Participation in a population-based physical activity programme as an aid for smoking cessation:

a randomised trial

Author(s): Raphaël Bize, Carole Willi, Arnaud Chiolero, Rebecca Stoianov, Sylvie Payot, Isabella

Locatelli and Jacques Cornuz

Source: Tobacco Control, Vol. 19, No. 6 (December 2010), pp. 488-494

Published by: BMJ

Stable URL: http://www.jstor.org/stable/40997793

Accessed: 03-02-2016 11:27 UTC

REFERENCES

Linked references are available on JSTOR for this article: http://www.jstor.org/stable/40997793?seq=1&cid=pdf-reference#references_tab_contents

You may need to log in to JSTOR to access the linked references.

Your use of the JSTOR archive indicates your acceptance of the Terms & Conditions of Use, available at $\frac{http://www.jstor.org/page/info/about/policies/terms.jsp}{info/about/policies/terms.jsp}$

JSTOR is a not-for-profit service that helps scholars, researchers, and students discover, use, and build upon a wide range of content in a trusted digital archive. We use information technology and tools to increase productivity and facilitate new forms of scholarship. For more information about JSTOR, please contact support@jstor.org.

BMJ is collaborating with JSTOR to digitize, preserve and extend access to Tobacco Control.

http://www.jstor.org

Participation in a population-based physical activity programme as an aid for smoking cessation: a randomised trial

Raphaël Bize, ^{1,2} Carole Willi, ¹ Arnaud Chiolero, ^{1,2} Rebecca Stoianov, ³ Sylvie Payot, ² Isabella Locatelli, ¹ Jacques Cornuz^{1,3}

¹Department of Ambulatory Care and Community Medicine, University of Lausanne, Switzerland ²Institute of Social and Preventive Medicine, University of Lausanne, Switzerland ³Department of Internal Medicine, University Hospital

Center, Lausanne, Switzerland

Correspondence to

Dr Raphaël Bize, Department of Ambulatory Care and Community Medicine, University of Lausanne, Rue du Bugnon 44, CH-1011 Lausanne, Switzerland; raphael.bize@hospvd.ch

Received 6 March 2009 Accepted 10 June 2010 Published Online First 25 August 2010

ABSTRACT

Objectives Exercise combined with nicotine therapy may help smoking cessation and minimise weight gain after quitting. Low participation in vigorous-intensity physical activity programmes precludes their population-wide applicability. In a randomised controlled trial, we tested whether a population-based moderate-intensity physical activity programme increases quit rates among sedentary smokers receiving nicotine therapy.

Methods Participants (n=481; 57% male; mean age, 42.2 years (SD 10.1); mean cigarette consumption, 27 (SD 10.2) per day) were offered a nine-week smoking cessation programme consisting of a weekly 15-minute counselling session and the prescription of nicotine replacement therapy. In addition, participants in the physical activity group (n=229) also took part in a programme of moderate-intensity physical activity implemented at the national level, and offering nine weekly 60-minute sessions of physical activity. To ensure equal contact conditions, participants in the control group (n=252) attended weekly 60-minute health behaviour education sessions unrelated to physical activity. The primary outcome was continuous CO-verified smoking abstinence rates at 1-year follow-up.

Results Continuous smoking abstinence rates were high and similar in the physical activity group and the control group at the end of the intervention (47% versus 46%, p=0.81) and at 1-year follow-up (27% versus 29%, p=0.71). The mean weight gain after one year was 4.4 kg and 6.2 kg among sustained quitters of the physical activity and control groups, respectively (p=0.06).

Conclusion Participation in a population-based moderate-intensity physical activity programme for 9 weeks in addition to a comprehensive smoking cessation programme did not significantly increase smoking cessation rates. A non-significant reduction in weight gain was observed among participants who quit smoking in the physical activity group.

Trial registration ClinicalTrials.gov; US National Institutes for Health (available online at http://clinicaltrials.gov/; Clinical Trial Registration Number: NCT00521391)

Smoking and sedentary behaviours are among the leading causes of death and disease in Western countries.¹ Evidence-based smoking cessation interventions include counselling and first-line pharmacotherapy, such as nicotine replacement therapy (NRT), bupropion and varenicline.³ Smoking abstinence rates remain low with such clinical interventions and innovative approaches to

help smokers quit and prevent relapse have been called for. $^{\!4\,5}$

Initiating vigorous-intensity physical activity (usually defined as 60-80% of maximal oxygen uptake) in sedentary smokers willing to stop smoking increases the chances of quitting by reducing nicotine withdrawal symptoms, negative moods, perceived stress and weight gain. 6-13 The smoking cessation rate might be higher if addressed simultaneously with other behavioural changes. 14 Moreover, increasing physical activity contributes to the prevention of cardiovascular diseases independent of smoking cessation and should be advised by healthcare professionals.¹⁵ However, whether moderate-intensity physical activity (usually defined as 40-60% of maximal oxygen uptake) or physical activity counselling only facilitates smoking cessation is controversial. 16-19 Initiating vigorous-intensity physical activity is difficult for many smokers. Replicable and effective moderate-intensity physical activity programmes are needed.8 16-20

No trial has assessed whether participation in a programme of moderate-intensity physical activity already implemented at the population level increases the smoking cessation rate when added to a comprehensive evidence-based smoking cessation programme that offers individual counselling and nicotine replacement therapy. We designed a randomised controlled trial to evaluate the effect of such a programme on smoking cessation among sedentary smokers who were willing to stop smoking.

METHODS

The research protocol was approved on 15 January 2002, by the Lausanne Medical School Ethics Committee and was registered at ClinicalTrials.gov (Clinical Trial Registration Number: NCT00521391). Data were collected between June 2002 and January 2006.

Recruitment of participants

Participants were sedentary smokers from the general population who wanted to quit smoking. They were recruited through public advertisements in the daily lay press. Interested smokers were asked to call the study centre. The trial was explained on the phone and a pre-screening interview was undertaken at the same time. If the candidates met the initial screening criteria, they were scheduled for a first pre-inclusion visit. Once candidates were informed and agreed to participate,

Tobacco Control 2010;19:488-494. doi:10.1136/tc.2009.030288

a detailed smoking and medical history was obtained to confirm eligibility.

Inclusion criteria were the following: age between 18 and 65 years; smoking currently at least 10 cigarettes per day and having regularly smoked, on average, at least 10 cigarettes per day for 3 years or more; being willing to quit smoking; and being classified as insufficiently active based on the Swiss Health-Enhancing Physical Activity Survey 1999 screening instrument. Candidates were considered insufficiently active if they reported both less than 150 minutes of moderate-intensity physical activity (MPA) per week and less than 60 minutes of vigorous-intensity physical activity (VPA) per week.²¹ ²²

Exclusion criteria were: current use of a pharmacological agent to quit smoking; medical problems that could alter exercise tolerance or place the participant at risk for physical activity-related cardiovascular events, ²³ including known heart disease or a current or recent major cardiovascular event such as recent myocardial infarction (<12 months) or stroke, angina pectoris, or major arrhythmia; presence of an unstable medical condition; arthritis; orthopaedic problems; psychiatric illness (current diagnosis on DSM-IV Axis I); at-risk alcohol consumption (> 4 drinks per day for men; > 3 drinks per day for women); use of other psychotropic substances such as cannabis; current or planned pregnancy or any systematic skin disease that precludes the prescription of transdermal nicotine patches.

Eligible candidates were scheduled for a second pre-inclusion visit consisting of a baseline medical examination. Blood pressure and anthropometric measurements were assessed and standard laboratory tests (haematology, blood chemistry and urinalysis) were conducted.

Study design and procedure

The study design was a two-arm, randomised controlled trial. The sequence of allocation to each arm—the 'physical activity' group and the 'control' group—was remotely and randomly generated by a computer. Concealment of allocation was secured by means of sealed envelopes. Participants were allocated to a study arm by a study nurse at the end of the second preinclusion visit. To facilitate interactions between interveners and participants, the programme was delivered in successive waves of 20-25 participants per study arm. To minimise potential imbalance among these successive batches of participants, we used a blocked randomisation procedure, with a block size of 50 randomly permuted treatment assignments.

Participants in both groups attended a 9-week programme with a weekly 15-minute session that included an individualbased smoking cessation intervention combining nicotine replacement products and counselling. This intervention covered standard cognitive-behavioural topics, such as enhancing motivation, 24 25 highlighting relevant health benefits, identifying barriers, coping with cravings and high-risk situations (ie. socialisation and parties) and relapse prevention. This programme was based on the Swiss and international clinical guidelines for smoking cessation.^{4 26} To ensure standardised administration of the programme, we provided written manuals for tutors who underwent smoking cessation training for healthcare professionals.²⁷ Participants were prescribed NRT according to their past experiences and requests. We considered the following NRT products: 16-hour transdermal patch, 2-mg and 4-mg gum, 10-mg inhaler and 1-mg lozenge.

Participants were asked to set their quit date between the first and the second session of the smoking cessation programme. After that week, participants were considered smokers if they failed to quit or if they relapsed. Three follow-up visits were planned: 10, 26 and 52 weeks after the beginning of the smoking cessation programme. Data were collected at the study centre located in the Department of Ambulatory Care and Community Medicine, University of Lausanne, Switzerland. To improve retention, we reimbursed travel expenses of participants who completed the follow-up visits at both 26 and 52 weeks.

Physical activity programme

In addition to the comprehensive smoking cessation programme, the physical-activity group followed a 9-week physical activity intervention including both structured and lifestyle components.

The structured component of the physical activity intervention was provided through the Swiss 'Allez Hop' programme, an implemented population-based programme recommended for all adults in the general population. ²⁸ The Allez Hop programme consisted of a 60-minute group session once a week during which participants practised moderate-intensity physical activity under the supervision of a trained monitor. Sessions were performed in an open recreational centre without using specific exercise-related equipment. Each session was divided into three parts: (a) interactive discussion on physical activity (5 minutes), aimed at positively influencing the participants' attitude towards physical activity and perception of how easy performing this behaviour will be²⁹; (b) a warm-up period, a 45minute physical activity session (intended to target 40-60% of maximal aerobic power) that was mainly dedicated to brisk walking and slow jogging and a cool down period; (c) debriefing (5-10 minutes). The intensity of physical activity was monitored with the Borg Rating of Perceived Exertion Scale based on participants' subjective perception of their physical activity efforts (from no exertion at all to maximal exertion). 30 The target intensity of the physical intervention was between 11 ('easy') and 13 ('somewhat hard').31

The lifestyle component of the physical activity intervention consisted of encouraging the participants to practise physical activities, such as commuting on foot or by bicycle, leisure/recreational (eg, hiking or dancing), occupational (physical activity at work) or household activities (eg, lawn moving) that were at least moderate in their intensity for an equivalent of 30 minute four times per week. 32 33 These activities could be planned or unplanned activities that are part of everyday life. Each intervener was trained in the application of motivational interviewing principles as part of a standard professional curriculum. 27 34

Participants in this group were told that regular physical activity might increase their chance of successfully quitting for both weight and withdrawal symptom management.

Healthy lifestyle programme

In addition to the comprehensive smoking cessation programme and to ensure equal contact conditions in both groups, for 9 weeks participants in the control group followed a weekly 60-minute supervised group session during which they received a standard health education programme. Each session included lectures, handouts and discussion addressing prevention issues, such as healthy diet, prevention of cardiovascular disease and cancer and a screening programme to detect breast and colon cancers. These group sessions were based on a previously published protocol adapted for the Swiss epidemiological situation, 12 which was first qualitatively tested in our setting to ensure its acceptability. As part of the study design, we did not provide any practical advice for initiating physical activity. Adherence to the group sessions was encouraged by the

free provision of educational counselling and written health education materials.

Outcomes

The primary outcome was smoking cessation at the 1-year follow-up (52 weeks). Smoking cessation was defined as selfreported abstinence from smoking, confirmed by a carbon monoxide (CO) concentration in expired air of less than 10 ppm measured with a Micro Smokerlyser (Bedfont, Kent, UK). This CO threshold was considered to reflect abstinence from smoking during the past 24 hours. Study participants were counted as continuously abstinent when they declared themselves as being uninterruptedly non-smokers from week 2 (when all participants had gone through their quit dates) until week 10, 26 or 52 and when the CO concentration in their exhaled air was concomitantly below 10 ppm. Abstinence during the last seven days with CO confirmation was considered a secondary outcome at the three follow-up visits at 10, 26 and 52 weeks. These criteria complied with a common standard for outcome definition in smoking cessation trials.35

Physical activity was quantified using the self-administrated Physical Activity Frequency Questionnaire. This questionnaire was developed and validated in a random sample of 919 adult Swiss residents against a heart rate monitor. Respondents indicated the number of days during the last 7 days and the number of hours per day that they performed any of 70 activities or group of activities (including sedentary ones). About 20 minutes were required to complete the questionnaire. Sedentary lifestyle was defined as 10% or less of total daily energy expenditure spent in the performance of moderate-intensity and vigorous-intensity physical activities (defined as those activities requiring \geq 4 Metabolic Equivalents of Task (METS)). This questionnaire was completed at baseline and at weeks 10, 26 and 52. 37

Body weight was recorded to the nearest 0.1 kg with the participant wearing only underwear and socks. Height was measured to the nearest 0.5 cm. The body mass index (kg/m²) was calculated. Nicotine withdrawal was assessed using the Wisconsin withdrawal scale. Self confidence in being able to sustain smoking cessation was assessed by a 10-cm visual analogue scale. Self-reported symptoms associated with depression were assessed by the Center for Epidemiologic Studies Depression Scale. Perceived stress level was assessed by the 4-item Perceived Stress Scale, which has demonstrated good validity and reliability in other randomised clinical trials. Weight was assessed by the definition of the randomised clinical trials.

Statistical methods

Sample size calculation was based on the following assumptions: we estimated smoking cessation rate at the 52-week follow-up to be around 20% in the control group and around 30% in the physical activity group. This difference was considered relevant from a clinical and a public health perspective. We assumed an α error of 5% and targeted a statistical power of 80%. Three hundred participants were to be included in each arm of the study to account for these assumptions.

Proportions between groups were compared using the χ^2 test. Differences in continuous variables between the two arms of the study were analysed with the two-sample t-test, or with the Mann-Whitney test for variables showing an asymmetric distribution. We conducted a multiple logistic regression to model the relation between continuous smoking abstinence at one year and study group, while adjusting for age, sex, education and daily cigarette consumption at baseline. We also applied a longitudinal approach based on generalised estimating

equations to model the relation between the 7-day point prevalence abstinence at the three follow-up visits (10, 26 and 52 weeks) and the study arm, adjusting for the previously mentioned potential confounding factors. ⁴¹ We also used interaction testing and stratification to assess whether the effect of the intervention differed with respect to sex and age.

Participants who did not provide any information on smoking behaviour or who were lost during follow-up were considered persistent smokers (intention-to-treat analysis). Secondary outcomes were analysed on the basis of available data.

All statistical analyses were performed with Stata Statistical Software-Release 9 (StataCorp LP).

RESULTS

Out of 1069 smokers screened on the phone or during the first pre-inclusion visit, we randomised 543 smokers (51%) who agreed to participate. Reasons for exclusion are detailed in figure 1. Thirty-one participants in each arm of the study either did not attend the first group session, or were considered major protocol violators because they turned out to be prior regular exercisers or marijuana users during the first counselling sessions. These participants were excluded from further analyses and the resulting participation rate was 45%. The physical activity and control groups were composed of 229 and 252 participants, respectively (figure 1). The 52-week follow-up visit was completed by 127 participants in the physical activity group (follow-up rate: 55%) and 155 in the control group (follow-up rate: 62%).

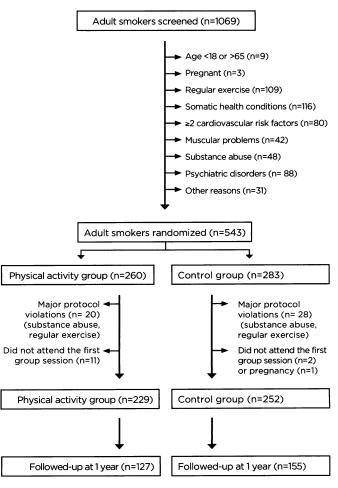


Figure 1 Flow chart of the study participants.

Tobacco Control 2010;19:488-494. doi:10.1136/tc.2009.030288

There were no differences at baseline between the two groups regarding sex, age, marital status, education level, number of cigarettes smoked per day, duration of smoking, nicotine dependence, weight, body mass index or weekly volume of physical activity (table 1). Participants in both arms reported a high baseline confidence in being able to sustain smoking cessation (7.0 on a visual analogue scale ranging from 0 to 10 in participants randomised to the physical activity group and 7.1 in those randomised to the control group).

At the end of the intervention, participants in both arms of the study reported an increase in their weekly volume of moderate-intensity and vigorous-intensity physical activity (ie, those activities requiring ≥ 4 METS) when compared with their baseline values (p<0.01 for the difference in both arms). The physical activity group reported a median of 1606 METS×min/ week (IQR: 595-3165) and the control group a median of 1275 METS×min/week (IQR: 164-2236). This difference between the two groups was statistically significant (p=0.04). Fifty per cent of the participants in the physical activity group and 40% of participants in the control group (p=0.12) were not considered sedentary at the end of the intervention, as they spent more than 10% of their total daily energy expenditure in the performance of moderate-intensity and vigorous-intensity physical activities (requiring ≥ 4 METS). At 1 year of follow-up, the weekly volume of moderate-intensity and vigorous-intensity physical activity was still higher than at baseline in both arms (p<0.01 for the difference in the physical activity arm and p=0.04 for the difference in the control arm) and higher in the physical activity group (medians: 1419 METS×min/week (IQR: 694-3094)) than in the control group (987 METS×min/week (IQR: 93-2749), p=0.03)

In each group, 75% of the participants were prescribed a combination of two or more NRT products, 13% received monotherapy and 12% declined using NRT products after quitting, as they felt confident enough to deal with withdrawal symptoms without pharmacotherapy.

Continuous CO-verified smoking abstinence rates were high and similar in both groups at the end of the intervention (47% in the physical activity group versus 46% in the control group, p=0.81). The rates decreased regularly after this period and remained similar in both groups, at 26 weeks (34% vs 35%, respectively, p=0.77) and at 52 weeks (27% vs 29%, respectively,

p=0.71) (table 2). About two-thirds of relapses (59% in the physical activity group and 66% in the control group) occurred during the first five weeks following smoking cessation.

The multiple logistic regression analysis, modelling the relation between continuous CO-verified smoking abstinence at 1 year and allocation to the physical activity group, while adjusting for age, gender, education and daily cigarette consumption at baseline, gave a similar result compared with the crude analysis (crude OR=0.93, 95% CI 0.62 to 1.38; adjusted OR=0.93; 95% CI 0.62 to 1.39). The generalised estimating equations model, taking into account the 7-day point prevalence abstinence at the three follow-up visits at 10, 26 and 52 weeks, gave comparable results with respect to the cross-sectional multiple logistic regression model (OR=0.92; 95% CI 0.67 to 1.27).

During the first 10 weeks, score changes in the withdrawal, depression and stress scales showed a trend (in both amplitude and direction) that favoured the physical activity group compared with the control group (table 3). However, these differences were statistically non-significant. Except for rare cases of skin intolerance to the transdermal patch, which was then replaced by an oral form of NRT, no clinically relevant adverse events were reported by study participants.

A statistically significant interaction between age and study arm was found in the multiple logistic regression model (p value for the interaction term=0.02). When split up into two subgroups based on the median age, participants in the younger age subgroup showed a higher rate of continuous CO-verified smoking abstinence in the physical activity group than in the control group, whereas the reverse was observed for the older participants (table 4). There was no statistically significant interaction between gender and study arm.

When considering all participants with complete weight data at one year, the weight gain (mean \pm SE) from baseline to the end of the 52-week follow-up was 3.1 \pm 0.5 kg (n=127) in the physical activity group and 3.7 \pm 0.3 kg (n=155) in the control group (p=0.27). The mean weight gain was 4.4 \pm 0.9 kg (n=59) and 6.2 \pm 0.5 kg (n=70) among CO-verified sustained quitters at 52 weeks in the physical activity and control groups, respectively (p=0.06). About half of the weight gain among sustained quitters at 52 weeks had already occurred by the 10-week visit (respectively 2.5 \pm 0.4 kg and 2.7 \pm 0.2 kg, p=0.57).

Table 1 Baseline characteristics of participants (n=481)

Characteristics	Physical activity group (n = 229) (unless otherwise specified)		Control group (n = 252) (unless otherwise specified)		p Value
Age, mean (SD) (years)	42.2	(10.0)	42.5	(9.5)	0.76*
Men, No (%)	128	(56)	144	(57)	0.78†
Married or cohabitating, No (%)	129	(56)	156	(62)	0.21†
High school education or higher, No (%)	86	(37.6)	92	(36.7)	0.84†
No of previous smoking cessation attempts, mean (SD)	2.5	(2.7)	2.7	(3.8)	0.46*
No of years smoked, mean (SD)	17.1	(2.8)	17.5	(3.5)	0.12*
No of cigarettes smoked per day, mean (SD)	26.6	(10.1)	27.0	(10.1)	0.71*
Fagerström score, mean (SD)	5.3	(2.1)	5.5	(2.3)	0.44*
Weekly volume of physical activity ≥ 4 METS, median (IQR) (METS×min/week)	659	(74-2085)	694	(105-1665)	0.63‡
Weight, mean (SD) (kg)	73.1	(16.5)	71.7	(13.1)	0.28*
Body mass index, mean (SD) (kg/m ²)	24.7	(4.4)	24.3	(3.6)	0.40*
Wisconsin Smoking Withdrawal Scale, mean (SD)	45.2 (N=175)	(16.0)	42.8 (N=178)	(14.3)	0.15*
Center for Epidemiologic Studies Depression Scale, mean (SD)	11.4 (N=180)	(8.1)	9.0 (N=195)	(7.3)	0.07*
4-item Perceived Stress Scale, mean (SD)	4.3 (N=186)	(2.6)	4.2 (N=208)	(2.8)	0.79*

^{*}Two-sided unpaired t-test.

 $^{+\}chi^2$ test.

[‡]Mann-Whitney rank sum test

Table 2 Continuous CO-verified smoking abstinence from quit date to weeks 10, 26 and 52

Continuous smoking abstinence, No (%)	Physical activity group (n = 229)		Control group (n = 252)		p Value*	
10th week	107	(46.7)	115	(45.6)	0.81	
26th week	78	(34.1)	89	(35.3)	0.77	
52nd week	62	(27.1)	72	(28.6)	0.71	

^{*}χ² test.

DISCUSSION

Participation in a weekly population-based programme of moderate-intensity physical activity for 9 weeks was not sufficient to increase smoking cessation rate when added to a comprehensive smoking cessation programme offering individual counselling and nicotine replacement therapy.

We observed high rates of continuous CO-verified smoking abstinence in both groups, exceeding what was found in the varenicline arm (23% at 1 year) of a recent smoking cessation trial comparing the efficacy of varenicline, bupropion and placebo for smoking cessation. 42 Three reasons may account for the high cessation rate in this trial: first, smokers who volunteered had placed very high expectations on the study per se, as illustrated by the high baseline confidence in being able to sustain smoking cessation in both groups; second, the relatively important involvement requested for candidates to participate in the study may have resulted in the selection of highly motivated participants; third, the study participants were positively influenced by the quality of the smoking cessation counselling provided in both groups by trained and motivated healthcare professionals. 26 27 Owing to the rather high baseline motivation of participants and counsellors, a ceiling effect may have limited the potential for a moderate-intensity physical activity intervention to increase the smoking cessation rate.

Although the physical activity group reported a higher weekly volume of physical activity than the control group, almost onehalf of the participants in the control group reported having increased their weekly volume of physical activity during the 9week programme. It may have helped them to remain abstinent. The tendency of control participants to increase their physical activity practice despite the absence of any intervention dedicated to that objective has already been described in other trials studying the impact of interventions promoting physical activity. $^{43-45}$ It has been attributed to different mechanisms (eg, previous health beliefs that physical activity is beneficial for smoking cessation, behavioural change induced by frequent assessments of physical activity practice, contamination between study arms and social desirability bias).⁴⁴ This increase in physical activity in the control group reduced the ability of the trial to demonstrate that the intervention had an effect. Partial blinding of study participants to the research hypothesis and to the physical activity measurements might have reduced the increase in physical activity among participants of the control group. However, this approach was not applicable to the current study given its incompatibility with the motivational interviewing principles underlying our behavioural interventions. Objective measurement of physical activity with an electronic device might have reduced the risk of misclassification, which also may account for this apparent paradox. As increasing physical activity contributes to the prevention of cardiovascular diseases independent of smoking cessation, the potential for participation in an integrated programme for smoking cessation to increase physical activity practice should be regarded as an interesting finding. ¹⁵

Marcus et al conducted two smoking cessation trials using respective vigorous-intensity and moderate-intensity physical activity as part of the intervention among female smokers. 13 16 Only the vigorous-intensity physical activity intervention was effective at increasing smoking cessation. 13 In the moderateintensity trial, participants who achieved at least 110 minutes/ week of moderate-intensity physical activity were more likely to abstain from smoking at the end of treatment than those who did not achieve this amount of physical activity. 16 Other recent trials also suggest that physical activity sessions of more vigorous intensity, higher frequency or longer duration than the one proposed in our study may be necessary to facilitate smoking cessation. $^{17\ 46\ 47}$ The age interaction found in our trial invites future researchers to consider age as a potential moderator of physical activity interventions and to test for possible explanatory mechanisms (eg, lower compliance with physical activity interventions or lower ability to address two behaviour changes at the same time among older individuals). Future trials on the benefit of physical activity for smoking cessation should also aim at better understanding which characteristics of physical activity (eg, type of activity, intensity, duration, frequency, isometric versus aerobic exercise, context of practice) are the most relevant and what is the shape of the dose-response relation. 48 49

Regarding two secondary outcomes, we found a non-significant trend in favour of the physical activity group (ie, a smaller weight gain and reduced withdrawal symptoms). Owing to the high exclusion rate among screened smokers, we included fewer participants than originally planned in our sample size calculation (ie, 300 in each arm of the study). This may have been responsible for a type II error (false negative). Given the potential for physical activity to have clinically relevant effects on weight gain after smoking cessation, these findings call for additional investigation.

Our study has some limitations. First, we had to exclude some randomised participants because of major protocol violation. As acknowledged by Hollis and Campbell in a contributing paper to the CONSORT statement, exclusion of participants who were falsely enrolled in a randomised controlled trial is justified under strict conditions. The cardinal condition is that reascertainment of the entry criteria is applied identically in each group. To assess the impact of these exclusions on our findings,

Table 3 Changes in the Wisconsin Smoking Withdrawal scale, the Center for Epidemiologic Studies (CES) Depression Scale and the 4-item Perceived Stress Scale scores between baseline and week 10 of the smoking cessation intervention

		Physical activity group		Control group		
		Mean (SD)	No	Mean (SD)	No	p Value*
Wisconsin Smoking Withdrawal Scale	Score change	-3.9 (16.7)	88	-1.5 (16.7)	85	0.36
CES Depression Scale	Score change	-2.0 (7.9)	87	+0.1 (7.9)	96	0.08
4-item Perceived Stress Scale	Score change	-1.3 (2.7)	115	-1.0 (3.2)	127	0.43

Note: negative changes in the scores over time correspond to an improvement in the symptoms.

^{*}Two-sided unpaired t-test.

Table 4 Continuous CO-verified smoking abstinence from quit date to week 52, by age group

	Continuous smoking abstinence, 52nd week, n/N (%)						
Age ≤42 years	Physical a	activity	Control gi	p Value*			
	40/118	(33.9)	32/126	(25.4)	0.15		
$Age > \!\! 42 \ years$	22/111	(19.8)	40/126	(31.7)	0.04		

^{*}χ² test.

What this paper adds

- Whether moderate-intensity physical activity facilitates smoking cessation is controversial. However, vigorousintensity physical activity is difficult for many smokers to sustain.
- This study shows that participation in a weekly 60-minute session of moderate-intensity physical activity for nine weeks, in addition to a comprehensive smoking cessation programme, is not sufficient to increase the likelihood of sedentary smokers to quit smoking.

we duplicated our analyses including all randomised participants. Our estimates for the study outcomes remained identical in this sensitivity analysis. Second, the data on physical activity practice were based on self-reporting. Objective measurement of physical activity would have strengthened our assessment of the actual 'dose' of physical activity. 52 The Physical Activity Frequency Questionnaire used was validated against heart rate monitor and accelerometer recordings in sociodemographically comparable population samples in Switzerland. 21 36 Compliance with the different components of the physical activity programme was assessed indirectly, through changes in the weekly volume of physical activity. Changing two health behaviours simultaneously in our physical activity group might have hampered success rates.⁸ The relevance of changing multiple health behaviours simultaneously is still questioned, 14 53 calling for more research in this field. Finally, the investigators who conducted the follow-up assessments were not blinded to the participants' allocation. 35 As smoking abstinence was confirmed using an objective biochemical test, it should have limited the potential for an information bias.

We conclude that participation in a population-based moderate-intensity physical activity programme provided no incremental benefit to smoking cessation rate at 1-year follow-up for sedentary smokers, when added to a comprehensive evidence-based smoking cessation intervention offering individual counselling and NRT products.

Acknowledgements All authors had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. We thank Nancy Rigotti and Michael Ussher for their advice about study design.

Funding This trial was supported by a grant from the Swiss National Science Foundation (SNSF 3200-067085). Other funders: Swiss National Science Foundation.

Competing interests None.

Ethics approval The research protocol was approved on 15 January 2002, by the Lausanne Medical School Ethics Committee.

Contributors Each author has participated sufficiently in the work to fulfil the criteria of authorship and to take public responsibility for appropriate portions of the content. There is no one else who fulfils the criteria who has not been included as an author.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

- Mokdad AH, Marks JS, Stroup DF, et al. Actual causes of death in the United States 2000. JAMA 2004;291:1238—45.
- Lopez AD, AbouZahr C, Shibuya K, et al. Keeping count: births, deaths, and causes
 of death. Lancet 2007;370:1744—6.
- Fiore MC, Jaén CR. A clinical blueprint to accelerate the elimination of tobacco use. JAMA 2008:299:2083—5.
- Fiore MC. US public health service clinical practice guideline: treating tobacco use and dependence. Respir Care 2000;45:1200—62.
- 5. Bize R, Cornuz J. Incentives to quit smoking in primary care. BMJ 2008;336:567-8.
- Taylor AH, Ussher MH, Faulkner G. The acute effects of exercise on cigarette cravings, withdrawal symptoms, affect and smoking behaviour: a systematic review Addiction 2007:102:534—43.
- Taylor AH, Katomeri M, Ussher M. Acute effects of self-paced walking on urges to smoke during temporary smoking abstinence. *Psychopharmacology* 2005:181:1—7
- Ussher M. Exercise interventions for smoking cessation. Cochrane Database Syst Rev. 2008; (4):CD002295
- Daniel J, Cropley M, Ussher M, et al. Acute effects of a short bout of moderate versus light intensity exercise versus inactivity on tobacco withdrawal symptoms in sedentary smokers. Psychopharmacology 2004;174:320—6.
- Bock BC, Marcus BH, King TK, et al. Exercise effects on withdrawal and mood among women attempting smoking cessation. Addict Behav 1999;24:399—410.
- Everson ES, Daley AJ, Ussher M. Moderate and vigorous intensity exercise acutely reduce cravings and withdrawal symptoms in abstaining young adult smokers. *Ment Health Phys Act* 2008;1:26—31.
- Marcus BH, King TK, Albrecht AE, et al. Rationale, design, and baseline data for commit to quit: an exercise efficacy trial for smoking cessation among women. Prev Med 1997;26:586–97.
- Marcus BH, Albrecht AE, King TK, et al. The efficacy of exercise as an aid for smoking cessation in women: a randomized controlled trial. Arch Intern Med 1999:159:1229—34
- Hyman DJ, Pavlik VN, Taylor WC, et al. Simultaneous vs sequential counseling for multiple behavior change. Arch Intern Med 2007;167:1152—8.
- 15. Thompson PD, Buchner D, Pina IL, et al. Exercise and physical activity in the prevention and treatment of atherosclerotic cardiovascular disease: a statement from the Council on Clinical Cardiology (Subcommittee on Exercise, Rehabilitation, and Prevention) and the Council on Nutrition, Physical Activity, and Metabolism (Subcommittee on Physical Activity). Circulation 2003;107:3109—16.
- Marcus BH, Lewis BA, Hogan J, et al. The efficacy of moderate-intensity exercise as an aid for smoking cessation in women: a randomized controlled trial. Nicotine Tob Res 2005;7:871—80.
- Ussher M, West R, McEwen A, et al. Randomized controlled trial of physical activity counseling as an aid to smoking cessation: 12 month follow-up. Addict Behav 2007;32:3060—4.
- Ussher M, West R, McEwen A, et al. Efficacy of exercise counseling as an aid for smoking cessation: a randomized controlled trial. Addiction 2003;98:523—32.
- Prochaska JJ, Hall SM, Humfleet G, et al. Physical activity as a strategy for maintaining tobacco abstinence: a randomized trial. Prev Med 2008;47:215—20.
- Marcus BH, Williams DM, Dubbert PM, et al. Physical activity intervention studies: what we know and what we need to know: a scientific statement from the American Heart Association Council on Nutrition, Physical Activity, and Metabolism (Subcommittee on Physical Activity); Council on Cardiovascular Disease in the Young; and the Interdisciplinary Working Group on Quality of Care and Outcomes Research. Circulation 2006;114:2739—52.
- Mader U, Martin BW, Schutz Y, et al. Validity of four short physical activity questionnaires in middle-aged persons. Med Sci Sports Exerc 2006;38:1255—66.
- Martin BW, Mäder U, Calmonte R. Représentations, connaissances et attitudes de la population suisse concernant l'activité physique: résultats de l'enquête sur l'exercice physique 1999. Schweiz Z Sport-med Sporttraumatol 1999;47:165—9.
- American College of Sports Medicine, American Heart Association. Exercise
 and acute cardiovascular events: placing the risks into perspective. Med Sci Sports
 Exerc 2007;39:886-97.
- Soria R, Legido A, Escolano C, et al. A randomised controlled trial of motivational interviewing for smoking cessation. Br J Gen Pract 2006;56:768—74.
- Cornuz J, Bize R. Motivating for cancer prevention. Recent Results Cancer Res 2006;168:7—21.
- Cornuz J, Humair JP, Seematter L, et al. Efficacy of resident training in smoking cessation: a randomized, controlled trial of a program based on application of behavioral theory and practice with standardized patients. Ann Intern Med 2002;136:429—37.
- Humair JP, Cornuz J. A new curriculum using active learning methods and standardized patients to train residents in smoking cessation. J Gen Intern Med 2003:18:1023-7.
- Martin BW, Jimmy G, Marti B. Promotion of exercise among the physically inactive: a challenge also in Switzerland. Ther Umsch 2001;58:196—201.
- Ajzen I. From intentions to actions: a theory of planned behavior. In: Kuhl J, Beckmann J, eds. Springer series in social psychology. Berlin: Springer, 1985:11–39.
- Borg G. Borg's perceived exertion and pain scales. Champaign, IL: Human Kinetics, 1998.

Tobacco Control 2010;19:488-494. doi:10.1136/tc.2009.030288

Research paper

- Fletcher GF, Balady GJ, Amsterdam EA, et al. Exercise standards for testing and training: a statement for healthcare professionals from the American Heart Association. Circulation 2001;104:1694—740.
- Dunn AL, Andersen RE, Jakicic JM. Lifestyle physical activity interventions. History, short- and long-term effects, and recommendations. Am J Prev Med 1998;15:398—412.
- Haskell WL, Lee IM, Pate RR, et al. Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. Med Sci Sports Exerc 2007;39:1423—34.
- Miller WR, Rollnick S. Motivational interviewing: preparing people to change addictive behavior. New York: Guilford, 1991.
- West R, Hajek P, Stead L, et al. Outcome criteria in smoking cessation trials: proposal for a common standard. Addiction 2005;100:299—303.
- 36. **Bernstein M**, Sloutskis D, Kumanyika S, *et al.* Data-based approach for developing
- a physical activity frequency questionnaire. Am J Epidemiol 1998;147:147–54.
 37. Bernstein MS, Morabia A, Sloutskis D. Definition and prevalence of sedentarism in an urban population. Am J Public Health 1999;89:862–7.
- West R, Ussher M, Evans M, et al. Assessing DSM-IV nicotine withdrawal symptoms: a comparison and evaluation of five different scales. *Psychopharmacology* 2006:184:619–27.
- Farmer ME, Locke BZ, Moscicki EK, et al. Physical activity and depressive symptoms: the NHANES | Epidemiologic Follow-up Study. Am J Epidemiol 1988;128:1340—51.
- Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. J Health Soc Behav 1983;24:385—96.
- Hall SM, Delucchi KL, Velicer WF, et al. Statistical analysis of randomized trials in tobacco treatment: longitudinal designs with dichotomous outcome. Nicotine Tob Res 2001;3:193–202.
- Jorenby DE, Hays JT, Rigotti NA, et al. Efficacy of varenicline, an alpha4beta2 nicotinic acetylcholine receptor partial agonist, vs placebo or sustained-release

- bupropion for smoking cessation: a randomized controlled trial. *JAMA* 2006;**296**:56—63.
- Kinmonth AL, Wareham NJ, Hardeman W, et al. Efficacy of a theory-based behavioural intervention to increase physical activity in an at-risk group in primary care (ProActive UK): a randomised trial. Lancet 2008;371:41—8.
- van Sluijs EM, van Poppel MN, Twisk JW, et al. Physical activity measurements affected participants' behavior in a randomized controlled trial. J Clin Epidemiol 2006;59:404—11.
- Jimmy G, Martin BW. Implementation and effectiveness of a primary care based physical activity counselling scheme. *Patient Educ Couns* 2005;56:323—31.
- Kinnunen T, Leeman RF, Korhonen T, et al. Exercise as an adjunct to nicotine gum in treating tobacco dependance among women. Nicotine Tob Res 2008:10:689—703.
- Prapavessis H, Cameron L, Baldi JC, et al. The effects of exercise and nicotine replacement therapy on smoking rates in women. Addict Behav 2007;32:1416—32.
- Kesaniemi YK, Danforth E Jr, Jensen MD, et al. Dose-response issues concerning physical activity and health: an evidence-based symposium. Med Sci Sports Exerc 2001:33:S351—8
- 49. **Duncan GE**, Anton SD, Sydeman SJ, *et al.* Prescribing exercise at varied levels of intensity and frequency: a randomized trial. *Arch Intern Med* 2005: **165**: 2362—9
- intensity and frequency: a randomized trial. Arch Intern Med 2005;165:2362—9.
 Hollis S, Campbell F. What is meant by intention to treat analysis? Survey of published randomised controlled trials. BMJ 1999;319:670—4.
- Moher D, Schulz KF, Altman D. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA* 2001: 285:1987—91.
- Ward DS, Evenson KR, Vaughn A, et al. Accelerometer use in physical activity: best practices and research recommendations. Med Sci Sports Exerc 2005;37:S582–8.
- Spring B, Pagoto S, Pingitore R, et al. Randomized controlled trial for behavioral smoking and weight control treatment: effect of concurrent versus sequential intervention. J Consult Clin Psychol 2004;72:785—96.