

Original investigation

# An Exploratory Analysis of the Smoking and Physical Activity Outcomes From a Pilot Randomized Controlled Trial of an Exercise Assisted Reduction to Stop Smoking Intervention in Disadvantaged Groups

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## Abstract

**Introduction:** Economically disadvantaged smokers not intending to stop may benefit from interventions aimed at reducing their smoking. This study assessed the effects of a behavioral intervention promoting an increase in physical activity versus usual care in a pilot randomized controlled trial.

**Methods:** Disadvantaged smokers who wanted to reduce but not quit were randomized to either a counseling intervention of up to 12 weeks to support smoking reduction and increased physical activity ( $n = 49$ ) or usual care ( $n = 50$ ). Data at 16 weeks were collected for various smoking and physical activity outcomes. Primary analyses consisted of an intention to treat analysis based on complete case data. Secondary analyses explored the impact of handling missing data.

**Results:** Compared with controls, intervention smokers were more likely to initiate a quit attempt (36 vs. 10%; odds ratio 5.05, [95% CI: 1.10; 23.15]), and a greater proportion achieved at least 50% reduction in cigarettes smoked (63 vs. 32%; 4.21 [1.32; 13.39]). Postquit abstinence measured by exhaled carbon monoxide at 4-week follow-up showed promising differences between groups (23% vs. 6%; 4.91 [0.80; 30.24]). No benefit of intervention on physical activity was found. Secondary analyses suggested that the standard missing data assumption of “missing” being equivalent to “smoking” may be conservative resulting in a reduced intervention effect.

**Conclusions:** A smoking reduction intervention for economically disadvantaged smokers which involved personal support to increase physical activity appears to be more effective than usual care in achieving reduction and may promote cessation. The effect does not appear to be influenced by an increase in physical activity.

## Introduction

Smoking is the biggest contributing factor to health inequalities,<sup>1</sup> and although smokers from disadvantaged backgrounds (ie, those of low socioeconomic status) attempt to quit at the same rate as others their success in quitting is lower.<sup>2</sup> This is leading to increasing disparities in smoking prevalence between the upper and lower social grades in the United Kingdom,<sup>3</sup> with similar trends being observed in the United States,<sup>4</sup> suggesting a need for interventions specifically designed for these groups.<sup>5</sup>

Good quality evidence for the effectiveness of smoking cessation interventions for disadvantaged groups is limited<sup>6,7</sup> and further research is needed on how best to both increase intervention reach and smoking cessation success.<sup>8</sup> It is likely that a range of intervention options may be needed to increase reach and to reduce smoking prevalence, such as locating services in community settings with most need, developing roles for outreach workers (eg, health trainers),<sup>9</sup> and developing multidimensional and complex behavior change interventions that are specifically designed for disadvantaged groups.<sup>10</sup>

Smoking reduction may be a viable alternative to the traditional abrupt approach to smoking cessation.<sup>11</sup> In the English Smoking Toolkit Study, 57 percent of current smokers reported they were in the process of cutting down<sup>3</sup> with a variety of approaches being used.<sup>12</sup> Smokers who do not intend to quit in the next month, but cut down with nicotine replacement therapy (NRT), are more likely to make a quit attempt and be abstinent at follow-up<sup>13</sup> than those who do not cut down. Smoking reduction may increase the motivation to quit, which is highly predictive of quit attempts, and reduce smoking dependence, which is related to successful quitting.<sup>14</sup> While NRT is popular as an aid for smoking reduction, 31% of smokers believed that sustained use of NRT was “very” or “quite” harmful to health<sup>15</sup> and disadvantaged groups may be sceptical of the effectiveness of NRT in meeting their needs if they were to quit.<sup>16</sup> Furthermore, stop smoking advisors and managers have expressed concern that combining NRT with smoking may have negative health consequences.<sup>17</sup> There is clearly a need for further research on supporting smoking reduction for those who do not wish to use NRT, among both those who do wish to quit and those who don't. Among those who do wish to quit, smoking reduction using pharmacotherapy and behavioral support appears to be as effective as abruptly quitting.<sup>11</sup>

A review of exercise interventions (vs. usual care) as an aid for long-term smoking cessation<sup>18</sup> identified 16 randomized controlled trials, but all were among smokers who wished to quit, and most were methodologically limited. Of the seven which were adequately powered, three found significant increases in abstinence at the end of treatment, but only one reported increased abstinence rates at 12-month follow-up. Variation in study length, type (eg, structured group-based exercise, physical activity counseling), and the content of the control condition complicated comparison of the studies in the review. The timing of the introduction of physical activity also varied across studies, with some studies promoting involvement in physical activity several weeks before a quit attempt. Almost all studies focused on the use of prescriptive exercise sessions supervised by an exercise professional, with only a few promoting changes in daily lifestyle activity as a way to manage cigarette cravings and withdrawal symptoms.

Epidemiological data suggesting that physically active smokers are more likely to attempt to quit<sup>19,20</sup> raises the possibility that physical activity could facilitate smoking reduction and cessation induction, among those who do not wish to quit immediately. There are several ways in which an increase in physical activity may putatively facilitate

smoking reduction and cessation induction<sup>21</sup> including acutely reducing cravings and withdrawal symptoms,<sup>22</sup> a shift away from a smoking identity<sup>21</sup> and reducing weight gain<sup>23</sup> (all mechanisms which may be putatively supported through other behavioral counseling approaches but may be further promoted through this innovative approach).

It is usual for smoking cessation intervention trials to use intention to treat analyses with an assumption that a participant lost to follow-up is still smoking,<sup>24</sup> which essentially reflects an assumption of baseline values carried forward. This assumption is problematic if it is not correct, as it could potentially bias results and statistical tests in favor of an effective treatment if attrition rates are higher in the control group. Also, there is some evidence to suggest that those lost to follow-up may not necessarily be smoking.<sup>25–29</sup> Different approaches to handling missing data on smoking status at follow-up have been suggested (eg, multiple imputation of missing data), which may provide more reliable estimates of treatment effects.<sup>30–32</sup>

The data within this article come from a pragmatic pilot randomized controlled trial assessing the feasibility and acceptability of a counseling-based intervention designed to support smoking reduction and increases in lifestyle and structured physical activity amongst disadvantaged groups. Unique to the current study was the focus on reduction as an outcome, without the need to set an abrupt quit date. This was to examine the role of reduction to induce quit attempts among those not wishing to quit immediately, which is different to other smoking reduction interventions which work to a set quit date<sup>11,13</sup> and reflects guidelines on tobacco harm reduction.<sup>33</sup>

We aimed to (1) explore the effects of the intervention on smoking and physical activity outcomes at 16 weeks compared with controls based on complete case data among disadvantaged smokers (defined as those from social class C2-E [skilled manual workers, semi-skilled and unskilled manual workers, and casual or lowest grade workers, pensioners, and others who depend on the welfare state for their income], those suffering from an indicated mental health problem, and single parents) and (2) conduct secondary analyses to explore both the implications of using different approaches to handling missing data and the effects this has on outcomes.

## Methods

More detailed information on the trial methods and intervention development can be found elsewhere.<sup>34</sup>

### Participants

Ethical approval for the study was granted by the NHS National Research Ethics Service Committee South West, in the United Kingdom. Recruitment took place in the neighborhoods of Devonport and Stonehouse (Plymouth) which are among the 3% most deprived areas in the United Kingdom.<sup>35</sup> The sample size calculations (via a scenario analysis), recruitment methods, and baseline characteristics of the sample, have been reported elsewhere.<sup>34</sup> In summary, 99 adult moderate to heavy smokers, who wanted to reduce smoking (without NRT) but who reported no plans to quit in the next month, were recruited by either a mailed invitation from their general practitioner (GP) or from NHS Stop Smoking Services (SSS), with follow-up telephone calls, or through other community approaches.

### Inclusion/Exclusion Criteria

Participants were eligible to enter the study if they were at least 18 years old, smoked at least 10 cigarettes per day (and had done so for at least 2 years), reported that they did not want to quit in

the next month but did wish to reduce their smoking, were able to engage in moderate intensity physical activity (walk without stopping for at least 15 minutes), were registered with a GP, and did not wish to use NRT to reduce smoking. The study focus was on initially reducing smoking, not quitting, so those who expressed an immediate desire to quit were referred directly to the SSS without entering the study. Those wishing to use NRT were excluded to avoid any confounding of the effects of physical activity on their smoking behavior. We excluded those with severe mental health problems and/or on-going substance misuse due to the potential difficulties of engaging them in the intervention given the large uncertainties and complexities of its delivery, and the potential to put the safety of researchers at risk. Given the exploratory nature of the study, participants were required to be able to converse in English. These criteria were assessed via screening by the researcher, and by approval from interested participants' GPs who confirmed the individual was eligible to enter the study based on the provided inclusion/exclusion criteria and did not pose any threat of violence towards the researcher in the opinion of the GP. Potential participants could not enter the study until approval was obtained.

## Procedures

After providing informed consent and baseline information, participants were randomized via a web-based randomization programme (provided by the accredited Peninsula Clinical Trials Unit) to receive either usual care or usual care plus the Exercise Assisted Reduction then Stop smoking intervention. Usual care involved brief advice and information on local SSS for specialist support to quit, as no support was available for smoking reduction as part of standard care. The Exercise Assisted Reduction then Stop smoking intervention consisted of up to eight weekly client-centered individual motivational support sessions (plus a possible further four sessions following a quit attempt), via telephone or in person, to assist with making self-directed changes in smoking and physical activity behavior, delivered by a team of three Health Trainers,<sup>9</sup> plus usual care. The intervention dose was driven by participants on the basis of need for further support to reduce. Those in both arms of the study wishing to make a quit attempt throughout the study period were encouraged to seek the support of specialist SSS. Full details of the intervention and uptake of SSS can be found in the trial's main report.<sup>34</sup> The primary end point was at 16 weeks post baseline for the majority of outcomes, except for data on 4-week postquit expired air carbon monoxide (CO) confirmed abstinence which was collected at the appropriate time as participants were free to make a quit attempt at any time point in the study.

## Measures

Given that the study was a pilot randomized controlled trial we did not formally assign outcomes to be primary or secondary. At baseline, 4, 8, and 16 weeks, data were collected in person (except week 4 which was collected by telephone) on the number of cigarettes smoked per day (also used to calculate percent reduction at 16 weeks), smoking dependence via the Fagerström Test for Cigarette Dependence,<sup>36,37</sup> expired air CO (Bedfont Smokerlyser, Kent, UK; used to calculate expired air CO reduction, not collected at week 4), self-reported physical activity (7-day recall),<sup>38</sup> and objectively assessed physical activity via accelerometer (Actigraph GT3X, Pensacola, FL) (participants were asked to wear the device for 7 days at baseline, week 9, and week 16; not collected at week 4). Physical activity data collected via self-report were used to calculate total

minutes of moderate and vigorous physical activity (MVPA) per week, the average minutes of MVPA per day, the number of those completing at least 30 minutes of MVPA per day, and the number of those completing at least 150 minutes of MVPA per week. Accelerometry data were used to calculate the average minutes of MVPA per day and the number of those completing at least 30 minutes of MVPA per day. Quit attempts made and 4-week postquit expired air CO were recorded accordingly throughout the trial with an expired air CO reading of less than 10 parts per million assumed to represent abstinence with self-reporting not smoking in the past 4 weeks.<sup>39</sup>

## Data Analyses

For the primary analyses outcomes were compared between groups based on the principle of intention to treat using complete case data. Multivariate logistic and linear regressions were used for binary and continuous outcomes respectively. For secondary intention to treat analyses using complete case data plus imputed data, binary smoking outcomes were analyzed using multivariate logistic regression based on the assumption that participants lost to follow-up were still smoking at baseline values, and by multiple imputation (chained equations); continuous smoking outcomes were analyzed by linear regression based on baseline values carried forward (BCF), last observation carried forward (LOCF), and by multiple imputation chained equations (MICE). For the MICE analyses, imputation models were built for each of the grouped outcomes of binary smoking outcomes, continuous smoking outcomes, binary physical activity outcomes, and continuous smoking outcomes. Predictors were selected by those related to missingness and those the research team thought to have a priori reason for being linked with missingness, these included: arm, baseline number of cigarettes smoked, baseline confidence to quit (high/low), baseline Fagerström Test for Cigarette Dependence score, baseline expired air CO, gender, age, 150 minutes of MVPA per week (yes/no), recruitment method (letter/phone call), Health Trainer allocation, and indicated mental health problem. In addition, baseline measure of each outcome variable if applicable (eg, baseline MVPA included for imputing week 16 MVPA). The logit command and predictive mean matching (for non-normal continuous variables) were used in imputations. Forty imputations were run for each model to reflect the 40% missingness at longest follow-up.<sup>40</sup> Both binary and continuous physical activity outcomes were analyzed by linear regression based on baseline values carried forward, last observation carried forward, and by MICE. All analyses were adjusted for baseline age, gender, Fagerström Test for Cigarette Dependence score (all variables which are reliably associated with smoking abstinence<sup>44</sup>), and Health Trainer allocation (as a minimization factor in randomization). Imputation models were built for each of the grouped outcomes (binary smoking outcomes, continuous smoking outcomes, binary physical activity outcomes, and continuous physical activity outcomes). All analyses were undertaken in Stata (V.12).

## Results

At 16 weeks, 62% ( $n = 61$ ) of participants provided outcome data, and loss to follow-up was similar between treatment groups (Figure 1). Intervention participants attended an average of 4.2 ( $SD = 2.7$ ) of the eight available support sessions. Detailed information on factors relating to attrition has been reported elsewhere (Thompson et al, under review).

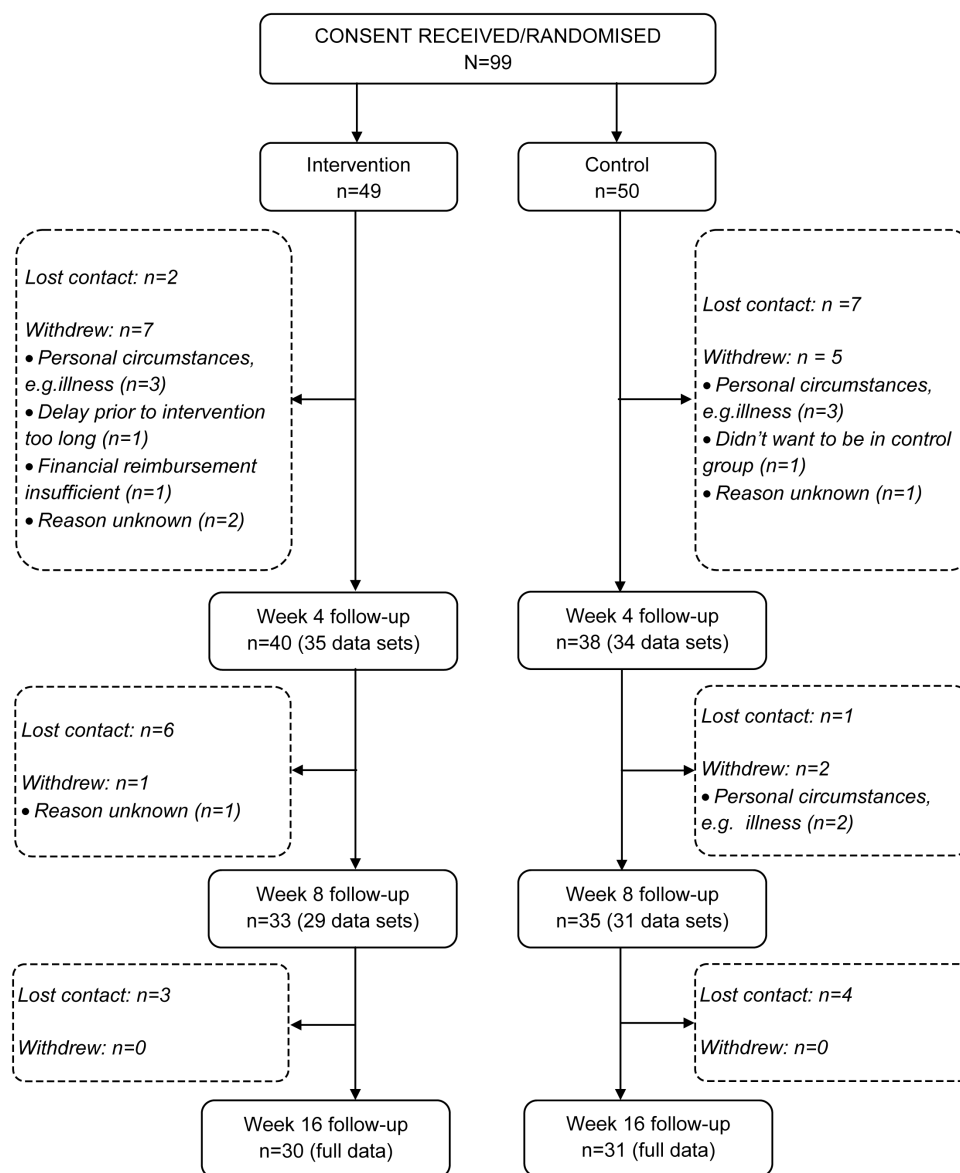


Figure 1. CONSORT chart showing attrition from randomization through to longest follow-up.

## Smoking Outcomes

More participants in the intervention arm (35.5%) than in the control arm (9.7%) made a quit attempt at any point in the study (odds ratio [OR]: 5.05, 95% confidence interval (CI): 1.10; 23.15), and a greater number of participants in the intervention arm (63.3%) compared with the control arm (32.3%) achieved at least a 50% reduction in smoking at 16 weeks (OR: 4.21, CI: 1.32; 13.39). Secondary sensitivity analyses showed that the increased odds of making a quit attempt during the study remained under both assumptions of assumed smoking (OR: 4.84, CI: 1.1; 20.31) and MICE (OR: 5.51, CI: 1.17; 25.98). The increased odds of achieving a reduction of 50% or more in smoking in the intervention arm remained under MICE (OR: 3.48, CI: 1.01; 12.03) but not based on the assumption of still smoking. The odds of achieving at least a 25% reduction in expired air CO only showed a difference under MICE (OR: 4.11, 95% CI: 1.43; 11.87) in the intervention arm (Table 1).

Primary analyses showed decreases in the adjusted mean difference (95% CI) on the number of self-reported cigarettes smoked per day (−5.14 [−9.09; −1.22]) and Fagerström Test for Cigarette Dependence score (−1.56 [−2.68; −0.43]), and a greater percentage reduction in the number of cigarettes smoked (−39.03 [−61.92; −16.15]) in the intervention arm at 16 weeks. Secondary sensitivity analyses supported these differences under all assumptions (BCF, LOCF, and MICE; Table 2).

## Physical Activity Outcomes

No differences in the odds of achieving any of the physical activity outcomes were shown in the primary analyses between arms. Secondary analyses showed increased odds of achieving at least 30 minutes of MVPA per day (OR: 2.54, CI: 1.05; 6.14) under LOCF, but not through BCF or MICE. Increased odds of achieving at least 150 minutes of MVPA per week in the intervention arm were shown under LOCF (OR: 3.61, CI: 1.48; 8.81) and BCF (OR: 3.21, CI: 1.33; 7.77; Table 3).

**Table 1. Binary Smoking Outcomes**

	Complete cases			Baseline carried forward			Last observation carried forward			MICE <sup>a</sup>		
	Intervention (N = 30)	Control (N = 31)	Odds ratio <sup>b</sup> (95% CI)	Intervention (N = 49)	Control (N = 50)	Odds ratio <sup>b</sup> (95% CI)	Intervention (N = 49)	Control (N = 50)	Odds ratio <sup>b</sup> (95% CI)	Intervention (N = 49)	Control (N = 50)	Odds ratio <sup>b</sup> (95% CI)
Self-reported quit attempt during study												
Yes, n (%)	11 (35.5)	3 (9.7)	5.05 (1.10; 23.15)	11 (22.5)	3 (6.0)	4.84 (1.15; 20.31)	N/A	N/A	N/A	16 (32.7)	5 (10.0)	5.51 (1.17; 25.98)
No, n (%)	20 (63.5)	28 (90.3)		38 (77.6)	47 (94.0)					33 (67.3)	45 (90.0)	
Confirmed quit at 4 weeks post quit-date												
Yes, n (%)	7 (23.3)	2 (6.5)	4.91 (0.80; 30.24)	7 (14.3)	2 (4.0)	4.33 (0.77; 24.39)	N/A	N/A	N/A	11 (22.4)	4 (8.0)	3.12 (0.60; 16.25)
No, n (%)	23 (66.7)	29 (93.5)		42 (85.7)	48 (96.0)					38 (75.6)	46 (92.0)	
Reduction of smoking by 50% or more by week 16												
Yes, n (%)	19 (63.3)	10 (32.3)	4.21 (1.32; 13.39)	19 (38.8)	10 (20.0)	2.51 (0.98; 6.46)	20 (40.8)	12 (24.0)	2.16 (0.87; 5.37)	30 (57.0)	15 (30.0)	3.48 (1.01; 12.03)
No, n (%)	11 (36.7)	21 (67.7)		30 (61.2)	40 (80.0)		29 (59.2)	38 (76.0)		19 (43.0)	35 (60.0)	
Expired air CO of $\geq 25\%$ at week 16												
Yes, n (%)	17 (56.6)	21 (67.7)	3.17 (0.98; 10.32)	17 (34.7)	10 (20.0)	2.15 (0.81; 5.71)	17 (34.7)	10 (20.0)	2.15 (0.81; 5.71)	28 (57.1)	15 (30)	4.11 (1.43; 11.87)
No, n (%)	13 (43.4)	10 (32.3)		32 (65.3)	40 (80.0)		32 (65.3)	40 (80.0)				

CI = confidence interval; CO = carbon monoxide.

<sup>a</sup>MICE: Multiple imputation chained equations.<sup>b</sup>Adjusted for baseline age, gender, Fagerström Test for Cigarette dependence score, and Health Trainer allocation.**Table 2. Continuous Smoking Outcomes**

	Complete cases			Baseline carried forward			Last observation carried forward			MICE <sup>a</sup>		
	Intervention (N = 30)	Control (N = 31)	Difference in means <sup>b</sup> (95% CI)	Intervention (N = 49)	Control (N = 50)	Difference in means <sup>b</sup> (95% CI)	Intervention (N = 49)	Control (N = 50)	Difference in means <sup>b</sup> (95% CI)	Intervention (N = 49)	Control (N = 50)	Difference in means <sup>b</sup> (95% CI)
Self-reported cigarettes per day, mean (SD)												
CO (ppm), mean (SD), n	12.3 (8.31)	15.77 (7.83)	-3.04 (-7.18; 1.10)	15.33 (8.70), 49	16.92 (8.57), 49	-1.33 (-4.65; 1.99)	15.51 (8.85), 49	16.64 (8.43), 50	-0.96 (-4.26; 2.33)	13.13 (1.35)	16.38 (1.46)	-3.16 (-6.92; 0.60)
Amount reduced (%), mean (SD)	-59.70 (32.54)	-20.13 (50.10)	-39.03 (-61.92; -16.15)	-36.55 (38.78)	-12.48 (40.42)	-23.08 (-38.87; -7.28)	-38.45 (40.31)	-16.70 (41.51)	-20.94 (-37.40; -4.47)	-55.96 (6.44)	20.74 (8.85)	-33.49 (-56.57; -10.41)
FTCD, mean (SD), n	3.09 (2.20), 22	4.21 (2.50), 29	-1.56 (-2.68; -0.43)	4.27 (2.22)	5.06 (2.51)	-0.70 (-1.38; -0.02)	5.02 (2.51)	4.04 (2.28)	-0.89 (-1.57; -0.21)	2.67 (0.39)	4.19 (0.50)	-1.57 (-2.72; -0.42)

CI = confidence interval; CO = carbon monoxide; FTCD = Fagerström Test for Cigarette Dependence; ppm = parts per million.

<sup>a</sup>MICE: Multiple imputation chained equations.<sup>b</sup>Adjusted for baseline age, gender, FTCD score, and Health Trainer allocation.



**Table 3. Binary Physical Activity Outcomes**

	Complete cases			Baseline carried forward			Last observation carried forward			MICE <sup>a</sup>	
	Intervention (N = 30)	Control (N = 31)	Odds ratio <sup>b</sup> (95% CI)	Intervention (N = 49)	Control (N = 50)	Odds ratio <sup>b</sup> (95% CI)	Intervention (N = 49)	Control (N = 50)	Odds ratio <sup>b</sup> (95% CI)	Intervention (N = 49)	Control (N = 50)
Self-report 30 min MVPA per day											
Yes, n (%)	17 (56.7)	16 (51.6)	1.31 (0.43; 3.94)	31 (63.3)	23 (46.0)	2.20 (0.93; 5.22)	31 (63.3)	22 (44.0)	2.54 (1.05; 6.14)	26 (53.1)	21 (42.0)
No, n (%)	13 (43.3)	15 (48.4)		18 (36.7)	27 (54.0)		18 (36.7)	28 (56.0)		23 (46.9)	29 (58.0)
Self-report >150 min MVPA per week											
Yes, n (%)	21 (70.0)	16 (51.6)	2.70 (0.85; 8.58)	35 (71.4)	23 (46.0)	3.21 (1.33; 7.77)	36 (73.5)	23 (46.0)	3.61 (1.48; 8.81)	33 (67.3)	21 (42.0)
No, n (%)	9 (30.0)	15 (48.4)		14 (28.6)	27 (54.0)		13 (26.5)	27 (54.0)		16 (32.7)	29 (58.0)
Accelerometer 30 min MVPA per day											
Yes, n (%)	8 (38.1)	6 (33.3)	1.18 (0.24; 5.68)	18 (50.0)	15 (45.5)	1.52 (0.53; 4.34)	18 (48.6)	15 (42.9)	1.58 (0.57; 4.36)	19 (38.8)	18 (36.0)
No, n (%)	13 (61.9)	12 (66.7)		18 (50.0)	18 (54.5)		19 (51.4)	20 (57.1)		30 (61.2)	32 (64.0)

CI = confidence interval; MVPA = moderate and vigorous physical activity.

<sup>a</sup>MICE: Multiple imputation chained equations.<sup>b</sup>Adjusted for baseline age, gender, Fagerström Test for Cigarette dependence score, and Health Trainer allocation.**Table 4. Continuous Physical Activity Outcomes**

	Complete cases			Baseline carried forward			Last observation carried forward			MICE <sup>a</sup>	
	Intervention (N = 30)	Control (N = 31)	Difference in means <sup>b</sup> (95% CI)	Intervention (N = 49)	Control (N = 50)	Difference in means <sup>b</sup> (95% CI)	Intervention (N = 49)	Control (N = 50)	Difference in means <sup>b</sup> (95% CI)	Intervention (N = 49)	Control (N = 50)
Total minutes MVPA per week, mean (SD)	400.00 (559.56)	378.55 (514.22)	23.53 (−261.72; 08.78)	490.61 (596.11)	309.52 (444.31)	185.29 (−17.89; 388.47)	509.49 (598.41)	297.52 (439.42)	220.79 (19.61; 421.97)	435.92 (576.35)	349.85 (488.08)
Total minutes MVPA per day, mean (SD)	57.14 (79.94)	54.08 (73.89)	3.36 (−37.39; 44.11)	70.09 (85.16)	44.22 (63.47)	26.47 (−2.56; 55.50)	72.78 (85.49)	42.50 (62.77)	31.54 (2.80; 60.28)	62.27 (82.34)	49.98 (69.73)
Accelerometer total minutes MVPA per day, mean (SD), n	27.34 (21.03), 21	26.22 (19.03), 18	0.44 (−14.40; 15.28)	30.60 (21.22), 33	30.79 (25.10), 36	1.95 (−8.76; 12.65)	31.60 (22.18), 37	28.66 (22.80), 35	5.36 (−4.49; 15.20)	26.65 (20.17), 49	25.29 (18.89), 50

CI = confidence interval; MVPA = moderate and vigorous physical activity.

<sup>a</sup>MICE: Multiple imputation chained equations.<sup>b</sup>Adjusted for baseline age, gender, Fagerström Test for Cigarette dependence score, and Health Trainer allocation.

There were no differences in any continuous physical activity outcome, assessed by accelerometer or self-report, in the primary or secondary analyses (Table 4).

## Discussion

This article presents data from a trial of a smoking reduction intervention with a focus on physical activity among disadvantaged smokers who did not want to initially quit. We believe our study is the first of its kind to give insight into the likely cessation induction rates for those entering a trial who do not want to quit but then do make a quit attempt, and illustrates potential variation in findings resulting from differing intention-to-treat assumptions. Whilst the findings were encouraging, the study was exploratory with no a priori sample size estimation. Caution is needed in interpreting the results due to the relatively small sample size and potential lack of statistical power and precision.

Individuals in the intervention arm were more likely to initiate a quit attempt when compared with those in usual care, suggesting that an intervention designed to support reduction could potentially lead to an increase in cessation attempts among those who initially had no desire to quit. The trend for greater success in the intervention compared with usual care for those achieving a 4-week postquit CO confirmed quit was promising. Along with positive effects of the intervention on reported smoking dependence and the amount of cigarettes smoked per day, it would seem that the intervention may impact on a variety of smoking outcomes among disadvantaged smokers.

Secondary analyses showed that the assumption that those lost to follow-up were still smoking was potentially conservative when compared with the primary complete case analysis or MICE. Despite the conservative nature of this assumption, the assumption that loss to follow-up meant participants were still smoking only contradicted one finding from the primary analyses (ie, those achieving a reduction of greater than 50% at week 16). It thus appears that this assumption has the potential to under-estimate the beneficial effects of the intervention,<sup>30–32</sup> and although this approach has been widely advocated, more research into dealing with missing data in smoking trials is justified.

Our intervention failed to demonstrate any positive effects on physical activity behavior at 16 weeks. Secondary analyses showed increased odds of those in the intervention completing 30 minutes of MVPA per day or 150 minutes of MVPA per week compared with usual care at 16 weeks. It is likely that the study was underpowered to detect changes in physical activity using only complete case data, but there is some support for increases in physical activity using imputation. Complete case analyses were conservative compared with the three approaches to imputation for missing physical activity data, where MICE showed 11% more people in the intervention completing 30 minutes of MVPA per day, BCF 17% more, and LOCF 19% more compared with only 5% more with complete cases. Similar differences were shown for the number of those completing at least 150 minutes of MVPA per week, suggesting using only complete case analysis for physical activity data may lead to an underestimation of intervention effects. In the present case, it is possible that the intervention's primary focus on smoking reduction meant that increasing physical activity was not as well addressed, particularly in regard to longer term maintenance and more support is needed to sustain increased physical activity levels. Disadvantaged groups undertake less leisure-time physical activity but undertake more activity associated with work and active transport (in part due to low car ownership).<sup>41,42</sup> This relationship clouds an understanding of the effectiveness of interventions to generally increase physical activity.<sup>43</sup> Despite minimizing the

focus on doing structured exercise rather than lifestyle physical activity in our participant recruitment materials we may have recruited more active smokers resulting in a potential ceiling effect when trying to increase physical activity in the intervention. Further investigation into physical activity levels among disadvantaged smokers is needed to better understand the influence of existing physical activity levels on changing behavior among such groups.

The pilot aspect of the trial and the current work mean the feasibility of the methods employed in analyzing the data show promise for application in a larger trial, where more confidence in the results could be demonstrated. Due to the relatively low sample size, it would be premature to draw any conclusions from this work with a view to influencing policy or practice. The trial was pragmatic in that the intervention was as close to what may happen in routine intervention delivery as possible. Because of uncertainties about trial methods it was designed as a pilot trial to resolve these uncertainties but with the opportunity to conduct exploratory analysis on the main outcomes. However, this study presents encouraging findings from a pilot pragmatic randomized controlled trial and adds to the limited literature on the role of physical activity for smoking reduction, rather than abrupt quitting. A fully powered trial to test the effectiveness of a counseling-based intervention with a focus on physical activity and smoking reduction among disadvantaged groups is now needed. Such a trial should examine the mediating role of changes in physical activity on smoking reduction as well as qualitatively explore how physical activity can help in self-regulation of smoking.

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## Declaration of Interests

*PA has been a consultant and done research for manufacturers of smoking cessation products. RW has undertaken research and consultancy for companies that develop and manufacture smoking cessation medications. He is co-Director of the National Centre for Smoking Cessation and Training and a trustee of the stop-smoking charity, QUIT. He has a share of a patent on a novel nicotine delivery device. All other authors have declared no competing interests.*

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