Randomised controlled trials of physical activity promotion in free living populations: a review

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Abstract

Objectives — To review evidence on the effectiveness of trials of physical activity promotion in healthy, free living adults. To identify the more effective intervention programmes.

Methods — Computerised databases and references were searched. Experts were contacted and asked for information about existing work.

Inclusion criteria — Randomised controlled trials of healthy, free living adult subjects, where exercise behaviour was the dependent variable were included.

Conclusions — Ten trials were identified. The small number of trials limits the strength of any conclusions and highlights the need for more research. No UK based studies were found. Previously sedentary adults can increase activity levels and sustain them. Promotion of these changes requires personal instruction, continued support, and exercise of moderate intensity which does not depend on attendance at a facility. The exercise should be easily included into an existing lifestyle and should be enjoyable. Walking is the exercise most likely to fulfil these criteria.

Methods

Searches were carried out using Medline, Excerpta Medica, SPORT (Data-Star), and Unicomp from 1966-93. Key words include "exercise", "community", "intervention", and "randomised controlled trial". Searches were also carried out on key authors identified from reviews. Only English language journals were searched. Two hundred and fifty abstracts were identified but only 18 described papers on randomised controlled trials. Additional searching was then carried out using the references from both existing reviews and the papers chosen from the abstracts. A further 37 papers were thus gathered. Each paper was read by two of us (MH and TA) and considered for inclusion.

The criteria for inclusion were as follows:

- A control group;
- Subjects were assigned to control or intervention by randomisation;
- Trials testing single factor interventions to increase activity;
- Interventions tested on apparently healthy, free living adults;
- Exercise behaviour was the dependent variable.

The quality of each paper was assessed using a three point scoring system. Each of three areas of potential bias in methodology were scored: (1) the quality of random allocation; (2) results analysed on intention to treat; (3) outcomes assessed without knowledge of assignment of subjects to groups by randomisation. Each of these areas then received a score of "0" or "1", allowing for a maximum quality score of 3 or a minimum of 0.
Results

Ten papers met the inclusion criteria and are listed in table 1. Only two of the papers were found from the computer searching. Nine trials were from the USA with one from Switzerland. None were from the UK. Most subjects were volunteers who responded to advertisements and were predominantly white, well educated, white collar workers. Overall, there was an even distribution between men and women with an age range of 24–72 years (mean age approximately 49 years).

INTERVENTIONS
A summary of the interventions is shown in table 1.

Length of intervention
Interventions ranged from one hour to two years and from a single educational session to regular contact with subjects.

Professional contact
In home based trials subjects usually received initial face to face instruction, which varied from simple exercise advice to the teaching of behavioural skills. Subjects attending facility based programmes and classes could have had more professional contact but no studies reported whether subjects did have such additional contact.

Subjects in home based interventions were usually telephoned after initial instruction. This was sometimes for support and problem solving counselling. In other cases, however, subjects were telephoned only if they did not return self monitoring forms. No details of these calls are provided and we do not know if they were perceived as supportive.

Behavioural techniques
Self monitoring and relapse prevention training have been developed by researchers in addictive behaviours for increasing adherence to behaviour change. The two techniques were frequently used to change exercise behaviour.

Exercise variables
Most programmes were home based, only four trials used a designated facility. Most of the trials involved jogging or walking, or sometimes the choice of either. Where these were not used, the activity was an exercise class or an unspecified aerobic exercise. Subjects were asked to exercise between three and five times per week. The intensity of the exercise was often unspecified. When specified it was "moderate" except for jogging which was more vigorous, at approximately 80% of maximum heart rate.
Table 2 Summary of results

<table>
<thead>
<tr>
<th>Study</th>
<th>Quality score (0-3)</th>
<th>No in study</th>
<th>Subjects</th>
<th>Post intervention follow up</th>
<th>Actual frequency intensity and duration of exercise intervention group</th>
<th>Main outcomes p&lt;0.05</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>50</td>
<td>Wives of graduate students</td>
<td>Nil</td>
<td>Mean frequency = 1-7/wk.</td>
<td>Subjects in relapse balance sheet group attended approximately twice as frequently as the relapse balance sheet and control group. Where duration of prescribed exercise was specified it ranged between 15 and 75 minutes.</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>124</td>
<td>Male firefighters aged 24-56 y</td>
<td>36 mth</td>
<td>Not stated.</td>
<td>No significant difference between groups at 2 mth follow up.</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>58</td>
<td>18-20 y old, previously sedentary, female psychology students</td>
<td>2 mth</td>
<td>Mean frequency JAR and G = 2-4/wk; GR = 1-4/wk.</td>
<td>83% of jogging alone + relapse subjects still exercising at follow up compared with 36% of control subjects. No significant difference between groups on post study fitness levels.</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>315</td>
<td>Males aged 53-72 y with one or no risk factors for CHD</td>
<td>12 y</td>
<td>Mean hours jogging/wk at year 13 = 0-3 h.</td>
<td>No difference between exercise and control conditions at follow up on jogging hours per week. Self reported walking level significantly higher at year 1 &amp; 2 compared with controls.</td>
</tr>
<tr>
<td>5</td>
<td>2</td>
<td>229</td>
<td>Post menopausal women aged 50-65 y</td>
<td>Annually</td>
<td>Mean miles walking/wk = 8-4.</td>
<td>Adoption arm = subjects receiving telephone support showed significant increase in VO2max. Maintenance arm = daily self monitoring resulted in greater exercise frequency than weekly self monitoring.</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>103</td>
<td>52 male and 51 female, middle aged subjects</td>
<td>Nil</td>
<td>Adoption arm = mean of 2-9 sessions/wk for 37 min.</td>
<td>Increase in VO2max in all three conditions. Behavioural interventions increased frequency of exercise compared to controls.</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>77</td>
<td>28 men (mean age 40) and 49 women (mean age 36)</td>
<td>Nil</td>
<td>Self monitoring group = mean of 2-5/wk for 26 mins.</td>
<td>Increase in VO2max in all exercise groups. Higher adherence in both home based conditions. No changes in other CHD risk factors.</td>
</tr>
<tr>
<td>8</td>
<td>2</td>
<td>357</td>
<td>Predominantly white and well educated 160 women and 197 men aged 50-65 y</td>
<td>On-going</td>
<td>Mean frequency = HIG = 1-2/wk</td>
<td>Only changes in vigour on psychometric test significantly correlated with 8 mth activity levels. No significant differences in lipids, blood pressure, body composition or endurance capacity.</td>
</tr>
<tr>
<td>9</td>
<td>1</td>
<td>2</td>
<td>Middle or upper class, middle aged, apparently healthy, male bank workers</td>
<td>4 mth</td>
<td>HIH = 2/wk</td>
<td>No significant difference in attendance at 18 wk or 2 mth follow up.</td>
</tr>
<tr>
<td>10</td>
<td>1</td>
<td>120</td>
<td>Previously sedentary, female university employees with a mean age of 35 y and mean body mass index of 25</td>
<td>2 mth</td>
<td>Mean of 12-9 km/wk.</td>
<td>Percentage of classes attended during the 18 wk RP = 51%, R = 49%.</td>
</tr>
</tbody>
</table>

Subjects in relapse balance sheet group attended approximately twice as frequently as the relapse balance sheet and control group. Where duration of prescribed exercise was specified it ranged between 15 and 75 minutes. Sustained improvement The development of coronary heart disease is a long process and evidence suggests that the health benefits of exercise cannot be saved up, so people must continue to exercise if they are to maintain their protection from coronary heart disease. Therefore, in this review more attention is paid to those trials with longer follow up periods. ASSESSING OUTCOMES Few studies included follow up of the subjects after the intervention. Of those which did, the average period was eight months with the exception of one trial which had a follow up period of 12 years. Definitions of good adherence ranged from exercising twice a week for 15 minutes to 7 miles of walking per week, or 100% of the prescribed sessions. Two trials measured VO2max (the highest oxygen uptake attained during exercise involving large muscle groups).^14^ OUTCOMES Table 2 shows the main outcomes. Professional contact Study 6 in table 1 varied the frequency of telephone contact and observed that subjects who received most contact exercised more frequently, for slightly longer, and achieved greater values than subjects receiving less contact and controls. In a later trial,^11^ the same team telephoned subjects performing home based exercise regularly, and compared adherence with that of subjects attending a facility based programme. After one year 79% and 75% of subjects in two home based groups were achieving over three quarters of prescribed exercise, compared to 53% of subjects randomised to a facility. Study 5 in table 1, a trial of post menopausal women walking, in which professional contact was a major component, achieved high adherence at two years. Sixty one per cent of women in the intervention group were exercising at the level prescribed and four fifths were achieving 70% of the prescribed level, an increase in self reported walking over baseline of 79% compared with 16% in the control group. Self monitoring In trial 10 (table 1) subjects were randomly assigned to three groups, one of which was taught self monitoring techniques. There was a low adherence rate at six months and the authors concluded that "self monitoring did not produce a further increase in compliance". However, 55% of the self monitoring subjects did not complete their records. Those who did, achieved an adherence rate of 56% – nearly double that of the other treatment group. It is impossible to know whether subjects were reluctant to complete the record or were not undertaking the exercise. Trial 6, took subjects...
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from an earlier trial and randomised them to two ‘maintenance’ groups with different frequency of self monitoring. During the next six months, subjects completing daily self monitoring forms performed 35% more exercise sessions that subjects completing weekly forms.

**Relapse prevention**

Relapse prevention training was used in several trials but not described in detail. In trial 3, a trial of jogging alone or in a group and of jogging with and without relapse prevention training, 83% of subjects with relapse prevention in the two jogging alone arms were still exercising at three months compared with 36% of those without this training. In the two group jogging arms, however, there was no significant difference in the group with relapse prevention training, with 39% of subjects exercising in both groups.

Relapse prevention was compared with reinforcement strategies in trial 10, a study of women attending 18 weekly exercise classes. Subjects in the relapse prevention group received 18 weekly sessions on relapse prevention, including a planned 10 day break from exercise at nine weeks to demonstrate the possibility of lapsing and restarting exercise. Subjects in the reinforcement group received T-shirts and other rewards for attendance, while controls subjects simply attended the exercise class. Attendance was not significantly higher in either intervention group compared with controls with the attrition rate (attendance at least two thirds of exercise sessions) for all groups averaging 72% at 18 weeks.

**Location of exercise**

Trial 8 compared facility and home based programmes of different exercise intensities. The home based groups completed significantly more exercise sessions than the facility based group.

**Exercise frequency**

At the end of the trials those subjects still exercising were usually exercising around twice per week. One trial found that subjects prescribed three exercise sessions per week achieved higher adherence rates than those prescribed five at two year follow up.

**Exercise intensity**

Few details of exercise intensity at follow up were reported. When they were, subjects exercised within the prescribed range (measured using telemetry heart rate monitors). Trial 8, a study with both high and low intensity groups, found that the high intensity group preferred to train at the bottom of their target heart range while the low intensity group preferred to exercise at the top of their range. Thus, both groups moved towards moderate intensity exercise.

**VO**, in trial 6, subjects increased their VO values by 7% to 8%. In trial 8, subjects in all three intervention arms who performed greater than 75% of prescribed exercise sessions improved their VO. In the two high intensity arms subjects improved by 7% and 9% respectively while in the low intensity arm they improved by 5%. These physiologically significant changes were achieved by easily performed moderate intensity exercise.

**Discussion**

The wide variation in methodology and definitions of adherence in these few trials, make a formal meta-analysis unhelpful. The important public health question is whether attempts to modify exercise behaviour result in health gain in sufficient numbers of people to make these cost effective, and this review suggests that it is possible to increase the exercise levels of sedentary subjects. Trials that showed sustained high levels of participation (studies 5, 6 and 8) shared a number of common features. These are:

- Home based programmes;
- Unsupervised, informal exercise;
- Frequent professional contact;
- Walking as the promoted exercise;
- Moderate intensity exercise.

Home based interventions were more successful than facility based programmes. One study (number 7) compared facility and home based exercise; the home based groups achieved significantly more exercise sessions. Another home based study (number 6) showed a positive relationship between the convenience of exercise and its adoption and maintenance, and this may explain why home based exercise seems preferable.

Subjects who exercised alone completed more exercise sessions than those who exercised in groups. In a short jogging trial (number 3 table 1), subjects assigned to jogging alone with relapse prevention training performed over double the exercise of subjects who exercised as a group and were taught cohesiveness skills. The inconvenience of meeting at a specific time and place may reduce adherence to group based programmes.

High participation (studies 5, 6, 8) was also associated with frequent professional contact. Contact was usually made by telephone or occasionally by home visits. The amount of contact was not great. In one trial (number 6) subjects received less than 60 minutes of total telephone contact over 6 months. In another study (number 8) the authors reported an average of 15 telephone contacts of approximately three minutes over one year. The two home based arms which received telephone support performed significantly more exercise than the group based arm which did not.

The interaction between professional and client may be of greater importance than any behavioural technique. Addictive behaviour re-
searchers have found that the way in which a therapist interacts with a client is a better predictor of treatment outcome than either the client characteristics or the therapist’s theoretical orientation.16 A review of therapist effectiveness with substance use disorders concluded that good interpersonal skills of the therapists was associated with high effectiveness.17

Three successful trials used walking, which is already a popular form of exercise3,18 and does not require special equipment, a formal facility, or fellow participants. The promotion of exercise which is popular and can be incorporated into existing lifestyles may be more successful. Walking is normally a moderate intensity activity, and moderate intensity is associated with higher participation. Even subjects randomised to high and low intensity exercise may prefer moderate intensity. In one trial, subjects assigned to high intensity exercise, exercised at a mean rate of perceived exertion (RPE – a validated, subjective rating of exercise intensity) of 13,18 whereas those assigned to low intensity exercised at a mean RPE of 11.7 (study 8), both moderate intensity levels.

A lesser frequency of prescribed exercise was associated with better maintenance. In study 3, subjects were prescribed four sessions per week but at one year subjects were averaging just over two sessions per week.7 In another trial, study 8, subjects were assigned to either five, 30 minute or three, 40 minute sessions per week. The proportion achieving over 75% of prescribed sessions did not differ at one year, but at two years the three sessions per week subjects maintained a higher percentage.15

These trials indicate that it is possible to increase physical activity levels in free living individuals, but that improvements in physical fitness (measured as VO_{2\text{max}}) are smaller than those found in laboratory studies.

The subjects in nine studies were volunteers who were considering increasing, or had decided to increase, their physical activity. In the one study that recruited by random digit dialling, 20,418 numbers were dialled of which only 9% yielded subjects for randomisation, mainly due to the exclusion criteria. Of those eligible, only 27% were randomised, suggesting considerable self selection.19 While some studies have been successful they tell us nothing about promoting physical activity in people who would not have accepted an offer of participation in an exercise programme.

The four trials which continued for at least 6 months (4, 5, 6, 8) provide the basis for most of our conclusions. Subjects were all over 47 years of age, well educated, and white. Whether these results can be generalised to other populations, including those in the UK, is not known.

Some of the 55 studies identified initially but not included because of methodological problems, involved techniques which might prove useful and should be evaluated. These included concepts of self efficacy, barriers to change, support and reinforcement,20 as well as a person’s “stage of change” with regard to physical activity.21,22 A further important question is whether subjects prescribed exercise as a treatment for a diagnosed condition are more likely to maintain it. That is, how important is the presence of ill health to compliance with prescribed exercise.

**FUTURE RESEARCH**

Further experimental research is urgently needed, particularly in three areas:

- Groups other than middle aged, middle class white people, looking at those at highest risk from coronary disease who might have the greatest capacity to gain from increased activity, particularly the elderly.
- Exploring the factors that might affect both initial uptake of the activity and subsequent adherence to a new activity level in subjects resident in the UK.
- Exercise prescription to treat specific conditions.

**Conclusion**

It is possible to increase activity and maintain the increase at sufficient frequency and intensity for long term health gain. This is best achieved when exercise is home based, of moderate intensity, can be performed alone or with others, is enjoyable, convenient, and can be completed in three sessions per week. Walking will satisfy all of these criteria. Self-monitoring and relapse prevention training may improve early adherence, and continuing support and reinforcement may improve long term adherence. An initial brief instructional session followed by short but frequent telephone support may be most effective. These interventions are low cost and easy to administer compared with facility based group exercise interventions where the barriers and costs associated with attendance may lead to high drop out rates.

These findings do not support the increasingly popular prescription for exercise schemes. A high proportion of these schemes involve general practitioners referring their patients to a leisure centre or similar facility, but we have found no evidence to support the efficacy of facility based interventions. These interventions are unlikely to be the most effective way of increasing population activity levels. Less than 1% of a practice list are referred into such schemes.23 Although they attract publicity, organisations would be wise not to rush into prescription for exercise schemes until evidence is available to support their efficacy.

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4 Hoyt MF, Janis JL. Increasing adherence to a stressful
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