin and may not reflect the particular issues relating to Muslim women, for example, which may limit participation.[102]

Chapter 12
Conclusions

This trial, of a large GP exercise referral scheme in a north London borough, showed that supervised leisure centre-based exercise classes and instructor-led walks are no more effective than advice only in initiating and sustaining increased physical activity, or modifying cardiovascular risk factors. There was a suggestion that some psychological parameters improved to a greater extent in the walking and leisure centre groups, namely stages of change and barriers to exercise relating to self-efficacy and external factors, but these are difficult to quantify with certainty, given the differential dropout rate in the three trial arms. There was no consistent evidence of a difference in outcomes between the leisure centre and walking groups.

All groups increased their quantity and intensity of physical activity. It may be surmised that there were similar personal costs for the advice-only group taking up physical activity (albeit not quantified) as for the other two groups. However, from the provider's perspective, advice only was clearly the most cost-effective option, followed by walking.

Implications for public health

In 2004, in its Public Health white paper 'choosing health',[103] the government set out its priorities for improving the health of the population, including promoting healthy and active life among older people. This was followed in 2005 by a delivery plan intended to help more people make more healthy choices and reduce health inequalities,[104] supported by an action plan aimed at increasing levels of physical activity in the English population.[15] The latter acknowledges an aspirational target of 70% of individuals undertaking 30 minutes of physical activity 5 days a week. To achieve this target by 2020, as originally proposed, would necessitate a year-on-year increase of 2%, whereas the most successful countries have achieved an annual increase of only around 1%. Even large-scale district-wide exercise referral programmes can reach only a small proportion of the physically inactive, with one such scheme in north-west England attracting about 4% of the district adult sedentary population over 5 years.[105] With a relatively small proportion of these referrals becoming active at the required level, it is clear that such schemes can play only a minor part in achieving the population goal.

Exercise referral schemes will thus need to fit within the range of actions indicated in the white paper and the physical activity action plan, including the proposal for NHS-accredited health trainers. Starting in the most deprived areas, they will help to provide personalised plans for individuals to improve their health and prevent diseases such as cancer and CHD, and could thus be a valuable conduit to exercise referral. However, the effectiveness of such initiatives in comparison with opportunistic GP advice or referral will need to be evaluated.

Implications for primary care

The main implication of this study is that advice itself may be effective, if delivered appropriately. This is consistent with the recommendations of the National Institute for Health and Clinical Excellence (NICE), which published guidance on interventions to increase physical activity in 2006.[106] It concluded that brief interventions incorporating follow-up sessions, but not exercise referral or walking schemes, could produce significant and sustained improvement in physical activity outcomes. The evidence[107] for a positive effect from brief interventions was based on six of 11 studies (one lacking long-term follow-up), five of which were non-UK based. It was considered, however, that the findings could potentially be applied to primary care in the UK with moderate training of health professionals and moderate additional resources.

The precise requirements for a successful brief intervention, however, remain unclear. The sole UK-based study[16] of those considered positive by NICE involved a 40-minute consultation with a health visitor and physical assessments, and the short-term improvement in the intervention groups in comparison to controls was no longer apparent at 1 year. Other studies incorporated various types of assessment process including involvement of researchers[29] and in one case a

20-minute consultation with an exercise specialist.[28] None of these interventions is typical of the way in which brief advice may be offered during a routine consultation in UK primary care, and the potential importance of an initial assessment remains to be clarified.

It should be noted that the advice-only arm of the trial consisted of referral for tailored advice, supported by written materials, including details of locally available facilities, supplemented by a detailed assessment and the prospect of further assessments, as well as a supervised programme in due course. It is not clear which components of this package are the most important, but it is self-evident that together, they are a considerable enhancement of what might be termed 'usual advice in primary care'. Other studies have shown that a combination of features used in primary care, namely exercise prescription, together with behavioural counselling and provision of a booklet, may be more effective, at least in initiating increased physical activity, than any of these on their own.[108] More widespread availability of such enhanced advice will require resources to support training of primary care personnel, development of written materials with general and local information, and provision of time for initial consultation and follow-up.

The new GP contract (April 2004) introduced a Quality and Outcome Framework (QOF), which directs GPs' activity towards aspects of care and practice management relevant to disease prevention. The QOF system rewards GPs with points for achievement against a range of evidence-based clinical indicators, as well as indicators covering practice organisation and management. Although there is no direct reference in the indicators to physical activity, they include parameters relevant to areas such as blood pressure control, which may be affected by exercise. It is currently unclear what impact this may have on physical activity promotion in primary care. A possible development would be the inclusion of a physical activity indicator in the QOF, which would be a more direct form of encouragement. This would require a method for routine assessment of physical activity in patients. It is noteworthy that in the present study, patients were referred who were physically active at baseline. NICE recommends the use of the General Practice Physical Activity Questionnaire (GPPAQ), developed for the Department of Health, which classifies individuals into four activity levels. Training would be required on the appropriate use of this instrument.

Implications for exercise referral schemes

Primary care remains a valuable opportunistic setting for the identification of patients at risk, who may benefit from increased physical activity. In some practices, the GPs and practice nurses may already have systems for initiating behaviour change. However, pending more widespread availability of mechanisms for providing effective advice in primary care, referral for such advice remains an option for achieving this outcome.

Commissioners of exercise referral schemes will need to take account of the results of this trial and of the NICE guidance, which recommends that exercise referral and walking schemes, *inter alia*, should only be endorsed when part of properly designed and controlled research studies to determine their effectiveness. The NICE review of the evidence for exercise referral[109] considered four schemes, only one of which[28] (also included in the review of brief interventions) had a positive long-term effect. However, it would be a reasonable assumption that some of the features of successful brief interventions, if applied to exercise referral, would have similarly beneficial outcomes, and this should be tested in the research design.

On cost-effectiveness grounds, assessment and advice alone from an exercise specialist may be appropriate to initiate action in the first instance. Subsidised schemes may be best concentrated on patients at higher absolute risk, or with specific conditions for which particular programmes may be beneficial. Providers of schemes should ensure that a range of options (including supervised leisure centre classes and walks) is available for referred patients, taking preferences into account. Efforts should be directed towards maintenance of increased activity, with proven measures such as telephone support.

There was a suggestion in the scheme of higher referral rates from less deprived wards. Data should be collected to enable commissioners to assess equity of access, to ensure that these schemes do not operate to the detriment of already disadvantaged groups.

Recommendations for research

One problem that emerges from comparisons with the results of other trials is the lack of standardised methodology for measuring and presenting outcomes. Measurement of physical

activity is commonly questionnaire based in trials of this type. Several questionnaires are in use and research should be commissioned to evaluate the alternatives, to determine the best validated and most practical means of measuring baseline levels of physical activity and the effects of an intervention. Research funding bodies should then agree on the use by researchers of a standard questionnaire and its method of application for adoption in future trials.

Agreement should also be reached on outcome measures for physical activity, based on the results of the questionnaires. Currently, outcomes are presented in a variety of ways, as both scaled values for change in duration and intensity of physical activity, or energy expenditure as METs and kilocalories over different periods, as well as categorical and dichotomous outcomes in relation to achievement of particular activity levels. Research should be commissioned to establish the best outcome measure for predicting health gain, and its use should be promulgated to enable comparison and pooling of future interventions. In the meantime, an updated meta-analysis of published exercise interventions should be undertaken, using the Cochrane standardised mean difference approach.

While questionnaires are a practical necessity in most trials, their imprecision will tend to attenuate the effects of interventions in comparison with control groups. Research should be directed to how they might best be supplemented by objective measurements in field trials. Further research should identify the optimum (and cheapest) approaches and compare alternative types of monitoring with the use of a measure of cardiorespiratory fitness, as part of the assessment procedure, as the latter may be a more reliable measure of change in physical activity than questionnaires. Research should also be directed towards establishing whether simple submaximal fitness tests, such as the double-step test currently under evaluation for use in epidemiological studies, can be incorporated into routine practice in primary care. Research questions to be addressed include whether they are helpful to practitioners in setting goals for patients and whether feedback from the assessment promotes initiation and maintenance of behaviour change.

Given the strong Hawthorne effect shown in many studies and the difficulty of establishing a 'no change' control group, future trials should aim to identify the components of interventions that may be beneficial for particular target groups in comparison with minimal intervention. These should include the frequency and intensity of support required to maximise exercise continuation, the value of physical assessment procedures and feedback as a stimulus to continue exercise, and the place of professional compared with lay advisers. Where possible, assessments should be carried out by independent assessors, to minimise the Hawthorne effect and possible bias due to knowledge of the allocated intervention by therapists.

The place of opportunistic referral by GPs and practice nurses versus proactive 'cold calling' of at-risk individuals on practice lists is unclear. The effectiveness and cost-effectiveness of the two strategies should be compared.

Research should also be directed towards establishing the best methods for involving groups under-represented in present schemes, including men and members of deprived communities and specific minority groups.

Few trials have measured outcomes beyond 1 year. Studies should be designed to allow long-term follow-up, to assess attrition rates over time.

Qualitative research should be undertaken both with referring clinicians and with trial participants to establish more clearly the factors leading to success and failure in particular cases, to enable continued refinement of referral schemes. Issues to be addressed include preconceptions of GPs and practice nurses about who might benefit from the scheme, reasons why some referred patients fail to start, and the factors associated with adherence to the programme, dropout from follow-up and maintenance of increased physical activity.

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Contribution of authors

Anthony J Isaacs (Consultant in Clinical Audit and Education, and Honorary Visiting Professor) initiated and led the project, and with Julia Critchley (Research Officer) designed and developed the trial. Ken Buckingham (Associate Professor of Health Economics) carried out the economic analysis. Sharon See Tai (Senior Research Fellow/Statistician) was responsible for the statistical analysis. David Westley (Psychology Academic Group Chair) was responsible for the psychological analysis. Steven Harridge (Professor of Human and Applied Physiology) prepared the physiological testing protocols. Chris Smith (Health and Fitness Officer) was responsible for programme design and operational management, and Julie Gottlieb (Research Officer) coordinated the project. All of the authors were involved in the preparation of the report.

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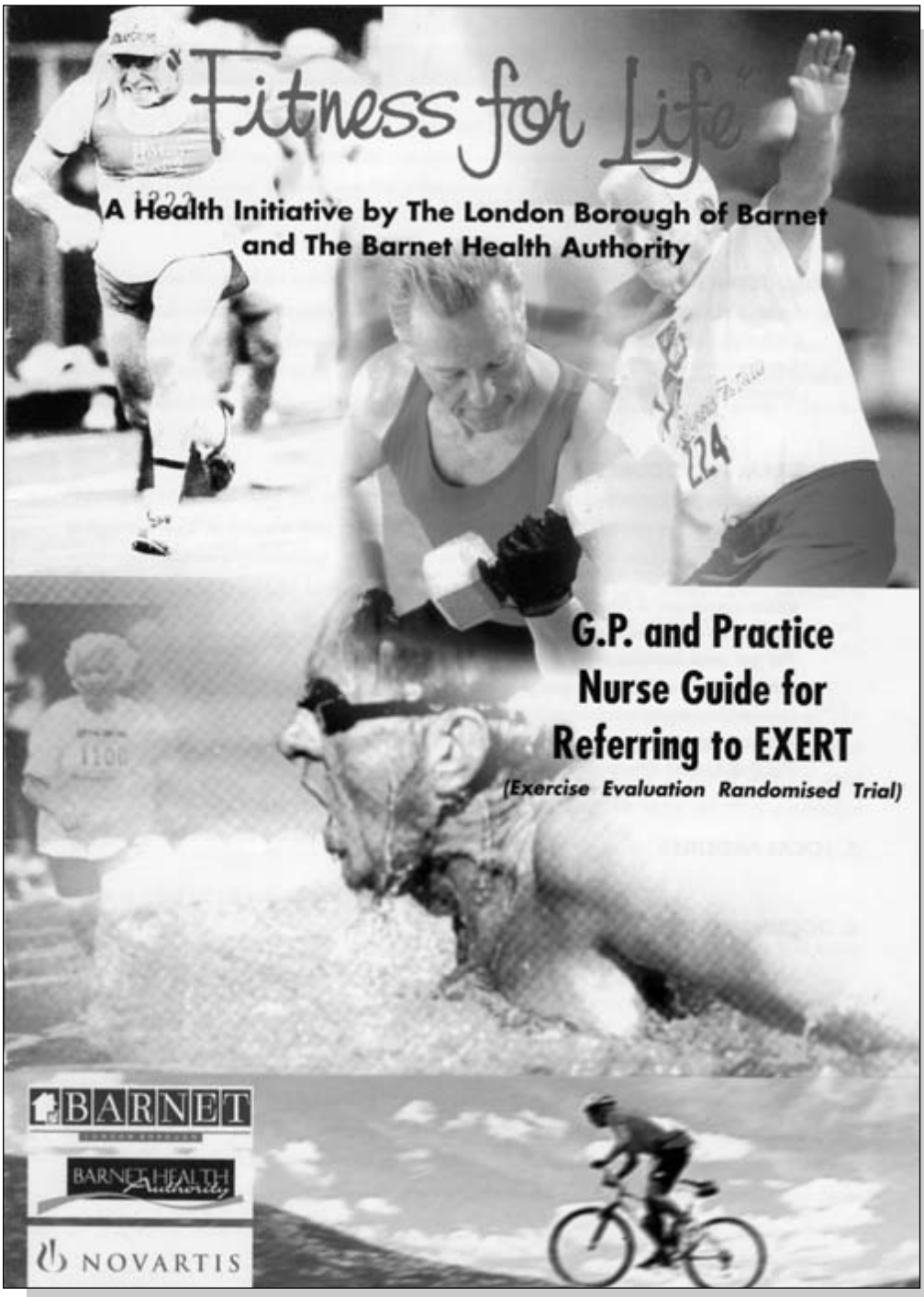
Appendix 1

Information for patients and GPs



CONTENTS

INTRODUCTION

The EXERT trial (Exercise Evaluation Randomised Trial), funded by the NHS Health Technology Assessment Programme, is simply an extension of the existing "Fitness for Life" Programme in Barnet. It is designed to evaluate the effectiveness of different ways of promoting physical activity in older adults.

Fitness of Life is based on similar schemes already working in other parts of the country. These have been developed in response to the extensive evidence regarding the wide range of health benefits obtainable through regular physical activity; together with the worrying indication that seven out of ten men and eight out of ten women in the UK are not sufficiently active to obtain these benefits (Allied Dunbar National Fitness Survey. The Sports Council and Health Education Authority, 1992).

Primary care teams have an important role to play in preventive and rehabilitative exercise programmes. It is thought that referral by a doctor or other health professional may be an important way of encouraging participants to adhere to their prescribed exercise programme for long enough to obtain lasting health benefits. "Fitness for Life" offers GPs and Practice Nurses the opportunity to refer suitable patients for a programme of exercise, appropriately adapted to their needs.

Many referred participants who have previously been sedentary, become habitual, regular exercisers and undergo other lifestyle changes, such as reduced smoking and increased dietary awareness. Participants also enjoy the companionship and sociability available within a small group. ***There will be no charge for participating in any of the exercise programmes in this trial.***

Why a trial of physical activity promotion?

There are very few randomised controlled trials of physical activity promotion in free living populations. A recent review found only 10, and none of these were based in the UK.

Many local schemes have been set up in conjunction with leisure centres to promote physical activity, but most are small, and none have been subjected to any longer-term evaluation to see whether health benefits are sustained. It is important to assess the effectiveness of such schemes in the longer term, and to determine whether simpler and cheaper interventions would be as effective. This study has been funded by the NHS Health Technology Assessment Programme to investigate the effectiveness of different ways of promoting physical activity for sedentary older adults (ages 45-74), at increased risk of cardiovascular disease.

TRIAL DETAILS

The trial is simply an extension of the existing scheme, but with minor differences in the age groups, inclusion and exclusion criteria (see below). It is important that these are adhered to in order to ensure scientific validity and safety.

INCLUSION CRITERIA

(Patients must be aged 45-74 and not be currently physically active. They must also have one or more of the risk factors below for cardiovascular disease.)

- *Raised cholesterol*
- *Controlled mild to moderate hypertension*
- *Obesity*
- *Current smokers*
- *Diabetes (non-insulin dependent or well controlled insulin dependent)*
- *Family history of MI at young age - close male relative <55 or close female relative <65*

EXCLUSION CRITERIA *(Please do not refer any patients in the following groups:)*

- *Previous Myocardial Infarction*
- *Overt cardiovascular disease*
- *Falls in past month*
- *Significant physical disability*
- *Significant psychiatric disorder*
- *Patients with pacemakers*
- *Patients already involved in other studies*
- *Patients with specific exercise requirements due to other medical conditions e.g. certain neuromuscular disorders*

RANDOMISATION PROCEDURE

Participants will be randomised to one of three groups on their first attendance at Barnet Copthall Leisure Centre. They will be provided with further information about the scheme, and asked to sign an informed consent form. One group will be randomised to receive a supervised Leisure Centre based physical activity programme at Copthall, Hendon Youth Sports Centre, Finchley Lido Centre or QE Girls School. A second group will be randomised to a community-based instructor-led "Walking Partners" programme, based on the "Walk Reebok" model. The third, "usual care" group will be given brief information, backed up with written materials, about the importance of physical activity and ways of increasing activity in their daily lives. They will be offered the opportunity and encouraged to join one of the other two schemes after approximately 6 months. All groups will have the opportunity to learn more about their overall health than would normally be available.

MONITORING OF PATIENTS

The Fitness Officer will monitor the participants' activity during the assessments and the ten week programme to ensure safe and satisfactory progress. On-going clinical responsibility for the general health of the patients remains with the GP, as with the existing scheme. However, the risk of serious illness or injury is extremely low. Over 1000 patients have gone through the existing programme with no serious incidents, and the potential benefits far outweigh any risks. Participants will be asked to perform tests of cardiovascular fitness, but these will be sub-maximal tests. Participants will be allowed to exercise up to a certain heart rate - 75% of their age-predicted maximum; this level will be reduced for "vulnerable" groups. All staff are trained in CPR and the use of defibrillators, and undergo refresher courses every three months. Defibrillators are available only during the fitness assessments. The assessments have been designed with the support of Physiologists at the Royal Free School of Medicine, who are expert in designing exercise courses for older people.

REFERRAL PROCEDURES

GPs and Practice Teams can refer patients who are not currently physically active, and who meet the trial inclusion criteria (ages 45-74, at least one additional risk factor for CHD) by completing an "Exercise Prescription Form". Please ensure that all sections are completed, and that patients do not have overt cardiovascular disease or other contra-indications (see ***'Exclusion Criteria****, page 3) for details.*

The Prescription Form must be completed and signed by the Prescribing GP or the Practice Nurse. Please use the form to advise, with the patients' knowledge and consent, of any medical or physiological limitations, which may be relevant to the course of exercise prescribed. This will be kept in a locked cabinet. The referring health professional should also advise that the patient is to be recruited to a Randomised Controlled Trial (RCT), so will have an equal chance of being allocated to one of three groups. This advice will be reiterated at the Leisure Centre.

INFORMATION FOR PATIENTS

You have been provided with an information sheet for any patients whom you refer. This gives brief details concerning the fitness scheme itself and the nature of the RCT. Patients will be sent further details about the time, date and place as well as practicalities such as what to wear and eat before the first assessment when they telephone for an appointment.

It is up to the participants to telephone Barnet Copthall to make an initial appointment to attend the Leisure Centre.

OUTLINE OF THE EXERT (FITNESS FOR LIFE) PROGRAMME

INITIAL ASSESSMENT AND FITNESS TEST

The introductory session is conducted by the Fitness Officer at Barnet Copthall, although participants randomised to the Leisure Centre component will have the opportunity of exercising at another Centre if more convenient.

THE INITIAL ASSESSMENT WILL INCLUDE:

Welcome and introduction
Explanation of what is involved in participating in the RCT
Request to sign the informed consent form
Random allocation to one of three groups
Detailed initial fitness test, establishing baseline levels of fitness

The fitness test will incorporate a number of recognised physiological tests which include; lung function, aerobic capacity, anthropometric measurements and body composition, strength, flexibility, and blood pressure monitoring. They will be more extensive than existing assessments, and may include some blood tests, with patients' permission. The results of those tests will be presented to the practice and the participant in a comprehensive personal report at a later date.

The introductory session is also tailored to address any potential misgivings on the part of the participant and to establish a rapport between participants and fitness staff. Participants will be reassured that the exercise will be within their capabilities and of benefit to their general health and well being.

USUAL CARE AND ADVICE GROUP

Patients randomised to the "usual care" group will then be given brief advice on the importance of and how to increase physical activity in their daily lives, backed up with written materials on increasing physical activity, as published by the Health Education Authority. They will be offered the opportunity to take part in one of the exercise programmes after approximately six months.

THE TEN WEEK EXERCISE PROGRAMMES

Both the Walking Partners and Leisure Centre programmes last for ten weeks. They are graduated programmes of exercise, aiming to improve the participants' basic level of fitness. During the hour-long session participants will be guided and encouraged through suitable exercise.

AFTER THE TEN WEEK PROGRAMME

At the end of the programme, participants will be encouraged to continue with a long term exercise programme. This could involve swimming, brisk walking, cycling, or taking up membership of a fitness facility.

LEISURE CENTRE GROUP

Patients allocated to this exercise scheme will be asked to attend a 10 week, graduated supervised exercise programme, at one of the participating leisure centres. They will be advised to attend 2-3 times per week. Participants will be offered a reduction in the cost of full membership of one of the Leisure Centres after the 10 week programme, should they wish to take this up.

WALKING PARTNERS SCHEME

Participants allocated to this programme will be asked to attend at least two community-based, instructor-led walks per week over the 10 week period. The walks incorporate some stretching and easy resistance exercises. They are available on a daily basis, at a variety of times and several locations in Barnet.

THE POST COURSE FITNESS ASSESSMENTS

These sessions (after 10 weeks for some patients, 6 months and one year) will repeat all those methods of testing incorporated in the "Pre-course Fitness Assessment". The results of these tests will be produced as a historical comparison and presented to all participants and their relevant GPs for their own records at a later date.

With permission, some GP's may be approached for information on subsequent medical history of participants. This information would be kept confidential.

LOCAL FACILITIES

The Leisure Centre *prescribed exercise programmes take place at;*

The Barnet Copthall Centre: *The largest borough owned facility containing 3 pools, fitness suite, a multi-activities aerobics room and an 8 lane running track. Activities in the Centre are frequent and varied ranging from yoga, golf to a 50+ club. The Centre also has on site a resident Nutritionist, Osteopath and Masseuse.*

The Hendon Youth Sports Centre: *This new Centre, situated opposite the Brent Cross Shopping Centre, boasts an international standard specialist gymnastics facility, five badminton courts, fitness suite, a rock climbing room and multi-purpose activity room.*

Finchley Lido Centre: *This facility opened on 1st April 1996 and comprises a 25metre six lane traditional pool, outdoor pool, free form leisure pool with sprays, jets, small slides and a river run, health suite, multi-use and fitness room.*

QE Girls School: *This fitness facility is attached to the school but open to the public. Its facilities include a swimming pool, gymnasium, fitness studio and sporting hall.*

Walking Partners Programme: *The Walking Partners Programme takes place in several locations, on each day of the week, and at different times of day. Each walk is led by a fitness instructor whose aim will be to increase the stamina, flexibility and strength of all participants. The walks are an hour long and all easily accessible. It is recommended that the participants attend at least two per week.*

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DOCUMENTATION

The GP Exercise Prescription Scheme will be administered using the following methods of documentation: please contact Dr. Julia Critchley, Research Officer, Barnet Health Authority, Hyde House, the Hyde, Edgware Road, London NW9 6QQ for additional copies of the Exercise Prescription Forms or Patient Information Leaflet.

Exercise Prescription Form with Trial Inclusion and Exclusion Criteria

To be completed and signed by an authorised staff member for each patient referral.

White Copy - To be given to the patient, in order that the individual can contact the Fitness Officer.

Green Copy - Retained by the GP for patients records.

Pink Copy - Sent to Fitness Officer.

Patient Information Sheet

To be given to all patients referred on to the programme.

Introductory Questionnaire

Completed at the initial assessment by the participant, provides details concerning the individual's demographic and socio-economic characteristics, lifestyle and other health behaviours, and medical background. These will be taken into account when prescribing the exercise, and analysing the trial results.

Participants will also be asked to complete similar questionnaires in conjunction with the post-course fitness assessments (10 weeks, 6 months, one year after referral), to see if any behavioural change has occurred.

Fitness Assessment Report

A detailed report compiled by the Fitness Officer at the beginning of the programme, and after each subsequent assessment. This is retained by the participant and a copy sent to the practice for patient records.

Participant Attendance Register

Kept by participants and used during the ten week programme to monitor attendance.

If you have any inquiries about the exercise programmes please contact:

Chris Smith,
Health & Fitness Officer,
Barnet Copthall Centre, Great North Way, Hendon, NW4 1PS.

Tel: 0181 202 6458

For queries about the trial please contact:

Dr. Julia Critchley,
Research Officer,
Barnet Health Authority, Hyde House, The Hyde, Edgware Road, London NW9 6QQ.

Tel: 0181 201 4845

EXERCISE PRESCRIPTION - EXERT STUDY

WHITE COPY FOR PATIENT, GREEN COPY FOR DOCTOR, PINK COPY FOR FITNESS OFFICER

'Fitness for Life'

To Chris Smith, Please arrange for this patient to be randomised into the EXERT study

Patient's Name .....
NHS Number .....
Title (circle one) Mr/Mrs/Ms/Miss .....
Other (please state) .....
Address .....
.....
Post Code .....
Tel. No. .....
Date of Referral .....

Name of Referrer .....
Profession (please circle one) GP / PN .....
(If PN, please give name of patients GP) .....
.....
Practice Address .....
.....
Practice Code .....
Tel. No .....

INCLUSION CRITERIA
(Patient's must be **AGED 40-74** and not be currently physically active. They must also have one or more of the risk factors below for cardiovascular disease. Please tick all that apply).

- Raised cholesterol ❑
- Controlled mild to moderate hypertension ❑
- Obesity ❑
- Current Smokers ❑
- Diabetes (non-insulin dependent or well controlled insulin dependent) ❑
- Family history of Myocardial infarction at young age - close male relative <55 or close female relative <65. ❑

EXCLUSION CRITERIA

(Please do not refer to any patients in the following groups:)

- Previous Myocardial Infarction ❑
- Overt Cardiovascular disease ❑
- Falls in past month ❑
- Significant physical disability ❑
- Significant psychiatric disorder ❑
- Patients with pacemakers ❑
- Patients already involved in other studies ❑
- Patients with specific exercise requirements due to other medical conditions e.g. certain neuromuscular disorders. ❑

Any additional Medical / Physiological Information

Any Medication Prescribed

PLEASE RING 'FITNESS FOR LIFE' ON **0181 202 6458** FOR AN APPOINTMENT

BARNET LONDON BOROUGH

NOVARTIS

EXERT (Exercise Evaluation Randomised Trial)

Patient Information Sheet

Your GP has recommended that you increase your level of physical activity. We currently have two schemes in Barnet to help people who need to take more exercise. One of these, called *'Fitness for Life'*, involves supervised sessions of exercise at a local leisure centre. The second scheme, called 'Walking Partners' involves going on walks with other people in a planned, instructor-led programme to improve your fitness. The schemes are free to participants in this study. The courses will last for 10 weeks and are graduated, with intensity increasing as you become fitter. You will only work at an appropriate individual level, and will be encouraged to continue on an exercise programme when the course finishes.

Although these programmes appear to help some people to become more active and fitter, we do not know if these benefits last after the end of the programme. It is important to compare the success of these two schemes, with a simpler scheme that gives verbal and written advice and support, to make sure that we are spending NHS and local government resources in the best possible way. To make sure the comparison is valid, it is necessary to allocate patients to the three schemes at random. If you agree to take part in the study, you may be assigned to one of the two exercise programmes straight away, or you may be allocated to receive advice. You will have an equal chance of being allocated to any one of the three groups. If you are allocated to the 'advice' group you will be encouraged to join one of the two exercise programmes after about six months. It is necessary for us to have this advice group to be able to show scientifically whether the other programmes are better at helping people become more physically active.

Whichever group you fall into, you will be assessed at Copthall Leisure centre on at least three occasions: when you are first referred, then after the first 10 weeks, again after 6 months, and at one year after referral. The assessments will involve filling in some simple questionnaires about yourself and your health, having a measurement of your blood pressure, and simple fitness tests, and if you agree, having a blood sample taken. We expect each assessment to take about 2 hours. You will be given a small payment of expenses (£10) if you attend all assessments. Both you and your GP will also be given detailed written feedback of the results at a later date, so that you can monitor your progress, and see how much fitter you are becoming.

If you are agreeable to taking part in the trial, please telephone for an initial appointment at Copthall. You will be given further practical details at this time. You have the right to change your mind and withdraw from this study at any stage, if you so wish. This would not affect the way you are treated by your Doctor, or by any Leisure Centre staff.

BARNET

BARNET HEALTH Authority

NOVARTIS

Appendix 2

Methods to boost recruitment

Primary care professionals

Several strategies were used to boost recruitment to the study. At the start of the study (August 1998), a letter and an information pack were sent to all GPs to inform them about the study. The information pack contained a booklet detailing the study rationale and exercise programmes available, a prescription pad for referrals, and a leaflet pad explaining the study which the referring professional could give to the patient. A number of preaddressed envelopes was also enclosed to encourage GPs to return the green copy. This letter and pack were sent to all GPs and practice nurses in Barnet. In addition, two of the study team arranged visits to each GP practice to discuss the study details and encourage recruitment. Virtually all GP practices in Barnet were visited within the first 6 months of starting the study.

Several local events to increase publicity with primary care were organised, including a demonstration evening for practice nurses in March 1999 and the launch of a physical activity strategy, including a 'Rockport Mile' test, in June 1999 (see below). The researchers also approached other relevant health professionals who work closely with primary care such as local diabetes nurses.

Newsletters

A first colour newsletter was produced and distributed in January 2000 to all local GPs, and other relevant organisations, such as the Health Education Authority, London Regional NHS Executive, and the London Borough of Barnet. Further, an accompanying poster was designed and displayed in appropriate public areas. This described the study rationale and procedures, and preliminary results from the first 6-month follow-up, including the response rates. A number of preaddressed envelopes was again enclosed to encourage GPs to complete and post referral forms to Barnet Copthall. This pack was distributed to GPs and practice nurses in Barnet, the main aim being to provide some early feedback and remind GPs that recruitment was still ongoing.

A second newsletter was distributed in January 2001. It contained an update on the trial and on other programmes available in the borough (such as Phase IV cardiac rehabilitation programmes, and new classes aimed at smokers). In addition, it highlighted events that involved many EXERT participants (the Rockport Mile and a day trip to hike in the Chilterns).

General public in Barnet

Rockport Mile tests

The Rockport Mile walk is a fitness test involving a timed 1-mile walk. With measurements of finishing heart rate and time taken, a prediction of maximal oxygen consumption ($VO_{2\ max}$) can be made. The test was run at approximately 6-monthly intervals on a measured course, starting and finishing at Barnet Copthall Stadium. Participants in the EXERT study and the previous 'Fitness for Life' referral programme, and those attending cardiac rehabilitation at Barnet Copthall were invited to attend. The walks thus provided a mechanism for assessing fitness and changes in fitness over time, recruiting new participants and allowing previous participants to keep in touch with the research team. They are also very popular, with typically over 200 people attending.

Local press

Recruitment to the EXERT study was also boosted through interviews of both the research team and EXERT study participants by several local newspapers. This resulted in a marked increase in the number of enquiries and referrals to the study.

Miscellaneous

The EXERT study was highlighted in numerous local publications and seminars including the Health Authority Annual Reports (1998/99 and 1999/2000), the Director of Public Health's Annual Report in 1999 and the Community Care Fairs (1999 and 2000). Information on the project was distributed at a pan-Barnet National Service Framework for Coronary Heart Disease Conference on 5 October 2000.

An article on EXERT was published in *HTA Update*. Two poster submissions were made at the NICE/HTA Clinical Excellence 2000 Conference at Harrogate. These covered perceived anxiety and depression before and after the 10-week exercise programme and continuation of exercise at 1 year.

Appendix 3

Physical activity questionnaire

Physical activity questionnaire

FOR OFFICE USE ONLY: EX00 ☐☐☐☐

We would like to find out about the amount and types of activity you have carried out in the past **7 days**. These are divided into six types: gardening, walking, DIY/ car maintenance, work in the home (housework), work outside the home, leisure and sports. For each of these please indicate:

(i) The number of separate occasions you did any or all of these activities in each category in the **last 7 days**,
(ii) On average, how long each occasion lasted,
(iii) On average, how hard the activity was (you may put a cross in more than one box e.g. you may perspire and breathe hard).

Gardening

Below is a list of different gardening activities which you may have done in the **past 7 days**. **Please cross all you have carried out**.

1) hoeing ☐ 2) weeding ☐ 3) pruning ☐ 4) mowing with a power mower ☐
5) planting flowers/seeds ☐ 6) mowing using a hand mower ☐
7) clearing rough ground ☐ 8) digging ☐
9) other (Please specify) ☐

In the table below, please write the number for the activity you have carried out in the first column and complete the rest of the row **for each activity you have crossed above**.

ACTIVITY	Number of occasions in last **7 days**	Average duration per occasion (in minutes)	Did the activity make you?			
			Warm	Perspire	Breathe Hard	None of these
☐	☐☐	☐☐☐	☐	☐	☐	☐
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EXERT Study - Barnet Health Authority and London Borough of Barnet, funded by NHS Health Technology Assessment Programme

Walking

Below is a list of types of walk you may have carried out in the past 7 days. **Please cross all you have done**. If you are employed, please do not include any walking you may do whilst at work. We will ask about this in a later section.

1) walks at a slow pace ☐ 2) walks at a steady pace ☐ 3) walks at a fast pace ☐

4) walking uphill ☐ 5) walks carrying heavy shopping ☐

6) other ☐

In the table below, please write the number for the activity you have carried out in the first column and complete the rest of the row **for each activity you have crossed above**.

ACTIVITY	Number of occasions in last **7 days**	Average duration per occasion (in minutes)	Did the activity make you?			
			Warm	Perspire	Breathe Hard	None of these
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DIY and car maintenance

Below is a list of DIY activities you may have carried out in the past 7 days. **Please cross all that apply**.

1) general building work ☐ 2) decorating ☐ 3) minor household repairs ☐

4) car washing and polishing ☐ 5) car repairs and maintenance ☐

6) other ☐

In the table below, please write the number for the activity you have carried out in the first column and complete the rest of the row **for each activity you have crossed above**.

ACTIVITY	Number of occasions in last **7 days**	Average duration per occasion (in minutes)	Did the activity make you?			
			Warm	Perspire	Breathe Hard	None of these
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☐	☐☐	☐☐☐	☐	☐	☐	☐

Work in the home

Below is a list of work in the home / housework which you may have carried out in the past 7 days.
Please cross all you have done.

1) bed making ☐ 2) spring cleaning ☐ 3) hoovering ☐
4) moving heavy furniture ☐ 5) cleaning windows ☐ 6) washing floors ☐
7) dusting ☐ 8) sewing ☐ 9) washing dishes ☐
10) preparing food ☐ 11) ironing ☐ 12) hanging out washing ☐
13) other (please specify) ☐

In the table below, please write the number of the activity you have carried out in the first column and complete the rest of the row **for each activity you have crossed above**.

ACTIVITY	Number of occasions in last **7 days**	Average duration per occasion (in minutes)	Did the activity make you? Warm	Perspire	Breathe Hard	None of these
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Work outside the home (please complete if you are currently in employment outside the home). Below is a list of activities you may have carried out at work in the past 7 days. **Please cross all that you have done.**

1) lifting ☐ 2) stacking shelves ☐ 3) climbing ladders ☐

4) building work ☐ 5) cleaning ☐ 6) walking at work ☐
e.g. up and down stairs, to and from desk, "doing rounds" etc

7) other ☐

In the table below, please write the number of the activity you have carried out in the first column and complete the rest of the row **for each activity you have crossed above**.

ACTIVITY	Number of occasions in last **7 days**	Average duration per occasion (in minutes)	Did the activity make you?			
			Warm	Perspire	Breathe Hard	None of these
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Sports and Leisure

Below is a list of sports and leisure activities you may have carried out in the past 7 days. **Please cross all you have done.**

1) aerobics/ keep fit ☐ 2) dancing ☐ 3) weight training ☐
4) swimming ☐ 5) running / jogging ☐ 6) badminton ☐
7) tennis ☐ 8) golf ☐ 9) yoga ☐ 10) bowls ☐
11) cycling ☐ 12) other ☐

In the table below, please write the number of the activity you have carried out in the first column and complete the rest of the row **for each activity you have crossed above**.

ACTIVITY	Number of occasions in last **7 days**	Average duration per occasion (in minutes)	Did the activity make you?			
			Warm	Perspire	Breathe Hard	None of these
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Appendix 4

Details of exercise classes

Walking

- **The first 10 minutes** of each class consisted of a warm-up, which was a gradual pulse raiser, and mobility exercises. This was followed by a series of short stretches and an explanation of the session's objectives and route.
- **The next 30–40 minutes** contained a prolonged period of walking. To accommodate differing levels of fitness and to ensure that everyone was exercising to their optimum, the faster walkers were sent on additional loops and diversions. This resulted in some of the class covering approximately 1–2 miles during the hour and others significantly greater distances.
- There then followed approximately **10 minutes** of strengthening exercises. Each instructor carried exercise bands (resistance bands) which enabled the group to have an extensive variety of strengthening exercises. These exercises adopted a whole-body approach, with consideration given to particular medical issues that participants might have.
- The final **5–10 minutes** was spent warming down, with slower walking and longer stretches.

All participants were encouraged to walk between 60 and 80% of their maximum (slightly breathless but able to carry on a conversation).

Leisure centre

The five class types are described below.

- Aerobics: two classes took place, one aimed at beginners and the other at those who were more able. The emphasis of this class was to improve aerobic capacity and it was based on movement to music.
- Body conditioning: a strengthening and conditioning class aimed at improving functional strength and core stability.
- Aqua-aerobics: took place in the water, mainly aerobic with a strengthening component. The pool had a floor that could be raised and lowered, to facilitate classes for those people who would otherwise have had difficulty in accessing the pool.
- Gymnasium: stationary bikes, rowing machines, treadmills and stepping machines as well as fixed weights were available. Machines were introduced to participants on a gradual basis over the 10 weeks until each member had a personal programme to work from. One gym class was based on everyone working to their own programme and one was a circuit training class.
- Learn to swim: normally offered as a third class option for those people who would have benefited from exercising in the water but did not have the confidence.

Appendix 5

Supplementary tables for Chapter 5

TABLE 75 *Geometric means of activity at baseline and 10 weeks by study group*

	Baseline	10 weeks	
		Available sample	ITT
Minutes of moderate and/or vigorous activity			
Leisure centre	26.22	92.44	
	23.04		92.99
Walking	32.47	120.11	
	28.22		105.93
Advice	18.94	65.18	
	18.63		76.20
Total minutes of activity			
Leisure centre	633.92	537.80	
	598.36		579.64
Walking	517.11	804.36	
	554.29		777.21
Advice	724.79	685.00	
	725.40		690.07
kcal kg^{-1} per week			
Leisure centre	34.09	31.88	
	31.64		33.80
Walking	28.27	46.23	
	28.78		42.12
Advice	37.13	37.76	
	37.59		37.57

TABLE 76 *Mean percentage change from baseline to 10 weeks by study group*

Completers			ITT		
Leisure centre (n = 113)	**Walking (n = 92)**	**Advice (n = 86)**	**Leisure centre (n = 158)**	**Walking (n = 154)**	**Advice (n = 152)**
Minutes of moderate or vigorous activity					
52% (133 to 433%)**	270% (123 to 513%)**	244% (94 to 511%)**	303% (182 to 478%)**	275% (153 to 457%)**	309% (171 to 518%)**
Total minutes of activity					
–15% (–31 to 4%)	55% (25 to 93%)**	–5% (28 to 14%)	–3% (–20 to 17%)	40% (17 to 67%)**	–5% (–19 to 12%)
kcal kg^{-1} per week					
–6% (–23 to 14%)	62% (32 to 103%)**	2% (–16 to 24%)	7% (–11 to 28%)	46% (22 to 76%)**	–0.06% (–15 to 17%)

Data are mean percentage change from baseline and 95% CI (antilog of transformed data).
** Significant increase ($p < 0.01$) using paired t-tests on log-transformed data.

TABLE 77 *Changes in levels of activity from baseline to 10 weeks: 'typical week'*

	Group 1 (<30 minutes) *n* (%)	**Group 2 (30–149 minutes) *n* (%)**	**Group 3 (≥150 minutes) *n* (%)**
'Typical week'			
All activities: baseline			
Leisure centre	20 (38.5)	17 (32.7)	15 (28.8)
Walking	20 (40.8)	19 (38.8)	10 (20.4)
Advice	19 (45.2)	12 (28.6)	11 (26.2)
'Typical week'			
All activities: 10 weeks			
Leisure centre	6 (11.5)	24 (46.2)	22 (42.3)
Walking	9 (18.4)	15 (30.6)	25 (51.0)
Advice	7 (16.7)	20 (47.6)	15 (35.7)
'Typical week'			
Sport and Walking: baseline			
Leisure centre	26 (51.0)	16 (31.4)	9 (17.6)
Walking	15 (45.5)	12 (36.4)	6 (18.2)
Advice	17 (47.2)	13 (36.1)	6 (16.7)
'Typical week'			
Sport and walking: 10 weeks			
Leisure centre	6 (11.8)	25 (49.0)	20 (39.2)
Walking	7 (21.2)	16 (48.5)	10 (30.3)
Advice	9 (25.0)	17 (47.2)	10 (27.8)

TABLE 78 *Changes in levels of activity from baseline to 10 weeks: 'high adherers'*

	Group 1 (<30 minutes) *n* (%)	**Group 2 (30–149 minutes) *n* (%)**	**Group 3 (≥150 minutes) *n* (%)**
'High adherers' ($n = 108$)			
All activities: baseline			
Leisure centre	26 (39.4)	24 (36.4)	16 (24.2)
Walking	14 (33.3)	16 (38.1)	12 (28.6)
'High adherers'			
All activities: 10 weeks			
Leisure centre	6 (9.1)	28 (42.4)	32 (48.5)
Walking	6 (14.3)	9 (21.4)	27 (64.3)
'High adherers' ($n = 98$)			
Sport and walking: baseline			
Leisure centre	35 (54.7)	17 (26.6)	12 (18.8)
Walking	16 (47.1)	14 (41.2)	4 (11.8)
'High adherers'			
Sport and walking: 10 weeks			
Leisure centre	7 (10.9)	33 (51.6)	24 (37.5)
Walking	4 (11.8)	17 (50.0)	13 (38.2)

TABLE 79 *Changes in levels of activity from baseline to 10 weeks, excluding the 72 advice subjects who reported attending health walks and/or the leisure centre since their baseline assessment*

	Group 1 (<30 minutes) *n* (%)	Group 2 (30–149 minutes) *n* (%)	Group 3 (≥150 minutes) *n* (%)
All activities ($n = 266$)			
Baseline			
Leisure centre	46 (40.7)	37 (32.7)	27 (44.3)
Walking	31 (33.7)	33 (35.9)	28 (30.4)
Advice	27 (44.3)	15 (24.6)	19 (31.1)
All activities			
10 weeks			
Leisure centre	10 (8.8)	55 (48.7)	48 (42.5)
Walking	13 (14.1)	26 (28.3)	53 (57.6)
Advice	10 (16.4)	29 (47.5)	22 (36.1)
Sport and walking ($n = 227$)			
Baseline			
Leisure centre	54 (51.9)	31 (29.8)	19 (18.3)
Walking	29 (39.7)	32 (43.8)	12 (16.4)
Advice	26 (52.0)	15 (30.0)	9 (18.0)
Sport and walking			
10 weeks			
Leisure centre	9 (8.7)	57 (54.8)	38 (36.5)
Walking	11 (15.1)	36 (49.3)	26 (35.6)
Advice	9 (18.0)	25 (50.0)	16 (32.0)

TABLE 80 *Geometric means of activity at baseline and 6 months by study group*

	Baseline	6 months	
		Available sample	ITT
Minutes of moderate and/or vigorous activity			
Leisure centre	24.03	50.77	
	22.44		63.53
Walking	36.19	99.03	
	28.73		91.79
Advice	22.24	45.72	
	23.83		57.81
Total minutes of activity			
Leisure centre	697.66	703.64	
	649.78		693.27
Walking	634.16	818.38	
	596.22		745.98
Advice	649.90	648.35	
	692.92		657.56
kcal kg^{-1} per week			
Leisure centre	36.27	38.16	
	33.61		37.92
Walking	33.95	45.77	
	31.08		41.37
Advice	33.36	34.95	
	35.90		35.87

TABLE 81 *Mean percentage change from baseline to 6 months by study group*

Completers			ITT		
Leisure centre (*n* = 179)	**Walking (*n* = 141)**	**Advice (*n* = 200)**	**Leisure centre (*n* = 301)**	**Walking (*n* = 300)**	**Advice (*n* = 305)**
Minutes of moderate or vigorous activity					
111% (52 to 193%)*	174% (83 to 309%)**	106% (42 to 197%)**	183% (117 to 269%)**	220% (142 to 323%)**	143% (81 to 225%)**
Total minutes of activity					
1% (–13 to 17%)	29% (9 to 52%)**	–0.2% (–13 to 14%)	7% (–5 to 20%)	25% (10 to 42%)**	–5% (–15 to 6%)
kcal kg^{-1} per week					
5% (–10 to 23%)	35% (14 to 59%)**	5% (–9 to 20%)	13% (–0.1 to 27%)†	33% (17 to 51%)**	–0.1% (–11 to 12%)

Data are mean percentage change and 95% CI (antilog of transformed data).
* $p < 0.05$, † $p = 0.051$, ** Significant increase ($p < 0.01$) using paired *t*-tests on log-transformed data.

TABLE 82 *Changes in levels of activity from baseline to 6 months: 'typical week'*

	Group 1 (<30 minutes) *n* (%)	**Group 2 (30–149 minutes) *n* (%)**	**Group 3 (≥150 minutes) *n* (%)**
'Typical week' (*n* = 217)			
All activities: baseline			
Leisure centre	30 (40.0)	26 (34.7)	19 (25.3)
Walking	19 (33.3)	23 (40.4)	15 (26.3)
Advice	30 (35.3)	30 (35.3)	25 (29.4)
'Typical week'			
All activities: 6 months			
Leisure centre	21 (28.0)	26 (34.7)	28 (37.3)
Walking	5 (8.8)	22 (38.6)	30 (52.6)
Advice	20 (23.5)	39 (45.9)	26 (30.6)
'Typical week' (*n* = 184)			
Sport and Walking: baseline			
Leisure centre	33 (52.4)	19 (30.2)	11 (17.5)
Walking	17 (39.5)	19 (44.2)	7 (16.3)
Advice	40 (51.3)	24 (30.8)	14 (17.9)
'Typical week'			
Sport and walking: 6 months			
Leisure centre	19 (30.2)	24 (38.1)	20 (31.7)
Walking	9 (20.9)	21 (48.8)	13 (30.2)
Advice	26 (33.3)	36 (46.2)	16 (20.5)

TABLE 83 *Changes in levels of activity from baseline to 6 months: 'high adherers'*

	Group 1 (<30 minutes) *n* (%)	Group 2 (30–149 minutes) *n* (%)	Group 3 (≥150 minutes) *n* (%)
'High adherers' (*n* = 144)			
All activities: baseline			
Leisure centre	39 (39.8)	36 (36.7)	23 (23.5)
Walking	18 (39.1)	15 (32.6)	13 (28.3)
'High adherers'			
All activities: 6 months			
Leisure centre	26 (26.5)	31 (31.6)	41 (41.8)
Walking	9 (19.6)	14 (30.4)	23 (50.0)
'High adherers' (*n* = 121)			
Sport and walking: baseline			
Leisure centre	42 (49.4)	30 (35.3)	13 (15.3)
Walking	16 (44.4)	17 (47.2)	3 (8.3)
'High adherers'			
Sport and walking: 6 months			
Leisure centre	27 (31.8)	30 (35.3)	28 (32.9)
Walking	8 (22.2)	17 (47.2)	11 (30.6)

TABLE 84 *Changes in levels of activity from baseline to 6 months, excluding the 72 control subjects who reported attending health walks and/or the leisure centre since their baseline assessment*

	Group 1 (<30 minutes) *n* (%)	Group 2 (30–149 minutes) *n* (%)	Group 3 (≥150 minutes) *n* (%)
All activities (*n* = 456)			
Baseline			
Leisure centre	73 (40.8)	58 (32.4)	48 (26.8)
Walking	45 (31.9)	53 (37.6)	43 (30.5)
Advice	57 (41.9)	38 (27.9)	41 (30.1)
All activities			
6 months			
Leisure centre	50 (27.9)	59 (33.0)	70 (39.1)
Walking	24 (17.0)	55 (39.0)	62 (44.0)
Advice	35 (25.7)	56 (41.2)	45 (33.1)
Sport and walking (*n* = 384)			
Baseline			
Leisure centre	77 (50.3)	51 (33.3)	25 (16.3)
Walking	43 (36.4)	55 (46.6)	20 (16.9)
Advice	65 (57.5)	29 (25.7)	19 (16.8)
Sport and walking			
6 months			
Leisure centre	48 (31.4)	59 (38.6)	46 (30.1)
Walking	27 (22.9)	58 (49.2)	33 (28.0)
Advice	39 (34.5)	52 (46.0)	22 (19.5)

TABLE 85 *Geometric means of activity at baseline and 1 year by study group*

	Baseline	1 year	
		Available sample	ITT
Minutes of moderate and/or vigorous activity			
Leisure centre	23.06	47.96	
	22.44		63.93
Walking	36.60	106.05	
	28.73		129.62
Total minutes of activity			
Leisure centre	665.80	741.08	
	649.78		714.40
Walking	635.59	815.54	
	596.22		899.83
kcal kg^{-1} per week			
Leisure centre	34.77	39.88	
	33.61		38.69
Walking	34.12	46.51	
	31.08		48.34

TABLE 86 *Mean percentage change from baseline to 1 year by study group*

Completers		ITT	
Leisure centre (*n* = 153)	**Walking (*n* = 132)**	**Leisure centre (*n* = 301)**	**Walking (*n* = 300)**
Minutes of moderate or vigorous activity			
108% (33 to 226%)**	190% (84 to 357%)**	185% (109 to 289%)**	351% (238 to 502%)**
Total minutes of activity			
11% (–5 to 31%)	28% (5 to 57%)*	10% (–2 to 23%)	51% (32 to 73%)**
kcal kg^{-1} per week			
15% (–3 to 36%)	36% (12 to 66%)**	15% (2 to 30%)*	56% (35 to 79%)**

Data are mean percentage change from baseline and 95% CI (antilog of transformed data).
** Significant increase ($p < 0.01$) using paired *t*-tests on log transformed data. * $p < 0.05$.

TABLE 87 *Changes in levels of activity from baseline to 1 year: 'typical week', leisure centre and walking groups only*

	Group 1 (<30 minutes) *n* (%)	Group 2 (30–149 minutes) *n* (%)	Group 3 (≥150 minutes) *n* (%)
'Typical week' (*n* = 120)			
All activities: baseline			
Leisure centre	27 (39.7)	26 (38.2)	15 (22.1)
Walking	23 (44.2)	15 (28.8)	14 (26.9)
'Typical week'			
All activities: 1 year			
Leisure centre	21 (30.9)	24 (35.3)	23 (33.8)
Walking	8 (11.5)	18 (34.6)	28 (53.8)
'Typical week' (*n* = 103)			
Sport and walking: baseline			
Leisure centre	34 (54.0)	22 (34.9)	7 (11.1)
Walking	18 (45.0)	14 (35.0)	8 (20.0)
'Typical week'			
Sport and walking: 1 year			
Leisure centre	20 (31.7)	25 (39.7)	18 (28.6)
Walking	10 (25.0)	15 (37.5)	15 (37.5)

TABLE 88 *Changes in levels of activity from baseline to 1 year: 'high adherers', leisure centre and walking groups only*

	Group 1 (<30 minutes) *n* (%)	Group 2 (30–149 minutes) *n* (%)	Group 3 (≥150 minutes) *n* (%)
'High adherers' (*n* = 132)			
All activities: baseline			
Leisure centre	37 (42.5)	31 (35.6)	19 (21.8)
Walking	12 (26.7)	16 (35.6)	17 (37.8)
'High adherers'			
All activities: 1 year			
Leisure centre	24 (27.6)	28 (32.2)	35 (40.2)
Walking	4 (8.9)	19 (42.2)	22 (48.9)
'High adherers' (*n* = 112)			
Sport and walking: baseline			
Leisure centre	40 (54.8)	25 (34.2)	8 (11.0)
Walking	15 (38.5)	18 (46.2)	6 (15.4)
'High adherers'			
Sport and walking: 1 year			
Leisure centre	24 (32.9)	29 (39.7)	20 (27.4)
Walking	8 (20.5)	16 (41.0)	15 (38.5)

TABLE 89 *Improvers at 6 months in each study group*

	Leisure centre	Walking	Advice	Total
≥60 minutes of moderate and/or vigorous activity	66 (20.8%)	63 (20.3%)	79 (25.1%)	208 (22.1%)
<60 minutes of moderate and/or vigorous activity	251 (79.2%)	248 (79.7%)	236 (74.9%)	735 (77.9%)

TABLE 90 *Improvers at 6 months in each study group: 'typical week'*

	Leisure centre	Walking	Advice	Total
≥60 minutes of moderate and/or vigorous activity	28 (31.1%)	30 (51.7%)	37 (38.1%)	95 (38.8%)
<60 minutes of moderate and/or vigorous activity	62 (68.9%)	28 (48.3%)	60 (61.9%)	150 (62.2%)

TABLE 91 *Participants doing no moderate activity at baseline and at least 60 minutes at 6 months*

	Leisure centre	Walking	Advice	Total
≥60 minutes of moderate and/or vigorous activity	20 (19.8%)	21 (24.7%)	29 (30.2%)	70 (24.8%)
<60 minutes of moderate and/ or vigorous activity	81 (80.2%)	64 (75.3%)	67 (69.8%)	212 (75.2%)

TABLE 92 *Participants doing no moderate activity at baseline and at least 60 minutes at 6 months: 'typical week'*

	Leisure centre	Walking	Advice	Total
≥60 minutes of moderate and/or vigorous activity	10 (33.3%)	13 (86.7%)	12 (44.4%)	35 (48.6%)
<60 minutes of moderate and/or vigorous activity	20 (66.7%)	2 (13.3%)	15 (55.6%)	37 (51.4%)

Appendix 6

Supplementary tables for Chapter 6

TABLE 93 *Baseline measurements of physical characteristics*

	Weight Mean (SEM)	BMI Mean (SEM)	% Body fat Mean (SEM)	Waist-hip ratio Mean (sem)
Leisure centre (n = 317)	83.0 (1.0)	30.7 (0.3)	37.6 (0.5)	0.88 (0.005)
Walking (n = 311)	82.4 (1.0)	30.6 (0.3)	37.7 (0.5)	0.87 (0.006)
Advice (n = 315)	81.8 (0.6)	30.3 (0.3)	37.8 (0.5)	0.87 (0.005)
Female (n = 635)	78.2 (0.7)	30.6 (0.2)	42.2 (0.2)	0.83 (0.003)
Male (n = 308)	91.0 (1.0)	30.3 (0.3)	28.4 (0.3)	0.97 (0.004)
Age (years)				
40–44 (n = 81)	89.5 (2.3)	32.3 (0.6)	36.6 (1.0)	0.88 (0.01)
45–54 (n = 338)	83.9 (1.0)	31.0 (0.3)	37.2 (0.5)	0.87 (0.005)
55–64 (n = 317)	82.1 (1.0)	30.5 (0.3)	37.9 (0.5)	0.87 (0.006)
65–74 (n = 207)	82.4 (2.0)	29.2 (0.3)	38.8 (0.6)	0.88 (0.006)

TABLE 94 *Changes in physical characteristics: completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (n = 122)					
Weight (kg)	81.0	80.4	–0.6 (–1.14 to –0.13)	–0.7%	*
BMI	29.5	29.2	–0.2 (–0.42 to 0.04)	–0.7%	*
% Body fat	35.9	36.0	0.1 (–0.31 to 0.42)	–0.3%	
Waist–hip ratio	0.88	0.88	0.0 (–0.01 to 0.01)	0.0%	
Walking (n = 104)					
Weight (kg)	82.3	81.9	–0.4 (–0.84 to 0.06)	–0.5%	
BMI	30.1	30.0	–0.1 (–0.31 to 0.03)	–0.3%	
% Body fat	37.3	36.7	–0.6 (–0.95 to –0.20)	–1.6%	**
Waist–hip ratio	0.87	0.87	0.0 (–0.01 to 0.01)	0.0%	
Advice (n = 93)					
Weight (kg)	80.1	79.7	–0.4 (–0.97 to 0.26)	–0.5%	
BMI	29.7	29.6	–0.1 (–0.34 to 0.10)	–0.3%	
% Body fat	37.4	37.7	0.3 (–0.23 to 0.82)	–1.6%	
Waist–hip ratio	0.88	0.88	0.0 (–0.004 to 0.02)	0.0%	
6 months					
Leisure centre (n = 193)					
Weight (kg)	82.1	81.9	–0.2 (–0.71 to 0.36)	–0.2%	
BMI	30.2	30.1	–0.1 (–0.25 to 0.14)	–0.3%	
% Body fat	36.9	37.2	0.3 (–0.02 to 0.61)	–0.8%	
Waist–hip ratio	0.88	0.87	–0.01 (–0.01 to 0.004)	–1.1%	
Walking (n = 153)					
Weight (kg)	80.0	79.9	–0.1 (–0.60 to 0.28)	–0.1%	
BMI	29.8	29.7	–0.1 (–0.21 to 0.11)	–0.3%	
% Body fat	37.5	38.0	0.5 (0.03 to 0.86)	0.1%	*
Waist–hip ratio	0.85	0.85	0.0 (–0.01 to 0.02)	0.0%	
Advice (n = 219)					
Weight (kg)	80.5	80.2	–0.3 (–0.87 to 0.13)	–0.4%	
BMI	29.7	29.6	–0.1 (–0.31 to 0.05)	–0.3%	
% Body fat	37.3	37.6	0.3 (–0.09 to 0.69)	0.8%	
Waist–hip ratio	0.87	0.87	0.0 (–0.003 to 0.008)	0.0%	
1 year					
Leisure centre (n = 167)					
Weight (kg)	81.8	81.6	–0.2 (–0.91 to 0.47)	–0.2%	
BMI	30.1	30.0	–0.1 (–0.35 to 0.17)	–0.3%	
% Body fat	37.1	37.7	0.6 (0.21 to 1.22)	1.6%	**
Waist–hip ratio	0.87	0.88	0.01 (–0.002 to 0.01)	1.1%	
Walking (n = 149)					
Weight (kg)	81.2	81.4	0.2 (–0.41 to 0.79)	0.2%	
BMI	30.1	30.2	0.1 (–0.15 to 0.31)	–0.3%	
% Body fat	37.3	38.1	0.8 (0.33 to 1.19)	2.1%	**
Waist–hip ratio	0.85	0.86	0.01 (–0.002 to 0.02)	1.2%	

** $p < 0.01$, * $p < 0.05$.

TABLE 95 *Physical characteristics; comparison of values between groups at each assessment: completers*

	Leisure centre Mean (95% CI)	**Walking Mean (95% CI)**	**Advice Mean (95% CI)**
10 weeks	*n* = 122	*n* = 104	*n* = 93
Weight (kg)	80.53 (80.04 to 81.03)	80.93 (80.38 to 81.49)	80.73 (80.13 to 81.32)
BMI	29.52 (29.34 to 29.70)	29.65 (29.45 to 29.86)	29.60 (29.38 to 29.82)
% Body fat	36.75 (36.34 to 37.16)	36.22 (35.77 to 36.67)	37.06 (36.58 to 37.54)
Waist–hip ratio	0.88 (0.87 to 0.89)	0.88 (0.87 to 0.89)	0.89 (0.88 to 0.89)
6 months	*n* = 193	*n* = 153	*n* = 219
Weight (kg)	80.85 (80.33 to 81.37)	80.79 (80.17 to 81.42)	80.58 (80.09 to 81.07)
BMI	29.86 (29.67 to 30.05)	29.84 (29.61 to 30.07)	29.76 (29.58 to 29.94)
% Body fat	37.37 (36.98 to 37.76)	37.54 (37.08 to 38.01)	37.30 (36.93 to 37.68)
Waist–hip ratio	0.87 (0.87 to 0.88)	0.87 (0.86 to 0.88)	0.88 (0.87 to 0.88)
1 year	*n* = 167	*n* = 149	
Weight (kg)	81.44 (80.77 to 82.11)	81.76 (81.02 to 82.50)	
BMI	30.04 (29.79 to 30.30)	30.17 (29.89 to 30.45)	
% Body fat	37.37 (37.23 to 38.12)	37.70 (37.20 to 38.19)	
Waist–hip ratio	0.88 (0.87 to 0.88)	0.88 (0.87 to 0.88)	

TABLE 96 *Baseline measurements for resting pulse*

	Resting pulse Mean (SEM)
Leisure centre (*n* = 316)	65.7 (0.6)
Walking (*n* = 311)	64.7 (0.6)
Advice (*n* = 314)	65.8 (0.6)
Female (*n* = 634)	65.6 (0.4)
Male (*n* = 307)	65.0 (0.6)
Age (years)	
40–44 (*n* = 81)	67.6 (1.1)
45–54 (*n* = 338)	66.7 (0.6)
55–64 (*n* = 316)	64.1 (0.5)
65–74 (*n* = 206)	64.5 (0.7)
Only age significant at baseline age 1 and 3, $p = 0.035$; 2 and 3, $p = 0.009$.	

TABLE 97 *Changes in physical characteristics: completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (n = 121)					
Resting pulse	65.4	64.2	–1.2 (–2.61 to 0.28)	–1.8%	
Walking (n = 102)					
Resting pulse	63.2	63.0	–0.2 (–1.39 to 1.08)	–0.3%	
Advice (n = 92)					
Resting pulse	66.3	66.4	0.1 (–1.29 to 1.66)	0.2%	
6 months					
Leisure centre (n = 191)					
Resting pulse	65.2	65.4	0.2 (–1.11 to 1.38)	0.3%	
Walking (n = 151)					
Resting pulse	63.5	64.1	0.6 (–0.58 to 1.91)	0.9%	
Advice (n = 219)					
Resting pulse	65.0	65.5	0.5 (–0.55 to 1.51)	0.8%	
1 year					
Leisure centre (n = 164)					
Resting pulse	65.1	64.3	–0.8 (–2.26 to 0.62)	1.2%	
Walking (n = 146)					
Resting pulse	63.5	64.9	1.4 (0.07 to 2.66)	2.2%	*

* $p < 0.05$.

TABLE 98 *Changes in resting pulse excluding subjects known to be taking β–blockers: completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (n = 108)					
Resting pulse	66.1	65.1	–1.0 (–2.61 to 0.59)	–1.5%	
Walking (n = 88)					
Resting pulse	64.0	63.8	–0.2 (–1.58 to 1.08)	–0.3%	
Advice (n = 84)					
Resting pulse	66.9	67.3	0.4 (–1.27 to 1.92)	0.6%	
6 months					
Leisure centre (n = 159)					
Resting pulse	66.3	66.5	0.2 (–1.33 to 1.54)	0.3%	
Walking (n = 127)					
Resting pulse	64.8	65.4	0.6 (–0.73 to 2.02)	0.9%	
Advice (n = 190)					
Resting pulse	66.0	66.3	0.3 (–0.78 to 1.46)	0.5%	
1 year					
Leisure centre (n = 130)					
Resting pulse	65.9	65.3	–0.6 (–2.15 to 1.05)	–0.9%	
Walking (n = 125)					
Resting pulse	64.2	65.5	1.3 (–1.74 to 2.69)	2.0%	

TABLE 99 *Changes in resting pulse excluding subjects known to be taking β–blockers: ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 week					
Leisure centre (*n* = 146)					
Resting pulse	66.5	65.8	–0.7 (–1.93 to 0.43)	–1.1%	
Walking (*n* = 142)					
Resting pulse	66.1	66.0	–0.1 (–0.97 to 0.66)	–0.2%	
Advice (*n* = 144)					
Resting pulse	65.9	66.0	0.2 (–0.74 to 1.11)	0.3%	
6 months					
Leisure centre (*n* = 272)					
Resting pulse	66.8	66.6	–0.2 (–1.11 to 0.71)	–0.3%	
Walking (*n* = 268)					
Resting pulse	65.8	66.0	0.2 (–0.49 to 0.91)	0.3%	
Advice (*n* = 277)					
Resting pulse	66.7	66.8	0.1 (–0.68 to 0.90)	0.1%	
1 year					
Leisure centre (*n* = 175)					
Resting pulse	66.5	66.1	–0.4 (–1.77 to 1.08)	–0.6%	
Walking (*n* = 163)					
Resting pulse	64.9	66.0	1.1 (–0.11 to 2.37)	1.7%	^

^ $p = 0.07$.

TABLE 100 *Resting pulse; comparison of values between groups at each assessment: completers*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 121	*n* = 102	*n* = 92
Resting pulse	63.7 (62.4 to 65.0)	64.0 (62.5 to 65.4)	65.6 (64.1 to 67.1)
6 months	*n* = 191	*n* = 151	*n* = 219
Resting pulse	64.9 (63.8 to 66.0)	64.4 (63.1 to 65.7)	65.3 (64.3 to 66.4)
1 year	*n* = 164	*n* = 146	
Resting pulse	63.7 (62.4 to 65.0)	65.1 (63.7 to 66.5)	

TABLE 101 *Resting pulse; comparison of values between groups at each assessment excluding subjects known to be taking β-blockers: completers*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
Completers			
10 weeks	*n* = 108	*n* = 88	*n* = 84
Resting pulse	64.8 (63.6 to 66.1)	64.5 (63.1 to 66.0)	67.0 (65.5 to 68.5)
6 months	*n* = 159	*n* = 127	*n* = 190
Resting pulse	66.1 (64.9 to 67.3)	65.6 (64.1 to 67.1)	66.3 (65.1 to 67.4)
1 year	*n* = 130	*n* = 125	
Resting pulse	64.7 (63.3 to 66.1)	65.6 (64.1 to 67.1)	
ITT			
10 weeks	*n* = 146	*n* = 142	*n* = 144
Resting pulse	65.5 (64.6 to 66.5)	65.8 (64.7 to 66.8)	66.4 (65.5 to 67.4)
6 months	*n* = 272	*n* = 268	*n* = 277
Resting pulse	66.3 (65.5 to 67.1)	66.3 (65.4 to 67.1)	66.6 (65.8 to 67.4)
1 year	*n* = 175	*n* = 163	
Resting pulse	65.8 (64.5 to 67.0)	66.2 (64.9 to 67.6)	

TABLE 102 *Changes in blood pressure: completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 121)					
SBP	134.9	130.6	–4.2 (–6.62 to –1.85)	–3.1%	**
DBP	83.9	80.7	–3.3 (–4.50 to –2.01)	–3.9%	**
Walking (*n* = 103)					
SBP	135.4	131.8	–3.6 (–6.07 to –1.18)	–2.7%	**
DBP	83.6	82.1	–1.5 (–3.05 to 0.07)	–1.8%	^
Advice (*n* = 93)					
SBP	138.0	131.5	–6.5 (–9.11 to –3.84)	–4.7%	**
DBP	85.7	82.1	–3.6 (–5.36 to –1.91)	–4.2%	**
6 months					
Leisure centre (*n* = 192)					
SBP	137.0	132.1	–5.0 (–7.10 to –2.89)	–3.6%	**
DBP	84.3	80.6	–3.7 (–4.83 to –2.59)	–4.4%	**
Walking (*n* = 151)					
SBP	134.6	129.2	–5.3 (–7.61 to –3.08)	–3.9%	**
DBP	84.0	80.0	–4.0 (–5.26 to –2.75)	–4.8%	**
Advice (*n* = 219)					
SBP	135.7	132.0	–3.7 (–5.58 to –1.87)	–2.7%	**
DBP	84.3	81.5	–2.8 (–3.83 to –1.79)	–3.3%	**
1 year					
Leisure centre (*n* = 167)					
SBP	137.1	129.6	–7.5 (–9.86 to –5.07)	–5.5%	**
DBP	84.5	79.7	–4.9 (–6.10 to –3.62)	–5.8%	**
Walking (*n* = 147)					
SBP	135.8	129.7	–6.0 (–8.46 to –3.62)	–4.4%	**
DBP	84.3	79.8	–4.5 (–5.78 to –3.26)	–5.3%	**

** $p < 0.01$, ^ $p = 0.06$.

TABLE 103 *Changes in blood pressure excluding subjects known to be taking blood pressure-lowering medication: completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre ($n = 69$)					
SBP	130.3	127.2	–3.2 (–6.13 to –0.21)	–3.1%	*
DBP	82.5	79.6	–2.9 (–4.42 to –1.41)	–3.5%	**
Walking ($n = 63$)					
SBP	128.4	126.0	–2.3 (–5.48 to 0.72)	–1.8%	
DBP	81.4	80.1	–1.3 (–3.40 to 0.84)	–1.6%	
Advice ($n = 53$)					
SBP	129.6	125.9	–3.7 (–6.62 to –0.70)	–2.9%	*
DBP	82.4	80.1	–2.3 (–4.28 to –0.26)	–2.8%	*
6 months					
Leisure centre ($n = 101$)					
SBP	132.0	128.5	–3.5 (–6.18 to –0.73)	–2.7%	*
DBP	81.9	79.1	–2.8 (–4.37 to –1.21)	–3.4%	**
Walking ($n = 89$)					
SBP	129.5	126.7	–2.9 (–5.27 to –0.44)	–2.2%	*
DBP	82.6	79.5	–3.2 (–4.62 to –1.71)	–3.9%	**
Advice ($n = 134$)					
SBP	129.4	128.2	–1.2 (–2.96 to –0.52)	–0.9%	
DBP	81.5	79.8	–1.6 (–2.76 to –0.51)	–2.0%	**
1 year					
Leisure centre ($n = 85$)					
SBP	131.8	125.5	–6.3 (–9.02 to –3.64)	–4.8%	**
DBP	81.4	77.1	–4.3 (–5.73 to –2.88)	–5.3%	**
Walking ($n = 84$)					
SBP	129.5	126.2	–3.3 (–6.35 to –0.28)	–2.5%	*
DBP	81.4	78.3	–3.2 (–4.71 to –1.63)	–3.9%	**

** $p < 0.01$, * $p < 0.05$.

TABLE 104 *Changes in blood pressure excluding subjects known to be taking blood pressure-lowering medication: ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 91)					
SBP	130.5	128.1	–2.4 (–4.66 to –0.16)	–2.7%	*
DBP	82.3	80.1	–2.2 (–3.37 to –1.04)	–2.7%	**
Walking (*n* = 100)					
SBP	130.5	129.0	–1.5 (–3.45 to 0.45)	–1.1%	
DBP	82.2	81.4	–0.8 (–2.13 to 0.52)	–1.0%	
Advice (*n* = 95)					
SBP	129.5	127.5	–2.0 (–3.71 to –0.37)	–1.5%	*
DBP	82.4	81.1	–1.3 (–2.40 to –0.14)	–1.6%	*
6 months					
Leisure centre (*n* = 185)					
SBP	131.7	129.2	–2.5 (–4.10 to –0.94)	–1.9%	**
DBP	82.4	80.3	–2.1 (–3.00 to –1.13)	–2.5%	**
Walking (*n* = 179)					
SBP	130.0	128.8	–1.2 (–2.59 to 0.13)	–0.9%	
DBP	81.8	80.3	–1.5 (–2.37 to –0.55)	–1.8%	**
Advice (*n* = 198)					
SBP	128.9	128.0	–0.9 (–2.15 to –0.28)	–0.7%	
DBP	81.7	80.5	–1.2 (–2.05 to –0.43)	–1.5%	**
1 year					
Leisure centre (*n* = 114)					
SBP	132.5	127.1	–5.4 (–7.74 to –3.03)	–4.1%	**
DBP	82.2	78.1	–4.1 (–5.29 to –2.82)	–5.0%	**
Walking (*n* = 126)					
SBP	128.1	124.9	–3.2 (–5.71 to –0.70)	–2.5%	*
DBP	81.5	78.2	–3.3 (–4.61 to –1.90)	–4.0%	**

** $p < 0.01$, * $p < 0.05$.

TABLE 105 *Blood pressure; comparison of values between groups at each assessment: completers*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 121	*n* = 103	*n* = 93
SBP	131.7 (129.6 to 133.8)	133.3 (131.0 to 135.6)	129.9 (127.4 to 132.4)
DBP	81.1 (79.9 to 82.3)	83.3 (81.9 to 84.6)	81.3 (79.8 to 82.7)
6 months	*n* = 192	*n* = 151	*n* = 219
SBP	131.5 (129.7 to 133.3)	131.3 (129.0 to 133.5)	132.8 (131.0 to 134.6)
DBP	80.6 (79.6 to 81.7)	80.5 (79.3 to 81.7)	81.8 (80.8 to 82.8)
1 year	*n* = 167	*n* = 147	
SBP	130.0 (127.9 to 132.1)	131.0 (128.6 to 133.3)	
DBP	80.0 (78.9 to 81.2)	80.4 (79.2 to 81.7)	

TABLE 106 *Blood pressure; comparison of values between groups at each assessment excluding subjects known to be taking blood pressure-lowering medication*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
Completers			
10 weeks	*n* = 69	*n* = 63	*n* = 53
SBP	126.7 (124.1 to 129.4)	128.0 (124.9 to 131.0)	125.0 (121.5 to 128.5)
DBP	79.5 (77.9 to 81.2)	81.2 (79.3 to 83.1)	79.8 (77.6 to 81.9)
6 months	*n* = 101	*n* = 89	*n* = 134
SBP	127.2 (124.9 to 129.5)	127.6 (125.0 to 130.2)	129.5 (127.5 to 131.5)
DBP	79.1 (77.7 to 80.5)	79.0 (77.5 to 80.6)	80.6 (79.4 to 81.8)
1 year	*n* = 85	*n* = 84	
SBP	125.6 (122.9 to 128.2)	127.2 (124.4 to 130.0)	
DBP	77.7 (76.3 to 79.1)	78.6 (77.1 to 80.1)	
ITT			
10 weeks	*n* = 91	*n* = 100	*n* = 95
SBP	128.0 (126.0 to 129.9)	129.6 (127.5 to 131.7)	127.8 (125.7 to 129.8)
DBP	80.3 (79.1 to 81.5)	82.0 (80.7 to 83.2)	81.1 (79.8 to 82.3)
6 months	*n* = 185	*n* = 179	*n* = 198
SBP	127.8 (126.4 to 129.3)	129.3 (127.8 to 130.8)	129.4 (128.0 to 130.9)
DBP	79.9 (79.0 to 80.8)	80.7 (79.8 to 81.7)	80.9 (80.0 to 81.8)
1 year	*n* = 114	*n* = 112	
SBP	126.4 (124.1 to 128.7)	127.1 (124.7 to 129.6)	
DBP	78.3 (77.1 to 79.6)	78.9 (77.6 to 80.3)	

TABLE 107 *Baseline measurements of lung function*

	FEV_1 Mean (SEM)	FVC Mean (SEM)	FEV_1/FVC Mean (SEM)	PEF Mean (SEM) (*n*)
Leisure centre (*n* = 313)	2.37 (0.04)	2.80 (0.04)	0.85 (0.004)	410.8 (7.59) (285)
Walking (*n* = 306)	2.33 (0.04)	2.76 (0.04)	0.85 (0.005)	399.9 (6.77) (278)
Advice (*n* = 310)	2.33 (0.04)	2.74 (0.04)	0.86 (0.004)	402.7 (7.58) (280)
Female (*n* = 623)	2.08 (0.02)	2.45 (0.02)	0.85 (0.003)	349.5 (3.37) (564)
Male (*n* = 306)	2.90 (0.04)	3.41 (0.04)	0.85 (0.004)	515.8 (7.10) (279)
Age (years)				
40–44 (*n* = 81)	2.66 (0.07)	3.03 (0.08)	0.88 (0.01)	448.5 (15.4) (76)
45–54 (*n* = 332)	2.50 (0.04)	2.91 (0.04)	0.86 (0.004)	427.6 (6.53) (296)
55–64 (*n* = 312)	2.29 (0.04)	2.72 (0.04)	0.84 (0.004)	396.0 (7.11) (289)
65–74 (*n* = 204)	2.07 (0.04)	2.50 (0.05)	0.83 (0.01)	362.3 (9.13) (182)

TABLE 108 *Changes in measures of lung function: completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 118)					
FEV_1	2.44	2.46	0.02 (–0.004 to 0.05)	0.8%	
FVC	2.90	2.89	–0.01 (–0.06 to 0.03)	–0.3%	
FEV_1/FVC	0.84	0.84	0.00 (–0.01 to 0.02)	0.0%	
PEF (*n* = 107)	427.8	433.2	5.41 (–6.24 to 17.07)	1.3%	
Walking (*n* = 100)					
FEV_1	2.32	2.34	0.02 (–0.01 to 0.05)	0.9%	
FVC	2.75	2.77	0.02 (–0.02 to 0.06)	0.7%	
FEV_1/FVC	0.85	0.85	0.00 (–0.01 to 0.01)	0.0%	
PEF (*n* = 88)	402.3	402.7	0.40 (12.16 to 12.91)	0.1%	
Advice (*n* = 88)					
FEV_1	2.31	2.30	–0.01 (–0.03 to 0.01)	0.4%	
FVC	2.73	2.67	–0.05 (–0.09 to –0.01)	–1.8%	**
FEV_1/FVC	0.85	0.86	0.01 (0.003 to 0.02)	1.2%	**
PEF (*n* = 76)	408.2	414.7	6.42 (–3.53 to 16.37)	1.6%	
6 months					
Leisure centre (*n* = 187)					
FEV_1	2.41	2.39	–0.02 (–0.05 to 0.01)	–0.8%	
FVC	2.85	2.79	–0.06 (–0.10 to 0.02)	–2.1%	**
FEV_1/FVC	0.85	0.86	0.01 (–0.001 to 0.02)	1.2%	
PEF (*n* = 167)	409.6	404.0	–5.66 (–13.66 to 2.34)	–1.4%	
Walking (*n* = 144)					
FEV_1	2.36	2.34	–0.01 (–0.04 to 0.02)	–0.4%	
FVC	2.77	2.74	–0.03 (–0.08 to 0.01)	–1.1%	
FEV_1/FVC	0.85	0.86	0.01 (–0.01 to 0.02)	1.2%	
PEF (*n* = 126)	400.0	403.3	3.30 (–6.33 to 12.92)	0.8%	
Advice (*n* = 213)					
FEV_1	2.35	2.32	–0.02 (–0.05 to 0.001)	–0.9%	
FVC	2.74	2.67	–0.07 (–0.11 to –0.04)	–2.6%	**
FEV_1/ FVC	0.86	0.88	0.02 (0.01 to 0.02)	2.3%	**
PEF (*n* = 185)	411.5	418.3	6.84 (0.91 to 14.60)	1.7%	
1 year					
Leisure centre (*n* = 161)					
FEV_1	2.41	2.37	–0.04 (–0.07 to –0.01)	–1.2%	**
FVC	2.87	2.78	–0.09 (–0.13 to –0.05)	–3.1%	**
FEV_1/FVC	0.84	0.86	0.02 (0.01 to 0.02)	2.4%	**
PEF (*n* = 141)	411.4	411.9	0.50 (8.35 to 9.47)	0.1%	
Walking (*n* = 143)					
FEV_1	2.35	2.31	–0.04 (–0.07 to –0.01)	–1.7%	**
FVC	2.79	2.71	–0.08 (–0.12 to –0.04)	–2.9%	**
FEV_1/FVC	0.85	0.86	0.01 (–0.001 to 0.02)	1.2%	+
PEF (*n* = 126)	402.6	402.1	0.50 (–10.34 to 9.37)	0.1%	

** $p < 0.01$, + $p = 0.08$.

TABLE 109 *Lung function; comparison of values between groups at each assessment: completers*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 118	*n* = 100	*n* = 88
FEV_1	2.40 (2.37 to 2.42)	2.39 (2.36 to 2.42)	2.36 (2.33 to 2.39)
FVC	2.80 (2.76 to 2.84)	2.84 (2.79 to 2.88)	2.76 (2.71 to 2.88)
FEV_1/FVC	0.85 (0.84 to 0.86)	0.85 (0.83 to 0.86)	0.86 (0.84 to 0.87)
PEF	424.7 (414.3 to 435.2) (*n* = 107)	417.5 (405.7 to 429.3) (*n* = 88)	426.3 (413.3 to 439.3) (*n* = 76)
6 months	*n* = 187	*n* = 144	*n* = 213
FEV_1	2.36 (2.33 to 2.39)	2.37 (2.34 to 2.40)	2.34 (2.32 to 2.37)
FVC	2.74 (2.70 to 2.78)	2.76 (2.71 to 2.81)	2.72 (2.68 to 2.75)
FEV_1/FVC	0.86 (0.85 to 0.87)	0.85 (0.84 to 0.86)	0.87 (0.86 to 0.88)
PEF	407.8 (399.6 to 416.0) (*n* = 167)	418.3 (408.5 to 428.0) (*n* = 126)	420.7 (412.9 to 428.5) (*n* = 185)
1 year	*n* = 161	*n* = 143	
FEV_1	2.35 (2.32 to 2.38)	2.35 (2.32 to 2.39)	
FVC	2.75 (2.71 to 2.79)	2.77 (2.72 to 2.81)	
FEV_1/FVC	0.86 (0.85 to 0.87)	0.85 (0.84 to 0.86)	
PEF	415.9 (406.7 to 425.1) (*n* = 141)	409.4 (399.6 to 419.2) (*n* = 126)	

TABLE 110 *Baseline measurements for subjects allocated to the cycle ergometer*

	Heart rate after bike test Mean (SEM) (*n*)	No. of minutes cycled Mean (SEM) (*n*)	Perceived exertion (Borg) Mean (SEM) (*n*)
Leisure centre	116.9 (1.3) (152)	8.5 (0.2) (142)	15.0 (0.2) (152)
Walking	117.8 (1.4) (133)	9.0 (0.2) (125)	15.1 (0.2) (133)
Advice	116.5 (1.3) (139)	8.9 (0.2) (130)	15.1 (0.2) (139)
Female	115.5 (1.0) (287)	8.6 (0.2) (269)	15.1 (0.1) (287)
Male	120.3 (1.3) (137)	9.2 (0.2) (128)	14.9 (0.2) (137)
Age (years)			
40–44	128.8 (2.9) (37)	8.4 (0.5) (34)	15.5 (0.4) (37)
45–54	122.5 (1.1) (153)	8.8 (0.2) (146)	15.4 (0.2) (153)
55–64	115.0 (1.2) (146)	8.8 (0.2) (134)	14.8 (0.2) (146)
65–74	106.0 (1.5) (88)	8.9 (0.3) (83)	14.7 (0.2) (88)

TABLE 111 *Baseline measurements for subjects allocated to the cycle ergometer excluding subjects known to be taking β-blockers*

	Heart rate after bike test Mean (SEM) (*n*)	No. of minutes cycled Mean (SEM) (*n*)	Perceived exertion (Borg) Mean (SEM) (*n*)
Leisure centre	119.6 (1.3) (134)	8.7 (0.3) (126)	15.0 (0.2) (134)
Walking	120.6 (1.4) (119)	9.0 (0.2) (113)	15.1 (0.2) (119)
Advice	117.9 (1.3) (128)	9.0 (0.2) (120)	15.2 (0.2) (128)
Female	117.8 (0.9) (258)	8.7 (0.2) (243)	15.2 (0.1) (258)
Male	122.4 (1.3) (123)	9.3 (0.2) (116)	14.9 (0.2) (123)
Age (years)			
40–44	128.8 (2.9) (37)	8.4 (0.5) (34)	15.5 (0.4) (37)
45–54	124.8 (1.0) (138)	8.9 (0.2) (132)	15.3 (0.2) (138)
55–64	117.7 (1.2) (127)	9.0 (0.2) (118)	15.0 (0.2) (127)
65–74	107.9 (1.4) (79)	9.0 (0.3) (75)	14.7 (0.2) (79)

TABLE 112 *Cycle ergometer – number of minutes cycled: completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 55)	8.29	9.55	1.25 (0.69 to 1.82)	15.1%	**
Walking (*n* = 35)	9.77	9.80	0.03 (–0.73 to 0.79)	0.3%	
Advice (*n* = 34)	9.03	8.91	–0.12 (–0.69 to 0.45)	–1.3%	
6 months					
Leisure centre (*n* = 78)	8.79	8.85	0.05 (–0.51 to 0.61)	0.6%	
Walking (*n* = 52)	9.38	9.42	0.04 (–0.50 to 0.59)	0.4%	
Advice (*n* = 77)	8.86	9.16	0.30 (–0.13 to 0.73)	3.4%	
1 year					
Leisure centre (*n* = 64)	9.22	9.42	0.20 (–0.40 to 0.81)	2.1%	
Walking (*n* = 49)	9.51	9.57	0.06 (–0.51 to 0.64)	0.6%	

** $p < 0.01$.

TABLE 113 *Cycle ergometer – number of minutes cycled excluding subjects known to be taking β-blockers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
Completers					
10 weeks					
Leisure centre (*n* = 48)	8.58	9.69	1.10 (0.48 to 1.73)	12.8%	**
Walking (*n* = 31)	9.87	9.84	–0.32 (–0.87 to 0.80)	–3.2%	
Advice (*n* = 30)	9.03	8.87	–0.17 (–0.80 to 0.46)	–1.9%	
6 months					
Leisure centre (*n* = 65)	9.06	9.00	–0.06 (–0.69 to 0.56)	–0.7%	
Walking (*n* = 43)	9.44	9.33	–0.12 (–0.74 to 0.51)	–1.3%	
Advice (*n* = 66)	8.80	9.20	0.39 (–0.06 to 0.85)	4.4%	
1 year					
Leisure centre (*n* = 50)	9.40	9.74	0.34 (–0.37 to 1.05)	3.6%	
Walking (*n* = 43)	9.56	9.79	0.23 (–0.29 to 0.75)	2.4%	
ITT					
10 weeks					
Leisure centre (*n* = 67)	8.43	9.22	0.79 (0.33 to 1.25)	9.4%	**
Walking (*n* = 63)	9.29	9.27	–0.02 (–0.41 to 0.38)	–0.2%	
Advice (*n* = 59)	9.10	9.02	–0.08 (–0.40 to 0.23)	–0.9%	
6 months					
Leisure centre (*n* = 122)	8.69	8.76	0.07 (–0.29 to 0.43)	0.8%	
Walking (*n* = 111)	9.02	9.06	0.05 (–0.26 to 0.35)	0.6%	
Advice (*n* = 116)	8.97	9.21	–0.23 (–0.03 to 0.50)	2.6%	
1 year					
Leisure centre (*n* = 72)	9.18	9.40	0.22 (–0.36 to 0.81)	2.4%	
Walking (*n* = 61)	9.38	9.39	0.01 (–0.45 to 0.48)	0.1%	

** $p < 0.01$.

TABLE 114 *Cycle ergometer – number of minutes cycled; comparison of values between groups at each assessment: completers*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 55	*n* = 35	*n* = 34
Minutes cycled	9.96 (9.48 to 10.44)*	9.21 (8.52 to 9.89)	8.84 (8.18 to 9.51)*
6 months	*n* = 78	*n* = 52	*n* = 77
Minutes cycled	8.87 (8.42 to 9.31)	9.28 (8.64 to 9.91)	9.24 (8.77 to 9.71)
1 year	*n* = 64	*n* = 49	
Minutes cycled	9.54 (9.03 to 10.04)	9.71 (9.06 to 10.36)	

* Significant difference between leisure centre and advice groups ($p = 0.024$) after adjusting for age, gender and baseline values and multiple testing (Bonferroni correction).

TABLE 115 *Cycle ergometer – number of minutes cycled; comparison of values between groups at each assessment excluding subjects known to be taking β-blockers*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
Completers			
10 weeks	*n* = 48	*n* = 31	*n* = 30
Minutes cycled	10.00 (9.47 to 10.53)	9.36 (8.60 to 10.13)	8.91 (8.14 to 9.68)
6 months	*n* = 65	*n* = 43	*n* = 66
Minutes cycled	8.92 (8.42 to 9.41)	9.18 (8.46 to 9.90)	9.38 (8.84 to 9.91)
1 year	*n* = 50	*n* = 43	
Minutes cycled	9.81 (9.27 to 10.35)	9.94 (9.30 to 10.58)	
ITT			
10 weeks	*n* = 67	*n* = 63	*n* = 59
Minutes cycled	9.65 (9.28 to 10.02)	8.95 (8.51 to 9.39)	8.93 (8.52 to 9.34)
6 months	*n* = 122	*n* = 111	*n* = 116
Minutes cycled	8.89 (8.59 to 9.19)	8.98 (8.64 to 9.33)	9.19 (8.87 to 9.52)
1 year	*n* = 72	*n* = 61	
Minutes cycled	9.41 (8.95 to 9.87)	9.57 (9.00 to 10.14)	

TABLE 116 *Cycle ergometer – heart rate at highest comparable workload and perceived exertion: completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre ($n = 61$)					
Heart rate	113.3	108.1	–5.2 (–9.23 to –1.07)	–4.6%	*
Borg	(14.7)	(14.0)	–0.8 (–1.28 to –0.24)	–5.0%	**
Walking ($n = 41$)					
Heart rate	110.5	105.5	–5.0 (–8.64 to –1.34)	–4.5%	**
Borg	(14.4)	(14.2)	–0.2 (–0.84 to 0.42)	–1.4%	
Advice ($n = 41$)					
Heart rate	112.9	109.3	–3.6 (–6.40 to –0.79)	–3.2%	*
Borg	(14.4)	(13.9)	–0.5 (–1.01 to 0.06)	–3.5%	
6 months					
Leisure centre ($n = 91$)					
Heart rate	111.6	107.5	–4.2 (–7.17 to –1.17)	–3.8%	**
Borg	(14.5)	(14.3)	–0.2 (–0.70 to 0.17)	–1.4%	
Walking ($n = 67$)					
Heart rate	113.3	110.4	–2.9 (–5.33 to –0.47)	–2.6%	*
Borg	(14.3)	(14.5)	0.2 (–0.41 to 0.65)	1.4%	
Advice ($n = 87$)					
Heart rate	115.1	109.9	–5.2 (–8.31 to –2.01)	–4.5%	**
Borg	(14.7)	(14.4)	–0.3 (–0.79 to 0.16)	–2.0%	
1 year					
Leisure centre ($n = 80$)					
Heart rate	113.4	109.3	–4.1 (–7.47 to –0.85)	–3.6%	*
Borg	(14.5)	(14.4)	–0.1 (–0.55 to 0.30)	0.7%	
Walking ($n = 59$)					
Heart rate	114.1	110.6	–3.5 (–6.76 to –0.24)	–3.0%	*
Borg	(14.6)	(14.1)	–0.5 (–1.16 to 0.13)	–3.4%	

** $p < 0.01$, * $p < 0.05$.

TABLE 117 *Cycle ergometer – heart rate at highest comparable workload and perceived exertion excluding subjects known to be taking β-blockers: completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre ($n = 54$)					
Heart rate	115.0	109.9	–5.2 (–9.47 to –0.83)	–4.5%	*
Borg	(14.9)	(14.1)	–0.8 (–1.32 to –0.17)	–5.0%	*
Walking ($n = 34$)					
Heart rate	114.6	109.0	–5.6 (–9.62 to –1.65)	–4.9%	**
Borg	(14.4)	(14.1)	–0.3 (–1.00 to 0.47)	–2.0%	
Advice ($n = 36$)					
Heart rate	114.9	111.2	–3.8 (–6.79 to –0.71)	–3.2%	*
Borg	(14.5)	(13.9)	–0.5 (–1.12 to 0.06)	–3.0%	
6 months					
Leisure centre ($n = 74$)					
Heart rate	115.3	110.5	–4.9 (–8.19 to –1.53)	–4.2%	**
Borg	(14.7)	(14.4)	–0.3 (–0.79 to 0.21)	–2.0%	
Walking ($n = 55$)					
Heart rate	117.7	114.2	–3.5 (–6.21 to –0.77)	–3.0%	*
Borg	(14.3)	(14.4)	0.1 (–0.49 to 0.76)	0.7%	
Advice ($n = 75$)					
Heart rate	117.4	111.6	–5.9 (–9.41 to –2.28)	–5.0%	**
Borg	(14.8)	(14.4)	–0.4 (–0.95 to 0.13)	–0.3%	
1 year					
Leisure centre ($n = 62$)					
Heart rate	116.3	112.7	–3.6 (–7.60 to 1.40)	–3.0%	
Borg	(14.5)	(14.5)	–0.0 (–0.49 to 0.45)	0.0%	
Walking ($n = 50$)					
Heart rate	116.9	113.5	–3.5 (–6.75 to –0.23)	–3.0%	*
Borg	(14.7)	(14.1)	–0.5 (–1.19 to 0.13)	–3.4%	

** $p < 0.01$, * $p < 0.05$.

TABLE 118 *Cycle ergometer – heart rate at highest comparable workload and perceived exertion excluding subjects known to be taking β-blockers: ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 71)					
Heart rate	116.8	112.9	–3.9 (–7.22 to –0.62)	–3.3%	*
Borg	(14.9)	(14.3)	–0.6 (–0.33 to –0.13)	–4.0%	*
Walking (*n* = 64)					
Heart rate	118.1	115.2	–3.0 (–5.18 to –0.81)	–2.5%	**
Borg	(14.8)	(14.7)	–0.1 (–0.52 to 0.24)	–0.7%	
Advice (*n* = 64)					
Heart rate	115.5	113.4	–2.1 (–3.85 to –0.37)	–1.8%	*
Borg	(14.9)	(14.6)	–0.3 (–0.63 to 0.03)	–3.0%	
6 months					
Leisure centre (*n* = 129)					
Heart rate	117.5	113.9	–3.6 (–5.55 to –1.58)	–3.1%	**
Borg	(14.7)	(14.5)	–0.2 (–0.56 to 0.07)	–1.4%	
Walking (*n* = 117)					
Heart rate	119.2	116.8	–2.4 (–3.91 to –0.83)	–2.0%	**
Borg	(14.8)	(14.8)	0.0 (–0.34 to 0.30)	0.0%	
Advice (*n* = 124)					
Heart rate	115.2	111.8	–3.3 (–5.28 to –1.28)	–2.9%	**
Borg	(15.0)	(14.7)	–0.3 (–0.59 to 0.08)	–2.0%	
1 year					
Leisure centre (*n* = 84)					
Heart rate	116.8	112.4	–4.3 (–7.63 to –1.04)	–3.7%	*
Borg	(14.5)	(14.3)	–0.2 (–0.69 to 0.17)	–1.4%	
Walking (*n* = 68)					
Heart rate	118.3	115.1	–3.2 (–5.87 to –0.62)	–2.7%	*
Borg	(14.5)	(14.3)	–0.2 (–0.82 to 0.30)	–1.4%	

** $p < 0.01$, * $p < 0.05$.

TABLE 119 *Cycle ergometer – heart rate at highest comparable workload and perceived exertion; comparison of values between groups at each assessment: completers*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 61	*n* = 41	*n* = 41
Heart rate	107.1 (104.4 to 109.8)	105.5 (102.0 to 109.0)	110.4 (106.8 to 114.0)
Borg	13.8 (13.38 to 14.29)	14.0 (13.5 to 14.6)	14.1 (13.5 to 14.7)
6 months	*n* = 91	*n* = 67	*n* = 87
Heart rate	108.4 (106.0 to 110.8)	108.9 (105.6 to 112.3)	109.0 (106.4 to 111.6)
Borg	14. 2 (13.8 to 14.6)	14.6 (14.05 to 15.16)	14.4 (14.0 to 14.8)
1 year	*n* = 80	*n* = 59	
Heart rate	109.3 (106.6 to 112.0)	109.7 (106.2 to 113.3)	
Borg	14.4 (13.95 to 14.83)	14.2 (13.6 to 14.8)	

TABLE 120 *Cycle ergometer – heart rate at highest comparable workload and perceived exertion; comparison of values between groups at each assessment excluding subjects known to be taking β-blockers*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
Completers			
10 weeks	*n* = 54	*n* = 41	*n* = 41
Heart rate	109.3 (106.5 to 112.1)	108.0 (104.2 to 111.7)	113.6 (109.8 to 117.5)
Borg	14.0 (13.46 to 14.46)	14.0 (13.33 to 14.64)	14.2 (13.51 to 14.86)
6 months	*n* = 74	*n* = 55	*n* = 75
Heart rate	111.1 (108.4 to 113.9)	111.9 (108.1 to 115.6)	111.5 (108.5 to 114.5)
Borg	14.3 (13.78 to 14.72)	14.6 (13.97 to 15.25)	14.4 (13.8 to 14.9)
1 year	*n* = 62	*n* = 50	
Heart rate	112.7 (109.7 to 115.6)	112.3 (108.6 to 115.9)	
Borg	14.6 (14.06 to 15.0)	14.2 (13.6 to 14.8)	
ITT			
10 weeks	*n* = 71	*n* = 64	*n* = 64
Heart rate	112.6 (110.5 to 114.8)	112.8 (110.2 to 115.5)	115.0 (112.5 to 117.5)
Borg	14.3 (13.94 to 14.65)	14.4 (14.00 to 14.85)	14.7 (14.26 to 15.1)
6 months	*n* = 129	*n* = 117	*n* = 124
Heart rate	114.1 (112.3 to 115.9)	115.2 (113.2 to 117.3)	114.0 (112.0 to 115.9)
Borg	14.5 (14.20 to 14.81)	14.7 (14.35 to 15.04)	14.6 (14.3 to 15.0)
1 year	*n* = 84	*n* = 68	
Heart rate	113.2 (110.8 to 115.6)	113.1 (110.0 to 116.2)	
Borg	14.3 (13.83 to 14.68)	14.3 (13.76 to 14.83)	

TABLE 121 *Baseline measurements for subjects who were allocated to the shuttle walking test*

	Heart rate after walking test Mean (SEM) (*n*)	No. of minutes covered Mean (SEM) (*n*)	Perceived exertion (Borg) Mean (SEM) (*n*)
Leisure centre	117.1 (1.5) (123)	416.8 (13.8) (127)	13.0 (0.2) (123)
Walking	119.8 (1.5) (141)	424.8 (12.1) (141)	12.6 (0.2) (141)
Advice	117.8 (1.5) (137)	415.0 (10.7) (139)	12.9 (0.2) (137)
Female	118.3 (1.1) (281)	390.6 (7.7) (287)	12.7 (0.1) (281)
Male	118.2 (1.5) (120)	486.8 (13.1) (120)	12.9 (0.2) (120)
Age (years)			
40–44	124.4 (2.9) (35)	463.2 (21.4) (37)	13.5 (0.4) (35)
45–54	124.8 (1.1) (159)	445.2 (11.1) (159)	12.7 (0.2) (159)
55–64	114.9 (1.7) (123)	415.5 (11.6) (126)	12.8 (0.2) (123)
65–74	108.3 (1.6) (84)	355.7 (15.8) (85)	12.6 (0.2) (84)

TABLE 122 *Baseline measurements for subjects who were allocated to the shuttle walking test excluding subjects who were known to be taking β-blockers*

	Heart rate after walking test Mean (SEM) (*n*)	No. of minutes covered Mean (SEM) (*n*)	Perceived exertion (Borg) Mean (SEM) (*n*)
Leisure centre	118.6 (1.5) (112)	416.9 (14.4) (115)	13.1 (0.2) (112)
Walking	121.9 (1.4) (126)	429.9 (12.7) (124)	12.5 (0.2) (126)
Advice	119.1 (1.6) (126)	416.3 (10.8) (128)	12.9 (0.2) (126)
Female	116.3 (2.0) (59)	358.8 (17.9) (60)	12.6 (0.3) (59)
Male	110.5 (3.1) (27)	440.4 (31.8) (28)	12.7 (0.4) (27)
Age (years)			
40–44	125.5 (2.9) (33)	455.0 (22.6) (34)	13.5 (0.4) (33)
45–54	126.4 (1.1) (147)	445.7 (11.5) (147)	12.7 (0.2) (147)
55–64	116.3 (1.7) (111)	421.2 (12.1) (111)	13.0 (0.2) (111)
65–74	109.9 (1.6) (75)	357.5 (16.5) (75)	12.5 (0.3) (75)

TABLE 123 *Shuttle walking test – total distance covered (m): completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre ($n = 41$)	440.0	485.4	45.37 (14.83 to 75.90)	10.3%	**
Walking ($n = 45$)	441.3	463.6	22.22 (–24.25 to 68.70)	5.0%	
Advice ($n = 31$)	425.2	448.1	22.90 (–19.33 to 65.13)	5.4%	
6 months					
Leisure centre ($n = 60$)	420.0	463.7	43.67 (14.44 to 72.90)	10.4%	**
Walking ($n = 60$)	424.7	483.5	58.83 (28.26 to 89.41)	13.9%	**
Advice ($n = 96$)	418.5	431.7	13.13 (–8.18 to 34.43)	3.1%	
1 year					
Leisure centre ($n = 56$)	432.9	457.0	24.11 (–12.53 to 60.70)	5.6%	
Walking ($n = 58$)	443.3	465.0	21.72 (–12.21 to 55.70)	4.9%	

** $p < 0.01$.

TABLE 124 *Shuttle walking test – total distance covered (m) excluding subjects known to be taking β-blockers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
Completers					
10 weeks					
Leisure centre (*n* = 36)	437.5	476.7	39.17 (9.68 to 68.66)	9.0%	*
Walking (*n* = 41)	449.5	470.2	20.73 (–30.29 to 71.75)	4.6%	
Advice (*n* = 27)	426.7	454.1	27.41 (–17.33 to 72.14)	6.4%	
6 months					
Leisure centre (*n* = 50)	429.0	471.6	42.60 (9.34 to 75.86)	9.9%	*
Walking (*n* = 54)	432.0	485.9	53.89 (21.78 to 85.99)	12.5%	**
Advice (*n* = 85)	416.4	430.0	13.65 (–10.14 to 37.43)	3.3%	
1 year					
Leisure centre (*n* = 47)	423.8	446.8	22.98 (–16.15 to 62.10)	5.4%	
Walking (*n* = 50)	454.6	476.6	22.00 (–14.12 to 58.12)	4.8%	
ITT					
10 weeks					
Leisure centre (*n* = 56)	422.3	447.5	25.18 (5.88 to 44.48)	6.0%	*
Walking (*n* = 66)	424.9	437.7	12.88 (–18.39 to 44.15)	3.0%	
Advice (*n* = 63)	415.9	427.6	11.75 (–7.02 to 30.51)	2.8%	
6 months					
Leisure centre (*n* = 111)	417.2	438.7	21.53 (5.62 to 37.45)	5.2%	*
Walking (*n* = 124)	425.7	443.4	17.74 (0.25 to 35.24)	4.2%	*
Advice (*n* = 123)	412.1	421.5	9.43 (–7.04 to 25.90)	2.3%	
1 year					
Leisure centre (*n* = 64)	429.7	444.1	14.38 (–20.09 to 48.84)	3.3%	
Walking (*n* = 71)	436.6	468.6	32.25 (–1.42 to 63.09)	7.4%	

** $p < 0.01$, * $p < 0.05$.

TABLE 125 *Shuttle walking test – total distance; comparison of values between groups at each assessment: completers*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 41	*n* = 45	*n* = 31
Total distance	497.2 (458.1 to 536.2)	470.0 (432.8 to 507.3)	476.1 (425.5 to 526.8)
6 months	*n* = 60	*n* = 60	*n* = 96
Total distance	475.0 (446.4 to 503.6)	511.6 (482.6 to 540.7)	445.2 (422.3 to 468.0)
1 year	*n* = 56	*n* = 58	
Total distance	475.6 (438.8 to 512.5)	475.4 (438.7 to 512.1)	

TABLE 126 *Shuttle walking test – total distance; comparison of values between groups at each assessment excluding subjects known to be taking β-blockers*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
Completers			
10 weeks	*n* = 36	*n* = 41	*n* = 27
Total distance	491.6 (448.2 to 535.1)	473.4 (434.0 to 512.9)	485.2 (430.0 to 540.3)
6 months	*n* = 50	*n* = 54	*n* = 85
Total distance	475.0 (443.3 to 506.8)	510.9 (479.0 to 542.9)	446.5 (421.9 to 471.0)
1 year	*n* = 47	*n* = 50	
Total distance	464.8 (424.6 to 505.1)	472.4 (433.0 to 511.9)	
ITT			
10 weeks	*n* = 56	*n* = 66	*n* = 63
Total distance	451.3 (424.2 to 478.5)	440.0 (415.9 to 464.0)	437.8 (412.3 to 463.3)
6 months	*n* = 111	*n* = 124	*n* = 123
Total distance	444.3 (426.2 to 462.5)	446.4 (429.2 to 463.5)	435.4 (418.0 to 452.8)
1 year	*n* = 64	*n* = 71	
Total distance	452.3 (419.7 to 484.9)	484.6 (451.8 to 517.4)	

TABLE 127 *Shuttle walking test – heart rate at highest comparable level and perceived exertion: completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 41)					
Heart rate	116.3	111.5	–4.8 (–8.22 to –1.44)	–4.1%	**
Borg	(13.0)	(12.5)	–0.5 (–1.11 to 0.18)	–3.8%	
Walking (*n* = 45)					
Heart rate	116.2	113.8	–2.4 (–5.54 to 0.82)	–2.1%	
Borg	(12.2)	(12.4)	0.2 (–0.43 to 0.70)	1.6%	
Advice (*n* = 31)					
Heart rate	117.5	112.8	–4.7 (–7.51 to –1.85)	–3.4%	**
Borg	(12.7)	(11.8)	–0.9 (–1.53 to –0.21)	–7.1%	*
6 months					
Leisure centre (*n* = 60)					
Heart rate	114.1	110.7	–3.4 (–5.97 to –0.83)	–3.0%	**
Borg	(13.0)	(12.2)	–0.8 (–1.26 to –0.36)	–6.2%	**
Walking (*n* = 60)					
Heart rate	118.0	114.0	–4.0 (–7.16 to –0.85)	–3.4%	*
Borg	(12.5)	(12.3)	–0.2 (–0.71 to 0.27)	–1.6%	
Advice (*n* = 96)					
Heart rate	113.3	116.3	1.3 (–4.59 to 2.02)	1.1%	
Borg	(12.5)	(12.3)	–0.2 (–0.71 to 0.31)	–1.6%	
1 year					
Leisure centre (*n* = 56)					
Heart rate	114.1	110.9	–3.2 (–7.18 to 0.75)	–2.8%	
Borg	(12.5)	(12.3)	–0.2 (–0.87 to 0.46)	–1.6%	
Walking (*n* = 58)					
Heart rate	115.4	113.9	–1.5 (–4.75 to 1.79)	–1.3%	
Borg	(12.1)	(11.8)	–0.3 (–0.94 to 0.21)	–2.5%	

** $p < 0.01$, * $p < 0.05$.

TABLE 128 *Shuttle walking test – heart rate at highest comparable level and perceived exertion excluding subjects known to be taking β-blockers: completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre ($n = 36$)					
Heart rate	118.1	113.5	–4.6 (–8.38 to –0.90)	–3.9%	*
Borg	(13.2)	(12.7)	–0.5 (–1.20 to 0.25)	–3.8%	
Walking ($n = 41$)					
Heart rate	117.1	115.7	–2.1 (–5.35 to 1.25)	–1.7%	
Borg	(12.2)	(12.4)	0.2 (–0.38 to 0.77)	1.6%	
Advice ($n = 27$)					
Heart rate	120.2	116.0	–4.1 (–7.27 to –0.95)	–3.4%	*
Borg	(12.9)	(11.8)	–1.1 (–1.77 to –0.38)	–8.5%	**
6 months					
Leisure centre ($n = 50$)					
Heart rate	116.9	113.6	–3.3 (–6.06 to –0.54)	–2.8%	*
Borg	(13.3)	(12.2)	–1.1 (–1.59 to –0.62)	–8.3%	**
Walking ($n = 54$)					
Heart rate	120.1	115.9	–4.2 (–7.56 to –0.66)	–3.5%	*
Borg	(12.5)	(12.3)	–0.2 (–0.67 to 0.26)	–1.6%	
Advice ($n = 85$)					
Heart rate	114.3	113.4	–0.9 (–4.50 to 2.64)	–0.8%	
Borg	(12.5)	(12.2)	–0.3 (–0.84 to 0.28)	–2.4%	
1 year					
Leisure centre ($n = 47$)					
Heart rate	115.5	113.1	–2.4 (–6.66 to 1.85)	–2.1%	
Borg	(12.8)	(12.4)	–0.4 (–1.13 to 0.26)	–3.1%	
Walking ($n = 50$)					
Heart rate	118.7	116.8	–1.9 (–5.46 to 1.58)	–1.6%	
Borg	(12.1)	(11.7)	–0.3 (–0.99 to 0.31)	–2.5%	

** $p < 0.01$, * $p < 0.05$.

TABLE 129 *Shuttle walking test – heart rate at highest comparable level and perceived exertion excluding subjects known to be taking β-blockers: ITT*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 56)					
Heart rate	118.1	115.1	–3.0 (–5.42 to –0.54)	–2.5%	*
Borg	(13.2)	(12.9)	–0.3 (–0.77 to 0.16)	–2.3%	
Walking (*n* = 66)					
Heart rate	118.8	117.5	–1.3 (–3.30 to 0.75)	–1.1%	
Borg	(12.4)	(12.5)	0.1 (–0.23 to 0.48)	0.8%	
Advice (*n* = 63)					
Heart rate	120.9	119.2	–1.7 (–3.08 to –0.25)	–1.4%	*
Borg	(13.1)	(12.6)	–0.5 (–0.78 to –0.14)	–3.8%	**
6 months					
Leisure centre (*n* = 111)					
Heart rate	117.6	115.4	–2.2 (–3.75 to –0.64)	–1.9%	**
Borg	(13.1)	(12.5)	–0.6 (–0.86 to –0.35)	–4.6%	**
Walking (*n* = 124)					
Heart rate	120.1	118.4	–1.7 (–3.36 to –0.10)	–1.4%	*
Borg	(12.4)	(12.4)	0.0 (–0.23 to 0.26)	0.0%	
Advice (*n* = 123)					
Heart rate	116.0	115.3	–0.7 (–3.17 to 1.80)	–0.6%	
Borg	(12.6)	(12.3)	–0.3 (–0.63 to 0.16)	–2.4%	
1 year					
Leisure centre (*n* = 64)					
Heart rate	114.9	112.8	–2.1 (–5.41 to 1.19)	–1.8%	
Borg	(13.0)	(12.5)	–0.5 (–1.00 to 0.04)	–3.8%	
Walking (*n* = 71)					
Heart rate	119.3	116.4	–2.9 (–5.76 to 0.01)	–2.4%	
Borg	(12.1)	(11.8)	–0.3 (–0.85 to 0.15)	–2.5%	

** $p < 0.01$, * $p < 0.05$.

TABLE 130 *Shuttle walking test – heart rate at highest comparable level and perceived exertion; comparison of values between groups at each assessment: completers*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
10 weeks	*n* = 41	*n* = 45	*n* = 31
Heart rate	111.7 (108.6 to 114.7)	120.5 (116.6 to 124.5)	118.3 (112.8 to 123.7)
Borg	12.2 (11.64 to 12.81)	12.7 (12.12 to 13.25)	11.9 (11.09 to 12.62)
6 months	*n* = 60	*n* = 60	*n* = 96
Heart rate	111.3 (108.0 to 114.6)	111.2 (107.9 to 114.6)	112.3 (109.7 to 115.0)
Borg	12.0 (11.52 to 12.56)	12.4 (11.88 to 12.92)	12.2 (11.77 to 12.59)
1 year	*n* = 56	*n* = 58	
Heart rate	110.0 (106.2 to 113.7)	112.9 (109.2 to 116.6)	
Borg	12.3 (11.70 to 12.89)	11.9 (11.3 to 12.5)	

TABLE 131 *Shuttle walking test – heart rate at highest comparable level and perceived exertion; comparison of values between groups at each assessment excluding subjects known to be taking β-blockers*

	Leisure centre Mean (95% CI)	Walking Mean (95% CI)	Advice Mean (95% CI)
Completers			
10 weeks	*n* = 36	*n* = 41	*n* = 27
Heart rate	113.9 (110.5 to 117.2)	116.1 (113.1 to 119.2)	114.5 (110.2 to 118.7)
Borg	12.3 (11.66 to 12.94)	12.8 (12.22 to 13.39)	11.8 (11.02 to 12.65)
6 months	*n* = 50	*n* = 54	*n* = 85
Heart rate	113.6 (110.1 to 117.1)	113.3 (109.7 to 116.8)	113.9 (111.2 to 116.7)
Borg	11.9 (11.37 to 12.51)	12.5 (11.93 to 13.04)	12.1 (11.67 to 12.53)
1 year	*n* = 47	*n* = 50	
Heart rate	113.3 (109.3 to 117.3)	111.3 (111.3 to 119.0)	
Borg	12.3 (11.66 to 13.02)	12.0 (11.35 to 12.61)	
ITT			
10 weeks	*n* = 56	*n* = 66	*n* = 63
Heart rate	115.9 (113.7 to 118.0)	117.9 (116.0 to 119.8)	117.9 (115.9 to 120.0)
Borg	12.5 (12.12 to 12.94)	12.9 (12.54 to 13.27)	12.5 (12.12 to 12.89)
6 months	*n* = 111	*n* = 124	*n* = 123
Heart rate	115.6 (113.6 to 117.6)	116.5 (114.7 to 118.4)	116.1 (114.2 to 118.0)
Borg	12.1 (11.77 to 12.41)	12.6 (12.34 to 12.94)	12.3 (12.0 to 12.56)
1 year	*n* = 65	*n* = 71	
Heart rate	113.2 (110.1 to 116.3)	114.0 (110.8 to 117.2)	
Borg	12.3 (11.82 to 12.81)	12.0 (11.54 to 12.52)	

TABLE 132 *Baseline measurements of muscle function and flexibility*

	IKES (N) Mean (SEM) (*n*)	LEP (W) Mean (SEM) (*n*)	Power relative to body weight Mean (SEM) (*n*)	Shoulder abduction Mean (SEM) (*n*)
Leisure centre	252.7 (6.5) (274)	153.2 (4.4) (310)	1.8 (0.04) (310)	143.9 (0.9) (315)
Walking	263.6 (6.7) (265)	157.7 (4.3) (309)	1.9 (0.04) (309)	144.2 (0.9) (311)
Advice	263.8 (6.6) (267)	157.9 (4.7) (309)	1.9 (0.05) (309)	143.3 (0.9) (312)
Female	224.5 (3.6) (561)	121.7 (1.8) (624)	1.6 (0.02) (624)	143.5 (0.6) (631)
Male	341.2 (7.0) (245)	227.3 (4.8) (304)	2.5 (0.05) (304)	144.5 (0.9) (307)
Age (years)				
40–44	294.9 (13.9) (73)	186.0 (9.7) (79)	2.1 (0.09) (79)	143.9 (1.8) (80)
45–54	280.2 (6.1) (303)	169.5 (4.5) (331)	2.0 (0.04) (331)	145.8 (0.8) (336
55–64	253.4 (6.7) (270)	153.1 (4.2) (313)	1.9 (0.04) (313)	143.5 (1.0) (316)
65–74	216.7 (6.8) (160)	128.4 (4.7) (205)	1.3 (0.05) (205)	141.1 (1.0) (206)

TABLE 133 *Changes in muscle function and flexibility: completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure centre (*n* = 120)					
IKES (N) (*n* = 101)	252.3	267.0	14.7 (–1.01 to –28.35)	5.8%	*
LEP (W)	155.7	174.0	18.3 (10.78 to 25.89)	11.8%	**
LEP (W kg^{-1})	1.9	2.2	0.3 (0.16 to 0.34)	15.8%	**
Shoulder abduction	144.5	145.6	1.1 (–1.50 to 3.70)	0.8%	
Walking (*n* = 104)					
IKES (N) (*n* = 89)	269.1	274.3	5.3 (–9.41 to 19.94)	2.0%	
LEP (W)	160.1	169.6	9.5 (1.96 to 17.10)	5.9%	*
LEP (W kg^{-1})	1.9	2.1	0.1 (0.04 to 0.21)	5.3%	**
Shoulder abduction	141.1	145.1	4.0 (0.91 to 7.05)	2.8%	*
Advice (*n* = 91)					
IKES (N) (*n* = 69)	256.8	254.5	–2.30 (–18.36 to 13.76)	0.9%	
LEP (W)	149.4	157.4	8.1 (2.41 to 13.69)	5.4%	**
LEP (W kg^{-1})	1.9	2.0	0.1 (0.06 to 0.20)	5.3%	**
Shoulder abduction	145.5	144.8	–0.7 (–3.49 to 1.98)	–0.5%	
6 months					
Leisure centre (*n* = 192)					
IKES (N) (*n* = 159)	256.3	253.7	–2.6 (–15.39 to 10.17)	–1.0%	
LEP (W)	155.4	175.1	19.7 (14.21 to 25.20)	12.7%	**
LEP (W kg^{-1})	1.9	2.1	0.2 (0.18 to 0.31)	10.5%	**
Shoulder abduction	144.0	145.9	1.9 (–0.29 to 4.17)	1.3%	
Walking (*n* = 153)					
IKES (N) (*n* = 121)	252.1	248.3	–3.9 (–17.16 to 9.35)	–1.5%	
LEP (W)	156.7	164.4	7.7 (1.91 to 13.56)	4.9%	*
LEP (W kg^{-1})	2.0	2.1	0.1 (0.03 to 0.18)	5.0%	**
Shoulder abduction	143.2	144.3	1.1 (–1.74 to 4.04)	0.8%	
Advice (*n* = 217)					
IKES (N) (*n* = 174)	266.3	262.4	–3.9 (–15.85 to 8.08)	–1.5%	
LEP (W)	158.4	172.5	14.1 (–2.12 to 30.42)	9.0%	
LEP (W kg^{-1})	1.9	2.1	0.2 (0.02 to 0.43)	10.5%	**
Shoulder abduction	143.8	144.0	0.2 (–2.33 to 2.74)	0.1%	
1 year					
Leisure centre (*n* = 165)					
IKES (N) (*n* = 133)	255.4	254.8	–0.6 (–13.53 to 12.34)	–0.2%	
LEP (W)	157.3	178.7	21.4 (15.28 to 27.53)	13.6%	**
LEP (W kg^{-1})	1.9	2.2	0.3 (0.19 to 0.33)	15.8%	**
Shoulder abduction	144.1	143.8	–0.3 (–2.85 to 2.12)	–0.2%	
Walking (*n* = 147)					
IKES (N) (*n* = 113)	255.0	243.2	–11.8 (–28.60 to 4.98)	–4.6%	
LEP (W)	157.5	172.7	15.3 (8.69 to 21.86)	9.7%	**
LEP (W kg^{-1})	1.9	2.1	0.2 (0.13 to 0.29)	10.5%	**
Shoulder abduction	143.5	142.2	–1.3 (–4.51 to 1.98)	–0.9%	

** $p < 0.01$, * $p < 0.05$.

TABLE 134 *Muscle function and flexibility; comparison of values between groups at each assessment: completers*

	Leisure centre Mean (95% CI) (*n*)	**Walking Mean (95% CI) (*n*)**	**Advice Mean (95% CI) (*n*)**
10 weeks	*n* = 120	*n* = 104	*n* = 91
IKES (N)	279.9 (267.1 to 292.7) (101)	278.4 (264.0 to 292.8) (89)	259.9 (243.3 to 276.5) (69)
LEP (W)	177.6 (171.1 to 184.1)	169.0 (161.7 to 176.3)	165.1 (157.2 to 173.0)
LEP (W kg^{-1})	2.19 (2.11 to 2.26)	2.06 (1.97 to 2.15)	2.04 (1.94 to 2.13)
Shoulder abduction	145.5 (143.2 to 147.8)	146.6 (144.1 to 149.2)	144.0 (141.2 to 146.7)
6 months	*n* = 192	*n* = 153	*n* = 217
IKES (N)	263.1 (251.9 to 274.3) (159)	261.7 (247.5 to 275.8) (121)	269.5 (258.0 to 281.0) (174)
LEP (W)	181.2 (169.2 to 193.1)	169.0 (154.5 to 183.5)	172.0 (160.6 to 183.4)
LEP (W kg^{-1})	2.21 (2.05 to 2.38)	2.09 (1.89 to 2.29)	2.13 (1.97 to 2.29)
Shoulder abduction	146.2 (143.9 to 148.5)	145.3 (142.5 to 148.1)	143.4 (141.2 to 145.6)
1 year	*n* = 165	*n* = 147	
IKES (N)	263.3 (250.2 to 276.4) (133)	249.3 (233.8 to 264.8) (113)	
LEP (W)	184.4 (178.2 to 190.7)	177.1 (170.1 to 184.0)	
LEP (W kg^{-1})	2.23 (2.15 to 2.30)	2.17 (2.09 to 2.25)	
Shoulder abduction	143.9 (141.4 to 146.3)	142.5 (139.8 to 145.2)	

TABLE 135 *Changes in biochemical markers: completers*

	Baseline	Assessment point	Mean change (95% CI)	% Change	*p*
10 weeks					
Leisure					
Cholesterol (*n* = 92)	5.84	5.71	–0.13 (–0.25 to –0.01)	–2.2%	*
HDL (*n* = 91)	1.33	1.35	0.01 (–0.03 to 0.06)	0.1%	
Cholesterol/HDL (*n* = 91)	4.53	4.45	–0.08 (–0.24 to 0.07)	–1.8%	
LDL (*n* = 87)	3.59	3.44	–0.14 (–0.26 to –0.03)	–3.9%	*
Triglycerides (*n* = 93)	2.20	2.14	–0.05 (–0.26 to 0.16)	–2.3%	
Walking					
Cholesterol (*n* = 75)	5.90	5.74	–0.16 (–0.33 to 0.005)	–2.7%	^
HDL (*n* = 73)	1.42	1.40	–0.02 (–0.06 to 0.02)	–1.4%	
Cholesterol/HDL (*n* = 73)	4.41	4.33	–0.07 (–0.25 to 0.09)	–1.6%	
LDL (*n* = 72)	3.57	3.47	–0.09 (–0.24 to 0.06)	–2.5%	
Triglycerides (*n* = 75)	2.09	1.95	–0.14 (–0.36 to 0.07)	–6.7%	
Advice					
Cholesterol (*n* = 73)	5.72	5.57	–0.15 (–0.31 to 0.01)	–2.6%	
HDL (*n* = 73)	1.34	1.36	0.02 (–0.03 to 0.07)	1.5%	
Cholesterol/HDL (*n* = 73)	4.47	4.32	–0.15 (–0.31 to 0.01)	–3.4%	
LDL (*n* = 70)	3.50	3.32	–0.18 (–0.33 to –0.03)	–5.1%	*
Triglycerides (*n* = 73)	1.96	2.04	0.08 (–0.33 to 0.03)	4.1%	
6 months					
Leisure centre					
Cholesterol (*n* = 132)	5.82	5.70	–0.13 (–0.24 to 0.01)	–2.2%	*
HDL (*n* = 131)	1.33	1.34	0.01 (–0.03 to 0.05)	0.8%	
Cholesterol/HDL (*n* = 131)	4.56	4.42	–0.14 (–0.28 to 0.004)	–3.1%	^
LDL (*n* = 124)	3.63	3.48	–0.15 (–0.26 to –0.04)	–4.1%	*
Triglycerides (*n* = 133)	2.10	2.10	0.00 (–0.19 to 0.17)	0.0%	
Walking					
Cholesterol (*n* = 107)	5.91	5.53	–0.38 (–0.52 to 0.24)	–6.4%	**
HDL (*n* = 105)	1.45	1.45	0.00 (–0.05 to 0.05)	0.0%	
Cholesterol/HDL (*n* = 105)	4.36	4.07	–0.29 (–0.46 to 0.12)	–6.7%	**
LDL (*n* = 101)	3.57	3.30	–0.27 (–0.39 to –0.14)	–7.6%	**
Triglycerides (*n* = 107)	2.04	1.83	–0.21 (–0.43 to –0.01)	–10.3%	*
Advice					
Cholesterol (*n* = 168)	5.67	5.52	–0.15 (–0.25 to –0.06)	–2.6%	**
HDL (*n* = 168)	1.35	1.39	0.04 (–0.02 to –0.07)	0.0%	
Cholesterol/HDL (*n* = 167)	4.43	4.23	–0.21 (0.32 to 0.09)	–4.7%	**
LDL (*n* = 160)	3.50	3.34	–0.16 (–0.25 to –0.06)	–4.6%	**
Triglycerides (*n* = 168)	1.91	1.85	–0.06 (–0.19 to 0.07)	–3.1%	
1 year					
Leisure					
Cholesterol (*n* = 112)	5.88	5.43	–0.45 (–0.61 to –0.30)	–7.7%	**
HDL (*n* = 111)	1.34	1.37	0.02 (–0.02 to –0.06)	1.5%	*
Cholesterol/HDL (*n* = 111)	4.55	414	–0.41 (0.58 to 0.24)	–9.0%	**
LDL (*n* = 106)	3.65	3.23	–0.42 (–0.57 to –0.28)	–11.5%	**
Triglycerides (*n* = 112)	2.09	1.94	–0.05 (–0.34 to 0.04)	–2.4%	
Walking					
Cholesterol (*n* = 98)	5.98	5.59	–0.38 (–0.54 to –0.22)	–6.4%	**
HDL (*n* = 96)	1.45	1.39	–0.06 (–0.10 to –0.02)	–4.1%	**
Cholesterol/HDL (*n* = 96)	4.37	4.29	–0.09 (–0.25 to 0.07)	–2.1%	
LDL (*n* = 91)	3.59	3.35	–0.24 (–0.38 to 0.09)	–6.7%	**
Triglycerides (*n* = 98)	2.11	1.90	–0.21 (–0.42 to 0.00)	–10.0%	+

** $p < 0.01$, * $p < 0.05$, + $p = 0.052$, ^ $p = 0.057$.

TABLE 136 *Biochemical markers – comparison of values between groups at each assessment: completers*

	Leisure centre Mean (95% CI) (*n*)	Walking Mean (95% CI) (*n*)	Advice Mean (95% CI) (*n*)
Completers			
10 weeks			
Cholesterol	5.69 (5.57 to 5.82) (92)	5.68 (5.53 to 5.83) (75)	5.68 (5.53 to 5.83) (73)
HDL	1.37 (1.33 to 1.41) (91)	1.35 (1.30 to 1.40) (73)	1.38 (1.33 to 1.43) (73)
Cholesterol/HDL	4.40 (4.25 to 4.54) (91)	4.44 (4.27 to 4.62) (73)	4.36 (4.19 to 4.53) (73)
LDL	3.42 (3.30 to 3.54) (87)	3.46 (3.32 to 3.59) (72)	3.41 (3.27 to 3.55) (70)
Triglycerides	2.09 (1.91 to 2.27) (93)	1.98 (1.77 to 2.19) (75)	2.13 (1.92 to 2.34) (73)
6 months			
Cholesterol	5.68 (5.57 to 5.79) (132)	5.42 (5.29 to 5.55) (107)	5.56 (5.46 to 5.67) (168)
HDL	1.37 (1.33 to 1.41) (131)	1.37 (1.33 to 1.42) (105)	1.39 (1.35 to 1.42) (168)
Cholesterol/HDL	4.40 (4.27 to 4.53) (131)	4.18 (4.03 to 4.33) (105)	4.29 (4.18 to 4.41) (167)
LDL	3.46 (3.36 to 3.56) (124)	3.27 (3.15 to 3.40) (101)	3.38 (3.29 to 3.47) (160)
Triglycerides	2.06 (1.90 to 2.21) (133)	1.65 (1.66 to 2.03) (107)	1.93 (1.79 to 2.07) (168)
1 year			
Cholesterol	5.45 (5.31 to 5.59) (112)	5.53 (5.37 to 5.68) (98)	
HDL	1.40 (1.36 to 1.44) (111)	1.34 (1.30 to 1.39) (96)	
Cholesterol/HDL	4.11 (3.96 to 4.26) (111)	4.37 (4.20 to 4.53) (96)	
LDL	3.22 (3.09 to 3.34) (106)	3.34 (3.20 to 3.48) (91)	
Triglycerides	1.95 (1.79 to 2.12) (112)	1.94 (1.76 to 2.12) (98)	
ITT			
10 weeks			
Cholesterol	5.68 (5.60 to 5.77) (133)	5.69 (5.60 to 5.78) (131)	5.71 (5.60 to 5.78) (136)
HDL	1.35 (1.32 to 1.38) (131)	1.33 (1.30 to 1.36) (129)	1.35 (1.33 to 1.38) (135)
Cholesterol/HDL	4.48 (4.38 to 4.58) (131)	4.52 (4.41 to 4.62) (129)	4.46 (4.36 to 4.56) (135)
LDL	3.41 (3.34 to 3.49) (127)	3.45 (3.37 to 3.53) (126)	3.44 (3.36 to 3.52) (133)
Triglycerides	2.12 (2.00 to 2.24) (134)	2.05 (1.92 to 2.18) (131)	2.14 (2.01 to 2.26) (136)
6 months			
Cholesterol	5.65 (5.58 to 5.71) (262)	5.56 (5.50 to 5.63) (258)	5.60 (5.53 to 5.66) (272)
HDL	1.37 (1.35 to 1.40) (258)	1.37 (1.35 to 1.39) (256)	1.38 (1.36 to 1.40) (272)
Cholesterol/HDL	4.36 (4.28 to 4.43) (258)	4.31 (4.23 to 4.39) (256)	4.33 (4.25 to 4.40) (271)
LDL	3.40 (3.34 to 3.46) (251)	3.36 (3.30 to 3.42) (250)	3.37 (3.31 to 3.43) (264)
Triglycerides	2.04 (1.95 to 2.13) (263)	1.95 (1.85 to 2.04) (258)	2.00 (1.91 to 2.10) (272)
1 year			
Cholesterol	5.50 (5.39 to 5.62) (159)	5.49 (5.35 to 5.62) (132)	
HDL	1.38 (1.35 to 1.41) (158)	1.35 (1.31 to 1.38) (129)	
Cholesterol/HDL	4.24 (4.12 to 4.37) (158)	4.32 (4.18 to 4.47) (129)	
LDL	3.25 (3.15 to 3.36) (148)	3.32 (3.21 to 3.44) (125)	
Triglycerides	2.05 (1.91 to 2.18) (159)	1.93 (1.77 to 2.09) (132)	

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We look forward to hearing from you.

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