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Randomised controlled trial of a healthy lifestyle intervention among smokers with psychotic disorders

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ABSTRACT

Introduction: People with severe mental disorders typically experience a range of health problems; consequently, interventions addressing multiple health behaviours may provide an efficient way to tackle this major public health issue. This two-arm randomised controlled trial among people with psychotic disorders examined the efficacy of nicotine replacement therapy (NRT) plus either a face-to-face or predominantly telephone delivered intervention for smoking cessation and cardiovascular disease (CVD) risk reduction.

Methods: Following baseline assessment and completion of a common, individually delivered 90 minute face-to-face intervention, participants ($n = 235$) were randomised to receive NRT plus: (a) a “Healthy Lifestyles” intervention for smoking cessation and CVD risk behaviours; or (b) a predominantly telephone-based intervention (designed to control for NRT provision, session frequency, and other monitoring activities). Research assistants blind to treatment allocation performed assessments at 15 weeks (mid-intervention) and 12 months after baseline.

Results: There were no significant differences between intervention conditions in CVD risk or smoking outcomes at 15 weeks or 12 months, with improvements in both conditions (e.g., 12 months: 6.4% confirmed point prevalence abstinence rate; 17% experiencing a 50% or greater smoking reduction; mean reduction of 8.6 cigarettes per day; mean improvement in functioning of 9.8 points).

Conclusions: The health disparity experienced by people with psychotic disorders is high. Face-to-face healthy lifestyle interventions appear to be feasible and somewhat effective. However, given the accessibility of telephone delivered interventions, potentially combined with lower cost, further studies are needed to evaluate telephone delivered smoking cessation and lifestyle interventions for people with psychotic disorders.

Keywords: smoking cessation; psychosis; cardiovascular disease; counselling; cognitive behaviour therapy

INTRODUCTION

Psychotic disorders (e.g., schizophrenia spectrum and bipolar disorders) are severe forms of mental illness characterized by distortions of thinking, perception and emotional response, and are ranked in the top 10 causes of disability worldwide.¹

The life expectancy of people with schizophrenia or bipolar disorder is 12 to 19 years shorter than that of the general population.² Cardiovascular disease (CVD) is the single largest cause of death among this group, accounting for more premature deaths than suicide.³⁻⁶

Rates of major behavioural risk factors for CVD (smoking, physical inactivity, alcohol use and low fruit and vegetable intake)^{1,7} are higher in people with psychotic disorders,^{8,9} and smoking stands as a vitally influential and common risk factor.¹⁰

Recent reports also suggest that all socioeconomic status indicators associated with current smoking are also associated with 12-month mental illness.¹¹ Smokers with severe mental disorders spend over a quarter of their income on tobacco¹² and, when compared to non-smokers with severe mental disorders, they are more likely to go without basic necessities such as meals.¹³

A window of opportunity may exist within smoking cessation interventions to address the common clusters of CVD risk behaviours¹⁴ among people with severe mental disorders, as smoking reduces and alternative behaviours and better diet become more affordable. Among the general population, simultaneously addressing multiple health behaviours is increasingly being investigated as a potentially efficient way to tackle CVD risk.¹⁵ Although evidence supports the efficacy of smoking interventions among people with psychotic disorders,¹⁶ as far as we are aware, no randomised

controlled trials in this population have been published evaluating interventions targeting smoking and other health risk behaviours.

Given the high prevalence of smoking and other CVD risk behaviours among people with psychotic disorders,^{7,17} we compared the efficacy of an intensive face-to-face intervention focused on smoking and other CVD risk behaviours (the “Healthy Lifestyles” intervention) versus a predominantly telephone-delivered intervention (Comparison Condition), which was designed to control for pharmacotherapy provision (nicotine replacement therapy, NRT), number of and interval between sessions, and other monitoring (e.g., smoking, medication side-effects, diet and activity). It was hypothesised that the Healthy Lifestyles intervention would produce greater improvements at 12-months following baseline in CVD risk and smoking status relative to the comparison condition.

METHODS

Study design

We conducted a conventional two-arm randomised controlled trial (i.e., primary intervention condition hypothesised to be superior to comparison condition), which is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12609001039279). Study design, sample size estimates and intervention content have been described elsewhere¹⁸ and intervention manuals are available from the first author.

All participants provided written informed consent and were assessed at baseline, 15 weeks (mid-intervention) and 12 months after baseline; study recruitment occurred between July 2009 and April 2011, with the 12 months follow-up finalised during May

2012. Following baseline assessment, all participants completed an initial, individually-delivered 90 minute face-to-face session, where after they were randomly allocated to receive NRT plus one of two conditions: (a) a “Healthy Lifestyles” intervention for smoking cessation and CVD risk reduction (comprising an additional 16 face-to-face one hour counselling sessions delivered over approximately 9 months – see supplementary Table S1 for details); or (b) a predominantly telephone delivered intervention, designed to control for administration of NRT, number of and interval between sessions, and other monitoring activities (e.g., nicotine withdrawal; anti-psychotic medication side-effects, possibly related to smoking reduction; distress; smoking behaviour; diet and physical activity). Telephone sessions were scheduled to be approximately 10 minutes and at weeks 4 and 8 participants attended 30-minute face-to-face sessions, where NRT was dispensed and biomedical measures taken (see Table S1 for details).

Assessments at 15 weeks and 12 months were conducted by members of the research team, blind to allocation condition. Participants were reimbursed \$20 for their time, travel and participation on each assessment occasion, with no reimbursement for treatment session attendance (face-to-face or telephone-based).

Participants and procedure

Participants were 235 smokers with a stable psychotic disorder who were recruited across three sites (in Newcastle, Sydney and Melbourne, Australia). Ethical approval was obtained through the lead site (from Hunter New England Human Ethics Committee) and at each site. Referral sources included: health services, such as

community mental health centres and General Practitioners (148, 63%); media campaigns (59, 25%); and other research programs or registers (28, 12%).

Inclusion criteria were: a) aged at least 18 years; b) smoking at least 15 cigarettes per day (at any stage of change for quitting smoking); and c) diagnosis of a schizophrenia spectrum or bipolar disorder, as confirmed by the Mini International Neuropsychiatric Interview;¹⁹ and d) taking antipsychotic medication as prescribed for a period of at least two months, with intention to continue for the duration of the study. Exclusion criteria were: a) inability to speak English; b) organic brain diseases; and c) medical conditions that would preclude NRT or other treatment.

Randomisation was stratified by study site, Body Mass Index (BMI) category (normal; overweight: ≥ 25 and < 30 ; obese: ≥ 30) and type of antipsychotic medication (typical; atypical). A permuted block randomisation approach was used so that the distribution of these characteristics across conditions was maintained. Following the baseline assessment, study therapists were issued with a sealed randomisation envelope (by an independent person) displaying a participant identification code. The envelope was opened by the participant upon conclusion of the initial treatment session.

Treatment sessions were preferentially conducted at the local research centre or a nearby community clinic.

Measures

Key demographic, clinical and outcome measures are reported here. The assessment instruments have been reported previously¹⁸ and are described only briefly. The two primary outcomes were: (i) overall CVD risk index; and (ii) smoking

status (e.g., confirmed 7-day point prevalence abstinence; 50% or greater reduction in cigarettes per day relative to baseline; nicotine dependence). Secondary outcome variables included: psychiatric symptomatology; global functioning; weight and its impact on quality of life; health behaviours (e.g., physical activity; unhealthy eating); substance use; biomedical measures; and treatment retention. We also examined the impact of baseline smoking stage of change on cigarette consumption changes. Table S2 provides further information about these measures, including references, and scoring or related details.

Therapy

Content of interventions

The interventions have been described elsewhere.¹⁸ They were delivered by psychologists guided by intervention manuals.²⁰ All participants received an identical first session, after which they received up to 24 week's supply of NRT, delivered at weeks 1, 4 and 8, and thereafter by arrangement. The NRT protocol has also been described elsewhere²¹ – see Table S1 for details. Consent was sought to liaise with treating health professionals regarding: assessment results and treatment progress; management of any acute episodes; and arranging follow-up. The initial session focused on providing feedback regarding smoking (e.g., level of dependence) and other CVD risk factors; a case formulation was also developed with the participant regarding CVD status and unhealthy behaviours, using methods consistent with a motivational interviewing (MI) approach.

Intensive face-to-face Healthy Lifestyles intervention condition

The Healthy Lifestyles intervention encouraged smoking cessation and improvements in diet and physical activity, using a combination of MI and cognitive behaviour therapy (CBT) techniques. There was an initial focus on smoking, followed by risk behaviours considered most problematic by the participant. The Healthy Lifestyles intervention included education about: the interaction between nicotine and symptomatology; medication and cognition; options for NRT; and examining beliefs regarding the relationship between smoking and symptoms. A supportive follow-up telephone call was made 2-3 days following the initial quit attempt. Nicotine withdrawal severity, cravings to smoke, and adverse medication side-effects were monitored at each session. Contingent reinforcement was utilised, with positive reinforcement provided in the form of certificates and financial reimbursement (cash and vouchers) when participants met predetermined criteria for smoking reduction or abstinence (see Baker et al., 2011 for further details).¹⁸

Physical activity strategies were usually introduced in session 4, unless participants expressed a desire to work on these earlier. Ways of increasing levels of physical activity in everyday life were discussed and a graded walking program introduced with provision of pedometers. Healthy eating habits were introduced in session 7, with food planning and goal setting following in session 8. Participants were encouraged to eat a variety of foods, high in fibre and low in fat, to try to eat seven or more servings of fruits and vegetables a day, and to drink plenty of water. Participants were encouraged to address barriers to making healthy choices and to eat regularly.

Booster sessions were scheduled after session 8 (3 fortnightly, followed by 6 monthly sessions), at which a range of issues could be covered (e.g., relapse prevention, NRT tapering). During each session, the following were assessed: side-effects from medication; nicotine withdrawal; weight; cigarettes per day; expired carbon monoxide (CO); NRT use; and physical activity.

Telephone-based intervention condition

Following baseline assessment and provision of the initial face-to-face session, participants received up to 16 further brief, manual-guided sessions (14 by telephone and two additional face-to-face sessions – see Table S1). Telephone calls were scheduled to be around 10 minutes each. These calls monitored: smoking and NRT use; side-effects from medication; nicotine withdrawal; and current symptoms of psychosis and mood. Self-report measurements of cigarettes per day, exercise and dietary intake were taken each week. Comparable content areas to the Healthy Lifestyles intervention were discussed in the telephone-based intervention, but less intensively, and without either CBT or contingent reinforcement. For both conditions, approximately half of the total session time was devoted to discussion about CVD risk behaviours, with smoking related discussion occupying the bulk of that time.

Treatment fidelity

Throughout the treatment period, therapists received weekly clinical supervision. In addition, approximately two-thirds of face-to-face intervention sessions were audio recorded, from which a representative sample was randomly selected and rated by independent clinical psychologists for fidelity and competence, using the Cognitive Therapy Scale (CTS).²² Similarly, approximately half of the telephone-based

sessions were audio recorded, with a representative sample randomly selected for rating to ensure treatment session adherence; see supplementary Table S3 for further details.

Statistical analysis

Data analysis was carried out using SAS 9.2 (SAS Institute Inc., Cary, NC, USA). Change over time and group effects for the continuous outcome measures were examined using generalised linear mixed models to take account of the repeated measurements on individuals and missing data, whilst controlling for study site and baseline scores. The primary binary outcome measures were analysed according to the intention-to-treat principle, with study dropouts classified as non-abstinent/continuing smokers. Logistic regressions were used for the binary outcome analyses, with study site included as a covariate. Supplementary outcome analyses were based on the amount of treatment actually received (e.g., treatment session attendance; any reported NRT usage, but not NRT dosage). The significance level was set at $p < 0.01$ to partially control for potential type I errors associated with multiple comparisons; this is the equivalent of a Bonferroni-adjusted family-wise error rate with five members per family (e.g., analysis families: CVD risk and smoking measures; psychiatric symptomatology and quality of life measures; and health behaviour measures).

RESULTS

Sample characteristics

Figure 1 presents recruitment and attrition profiles. Of the 464 people referred, 229 were excluded (49.4%), including 52 (11.2%) who did not meet the inclusion criteria

(main reasons: had already quit smoking; smoked < 15 cigarettes per day; or non-psychosis) and 118 (25.4%) who declined, leaving a recruited and randomised sample of 235 (Healthy Lifestyles condition: $n = 122$; telephone condition: $n = 113$). Mean age of participants was 41.6 (SD 11.1) years, and just over half were male (138, 59%). Most were: Australian born (194/234, 84%); unemployed (176/217, 81%); receiving welfare support (218, 93%); had not finished secondary school (143/233, 61%); and had never married (157/233, 67%). Diagnoses were: schizophrenia spectrum (138, 59%); bipolar disorder (52, 22%); and non-organic psychotic syndrome (45, 19%). Average duration of psychosis was 18.6 years (SD 11.55) and one-third (82, 35%) had been admitted to a psychiatric hospital in the last year.

Most participants had been advised to quit smoking (189/230, 82%) and three-quarters had unsuccessfully tried previously (178/233, 76%). On average, participants reported smoking their first full cigarette at age 15.1 (SD 5.9) and started smoking daily at age 18.3 (SD 5.6). The mean BMI was 30.6 (SD 6.3) and the majority (184/227, 81%) had a BMI over 25, placing them in the overweight or obese categories. One-third (73/217, 34%) reported a family history of heart disease and 11% (25/235) had been diagnosed with diabetes.

Table 1 shows mean baseline scores for the key measures; see Table S4 for baseline biomedical measures. There were no significant baseline differences between intervention conditions, except for a difference in blood glucose levels. The typical participant reported heavy smoking, a sedentary lifestyle, and consumed well below the recommended servings of two fruits and five vegetables per day.²³ The

average 10-year risk of CVD of 7.3% (SD 10.9) fell below the high-risk threshold of 20%, largely due to the age of the sample.

Study recruitment rates were below expectations, relative to the 250 subjects initially planned,¹⁸ as were the retention rates. Overall, 186 individuals (79.1%) completed at least one of the follow-up assessments, however, there were no baseline differences between this subgroup and those who did not complete any follow-up assessments ($n = 49$).

Intervention attendance

Among those who attended at least one treatment session ($n = 211$), there was a significant overall difference in session attendance between the Healthy Lifestyles (mean 9.2, SD 6.0) and telephone (mean 12.4, SD 5.2) conditions ($p < .001$); see Table S1 and Figure 1 for attendance pattern details. Three levels of session completion were generated (see Figure 1): Low (1-3 sessions); Midrange (4-8 sessions) and High (9-17 sessions); which largely corresponded with changes in intervention content or timing across sessions (e.g., smoking focus; physical activity focus; non-weekly sessions). In the telephone condition, two-thirds (76/113, 67%) had high levels of attendance, compared with 48% (58/122) for the Healthy Lifestyles condition.

Session duration, fidelity, and competence

Table S3 presents an evaluation of the random subsample of recorded therapy sessions, with respect to overall session duration, minutes discussing CVD risk behaviours, and therapist adherence and competence. Session durations were

generally consistent with the session plans in Table S1, while therapy adherence rates averaged around 90%. Approximately two-thirds of the discussion about CVD risk behaviours focused on smoking. For the Healthy Lifestyles condition, the mean CTS score was 3.71 (SD 0.78), indicating that the typical CBT skills utilised were between “good” and “very good”.

Patterns of NRT use

NRT usage patterns are reported in Table S1. At the first session, only 17 participants (8.1%) reported using NRT in the previous week. By sessions 2-3, 58% reported using NRT, comprising 49% of the Healthy Lifestyles and 67% of the telephone condition ($p = 0.005$). However, at 12 months, comparable NRT rates were reported across the intervention period (85% vs 88%). A total of 40 participants (Healthy Lifestyles: 16%; telephone: 19%) reduced the number of cigarettes smoked per day by 50% or greater at 12 months relative to baseline and, of these, 93% had used NRT and 83% had high session attendance.

Primary outcomes: CVD risk and smoking status

Mean changes from baseline for the continuous outcome measures by intervention condition are reported in Table 2, while sub-group comparisons for the categorical outcomes are reported in Table 3.

Cardiovascular disease risk

As shown in Table 2, there were no significant differential changes (relative to baseline) in 10-year CVD risk between intervention conditions at 15 weeks or 12

months. However, there was a statistically significant reduction in 10-year CVD risk in both conditions at 15 weeks and at 12 months for the telephone condition.

Confirmed 7-day point prevalence abstinence

Point prevalence abstinence was analysed using self-report confirmed by a CO reading of <10ppm. As detailed in Table 2, there were no differences between the telephone and Healthy Lifestyle conditions in CO changes. However, for both conditions there were significant reductions at 15 weeks and for the telephone condition at 12 months. There were no significant overall differences between the conditions in confirmed 7-day point-prevalence abstinence rates at 15 weeks and 12 months (see Table 3); in total, 11% of the Healthy Lifestyles condition and 12% of the telephone condition reported abstinence from smoking in the previous week at 15 weeks, falling to 6.6% and 6.2% respectively at 12 months. Notwithstanding, at 15 weeks, participants with high attendance (9-17 sessions) were more likely to report point prevalence abstinence than those who had low to midrange attendance; however, these subgroup differences were not significant at 12 months (see Table 3).

Continuous abstinence

Only a small number of participants (9/235, 3.8%) reported continuous abstinence across the 12 month follow-up period; consequently, separate analyses are not reported for this outcome, with these participants included among the point prevalence abstinence findings described above.

Daily cigarette consumption

As detailed in Table 2, no significant differences existed between the conditions with respect to changes in daily cigarette consumption or nicotine dependence, although both conditions reported significant reductions at 15 weeks and 12 months (e.g., a mean overall reduction of 8.6 cigarettes per day at 12 months). Furthermore, based on supplementary analyses, there were no significant stage of change by treatment condition interactions (see online supplement).

Smoking reduction status

As already noted, there were no significant differences between conditions in smoking reduction status, measured by a 50% or greater reduction in the number of cigarettes smoked per day relative to baseline. However, as shown in Table 3, smoking reduction at both 15 weeks and 12 months was significantly greater in those who attended more treatment sessions. In addition, at 15 weeks, participants who used NRT were significantly more likely to report smoking reduction. Among the subgroup whose consumption fell by 50% or greater at 12-months ($n = 40$), there was a mean reduction from 27.7 to 5.3 cigarettes per day, with a corresponding mean CO reduction from 27.4 to 13.8ppm.

Secondary outcomes

Psychiatric symptomatology and quality of life

Table 2 also shows that there were no significant differences between conditions in the change from baseline for any of the mental health or quality of life indices, with significant improvements on some measures at 12 months (e.g., a 9.8 point mean GAF improvement) and, importantly, no measures showing significant worsening.

Health behaviours and other measures

There were no significant differential changes from baseline in any of the health behaviours (see Table 2) or the biomedical measures (see Table S5). Likewise, neither group showed improvement over time on any of these measures; however, there was a deterioration in total cholesterol in the Healthy Lifestyles condition (see Table S5). Alcohol, cannabis and other substance use also remained relatively constant, with no significant differences between conditions.

DISCUSSION

A major finding of the present study was that NRT plus a predominantly telephone-based intervention for smoking cessation (monitoring and discussing CVD risk behaviours) was at least as effective as NRT plus an intensive face-to-face Healthy Lifestyles intervention among smokers with a psychotic disorder. Both interventions were associated with significant reductions in CVD risk (predominantly during the intervention phase), cigarette consumption and nicotine dependence, together with associated quality of life improvements. The confirmed 7-day point prevalence smoking abstinence rate of 6.4% at 12 months is consistent with the 3.8% to 13.3% range (for 6-13 months) reported by Banham and Gilbody.¹⁶ Likewise, the finding that 17% experienced a 50% or greater reduction in smoking at 12 months is consistent with the 21% rate reported by Morris et al.²⁴ for a quitline plus group smoking cessation program. Both of these comparator studies were also conducted among smokers with severe mental illness.

Our hypothesis that a Healthy Lifestyles intervention would be more efficacious for

smoking cessation was thus not supported in this sample. We had expected the combination of a more intensive face-to-face intervention (comprising MI and CBT), together with contingency management, would be more powerful than a predominantly telephone-delivered intervention consisting mainly of NRT delivery and CVD risk monitoring and discussion.

There are several possible reasons why the interventions were associated with equivalent smoking outcomes. Firstly, potential participants were invited to join a Healthy Lifestyles study among smokers with a psychotic illness. As overall health was the focus, smoking outcomes may have been different if the study had been advertised as focussed primarily on smoking cessation (e.g., potentially improving the fit between participants' treatment expectations and actual intervention content and delivery, which focused predominantly on smoking in the current trial). Secondly, the scheduled duration of sessions (one hour versus 10 minutes) was designed to allow for greater treatment intensity in the face-to-face condition. However, ongoing discussions about CVD risk behaviours occurred in both conditions and attendance was somewhat better in the telephone-based condition, acting to reduce differences in the 'dose' of the intervention.

In our pilot healthy lifestyles study, 36 of the 43 participants attended all nine face-to-face sessions.²⁵ Acting on participant feedback, we extended the duration of interventions in the present study to 17 sessions. However, attendance rates suggest that treatment fatigue may be a factor, with the burden of face-to-face interventions (e.g., more time in travel and session attendance; transport issues) being greater than telephonic interventions. However, similar to previous studies,²⁶⁻²⁸ greater

session attendance and NRT use were associated with better outcomes. In their study of smoking cessation in homeless populations, Okuyemi et al.²⁸ suggested that increasing NRT adherence has the potential to enhance quitting outcomes. This may be worthy of further investigation among smokers with psychotic disorders.

A third possibility is that the content of the telephone-based intervention may have been especially suitable for people with psychotic disorders. Consisting largely of monitoring and discussing aspects of smoking cessation, the targeted and concrete nature of the intervention may have enhanced its efficacy. Interestingly, the telephone-based intervention was similar in content to the nine-session 'medication management' condition employed by Williams et al.,²⁷ which was found to be as effective as a 24 session intervention similar to the one described above.

Given the efficacy of the telephone-based intervention, a trial of a telephone intervention without any face-to-face component seems warranted among smokers with severe mental illnesses. Few such studies have yet been conducted, although quitlines are being increasingly recognised as potentially effective for smokers with severe mental illnesses.^{24,29} There is also evidence that quitline–doctor co-management of smoking cessation and depression is feasible, valued by smokers, and increases the probability of quit attempts,³⁰ without exacerbation of depression. The current findings are also consistent with our previous studies,^{25-27,31} in that smoking reduction or cessation is not associated with any worsening of psychiatric symptomatology.³²

Contrary to our prediction, there were no significant differences between conditions with respect to changes in physical activity, BMI, or self-reported diet. There was wide variability in activity measures, making detection of change difficult. In our pilot trial,²⁵ eligibility criteria included smoking and being overweight, and we demonstrated improvements in both variables. Our goal in the present study was to improve overall diet and not weight *per se*, as people with severe mental illnesses have poor diets, regardless of weight.¹ In future studies, it may be advantageous to establish stricter eligibility criteria for the health behaviours under investigation. Moreover, it is possible that the first face-to-face session received by all participants, involving feedback of assessment results and MI, combined with weekly monitoring in the telephone condition also contributed to our failure to detect differences.

Banham and Gilbody¹⁶ found no cost-effectiveness studies of smoking cessation/reduction measures in people with psychotic disorders. They suggested that future research must consider both cost and how new interventions will fit into existing service structures. Telephone-based interventions are likely to be more cost-effective than face-to-face interventions, and potentially deliverable by a broader cross-section of health and/or research staff. Evaluation of a quitline delivered intervention employing the manual used in the telephone-based intervention in the present study, including cost-effectiveness and feasibility of fit, are warranted. More broadly, the modest gains achieved in the current study, together with the health disparities typically experienced by those with psychotic disorders, should strengthen our resolve to develop better, more integrated multi-component interventions, which can be delivered in an acceptable, effective and sustainable manner.

There are several limitations of the present study. The CVD risk measure used here partly reflects age, so that younger participants do not score highly on such measures at baseline. Apart from number of cigarettes per day, the sample was not selected on the basis of other problematic health behaviours, making comparisons across conditions difficult. Inclusion of participants at all stages of change for quitting smoking, while justifiable, also complicates comparisons with other studies using different recruitment criteria. The follow-up rate of 59% is lower than we have achieved in similar studies³³ and may have been partly due to the burden of assessment in measuring multiple health domains.

In conclusion, face-to-face healthy lifestyle and telephone-based interventions for smoking among people with psychotic disorders appear to be feasible and somewhat effective. Given the accessibility of telephone delivered interventions, combined with lower cost, further studies are needed to evaluate telephonic interventions for people with severe mental disorders. We have conducted a small pilot study showing a telephone intervention to be effective for increasing fruit and vegetable consumption and decreasing leisure screen time among people with schizophrenia.³⁴ If telephonic smoking interventions are shown to be effective in this group, further combinations of sequential or combined behaviour change interventions would be of great interest.

SUPPLEMENTARY MATERIAL

Supplementary Tables S1 to S5 and supplementary analysis can be found online at:
xxxx.

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DECLARATION OF INTERESTS

The authors have no competing interests to declare.

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Figure 1. Recruitment and Attrition Profiles for the Healthy Lifestyles Project (CONSORT Diagram)

Table 1. Mean (SD) for Selected Baseline Measures (Overall and by Treatment Condition): CVD Risk, Smoking, Psychiatric Symptomatology and Quality of Life, and Key Health Behaviours

Measure	Overall (<i>n</i> = 235)	Healthy Lifestyle condition (<i>n</i> = 122)	Telephone condition (<i>n</i> = 113)	Condition comparison p-value
10 year CVD risk (ASSIGN score)	7.3 (10.9)	6.6 (8.7)	8.0 (12.6)	.345
Smoking measures				
Cigarettes per day	28.6 (15.3)	29.9 (17.9)	27.2 (11.8)	.187
Expired carbon monoxide (CO)	25.6 (19.0)	24.2 (15.8)	27.1 (21.9)	.240
Fagerstrom Test for Nicotine Dependence (FTND)	6.8 (2.0)	6.8 (2.2)	6.8 (1.8)	.885
Cannabis (use occasions per day)	1.3 (5.8)	1.2 (4.8)	1.3 (6.7)	.868
Psychiatric symptomatology and quality of life				
Brief Psychiatric Rating Scale (BPRS-24)	42.6 (12.9)	42.5 (12.9)	42.7 (12.9)	.917
Beck Depression Inventory (BDI-II)	17.4 (12.8)	17.7 (13.0)	17.0 (12.6)	.729
Global Assessment of Functioning (GAF)	51.2 (10.8)	51.6 (10.9)	50.6 (10.7)	.474
Impact of Weight on Quality of Life (IWOQOL-Lite)	59.1 (28.6)	58.2 (26.5)	60.0 (31.0)	.682
SF-12 Mental Component Scale (MCS)	47.0 (8.4)	46.8 (8.1)	47.2 (8.8)	.706
SF-12 Physical Component Scale (PCS)	45.4 (8.1)	45.8 (7.8)	45.1 (8.4)	.540
Health behaviours				
Walking time (mins per week)	231 (393)	231 (374)	232 (414)	.988
Sitting time (mins per week)	2909 (1705)	2855 (1646)	2965 (1768)	.640
Alcohol (standard drinks per day)	1.19 (5.23)	1.39 (6.46)	0.98 (3.49)	.561
Number of daily vegetable servings	1.9 (1.4)	1.9 (1.4)	1.8 (1.4)	.411
Number of daily fruit servings	1.2 (1.1)	1.2 (1.3)	1.1 (1.0)	.616
Combined number of daily fruit and vegetable servings	3.0 (2.0)	3.2 (2.0)	2.9 (1.9)	.337

Note. See online supplement for further details about the measures (Table S2) and baseline biomedical indices (Table S4).

Table 2. Mean Change from Baseline (99% CI) for a Range of Continuous Outcome Measures by Intervention Condition

Measure	Follow-up time	Healthy Lifestyle condition		Telephone condition		Difference between groups	
		Mean change (99% CI)	p-value	Mean change (99% CI)	p-value	Least square mean difference or #ratio (from Poisson analysis) (99% CI)	Group effect p-value
10 year CVD risk	15 weeks	-2.0 (-3.6, -0.4)	.002	-2.8 (-4.8, -0.7)	.001	-0.6 (-2.5, 1.3)	.420
	12 months	-0.7 (-2.4, 1.0)	.276	-1.6 (-3.2, -0.0)	.009	-0.2 (-2.3, 1.9)	.789
Smoking measures							
Cigarettes per day	15 weeks	-14.8 (-21.4, -8.2)	<.001	-13.7 (-17.1, -10.3)	<.001	-1.2 (-6.9, 4.4)	.565
	12 months	-8.5 (-12.8, -4.2)	<.001	-8.7 (-13.1, -4.4)	<.001	-0.5 (-6.1, 5.0)	.796
Expired carbon monoxide (CO)	15 weeks	-5.9 (-11.7, -0.2)	.008	-10.3 (-16.4, -4.2)	<.001	-3.1 (-9.8, 3.7)	.233
	12 months	-4.9 (-10.7, 0.8)	.026	-7.9 (-13.6, -2.1)	<.001	0.4 (-6.3, 7.2)	.864
Fagerstrom Test for Nicotine Dependence (FTND)	15 weeks	-2.0 (-2.8, -1.1)	<.001	-1.9 (-2.6, -1.2)	<.001	0.3 (-0.9, 1.5)	.486
	12 months	-0.8 (-1.7, 0.1)	.015	-1.2 (-2.1, -0.3)	<.001	-0.1 (-1.2, 1.0)	.814
Cannabis (use occasions per day)	15 weeks	0.8 (-0.9 to 2.6)	.218	-0.5 (-2.0 to 1.0)	.367	-0.3 (-1.3, 0.7)	.439
	12 months	-0.2 (-0.7 to 0.3)	.265	-0.9 (-2.2 to 0.4)	.077	-0.7 (-1.6, 0.2)	.045
Psychiatric symptomatology and quality of life							
Brief Psychiatric Rating Scale (BPRS-24)	15 weeks	0.6 (-2.5, 3.7)	.632	-2.3 (-5.0, 0.5)	.032	-1.8 (-6.1, 2.4)	.252
	12 months	-0.5 (-4.5, 3.5)	.758	-4.6 (-8.8, -0.4)	.005	-2.9 (-7.1, 1.2)	.066
Beck Depression Inventory (BDI-II)	15 weeks	-3.0 (-7.0, 0.9)	.046	-2.8 (-6.0, 0.3)	.018	-0.2 (-4.9, 4.5)	.915
	12 months	-3.6 (-6.8, -0.3)	.005	-3.8 (-8.1, 0.4)	.018	-0.1 (-4.6, 4.4)	.940
Global Assessment of Functioning (GAF)	15 weeks	3.9 (0.6, 7.1)	.002	5.3 (1.6, 9.1)	<.001	-0.1 (-6.0, 5.7)	.950
	12 months	9.7 (5.3, 14.0)	<.001	9.9 (4.5, 15.2)	<.001	1.2 (-4.2, 6.6)	.556
Impact of Weight on Quality of Life (IWOQOL-Lite)	15 weeks	-0.6 (-5.6, 4.4)	.755	-3.8 (-8.0, 0.4)	.018	-3.1 (-12.4, 6.2)	.380
	12 months	-2.4 (-8.4, 3.6)	.286	-8.4 (-18.7, 2.0)	.035	-6.7 (-15.7, 2.2)	.051
SF-12 Mental Component Scale (MCS)	15 weeks	0.3 (-2.5, 3.0)	.801	1.1 (-1.6, 3.8)	.290	-0.5 (-4.6, 3.6)	.741
	12 months	0.8 (-2.9, 4.4)	.571	1.6 (-2.4, 5.6)	.287	1.0 (-3.5, 5.5)	.547
SF-12 Physical Component Scale (PCS)	15 weeks	-0.1 (-1.8, 1.7)	.913	1.5 (-0.4, 3.5)	.042	1.5 (-1.6, 4.6)	.208
	12 months	1.4 (-1.5, 4.3)	.200	1.0 (-2.4, 4.4)	.420	-0.1 (-3.5, 3.4)	.961
Health behaviours							
Walking time (mins per week)	15 weeks	39.6 (-173, 252)	.624	-10.1 (-159, 139)	.860	-76.3 (-321, 168)	.415
	12 months	96.3 (-113, 306)	.226	-38.9 (-179, 101)	.464	-155.4 (-385, 74.3)	.079
Sitting total (mins per week)	15 weeks	-294.4 (-843, 254)	.160	-77.0 (-601, 447)	.700	200.5 (-482, 883)	.443
	12 months	-27.3 (-628, 574)	.904	-210.6 (-784, 363)	.333	-136.3 (-770, 498)	.574
Alcohol (standard drinks per day)	15 weeks	0.4 (-0.2, 1.1)	.072	-0.1 (-0.6, 0.4)	.520	0.1 (-1.2, 1.4)	.901

Number of daily vegetable servings#	12 months	-0.7 (-3.5, 2.0)	.495	-0.3 (-1.2, 0.7)	.443	0.2 (-1.1, 1.5)	.679
	15 weeks	0.1 (-0.4, 0.5)	.638	-0.1 (-0.5, 0.3)	.417	0.82 (0.60, 1.12)	.100
Number of daily fruit servings#	12 months	0.0 (-0.5, 0.6)	.908	-0.4 (-0.9, 0.1)	.021	0.78 (0.54, 1.12)	.078
	15 weeks	0.1 (-0.3, 0.5)	.569	-0.0 (-0.4, 0.4)	.994	0.92 (0.63, 1.34)	.567
Combined number of daily fruit and vegetable servings#	12 months	-0.1 (-0.4, 0.3)	.631	0.0 (-0.3, 0.4)	.771	1.11 (0.72, 1.70)	.530
	15 weeks	0.2 (-0.5, 0.8)	.494	-0.1 (-0.8, 0.5)	.544	0.86 (0.66, 1.12)	.151
	12 months	-0.1 (-0.8, 0.7)	.830	-0.4 (-1.1, 0.3)	.106	0.89 (0.66, 1.21)	.330

Note. See online supplement for further details about the measures (Table S2) and change analyses for the biomedical indices (Table S5); generalised linear mixed models were used to examine change over time and group effects, controlling for study site and baseline scores; # comparable Poisson loglinear analyses were used for these outcomes.

Table 3. Categorical Smoking Outcome Measures by Intervention Condition, Level of Attendance, and Use of NRT

Measure/group	15 weeks			12 months		
	<i>n</i> (% yes)	Odds Ratio (99% CI)	Group effect p-value	<i>n</i> (% yes)	Odds Ratio (99% CI)	Group effect p-value
Confirmed point prevalence abstinence						
Healthy Lifestyles condition	13 (11%)	0.92 (0.31, 2.70)	.837	8 (6.6%)#	1.06 (0.31, 4.35)	.910
Telephone condition	13 (12%)	referent		7 (6.2%)#	referent	
High attendance (9-17 sessions)	22 (16%)	4.76 (1.11, 20.0)	.006	11 (8.2%)	2.17 (0.46, 10.0)	.199
Low-midrange attendance (1-8 sessions)	4 (4.0%)	referent		4 (4.0%)	referent	
Any NRT use	25 (14%)	4.55 (0.31, 100)	.142	13 (7.2%)	1.09 (0.14, 8.33)	.919
No NRT use	1 (3.3%)	referent		2 (6.7%)	referent	
Smoking reduction of 50% or greater relative to baseline						
Healthy Lifestyles condition	38 (31%)	0.64 (0.31, 1.30)	.099	19 (16%)	0.81 (0.33, 2.00)	.542
Telephone condition	47 (42%)	referent		21 (19%)	referent	
High attendance (9-17 sessions)	69 (51%)	5.56 (2.44, 12.5)	<.001	33 (25%)	4.35 (1.39, 14.3)	<.001
Low-midrange attendance (1-8 sessions)	16 (16%)	referent		7 (6.9%)	referent	
Any NRT use	81 (45%)	7.14 (1.43, 33.3)	.002	37 (20%)	2.33 (0.44, 12.5)	.190
No NRT use	3 (10%)	referent		3 (10%)	referent	

Note. Binary logistic regressions were used for these analyses, controlling for study site. NRT = Nicotine replacement therapy; # includes those who were continuously abstinent across the 12 months follow-up period (Healthy Lifestyles condition, *n* = 4; Telephone condition, *n* = 5).

SUPPLEMENTARY TABLES

Table S1. Session Attendance Pattern and NRT Distribution by Treatment Condition

Contact frequency	Session	Healthy Lifestyle condition (<i>n</i> = 122)			Telephone condition (<i>n</i> = 113)			Assessment phase
		Planned contact (duration)	Average attendance % (<i>n</i>)	Average using NRT % (<i>n</i>)	Planned contact (duration)	Average attendance % (<i>n</i>)	Average using NRT % (<i>n</i>)	
Weekly	1	Face-to-face (90 mins)	89.3 (109)	6.6 (8)	Face-to-face (90 mins)	90.3 (102)	8.0 (9)	Baseline
	2-3	Face-to-face (60 mins)	76.2 (93)	49.2 (60)	Telephone (10 mins)	84.1 (95)	67.3 (76)	
	4	Face-to-face (60 mins)	63.9 (78)	47.5 (58)	Face-to-face (30 mins)	81.4 (92)	62.8 (71)	
	5-7	Face-to-face (60 mins)	55.7 (68)	39.3 (48)	Telephone (10 mins)	71.7 (81)	57.5 (65)	
	8	Face-to-face (60 mins)	49.2 (60)	33.6 (41)	Face-to-face (30 mins)	69.9 (79)	50.4 (57)	
Fortnightly	9-11	Face-to-face (60 mins)	41.8 (51)	25.4 (31)	Telephone (10 mins)	66.4 (75)	42.5 (48)	15 weeks
Monthly	12-17	Face-to-face (60 mins)	28.7 (35)	12.3 (15)	Telephone (10 mins)	49.6 (56)	20.4 (23)	12 months

Note. There was a significant overall difference in session attendance between the Healthy Lifestyles (mean 9.2, SD 6.0) and telephone (mean 12.4, SD 5.2) conditions ($p < .001$) among those who attended at least one session ($n = 211$). NRT = Nicotine Replacement Therapy; maximum eligible NRT dose = 7mg, 14mg or 21mg patches + 12 x 2mg lozenges per day; heavy smokers (at least 30 cigarettes per day) were eligible to receive double patching (2 x 21mg patch), in addition to up to 12 x 2mg lozenges per day (with a maximum total dose of 66mg of NRT per day); NRT supply typically ceased around session 14. By sessions 2-3, the two treatment conditions differed in their reported NRT rates (49% vs 67%, $\chi^2 = 7.86$, $p = 0.005$); however, at 12 months, comparable NRT rates were reported across the intervention period (85% vs 88%).

Table S2. Assessment Measures by Domain Type across the Baseline, 15 weeks and 12 months Assessments

Domain	Measures	References	Selected scoring or other details
Cardiovascular Disease (CVD) risk	ASSIGN score: calculated from age, gender, total cholesterol, high-density lipoprotein, systolic blood pressure, diabetes, family history of heart disease, cigarettes per day (Primary Outcome) Blood pressure Cholesterol and blood glucose	(Woodward, Brindle, & Tunstall-Pedoe, 2007)	Estimated CVD risk scores were derived using the ASSIGN algorithm, based on numerous biomedical parameters (see Column 2), and taking into account the social gradients of CVD. The ASSIGN score has been validated against the Framingham score (Woodward et al., 2007) and provides a measure of the likelihood of having a CVD related event within the next 10 years. Omron Automatic Blood Pressure Monitor - taking the average of three blood pressure measurements. Blood cholesterol and blood glucose levels were measured using finger-prick blood tests and a Cardiochek PA analyser - using the Total Cholesterol (TC), High-density lipoprotein (HDL) and glucose (GLU) test panels and the Low-density lipoprotein (LDL) test panel.
Smoking measures	Cigarettes per day – using the Opiate Treatment Index (OTI) 7-day point prevalence abstinence (Primary Outcome) Continuous abstinence Expired carbon monoxide (CO): Self-reported smoking 'abstinence' was confirmed using a Micro 11 Smokerlyser Smoking reduction status (Primary Outcome) Fagerstrom test for nicotine dependence (FTND) Readiness and Motivation to quit smoking (RQM) Additional questions on smoking history were also included	(OTI; Darke, Hall, Wodak, Heather, & Ward, 1992) (Carmody et al., 2012) (Carmody et al., 2012) (FTND; Heatherston, Kozlowski, Frecker, & Fagerstrom, 1991) (RQM; Crittenden et al., 1998)	Cigarettes per day was also included among the parameters included in the ASSIGN score. Seven-day point prevalence abstinence rate refers to the proportion who had been abstinent for the seven days preceding the follow-up assessment. This was verified using levels of expired CO, as measured by the Micro 11 Smokerlyser. Continuous abstinence rate refers to the proportion of participants who reported not smoking at all from the nominated quit date to the follow-up assessment. The Micro 11 Smokerlyser assesses breath levels of (CO). CO was measured one hour after participant arrival, to control partially for effects of travelling in traffic; a CO level of <10ppm signified that the participant was unlikely to have smoked in the last 8 hours. Smoking reduction status was based on an assessment of whether or not the participant had reduced their daily cigarette consumption by 50% or greater (including abstinence) relative to baseline. Motivation to quit smoking was measured using the 11-item RQM, which provides an elaborated stages of readiness scale, ranging from 0 (pre-contemplation level 1: not contemplating quitting or cutting down) to 4 (preparation stage).

Psychiatric symptomatology and quality of life	Diagnosis was determined using the MINI neuropsychiatric examination Brief Psychiatric Rating Scale (BPRS-24) Beck Depression Inventory (BDI-II) Global Assessment of Functioning (GAF) scale 12 item Short Form survey (SF-12) Recent hospital admissions	(Sheehan et al., 1998) (BPRS-24; Ventura, Nuechterlein, Subotnik, Gutkind, & Gilbert, 2000) (BDI-II; Beck, Steer, & Garbin, 1988) (GAF; American Psychiatric Association, 1994) (SF-12; Ware Jr, Kosinski, & Keller, 1996)	The SF-12 produces Mental Component Scores (MCS) and Physical Component Scores (PCS), with lower scores indicating greater disability. Number of hospital admissions in the past 12 months.
Health behaviours	International Physical Activity Questionnaire (IPAQ) Number of daily servings (of vegetables, fruit, or combined) Unhealthy eating index (Not used in current analysis)	(IPAQ; Craig et al., 2003)	Assessed overall activity level, including time spent walking and sitting (expressed as minutes per week). Physical activity level was assessed as average minutes walking continuously and briskly per week (based on diary entries). Diet and nutrition were assessed using 24 hour eating habits recall – see below for items covered. An overall unhealthy eating index was also created, with 1 point given for an answer to each question that indicated unhealthy eating habits. The index ranged from 0-12, with higher scores indicating more unhealthy eating habits. Unhealthy eating habits included: non-optimal servings per day of each of the five food groups (e.g., fruit, vegetables, breads, lean meats, and dairy); high fat or high sugar foods; choosing non-wholegrain products; consumption of full sugar soft drinks or cordials; missing breakfast; adding salt to food; using full fat dairy products; and consuming meat with visible fat.
Weight	Weight (Kg), Body Mass Index (BMI), Waist and hip circumference, & waist to hip ratio		Using Seca 770 digital scales.
	Impact of Weight On Quality Of Life (IWOQOL-lite) scale	(IWOQOL-lite; Abraham, 2003)	
Alcohol, cannabis and substance use	Opiate Treatment Index (OTI) Daily caffeine intake	(OTI; Darke, Hall, Wodak, Heather, & Ward, 1992)	Self-reported use of alcohol and cannabis in the previous 28 days were assessed using the Drug Use domain of the OTI. Alcohol consumption is reported as standard drinks per day. Participants were also asked to report their usual daily caffeine intake.

Table S3. Treatment Session Duration, Treatment Fidelity and Therapist Competence

Session	Measure	Healthy Lifestyle condition	Telephone condition
1	Overall duration (mins)	109.7 (35.6)	
	Discussion of CVD risk behaviours:		
	Diet (mins)	13.2 (8.5)	
	Exercise discussion (mins)	7.6 (5.1)	
	Smoking (mins)	36.9 (14.0)	
	Cognitive Therapy Scale:		
	Therapy adherence (%)	91.1 (<i>n</i> =31/34)	
2-17	Overall duration (mins)	59.6 (14.9)	16.7 (8.7)
			(Excl. Sess. 4 & 8): 13.2 (4.6)
			(Sess. 4 & 8): 28.9 (8.7)
	Discussion of CVD risk behaviours:		
	Diet (mins)	5.0 (6.71)	1.5 (0.9)
	Exercise discussion (mins)	3.7 (4.2)	1.0 (0.6)
	Smoking (mins)	24.2 (13.0)	4.8 (2.9)
	Cognitive Therapy Scale:		
	Therapy skills rating	3.71 (0.78)	-
	Therapy adherence (%)	89.4 (<i>n</i> =152/170)	93.3 (<i>n</i> = 126/135)

Note. Overall, 1271 sessions (56.3%) were recorded (Healthy Lifestyle condition = 65.1%; Telephone condition = 49.3%); technical problems (i.e., difficulties recording from the telephone) largely accounted for the differential rates across conditions. A randomly selected 25% representative subsample of the recorded sessions was included in the current evaluation (i.e., with proportionate coverage of treatment conditions and sessions). Therapy skills were rated on a six point scale (0-5): inadequate, mediocre, satisfactory, good, very good, and excellent.

Table S4. Baseline Biomedical Measures: Overall and by Treatment Condition

Measure	Overall (<i>n</i> = 235)	Healthy Lifestyle condition (<i>n</i> = 122)	Telephone condition (<i>n</i> = 113)	Condition comparison p-value
Body Mass Index (BMI)	30.6 (6.3)	30.5 (6.0)	30.6 (6.6)	.853
Waist circumference (cm)	104.61 (16.92)	104.82 (16.71)	104.38 (17.20)	.845
Weight (kg)	90.91 (20.83)	91.68 (21.40)	90.11 (20.28)	.570
Waist to hip ratio	0.95 (0.09)	0.95 (0.09)	0.95 (0.10)	.752
Diastolic blood pressure	80.54 (11.75)	80.97 (11.52)	80.06 (12.04)	.560
Systolic blood pressure	123.06 (16.09)	123.08 (14.32)	123.05 (17.85)	.989
HDL cholesterol	1.08 (0.77)	1.09 (0.97)	1.08 (0.49)	.957
LDL cholesterol	3.56 (1.26)	3.58 (1.23)	3.53 (1.29)	.770
Total cholesterol	5.00 (1.60)	4.85 (1.46)	5.15 (1.74)	.171
Blood glucose	5.55 (2.13)	5.18 (1.42)	5.94 (2.63)	.007

Note. HDL = High-density lipoprotein; LDL = Low-density lipoprotein.

Table S5. Mean Change from Baseline (99% CI) for Biomedical Measures by Intervention Condition

Measure	Follow-up time	Healthy Lifestyle condition		Telephone condition		Difference between groups	
		Mean change (99% CI)	p-value	Mean change (99% CI)	p-value	Least square mean difference (99% CI)	Group effect p-value
Body Mass Index (BMI)	15 weeks	0.4 (-0.3, 1.0)	.133	0.0 (-0.5, 0.6)	.948	-0.4 (-1.6, 0.8)	.379
	12 months	0.2 (-0.9, 1.2)	.688	-0.5 (-1.4, 0.3)	.102	-0.8 (-1.9, 0.4)	.077
Waist circumference (cm)	15 weeks	-0.4 (-2.6, 1.8)	.651	-0.6 (-2.4, 1.2)	.373	-0.6 (-4.2, 2.9)	.640
	12 months	-0.7 (-3.6, 2.3)	.556	-1.7 (-4.8, 1.5)	.161	-1.1 (-4.6, 2.4)	.411
Weight (kg)	15 weeks	0.6 (-0.8, 2.0)	.258	-0.1 (-1.8, 1.6)	.904	-1.9 (-4.9, 1.2)	.111
	12 months	-0.7 (-3.6, 2.3)	.556	-1.7 (-4.8, 1.5)	.161	-1.1 (-4.6, 2.4)	.411
Waist to hip ratio	15 weeks	0.00 (-0.02, 0.02)	.747	-0.01 (-0.04, 0.02)	.214	-0.0 (-0.1, 0.0)	.340
	12 months	0.00 (-0.02, 0.03)	.685	-0.01 (-0.04, 0.02)	.312	-0.0 (-0.1, 0.0)	.307
Diastolic blood pressure	15 weeks	-1.1 (-6.1, 3.8)	.555	1.9 (-1.5, 5.3)	.143	2.0 (-4.2, 8.1)	.401
	12 months	-0.3 (-4.9, 4.4)	.875	-0.7 (-5.8, 4.4)	.715	-0.6 (-6.7, 5.6)	.811
Systolic blood pressure	15 weeks	-5.0 (-11.0, 1.0)	.030	-0.9 (-6.0, 4.2)	.644	4.3 (-3.4, 12.1)	.145
	12 months	-1.4 (-6.8, 3.9)	.484	-1.7 (-8.2, 4.9)	.495	-0.2 (-7.9, 7.5)	.946
HDL cholesterol	15 weeks	0.3 (-0.6, 1.2)	.435	0.1 (-0.1, 0.4)	.145	0.3 (-0.1, 0.7)	.071
	12 months	0.1 (-0.2, 0.4)	.477	0.3 (-0.2, 0.7)	.110	0.3 (-0.1, 0.8)	.068
LDL cholesterol	15 weeks	-0.1 (-0.5, 0.3)	.428	0.0 (-0.3, 0.3)	.800	0.1 (-0.4, 0.6)	.530
	12 months	-0.1 (-0.6, 0.3)	.428	-0.4 (-0.8, 0.1)	.035	-0.2 (-0.7, 0.3)	.383
Total cholesterol	15 weeks	0.4 (0.1, 0.8)	.004	-0.1 (-0.6, 0.4)	.642	-0.1 (-0.8, 0.7)	.849
	12 months	0.1 (-0.5, 0.7)	.674	-0.4 (-1.4, 0.6)	.273	-0.3 (-1.1, 0.4)	.254
Blood glucose	15 weeks	0.6 (-0.1, 1.2)	.024	0.7 (-1.5, 2.9)	.399	1.3 (-1.4, 4.0)	.215
	12 months	0.9 (-0.1, 1.8)	.015	-0.9 (-1.9, 0.1)	.024	-0.6 (-3.4, 2.2)	.560

Note. HDL = High-density lipoprotein; LDL = Low-density lipoprotein; generalised linear mixed models were used to examine change over time and group effects, controlling for study site and baseline scores.

SUPPLEMENTARY ANALYSIS: Impact of baseline smoking stage of change on cigarette consumption changes

At baseline, approximately 15% (33/221) of participants fell into the “pre-contemplation” stage of change for quitting smoking, 56% (124/221) were at the “contemplation” stage, and 29% (64/221) were at the “preparation” stage (Crittenden et al., 1998). Because the interventions addressed multiple health behaviours and included motivational elements, participants at all stages of change for quitting smoking were included. To assess the impact of this decision, we conducted some supplementary analyses of changes in cigarette consumption, using the same predictors and covariates as in the main generalised linear mixed model analyses (see Table 2 and Table S5), but with the addition of baseline stage of change (0-2: pre-contemplation; 3: contemplation; 4: preparation) and its interaction with treatment condition.

There were no significant stage of change by treatment condition interactions in the analysis of smoking reductions at 15 weeks and 12 months. However, baseline stage of change did predict changes in cigarettes per day at 12 months ($F_{(2, 124)} = 5.02$, $p = .008$). Consequently, it is likely that the magnitude of the observed mean overall reduction at 12 months (of 8.6 cigarettes per day) would have been greater had those at earlier stages of change been excluded; for example, if the pre-contemplators were dropped from this analysis ($n = 18$), the mean reduction from baseline would have been larger by 1.1 cigarettes per day ($n = 115$). Conversely, from an intervention delivery perspective, these findings suggest that possibly we should have included a more formal and comprehensive motivational interviewing (MI) component in the current trial to more fully engage with participants at earlier stages of change.

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