

Cost effectiveness of a community based exercise programme in over 65 year olds: cluster randomised trial

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Objective: To assess the cost effectiveness of a community based exercise programme as a population wide public health intervention for older adults.

Design: Pragmatic, cluster randomised community intervention trial.

Setting: 12 general practices in Sheffield; four randomly selected as intervention populations, and eight as control populations.

Participants: All those aged 65 and over in the least active four fifths of the population responding to a baseline survey. There were 2283 eligible participants from intervention practices and 4137 from control practices.

Intervention: Eligible subjects were invited to free locally held exercise classes, made available for two years.

Main outcome measures: All cause and exercise related cause specific mortality and hospital service use at two years, and health status assessed at baseline, one, and two years using the SF-36. A cost utility analysis was also undertaken.

Results: Twenty six per cent of the eligible intervention practice population attended one or more exercise sessions. There were no significant differences in mortality rates, survival times, or admissions. After adjusting for baseline characteristics, patients in intervention practices had a lower decline in health status, although this reached significance only for the energy dimension and two composite scores ($p < 0.05$). The incremental average QALY gain of 0.011 per person in the intervention population resulted in an incremental cost per QALY ratio of €17 174 (95% CI = €8300 to €87 120).

Conclusions: Despite a low level of adherence to the exercise programme, there were significant gains in health related quality of life. The programme was more cost effective than many existing medical interventions, and would be practical for primary care commissioning agencies to implement.

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Those with active lifestyles enjoy better physical and mental health than sedentary people.^{1,2} Observational studies have shown that exercise is associated with lower all cause mortality³ and a reduced risk of coronary heart disease,^{3,4} stroke,^{5,6} and hip fracture,^{7,8} and may prevent type II diabetes and mild to moderate depression.⁹ There are many claims, and some evidence, that several other conditions may be prevented or improved by exercise. While this epidemiological evidence is considerable, there is only limited experimental evidence on the cost effectiveness of exercise interventions to promote health or prevent injury or disease.^{10,11}

As most of the diseases associated with sedentary lifestyles are also associated with increasing age, it is in older adults that the greatest benefits of exercise might be expected. One review of the evidence for benefit in adults aged 65 and over concluded that exercise would improve cardiovascular status, functional ability and mental functioning, and reduce fracture risk.¹² It also noted the virtual absence of reports of serious cardiovascular or musculoskeletal complications in older adults in any published trials. However, in practice we do not know how great the benefits might be or the costs of achieving them. Nor is it clear whether or not worthwhile public health benefits can be achieved for a population, as compared with benefits simply for few people at high risk.

We therefore undertook a pragmatic trial of an exercise programme that offered free supervised exercise sessions to all people over 65 in a defined population, who were not already in the most active quintile. The aim was to assess, in a similar way to other public health interventions, the cost effectiveness of a community based exercise programme for older adults from a health service perspective.

METHODS

Recruitment

Twelve general practices in Sheffield were recruited to the study. Practices were selected at random from those practices with two to five partners that were not already running an exercise programme, exercise prescription scheme, or related activity. Of 13 practices approached, 12 agreed to participate. Four practices were selected, using a computer random number programme, to act as intervention practices, with the remaining eight acting as controls.

All people aged 65 or over on both intervention and control practice lists were sent a baseline postal questionnaire to determine their general health status (using the SF-36) and current levels of habitual physical activity (using the physical activity questionnaire (PAQ) for the elderly).¹³ Those with a physical activity score in the top 20% were excluded, as we assumed that they had little to gain from additional exercise. General practitioners were given an opportunity to exclude from the study any patient they felt was unsuitable for exercise.

A letter was sent from the research team to those meeting the inclusion criteria, inviting respondents to indicate an interest in attending local exercise sessions twice weekly. Once a timetable was arranged in each area a second letter was sent to respondents inviting them to the first session.

The intervention

The intervention was defined pragmatically, as an invitation to attend locally organised, free, twice weekly exercise classes

Abbreviations: QALY, quality adjusted life year; PAQ, physical activity questionnaire

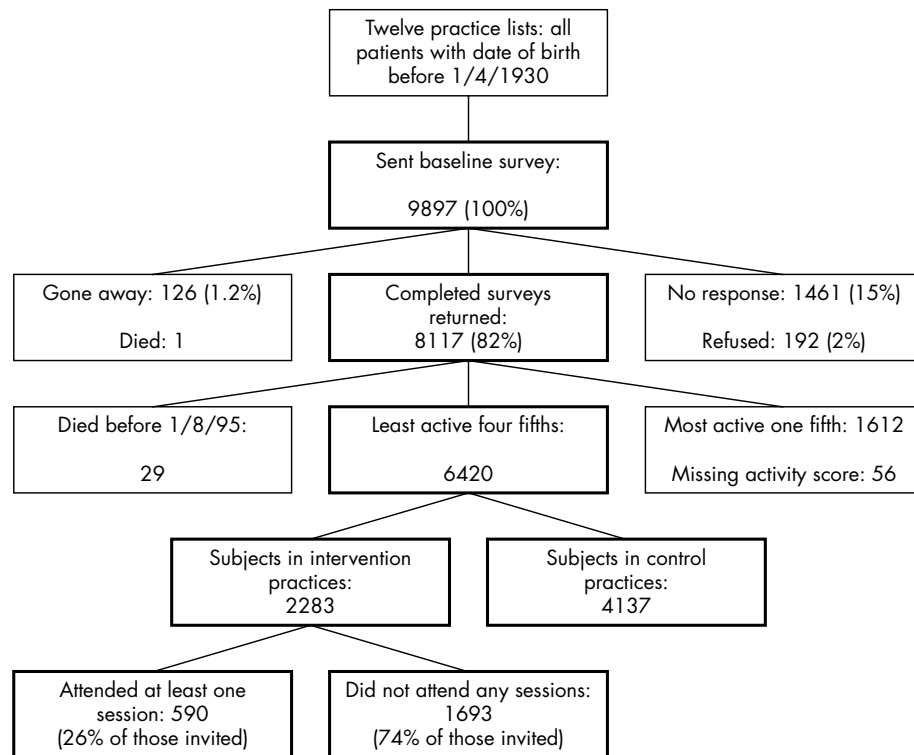


Figure 1 Study subjects.

provided for up to two years. Classes included activities aimed at improving joint mobility, muscle strength and endurance, flexibility, balance and coordination, and cardio-respiratory fitness. Strength training was carried out using resistance bands, with the number of repetitions increasing according to individual progress. These activities were led by a qualified exercise leader and typically performed to music.

Each session had a slow warm up with gentle stretch and mobility exercises to minimise the risk of injury, a more vigorous middle section focused on aerobic endurance and strength conditioning, and a cool down section at the end. Time for meeting and talking with friends was incorporated into the timetable. Most classes lasted for 75 minutes, of which 45 minutes was physical activity. A range of other activities (such as bowling, swimming, country walking, and

tea dances) were also organised to try to appeal to a broad range of people of varying interests and abilities.

Most classes were held in church halls, community centres, and less frequently in residential homes, and all attendances at the classes were recorded. The programme was designed without reference to any explicit behavioural model or theory, and there was no attempt to assess individual psychological state in any way. It was intended as a pragmatic intervention that could easily be organised for a large population by a public health agency.

Outcomes

The main outcomes were all cause and cause specific mortality (from coronary heart disease, stroke, hip fracture, diabetes, or mental disorder), hospital admission, and change

Table 1 Characteristics of study practices and participants

	Study practices				Study participants				
	Number of GPs*	Total list size	Townsend deprivation score	Survey response rate (%)	Subjects in study	Mean age	Female (%)	Physical activity score at baseline	Living alone (%)
Intervention practices									
A	2.75	6385	0.78	82.7	609	74.3	65.0	2.9	37.1
B	5	8016	0.40	75.2	525	76.4	69.1	3.0	41.3
C	3	6252	0.82	80.1	622	75.7	65.3	3.1	37.9
D	2.5	5690	1.64	74.8	527	75.8	68.3	3.9	43.1
Control practices									
E	3	5385	-0.05	87.3	810	74.8	66.2	3.6	40.5
F	2	4846	0.49	81.7	611	76.1	61.5	2.9	46.2
G	2.5	3125	0.85	81.6	339	75.6	68.1	2.2	46.3
H	4.5	8943	-2.18	90.3	473	75.9	27.5	5.1	30.4
I	4	8212	-1.54	80.6	462	75.5	62.6	2.2	44.2
J	2	4862	-1.11	87.1	562	75.9	64.2	3.6	40.0
K	3	5442	1.44	82.6	605	74.1	64.5	2.4	40.3
L	2	1969	0.48	79.5	275	76.4	63.3	2.8	42.5
All practices				82.0	6420	75.4	62.5	3.2	40.6

*Whole time equivalent general practitioners.

Table 2 Mortality and morbidity outcomes in intervention and control participants

Outcome	Participants in control practices (n = 4137)		Participants in intervention practices (n = 2283)		p Value†
	number	%	number	%	
Deaths					
All cause two years	505	12.2	283	12.4	0.91
All cause three years	638	15.4	352	15.4	0.91
Specific causes two years*	222	5.4	108	4.7	0.25
Specific causes three years*	284	6.9	136	6.0	0.13
Admissions					
All cause two years	1473	35.6	853	37.4	0.13
Specific causes two years*	391	9.5	219	9.6	0.78
Death or admission					
All cause two years	1613	39.0	941	41.2	0.09
Specific causes two years*	523	12.6	280	12.3	0.71

*"Exercise related" causes of death were coronary heart disease, stroke, hip fracture, type II diabetes, and mental disorder. †p value from multilevel model (see methods).

in health status. Deaths were identified by querying the study practices, local health authority records, and National Health Service Central Register. Hospital admissions were identified through the local health authority database, and using this we also recorded the use of outpatient and accident and emergency services during the two years before and after the intervention began. Health related quality of life was measured using the SF-36, by postal survey at baseline, and one and two years after the intervention began. We also used this survey to ask about use of GP services.

Economic analysis

The analysis was undertaken from a health service perspective and designed to enable a cost utility analysis to be performed if the intervention proved to be both more costly and more beneficial. Results were expressed as an incremental cost per quality adjusted life year (QALY), which can be compared with other interventions purchased by health services. The problems and limitations of this approach are well known,¹⁴ but it provides some guidance to policymakers on the cost effectiveness of offering exercise to older people compared with other possible uses of these resources.

The costs of running an exercise programme include recruitment, administration, hire of halls, payments to the exercise leaders, and refreshments. Despite being a highly pragmatic trial, there were some features of the programme that were specific to the research study and it was necessary to adjust for these to allow the costs to be generalisable to

healthcare providers. For example, the input of the administrators was adjusted to allow for the proportion of their time spent on data collection rather than the exercise programme. Resources used in the exercise programme were based on actual prices paid. All costs have been inflated to 2003/04 price levels using the Hospital and Community Health Services pay and price index and gross domestic product deflator.

SF-36 data have been converted into health state utility values using a recently estimated preference based algorithm.^{15, 16} The area under the curve between assessments was used to provide an overall estimate of the QALY difference between the intervention and control arm after adjusting for significant baseline variables.¹⁷

Because cost and benefit data have been collected only for two years, the ongoing costs and health benefits have not been discounted, although the start up costs of the exercise programme have been annuitised over a five year period. The ratio of the differences in cost and QALY between the intervention and control arms has been estimated at the individual level after adjustment, with 95% confidence intervals estimated by bootstrapping. The sensitivity of the results to possible uncertainties in key parameters has been explored.

Sample size

The sample size was calculated with respect to the incidence of exercise related cause specific death or admission. The expected two year incidence of these conditions in the population aged over 65 eligible to be offered exercise was 14%. To have an 80% chance of detecting as significant (at $p < 0.05$) the fact that the risk of admission or death from these causes in those offered exercise is reduced to 11%, about 1400 people in the intervention group and 2800 in the non-intervention (control) group would need to be randomised.¹⁸ These sample sizes give over 90% power to detect a change of five points or more in the quantitative SF-36 scores. The implications of cluster randomisation for the power of the study are discussed below.

The trial was designed with twice as many controls as intervention subjects because the relative costs of including controls were very small. To achieve the sample sizes we recruited and randomised four intervention practices and eight control practices.

Analysis

In line with the policy related and pragmatic design of the study, the primary analyses were carried out for the whole study population whether or not they took up exercise, and compared estimates of outcome between the four

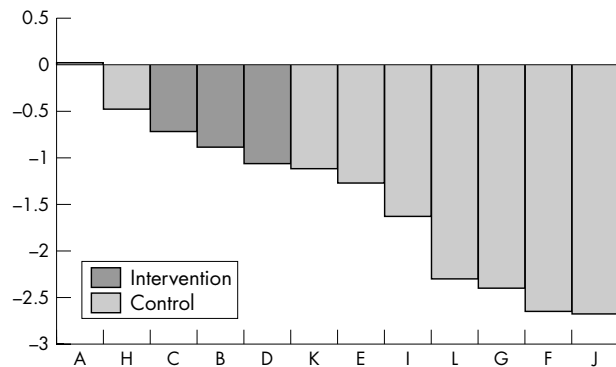


Figure 2 Adjusted* mean change in the preference based single health index ($\times 100$) by practice. *Adjusted for age, baseline physical activity score, sex, smoking, whether living alone, type of accommodation, and hospital admissions in the previous two years. Fixed effects randomisation test: $p = 0.07$. Random effects MLM: $t_{10} = 2.2$ $p = 0.05$.

Table 3 Differences in mean health dimension scores between intervention and control participants

SF-36 dimension	Crude difference	Adjusted difference*	95% CI*	p Value*	Estimated effect in ever exercisers
Physical functioning	0.57	1.01	-0.98 to 3.0	0.36	3.9
Social functioning	1.60	1.73	-0.23 to 3.69	0.10	6.7
Physical role	4.04	3.52	-0.62 to 7.66	0.10	13.5
Emotional role	2.13	1.57	-3.24 to 6.39	0.55	6.0
Mental health	0.93	0.98	-0.76 to 2.72	0.29	3.8
Energy	2.01	2.12	0.47 to 3.77	0.01	8.2
Pain	0.50	0.38	-1.81 to 2.57	0.80	1.5
General health perception	1.45	1.67	-0.00 to 3.34	0.06	6.4
Extended physical functioning	0.37	0.91	-1.02 to 2.83	0.41	3.5
Composite indices					
Mental health	2.62	2.65	-0.13 to 5.42	0.06	10.2
Physical health	2.93	2.95	0.17 to 5.74	0.04	11.3
Single index	0.01	0.01	0.001 to 0.02	0.03	4.08

*From multilevel model (see methods).

intervention practices and eight control practices—that is, at the cluster level.

The nested or clustered structure of the data was formally taken into account using random effects multilevel models, fitted using Stata and adjusted for person level covariates. The covariates used in the model were age and baseline physical activity score (as continuous), sex, smoking, whether living alone, type of accommodation, and hospital admissions in the two years before the intervention period (as categorical). No practice level covariates were used. The models were used to test for differences between the intervention and control practice populations in the proportions who had died by two years and three years, the proportion admitted to hospital within two years and the proportion who had either died or been admitted within two years. Each of these analyses was carried out both for all cause end points and for exercise related (cause specific) end points, as described above.

The possibility of differences in the timing of deaths and any differences in sample characteristics was taken into account using a Cox regression model for time until death and adjusting for the covariates given above. The adjusted practice effects (the Cox regression coefficients) were tested to see whether mortality hazard rates differed between intervention and control practices using a simple Mann-Whitney rank test.

The SF-36 results were analysed using the eight dimensions, our additional “extended physical function” dimension aimed at older people¹⁹ and three composites: the physical

component score, the mental component score, and a preference based single index of health.^{15 16} The area under the “curve” described by the scores at baseline, one year and two years, net of the baseline score, was used as the measure of change. Comparisons between intervention and control practices, adjusted for the covariates given above, were made using random effects multilevel models as described.

RESULTS

Response

Table 1 shows the characteristics of the 12 practices recruited into the study, and their patients. After two reminders, the overall response rate to the first recruitment survey was 82%. After excluding the most active one fifth, 6420 people formed the total study population (fig 1). No person was excluded from the study by their GP.

During the two year intervention period 2040 sessions of exercise were provided, resulting in a total of 27 800 person sessions of exercise. In all, 26% (590 of 2283) of the eligible study population attended one or more sessions. Attendance was more likely among women than men (29% v 20%, p<0.001), younger than older (29% among those aged under 75 v 23% among those 75 and older, p = 0.001), and most active than least active people (37% among those with PAQ score 5 or more v 23% among those with PAQ score below 5, p<0.001). Of those ever participating in the programme, 50% attended at least 28 sessions and 30% attended at least 60 sessions during the intervention period.

Table 4 Costs of the two year trial exercise programme*

Resource	Resources used	Valuation†	Central cost estimate (€)
Recruitment	Initial survey of activity (n = 3520) with two reminders and a second survey with an invitation and leaflet (n = 2283)	Commercial quotation	10725
Facilitators	4×0.5 wte university technicians grade D	€22969 pro rata plus ongoing costs	113928
Coordinator	0.3 wte RII for 6 months	€43898 pro rata plus ongoing costs	8165
Ongoing	0.2 RII per year		21773
Accommodation	Office space for three work stations	Standard rental	19637
Hire of halls	Hire of halls for 2040 sessions	Mean of €16.0 per session across 13 venues	32645
Exercise leaders	1337 sessions (excluding sessions undertaken by facilitators)	€31.24 per session	41769
Travel	Average 3.5 miles per session	€0.54 per mile (actual paid)	3824
Refreshments	Tea, coffee and biscuits per session	€8.03 per session	14566
Total cost of two year programme			267033

*2003/04 prices.

Of the 6420 people replying to the baseline survey, 39% had missing health status outcome data, due mainly to not responding to either or both the follow up surveys. There was slightly more missing data in the intervention group (41.8%) than the control group (37.5%), which was inversely related to baseline health status.

Mortality

After two years, 788 of the 6 420 subjects had died (12.3%). The proportion was similar in each cohort: 12.4% (283 of 2283) of the intervention cohort and 12.2% (505 of 4137) of the control cohort. After three years 990 people had died (15.4%), and again this proportion was the same in each cohort (table 2). For exercise related conditions there was a suggestion of lower mortality in the exercise arm at both two and three years but this did not reach statistical significance. The individual survival times until death from any of the selected exercise specific conditions were examined using Cox regression models as described, and showed no significant differences between trial arms ($p = 0.50$).

Use of health services

At two year follow up there was no evidence that fewer people were admitted from any cause or from the exercise related causes in the intervention populations compared with the control populations (table 2). Indeed, slightly more of the intervention population were admitted (37.4%) than of the control population (35.6%). There was no evidence of any difference in the use of other health services.

Death or admission

For all causes there was little evidence of any difference between the intervention group and the control group in the proportions who died or were admitted to hospital in the two years from the start of the exercise classes (table 2) and, for the primary outcome looking at numbers who were admitted or died from the selected exercise specific causes, the rates were similar: 12.3% in the intervention group and 12.6% in controls.

Health related quality of life

After adjusting for baseline characteristics, patients in intervention practices were estimated to have had less decline in health status than controls in every SF-36 dimension, although this reached conventional levels of significance only for the energy dimension (table 3). The composite scores also showed less decline in health status over the two year period in intervention than control populations, which was sig-

nificant for the physical component score and the preference based single index (fig 2).

Assuming an additive effect, the effect of exercise on those who actually attended the exercise programme can be estimated as the difference in effect between the intervention and control practice populations divided by the proportion who ever attended (0.26).²⁰ Using this method table 3 also shows that the estimated average effect, in those who actually attended sessions, for both mental and physical health and some individual dimensions, exceeded the levels regarded by the SF-36 developers as indicating a clinically worthwhile gain in health related quality of life.²¹

Economic evaluation

The annual cost of the exercise programme was estimated to be €128 302. This yields a mean cost per session of €125.78 and a cost per attendee per session of €9.06, assuming activity levels equal to those found in the trial (table 4). As we found no evidence of any difference in the use of hospital services between trial arms, these services have not been costed.

The main uncertainties concern the costs of the administrators and coordinator, the fees paid to exercise leaders, and the number of participants per exercise session. Administration and coordination may have been better resourced in terms of person hours than would be the case in a routine service, but a practice based programme may have used the more expensive resource of a practice nurse. The sensitivity analysis explored the consequences of halving the time and employing practice nurses rather than technicians. The session fee of exercise leaders was varied at plus or minus €4.46. Finally, the number of attendees was varied between 8 and 20 per session.

QALY benefits could be estimated only for the 3149 people who completed the SF-36 at all three assessments (2097 control and 1052 intervention persons), so we examined three different approaches to calculating cost per QALY:

- the total cost of the programme divided by the QALY gain for survey completers only (that is, $n = 1052$);
- the cost for survey completers only divided by their QALY gain ($n = 1052$);
- the total cost divided by the QALY gain assuming all the participants in the intervention arm experience the average gain (that is, $n = 2283$).

We took the second assumption as the central estimate. Combining this with the central cost estimate yields a mean cost per QALY of €17 172 (95% CI = €8300 to €87 115). Changing these assumptions resulted in the cost effectiveness of the exercise programme varying between €4739 and €32 533 per QALY, depending on the cost estimate and extrapolation assumptions.

Policy implications

The programme we have evaluated would be a practical, affordable, and probably popular investment for local healthcare commissioners, producing modest health gain at a reasonable cost. The economic evaluation provides support for the contention that exercise is a "best buy" in public health terms, and the programme we have described is an example of how the "exercise services" envisaged by the UK's National Service Framework for Older People might be developed.

Key points

- Many epidemiological studies have shown an association between physical activity and increased health and longevity.
- There is also some experimental evidence that exercise may improve health and prevent injury, but little economic evidence available on the costs and health benefits of exercise programmes.
- This study shows that a large scale, community based programme of exercise classes for older adults can be effective in producing improvements in physical and mental health at reasonable cost.
- Such a programme would be a practical, affordable, and popular investment for local healthcare commissioners.

DISCUSSION

The programme we provided and evaluated generated both worthwhile changes in health related quality of life for the substantial number of regularly active participants, constantly remarked upon and appreciated by the participants themselves, as well as an affordable average health gain at the population level. A community based intervention of this sort is practical, affordable, and enjoyable for participants and, our evidence suggests, may be justifiable in terms of health gain.

Despite the absence of evidence for some of the expected gains in mortality and potential savings from reductions in use of health services, the central cost per QALY estimate of €17 172 compares favourably with other healthcare interventions.²² The uncertainty in this result depends less on the specific assumptions underlying the costing of the programme or the application of the estimated benefits than on statistical uncertainty surrounding the size of the improvement in health status.

Although a number of previous trials of physical activity have included an economic evaluation, few have assessed health outcomes and so have been unable to estimate a cost per QALY. We have been able to identify only one trial—of aquatic exercise for adults with osteoarthritis—in which a cost per QALY was estimated (in this case, ranging from \$32 000 to \$205 000).²³ Our trial therefore seems to be the first that has attempted to evaluate empirically the cost effectiveness of exercise as a community level intervention.

This was a highly pragmatic trial of the effectiveness of exercise when offered as a public health intervention to a comparatively unselected sedentary population, and we have analysed the trial in a pragmatic, area based way to reflect this approach. This has enabled us to avoid the considerable difficulties of selection bias in both participation and adherence that can afflict individual level studies. Our analysis has focused on simplicity and is generally conservative. However, although the results of the trial are modest, there are a number of reasons to suppose that they may tend to underestimate the true health benefits achieved by the programme.

Firstly, the follow up period may not have been sufficient to measure some of the longer term benefits, notably for mortality and admission rates. Secondly, missing SF-36 scores from non-respondents has led us to assume no benefit in these non-responders for the purposes of calculating QALY gain. Thirdly, the benefit enjoyed by people who exercised, particularly those who participated throughout the programme, was certainly far greater than the modest average suggests. Simple assumptions suggest that the benefits for those who actually took up exercise were often of clinical as well as statistical significance. Fourthly, we originally designed this study as a community intervention trial to be analysed at an individual level.²⁴ However, because we chose the intervention practices at random we have been able to analyse it using multilevel techniques developed after our study protocol was completed. Although the estimated intraclass correlations are small, this has resulted in some loss of power for testing for mortality and admission rate reductions, and so the absence of evidence of benefit for these outcomes should not be interpreted as evidence of absence of benefit.

Although there is considerable uncertainty around the central estimate, which might have been reduced with higher levels of participation and lower levels of missing data, we believe the finding is robust and reflects the fact that an exercise programme can, given adequate attendance, produce worthwhile physical and mental health gain in large numbers of older adults at low cost. The economic evaluation provides further support for Morris' contention that exercise

is a "best buy" in public health terms,²⁵ and the programme we have described is an example of how the "exercise services" envisaged by the UK's National Service Framework for Older People might be practically developed to worthwhile effect.²⁶

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CONTRIBUTORS

All authors participated in the design and conduct of the study, and the writing of the paper. JM and JN analysed the outcome data, and JB carried out the health status and economic analyses. RD managed the provision of the exercise programme. JM is the guarantor.

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Speaker's corner

Health proverbs

A proverb is a short popular saying that expresses effectively some commonplace truth or useful thought. It can help people remember important messages and therefore is an important tool for information dissemination.

Our ancestors have left us a great wealth of health proverbs, such as “Prevention is better than cure (1240)” (prevention), “Eat to live, not live to eat (1387)” (obesity), “Early to bed and early to rise, makes a man healthy, wealthy and wise (1496)” (sleep), “Better to wear out than to rust out (1557)” (physical activity), “Never let the sun go down on your anger (1642)” (stress), “A stitch in time saves nine (1732)” (early treatment), “An apple a day keeps the doctor away (1866)” (fruits), and “You are what you eat (1940)” (nutrition).¹

Health proverbs that we have today were created by our ancestors based on their personal experience and observations. However, many of those health proverbs have not been scientifically verified. Now that we have access to modern clinical trials and scientific studies, it is perhaps time for us to create new science based health proverbs for future generations.

For example, based on results of modern scientific dose-response studies, would it be more correct to say “One and a half apple a day keeps the doctor away”? Should there be health proverbs with advice on no smoking, drinking alcohol in moderation, maintaining a balanced diet, or being physically active? How about telling people to watch and keep within normal range their blood cholesterol, body fat, or blood pressure? While there are dozens of existing proverbs about general health problems such as the common cold, balanced diet, sleep, hygiene, etc, should there be modern proverbs warning people of the four major chronic diseases (heart disease, cancer, lung disease, and mental disorder)?

A proverb is usually a homely illustration of a general truth and is never meant to be a dry scientific statement. As long as it works to promote the health of the general population, it is a good proverb. In addition to health proverbs for the grown ups, we also need health proverbs for children.

On this note, here are some potentially promising health proverbs for the 21st century: “A smile is an inexpensive way to improve your looks” (optimism); “To get angry is to punish yourself with other people's mistakes” (stress management); “The more you smoke, the more you croak”

(smoking); “Smoking makes you ugly” (smoking—it causes facial wrinkles and hair loss)²; “Drinker's liver, smoker's lung, couch potato's flab, binger's bulge” (drinking, smoking, inactivity, overeating); “Drinking and driving don't mix” (traffic safety)³; “Seven days without exercise makes one weak” (physical activity); “Eat well, be active, feel good about yourself” (nutrition, physical activity, positive attitude)⁴; “Tri-colour meal is a good deal” (nutrition—tri-colour as in traffic lights—that is, red, yellow, green, for example, tomato, corn, lettuce, etc); “Imagine everyone has a fixed lifetime amount to eat: the less you eat, the longer you live” (diet); “Double cheeseburgers and large fries, How does diet pop make that wise?” (diet).

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