Randomised controlled trial of a healthy lifestyle intervention among smokers with psychotic disorders: Outcomes to 36 months

Abstract

Objective: People living with psychotic disorders (schizophrenia spectrum and bipolar disorders) have high rates of cardiovascular disease (CVD) risk behaviours, including smoking, physical inactivity and poor diet. We report CVD risk, smoking cessation and other risk behaviour outcomes over 36-months following recruitment into a two-arm randomised controlled trial among smokers with psychotic disorders.

Methods: Participants ($N = 235$) drawn from three sites were randomised to receive nicotine replacement therapy (NRT) plus: (1) a Healthy Lifestyles intervention delivered over approximately 9 months; or (2) a largely telephone-delivered intervention (designed to control for NRT provision, session frequency, and other monitoring). The primary outcome variables were 10-year CVD risk and smoking status, while the secondary outcomes included weekly physical activity, unhealthy eating, waist circumference, psychiatric symptomatology, depression, and global functioning.

Results: Significant reductions in CVD risk and smoking were detected across the 36-month follow-up period in both intervention conditions, with no significant differences between conditions. One-quarter (25.5%) of participants reported reducing cigarettes per day by 50% or more at multiple post-treatment assessments; however, few (8.9%) managed to sustain this across the majority of timepoints. Changes in other health behaviours or lifestyle factors were modest; however, significant improvements in depression and global functioning were detected over time in both conditions. Participants experiencing worse 'social discomfort' at baseline (e.g., anxiety, mania, poor self-esteem, and social disability) had on average significantly worse global functioning, lower scores on the SF-12 physical scale, and significantly greater waist circumference.

Conclusion: Although the telephone-delivered intervention was designed as a comparison condition, it achieved excellent retention and comparable outcomes. Telephone-delivered smoking cessation support may potentially help to reduce smoking rates among people with psychotic disorders. Discomfort in social situations may also be a useful target for future health interventions, addressing confidence and social skills, and promoting social networks that reduce inactivity.

Keywords: smoking cessation; psychosis; cardiovascular disease; healthy lifestyle

Introduction

People living with psychotic disorders (schizophrenia spectrum and bipolar disorders) have a life expectancy approximately 20 years less than the general community and this gap is widening (Saha et al., 2007). Cardiovascular disease (CVD) is the largest single cause of death of people with psychotic disorders (Osby et al., 2001; von Hausswolff-Juhlin et al., 2009). In response to this disproportionately high illness burden, the first Australian National Report Card on Mental Health (National Mental Health Commission, 2012) stated that "the reduced life expectancies and ill health of people with the most severe mental illness … is a national disgrace and it should be a major public health concern" (P. 28). Similarly, the recent UK Schizophrenia Commission report (2012) described the poor physical health and neglect of healthcare among people with schizophrenia as "a civil rights issue" (P. 38).

Tobacco smoking is the leading preventable cause of death in people living with psychotic disorders (Callaghan et al., 2014). Smokers with severe mental ill-health are an increasing proportion of all smokers (Lasser et al., 2000), because smoking is not declining at the same rate relative to the general population, with 70% of people with schizophrenia and 61% of people with bipolar disorder being current smokers (Cook et al., 2014). Despite smoking cessation being associated with improved mental health (Taylor et al., 2014), better quality of life and greater longevity, the problem is often overlooked by health care providers, being seen as either too hard or a low priority (Kerr et al., 2013; McNally et al., 2006).

In addition to smoking, the most prevalent and preventable cardio-metabolic risk behaviours, affecting over 90% of people with psychotic illnesses (Morgan et al., 2012; Morgan et al., 2016), are low fruit and vegetable intake and high levels of inactivity. The high prevalence of these health behaviours in people with psychotic disorders has led to recommendations for a clear set of strategies to improve diet and reduce sedentary behaviour (National Mental Health Commission, 2012). As far as we are aware, no intervention research

has successfully targeted smokers, as well as their diet and sedentary behaviour, in combination, among people with psychotic illnesses despite these behaviours being so common.

To our knowledge, this is the first RCT among a sample of smokers with psychotic disorders to have evaluated the efficacy of a Healthy Lifestyles intervention. Results from a trial evaluating an intensive lifestyle coaching intervention among 428 clients with schizophrenia spectrum disorders and abdominal obesity have recently been reported (Speyer et al., 2016). However, in contrast to the present study, only half the sample reported daily smoking. Lifestyle coaching by physiotherapists, dietitians, or occupational therapists involved motivational interviewing and assertive community management, with weekly contacts (including home visits) for 12 months. Coaching occurred in conjunction with care coordination (psychiatric nurse facilitation with primary care) plus treatment as usual and was compared to care coordination plus treatment as usual or treatment as usual alone. There were no intervention effects on 10-year CVD risk, nor for any of the secondary outcome variables (e.g., cardio-respiratory fitness, physical activity, diet and smoking) (Speyer et al., 2016).

Previously we have reported on the design (Baker et al., 2011) and, in contrast to Speyer et al. (2016), positive outcomes to 12-months (Baker et al., 2015) of psychologist delivered interventions. Here we present the full set of outcomes to 36-months. All participants received a 90 minute initial face-to-face session followed by 16 further face-to-face sessions (the Healthy Lifestyles intervention) or 16 mostly telephone-delivered sessions (comparison condition), 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). We predicted that the Healthy Lifestyles intervention would produce greater improvement on two primary outcome variables: a CVD risk index and smoking status. Contrary to our prediction, at 15-weeks and

12-months there were significant improvements in CVD risk and smoking in both conditions, with no differences between conditions (Baker et al., 2015).

Secondary dependent variables included weight, physical activity, unhealthy eating, substance use, psychiatric symptomatology, treatment retention, and global functioning (Baker et al., 2015; Baker et al., 2011). While there were no significant improvements in health behaviours during the first 12 months, there were significant improvements in depression and global functioning across the sample as a whole (Baker et al., 2015). Among those who attended at least one session ($N = 211$), there was also 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 ($P < .001$) (Baker et al., 2015).

The excellent retention and positive outcomes seen in the largely telephone-delivered comparison condition following an initial 90 minute face-to-face session was intriguing, as engaging and retaining individuals with psychotic disorders in psychosocial treatments is difficult. We have also undertaken secondary data analyses, examining reasons for smoking (Clark et al., 2017) and associations between early therapeutic alliance, intervention retention and 12-month outcomes (Andrews et al., 2016); however, early therapeutic alliance did not predict treatment retention. Elements of both client- and therapist-rated alliance predicted some outcomes (e.g., higher confidence in the alliance at the initial session predicted improvements in 12-month depression) but not health behaviours. Some modest interactions were also detected between early alliance and intervention condition (e.g., clients initially with lower self-perceived initiative benefited preferentially from the telephone-delivered intervention), highlighting the need to further examine the interplay between treatment modality and client characteristics (Andrews et al., 2016), including possible provision of texted or other prompts as an aid to treatment engagement.

Study aims

As noted earlier, in developing this RCT, it was hypothesised that a more intensive face-to-face Healthy Lifestyles intervention would be differentially beneficial over the 36-month follow-up period (Baker et al., 2011). However, a failure to detect differential treatment effects during the first 12-months (i.e., 3 months after the intervention phase) (Baker et al., 2015) does not preclude the possibility that such differences might emerge subsequently; for example: consolidation of behavioural changes could be treatment condition or study engagement related; impacts on some outcomes may take longer to emerge (e.g., social functioning); and medium- to longer-term relapse trajectories might differ across conditions. On the other hand, as detailed below, it is also prudent to explore other possibilities (e.g., relationships between participant characteristics and treatment outcomes; and client-level improvement profiles).

An important recent finding has been that people with mental ill-health (other than psychotic disorders) have reported high levels of social anxiety in physical activity situations, potentially related to avoidance of physical activity, and contributing to worse health (De Herdt et al., 2013). Thus, given our failure to identify differences in health behaviour outcomes at 12-months by intervention condition (Baker et al., 2015) or therapeutic alliance (Andrews et al., 2016), we took the opportunity here to examine variability in selected post-treatment outcomes with respect to a composite social discomfort variable, for the first time among people with psychotic disorders, in addition to reporting outcomes to 36-months. It was anticipated that participants experiencing greater social discomfort at baseline would be less likely to benefit from either intervention condition, but potentially even more so in the Healthy Lifestyles condition, given the additional social interaction requirements (i.e., regular face-to-face contacts).

Methods

Study design

This was a conventional two-arm RCT (i.e., primary intervention condition hypothesized to be superior), registered with the Australian and New Zealand Clinical trials Registry (ACTRN12609001039279). The design, sample size estimates, and intervention content have been described elsewhere (Baker et al., 2011; Baker et al., 2015); and intervention manuals are available from the first author. Participants provided written informed consent and were assessed at baseline, 15 weeks (mid-intervention) and 12, 18, 24, 30, and 36 months after baseline. Recruitment occurred between July 2009 and April 2011 across three sites (Newcastle, Sydney and Melbourne, Australia). Ethics approval was obtained from each site.

All participants completed a baseline assessment and received an identical 90-minute face-to-face intervention session, after which they received up to 24 week's supply of NRT, delivered at weeks 1, 4 and 8, and thereafter by arrangement. 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 developed with the participant regarding CVD status and unhealthy behaviours, using a combination of motivational interviewing (MI) and cognitive behaviour therapy (CBT). Participants were randomised to receive NRT plus either: (i) a Healthy Lifestyles intervention aimed at CVD risk reduction and smoking cessation (comprising an additional 16 one-hour face-to-face counselling sessions delivered over 9 months); or (ii) a largely telephone-delivered intervention designed to control for administration of NRT, number of and interval between counselling sessions and monitoring of nicotine withdrawal, medication side-effects, distress, smoking, 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. Follow-up assessments were conducted by members of the research team who were blind to allocation condition. Participants were reimbursed $20 for their travel, time and participation on each assessment occasion.

Participants

Participants were 235 current smokers with a non-acute psychotic disorder; referral sources included: health services (148, 63%); media campaigns (59, 25%); and research programs or registers (28, 12%). Inclusion criteria were: a) aged at least 18 years; b) smoking at least 15 cigarettes per day; c) diagnosis of a schizophrenia spectrum or bipolar disorder, as confirmed by the Mini International Neuropsychiatric Interview (Sheehan et al., 1998); 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

Participants were stratified by study site, body mass index category (BMI, kg/m^2: healthy, 18.5 to <25; overweight, ≥ 25 to < 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. Study therapists were issued with a sealed randomisation envelope (by an independent person) displaying a participant identification code. The participant opened the envelope on conclusion of the initial intervention session. Sessions were conducted preferentially at the local research centre or a nearby community clinic.

Measures

Assessment instruments, which have been described previously (Baker et al., 2011; Baker et al., 2015), are listed in Supplementary Table S1 and are reported here only briefly. The two primary outcomes were: (i) overall 10-year CVD risk index (ASSIGN score; Woodward et al., 2007); and (ii) smoking status (e.g., confirmed 7-day point prevalence abstinence; 50% or greater reduction in cigarettes per day relative to baseline). Secondary outcome variables reported here include: weekly physical activity (walking time and sitting time) (IPAQ; Craig et al., 2003); overall diet score (unhealthy eating index, see Table S1); waist circumference; psychiatric symptomatology (BPRS-24; Ventura et al., 2000); depression (BDI-II; Beck et al., 1988); global functioning (GAF; American Psychiatric Association, 1994); and self-reported general health (SF-12; Ware et al., 1996). Biomedical measures were taken in order to derive the CVD risk score.

For the current analysis, a "social discomfort" score/category was derived for each participant using multiple observed baseline mental health symptoms, including: BPRS-24 (Ventura et al., 2000) symptom constructs potentially related to social impairment; the Rosenberg Self Esteem scale (GrayLittle et al., 1997); and a Social Disability Index score (Castle et al., 2006). Latent class analysis was used to identify underlying subgroups based on responses to these measures. The number of classes was determined by examining the Bayesian Information Criterion for up to 10 possible classes. A Rho prior of 1 was used to stabilise estimates. See Supplementary Tables S1 (measures included) and S4 (latent class probabilities) for further information about these analyses.

Healthy Lifestyles intervention

This intervention was designed to encourage smoking cessation and improvements in diet and physical activity, using a combination of motivational interviewing and cognitive behaviour

therapy (MI/CBT). In addition to smoking, the initial focus of treatment was based on the particular CVD risk factor(s) considered most problematic by the participant. Therapists integrated health messages and skill development about other CVD risk factors opportunistically; for example, mixing tobacco with cannabis would make cannabis use a high risk situation for smoking and best avoided whilst quitting tobacco. Self-help material was provided according to the CVD risk factors being discussed in each session. Following the initial common session across both conditions, the Healthy Lifestyles intervention comprised of 16 face-to-face one hour counselling sessions delivered over approximately 9 months. It was delivered by psychologists guided by an intervention manual. A further 7 weekly sessions were then offered (8 weekly sessions including session 1), after which participants received 3 fortnightly sessions and 6 monthly sessions. Session content has previously been described in detail (Baker et al., 2011) but incorporated: motivational techniques to increase readiness to change tobacco use, physical inactivity and poor dietary behaviours; cognitive behaviour strategies to build skills to make these changes; contingency reinforcement to support and encourage initiation and maintenance of change; NRT use and tapering; and relapse prevention. During each session, a range of monitoring activities also occurred, including review of medication side-effects, nicotine withdrawal, cigarettes per day, expired carbon monoxide (CO), NRT use, body weight, diet, and physical activity. Each component contained a range of strategies. Supplementary Table S2 provides an outline of the Healthy Lifestyles sessions.

Smoking cessation component. In addition to NRT provision, the 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. Despite a harm reduction focus, cessation as the ultimate goal was

encouraged for all participants, and a supportive follow-up telephone call was made 2-3 days following the initial quit attempt.

Contingency reinforcement component. 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 success. The contingency reinforcement schedule was based on a shaping model during weekly sessions. Components of this model included reimbursement contingent upon demonstrated reductions in expired CO, receipt of a bonus once the CO criterion for a given (set) number of consecutive weeks (e.g., three weeks in a row) was met, and an additional bonus every week for abstinence (≤10ppm expired CO). During the fortnightly and monthly sessions, reinforcement was contingent upon abstinence only.

Physical activity component. This component was integrated within the Healthy Lifestyles intervention. Specific strategies were introduced in session 4, with discussion of ways to increase levels of physical activity in everyday life and introduction of a graded walking program. Daily pedometer readings were incorporated into participant monitoring forms, and were also used to provide objective feedback to treating therapists about the extent of this activity in the day prior to each treatment session. If participants expressed a desire to work on their physical activity earlier than session 4, these strategies were brought forward, as required.

Dietary and nutrition component. This component emphasised increasing healthy food choices rather than an 'ideal' caloric intake. Healthy eating habits were initially discussed in session 7, with food planning and goal setting following in session 8. Participants were encouraged to eat a variety of foods, foods high in fibre and low in fat, to eat more servings of fruits and vegetables in a day and to drink plenty of water each day, eating regularly, and drinking alcohol within the recommended guidelines for Australia. Participants were

encouraged to consider issues that prevent them from making healthy choices (such as 'non-hungry eating', eating on a budget, cost effective meal plans and planning a shopping list). Finally, medication matters were addressed, including drug-nutrient interactions and tips for dealing with medication side-effects. As with physical activity, nutritional strategies were brought forward to earlier sessions if a participant wished to focus on these issues prior to session 7.

Monitoring. During each session, the following were assessed: cigarettes per day; side-effects from medication or nicotine withdrawal; weight; expired CO; NRT use over the past week; symptoms of psychosis and mood; diet; and average minutes walking continuously and briskly per week.

Booster sessions. Participants received six monthly booster sessions, focussing on relapse prevention, overcoming lapses, reviewing previous sessions, and NRT tapering.

Telephone-based intervention (comparison condition)

An individual 90 minute face-to-face session was delivered one week following baseline assessment, as described above. To control for the number of therapist contacts, manual guided telephone calls (around 10 minutes) were made at the same intervals as therapist visits for the Healthy Lifestyles condition (i.e., weekly for eight weeks, fortnightly for three sessions, followed by monthly calls for six months). Therapists monitored the following: cigarettes per day; side-effects from medication and nicotine withdrawal; NRT use over the past week; symptoms of psychosis and mood; diet; and average minutes walking continuously and briskly per week. In place of the phone-based sessions at weeks 4 and 8, participants attended face-to-face sessions of 30 minutes duration where NRT was dispensed, and where any problems with NRT or symptomatology were monitored. Biomedical measures (e.g.,

expired CO and weight) were also taken at these two sessions. Supplementary Table S3 provides an outline of the Telephone-based sessions.

Fidelity. As reported previously (Baker et al., 2015), session durations were generally consistent with session plans and therapy adherence rates averaged around 90%.

Statistical analyses

Data were analysed using SAS 9.2 (SAS Institute Inc., Cary, NC, USA). Change over time and group effects were examined using generalised linear mixed models to account for the repeated measurements on individuals, and were adjusted for potential differences across study site; for the continuous outcome measures, baseline scores were included in the linear mixed models as covariates. Outcome measures were analysed according to the intention-to-treat (ITT) principle, with study dropouts classified as non-abstinent/continuing smokers. The significance level was set at $P < 0.01$ to partially control for potential type 1 errors associated with multiple comparisons.

Confirmed point prevalence abstinence (at 7 days) was analysed as self-reported abstinence from smoking, confirmed by an expired CO reading of ≤10ppm (unless the participant indicated they had smoked cannabis in the past week). Smoking reduction status was determined by whether the participant reduced their daily number of cigarettes by 50% or more relative to baseline, with study dropouts regarded as not meeting this requirement. The primary CVD outcome (CVD risk calculated by the ASSIGN score) was also analysed as ITT, with study dropouts assigned as last observation carried forward. Secondary outcomes were analysed as complete case analysis.

Differences in treatment effects over time for the primary and secondary outcomes were also examined for a subgroup of participants with or without 'social discomfort'. Generalised linear mixed modelling (primary smoking outcomes) and linear mixed modelling

(cigarettes/day) were used to test the 3-way interaction for treatment by time by 'social discomfort' group for each outcome. The association between 'social discomfort' and the outcomes was also examined within the context of the original linear mixed models by adding this measure as a predictor.

To aid our overall evaluation of the relevance or meaningfulness of findings, we also conducted a descriptive analysis of client-level outcomes (ignoring treatment condition), focussing on improvements relative to baseline across the 12- to 36-months follow-up timepoints (i.e., beyond the 9 month intervention phase). As detailed in Supplementary Table S5, inclusion criteria and improvement thresholds were selected for identifying whether clients achieved a 'minimal clinically important difference' (MCID) for each outcome measure (cf., Andrews et al., 2016; Leucht et al., 2005), with evidence of clinical improvement at two or more follow-up phases viewed as the key MCID index.

Results

Participants

Baseline demographic characteristics are shown in Table 1. The majority of participants had a lifetime diagnosis of schizophrenia spectrum disorder (138, 59%), followed by bipolar disorder (52, 22%) and nonorganic psychosis (45, 19%). A total of 235 participants completed baseline surveys, were randomised and included in the analyses. Attrition profiles are reported in Figure 1. Follow-up surveys were completed at 15 weeks (165, 70.2%), 12 months (139, 59%), 18 months (132, 56.2%), 24 months (133, 56.6%), 30 months (129, 54.9%) and 36 months (134, 57%).

CVD risk and smoking

As detailed in Table 2, there were statistically significant reductions relative to baseline in 10-year CVD risk in both conditions, occurring at all timepoints for the Telephone condition and at the 15 week timepoint for the Healthy Lifestyles condition, with trends (P <0.05) at 12-months and 24-months. Table 3 shows that statistically significant reductions from baseline in daily cigarette consumption were reported at almost all timepoints, with no significant differences between treatment conditions over time. Table 3 also reports the rates of confirmed 7-day point prevalence abstinence from cigarettes (CO reading ≤ 10ppm), ranging from 6.2% to 12%, and the number of participants who had a 50% or greater reduction at each timepoint, ranging from 16% to 42% (mid-intervention). There were no significant differences between conditions on these measures.

Health behaviours

There were no statistically significant reductions relative to baseline on any of the lifestyle measures reported in Table 2, nor any significant between-group differences at any timepoint. However, total cholesterol, which contributes to CVD risk scores, was significantly lower in the Healthy Lifestyles condition at 30-months relative to baseline (mean change: -0.6; 99% CI: -1.2, -0.1; P = 0.004) and in the Telephone condition at 18-months (mean change: -0.8; 99% CI: -1.6, -0.1; P = 0.006) and 24-months (mean change: -0.69; 99% CI: -1.4, -0.1; P = 0.007).

Mental health symptoms and functioning

As detailed in Table 4, there were no significant between-group differences observed for any of the psychiatric symptomatology and quality of life measures at any timepoint. Psychiatric symptomatology (BPRS-24) was significantly lower in the Telephone condition at 12- and

36-months follow-up. Within the Healthy Lifestyles condition, depressive (BDI-II) symptoms significantly reduced from baseline levels at 12- and 24-months follow-up. Similarly, improvements in depression were detected in the Telephone condition, evident at 24-, 30- and 36-months follow-up. However, self-reported depression scores improved at trend levels (P <0.05) for most of the remaining timepoints in both conditions. Statistically significant improvements in GAF scores were observed from baseline for the Healthy Lifestyles condition up to the 18- to 24-month timepoints, and for the Telephone condition at most timepoints. SF-12 mental component scores were significantly higher (i.e., improved) for the Telephone condition at 36-months relative to baseline, and at trend levels at 30-months in the Healthy Lifestyles condition (see Table 4). Scores on the SF-12 physical scale were significantly improved for the Healthy Lifestyles condition at 30- and 36-months (relative to baseline), but this was not observed in the Telephone condition at any follow-up timepoint.

Social discomfort, mental health and lifestyle measures

We also examined treatment effect differences over time for several of the lifestyle and functioning outcomes by baseline 'social discomfort' status. As noted earlier, latent class analysis was used to examine a range of baseline symptom scores and diagnoses for underlying latent subgroups (or classes), and two 'social discomfort' classes were indicated (see Supplementary Table S4).

Participants were categorised into Class 1 ('social discomfort', 55.4%) or Class 2 (no or low 'social discomfort', 44.6%); members of Class 2 had high probabilities of having few symptoms at baseline across several domains, whereas members of Class 1 had high probabilities of reporting those symptoms. The effect of 'social discomfort' was examined for several outcome measures, including lifestyle factors (e.g., cigarettes per day, waist circumference, cholesterol), and functioning factors (e.g., SF-12 mental and physical

component scales). The interaction between baseline 'social discomfort' and treatment allocation over time was not statistically significant. However, people who were classified as experiencing 'social discomfort' (Class 1) had, on average, significantly lower scores (i.e., poorer functioning) than did their Class 2 counterparts on the GAF (mean difference: -4.1; 99% CI: -6.7, -1.5; $P = 0.002$), and the SF-12 physical scale (mean difference: -3.3; 99% CI: -5.3, -1.3; $P = 0.001$). In addition, Class 1 participants reported a 3.5cm greater waist measurement (99% CI: 1.6, 5.5; $P < 0.001$), than did those in Class 2.

Client-level outcomes

Based on our MCID analysis (see Table S5), 40.9% of participants (96/235) reported a 50% or greater reduction in cigarettes per day for at least one of the 12- to 36-months follow-up assessments, with relatively few achieving a sustained 50% reduction (4-5 timepoints: 21, 8.9%). There was evidence of such reductions in smoking at two or more follow-up phases (our key MCID index) for one-quarter of participants (60/235, 25.5%) [or one-third of those (60/180, 33.3%) with at least one follow-up]. Comparable client-level improvement profiles were found for several outcome measures: sitting time (24.6%); overall diet score (24.4%); psychiatric symptomatology (BPRS-24, 24.8%; GAF, 24.3%); and SF-12 mental component scores (22.1%). Higher rates of client-level improvement were found for depression (BDI-II, 47.%), walking time (32.0%) and 10-year CVD risk (31.0%), while the lowest MCID improvement rates were observed for waist circumference (18.2%) and SF-12 physical component scores (16.2%). Two-thirds of participants (151/235, 64.3%) experienced MCID improvement on *any* of these measures at multiple follow-up phases, with a sustained (albeit mixed) benefit detected for a sizeable minority (4-5 timepoints: 97, 41.3%; see Table S5). The mean number of measures (out of 11) with MCID improvement at two or more follow-up phases was 2.26 (SD = 2.39).

Discussion

This study was the first to examine a multi-component lifestyle intervention among people with psychotic disorders, and to report outcomes over 36 months. An intensive face-to-face Healthy Lifestyles intervention and a mostly telephone-delivered comparison condition were both associated with reductions in 10-year CVD risk and smoking. Contrary to our hypotheses, there were no between-group differences in the level of improvement in CVD risk or smoking-related outcomes at any timepoint. A recent Danish trial evaluating lifestyle coaching within a comparable population also failed to find differential treatment effects in terms of 10-year CVD risk, smoking, diet or physical health (Speyer et al., 2016). However, in the current study both the Healthy Lifestyles and Telephone conditions were associated with significant reductions in CVD risk (most strongly during the intervention phase) and in smoking over the 36 months of follow-up. This suggests that a largely telephone-delivered intervention for smoking and monitoring of related health behaviours, accompanied by NRT, was as effective in the longer-term as an ongoing face-to-face intensive lifestyle intervention among people with psychotic disorders.

Last year the Royal Australian and New Zealand College of Psychiatrists produced a comprehensive set of practice guidelines (updating the 2005 version) for the clinical management of schizophrenia and related disorders (Galletly et al., 2016). Within the framework of a clinical staging model, 173 recommendations were made, with 54% categorised by the level of available evidence and 46% as consensus-based recommendations. Lifestyle interventions and support were recommended (e.g., smoking cessation, diet and exercise programs) to improve physical health and wellbeing, reduce weight gain associated with antipsychotic medication use, and promote social engagement. Hopefully, findings from studies like the current one can add to the evidence-base underlying such practice guidelines.

Haddock and colleagues (2017) have recently explored service user modality preferences and outcomes of delivering CBT for psychosis. Options examined were: randomisation; treatment as usual; treatment as usual plus telephone-delivered CBT; or treatment as usual plus telephone-delivered CBT plus group sessions. Of 89 people, the option with the highest endorsement was treatment as usual plus telephone-delivered CBT (34/89), followed by treatment as usual alone (32/89), and then treatment as usual plus telephone-delivered CBT plus group sessions (23/89). Consequently, further studies of telephone-delivered interventions for smoking and broader health behaviour change among people living with severe mental ill-health appear warranted.

Despite significant reductions in CVD risk and smoking across both conditions in the present study, the majority (59.1%) never achieved a 50% or greater reduction in smoking at any post-treatment timepoint. We have previously reported that a 50% reduction in cigarette use between baseline and 12-month follow-up in people with psychotic disorders is sustainable at 4 years, can lead to longer-term abstinence (Baker et al., 2010), and is associated with concomitant health benefits (e.g., Baker et al., 2010; Baker et al., 2015). Furthermore, there was marked variability, with participants reporting abstinence at some timepoints but not others. Although many smokers in the current study made multiple quit attempts, few were able to sustain complete abstinence over the longer-term, suggesting that, where possible, cessation interventions in this population should be actively provided until abstinence is achieved. Ongoing smoking cessation treatment (and maintenance support) should then be routinely available to people with psychotic disorders, with flexibility to allow continued sessions in the event of relapse, or as motivation waxes and wanes. Telephone-based support shows promise, given its acceptability and efficacy in the current study, and its potential for a lower cost method of providing ongoing support for smoking cessation to people with psychosis. ‘Quitline’ workers (who provide smoking cessation support via

telephone to members of the general population) may be trained in this area of smoking cessation counselling to facilitate this, as preliminary evaluation indicates this is a feasible option (Segan et al., 2017). In addition, for smokers with severe mental illness who are unable to quit, electronic cigarettes are worthy of further investigation. They may appeal to heavily dependent smokers because they deliver a nicotine-containing vapor that is inhaled like a cigarette, with some devices resulting in rapid pulmonary absorption similar to a cigarette (Benowitz et al., 2017). The UK Royal College of Physicians has concluded that e-cigarettes could markedly reduce harm from smoking and has proposed that they be considered as part of tobacco control policy (Britton et al., 2016).

With regards to dietary improvements, Healthy Lifestyles condition participants were able to choose any dietary goals they wished. On reflection, it may have been better to provide some concrete goals and instructions regarding specific dietary changes they could make. For example, since conducting this large RCT, we have completed a small pilot of a telephone-delivered intervention which was associated with significant increases in fruit and vegetable consumption and a reduction in leisure screen time (Baker et al., 2014). These behaviours were the specific targets of the telephone-intervention in the pilot trial, given evidence that inadequate fruit and vegetable consumption and high levels of sedentary activity are almost universal among people with severe mental ill health (Morgan et al., 2012; Morgan et al., 2016). Thus, future studies might specifically target smoking, fruit and vegetable consumption and leisure screen time as key treatment targets in people with psychotic disorders, perhaps in conjunction with other goals, such as engagement in pleasant activities and additional dietary changes (e.g., less soft drink).

Global functioning significantly improved for participants as a whole, for both the Healthy Lifestyles and Telephone conditions. Most of this improvement occurred during the first two years, possibly reflecting the higher intensity of contact during year 1. Given that

many study participants were socially isolated, it is possible that the increased social support provided by our interventions had an overall beneficial effect on functioning. Improvements in depression were the most persistent, both in the aggregate analyses (Table 4) and in the client-level descriptive analysis (Table S5).

Related to social isolation, an important new finding was that participants who were classed as experiencing 'social discomfort' (i.e., a combination of social isolation, social difficulties, and social avoidance) were less physically healthy, as well as reporting significantly lower scores on the GAF and the SF-12 physical scale. Importantly, they reported significantly larger waist circumference measurements than did people without 'social discomfort'; waist circumference is a known risk factor for CVD (Janssen et al., 2002). This finding has potentially important implications for the development of interventions to improve physical health, suggesting that some of the baseline 'social discomfort' elements (e.g., anxiety, mania, poor self-esteem, social disability, suspicion) need due consideration in treatment planning for individuals with severe mental ill-health. Relevant interventions might involve enhancing confidence and skills in social situations, and building social networks to reduce inactivity, increase physical activity and improve diet. Social isolation can be associated with eating comfort foods and this aspect of diet may also need to be specifically addressed.

As noted in our 12-month outcomes paper (Baker et al., 2015), there are several study limitations, which include: the age related CVD risk score used, so that younger people may not score highly at baseline; participants were not selected on health behaviours or risk factors other than smoking, making comparisons difficult; smokers at all stages of change were selected, making specific comparisons more difficult with other studies which have recruited participants high on motivation to quit; and the longer-term follow-up rates of around 60%, which is lower than we have achieved in other studies among people with severe mental ill-

health at 12-months (Baker et al., 2006). However, this was a large sample and the first RCT to investigate the longer-term efficacy of a Healthy Lifestyles intervention for smoking and CVD risk behaviours among people with psychotic disorders. Moreover, based on our client-level MCID analysis (see Table S5), the majority of participants (64.3%) experienced clinical improvement (on *any* of the measures) at multiple follow-up phases. However, we did not directly examine individual's perceptions of these benefits or undertake other qualitative assessments.

Conclusion

Face-to-face Healthy Lifestyles and largely telephone-delivered interventions for smoking among people with severe mental ill-health are feasible and appear equally effective in encouraging reductions in 10-year CVD risk and smoking-related behaviours over three years. The variability in quit attempts over the three-year period indicates that smoking cessation support should be accessible over the longer-term, and at least continue actively until abstinence is achieved. The effectiveness of the Telephone condition suggests that smoking support telephone lines for the general population (e.g., Quitlines) could consider training their available workforce to support smoking cessation in people with psychosis. Social discomfort or dysfunction at baseline, marked by worse symptom scores (anxiety, mania, and suspicion), low self-esteem, and social disability was associated with worse physical functioning and is a likely target of future interventions among this group to improve physical health outcomes. To enhance the sustainability of any benefits arising from lifestyle interventions, where possible, such programs need to simultaneously address some of the broader determinants of health, such as financial and housing instability, social engagement, employment, stigma, and social exclusion (Morgan et al., 2016; Suetani et al., 2017).

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Declaration of Conflicting Interests

The authors declare no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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Table 1. Baseline demographic characteristics.

	Treatment condition	
Baseline characteristic	Healthy Lifestyles (*N* = 122)	Telephone (*N* = 113)
Demographic characteristics (*N*, %)		
Age (mean, SD)	40.6 (10.8)	42.7 (11.2)
Sex (Male)	71 (58%)	67 (59%)
Single, Never married	82 (68%)	75 (67%)
Aboriginal or Torres Strait Islander	3 (2.5%)	3 (2.7%)
Born in Australia	103 (84%)	94 (84%)
Finished secondary school	49 (40%)	41 (37%)
Currently employed	24 (21%)	17 (17%)
Receiving welfare support	110 (90%)	108 (96%)
Psychiatric symptomatology and quality of life (Mean, SD)		
Brief Psychiatric Rating Scale (BPRS-24)	42.5 (12.9)	42.7 (12.9)
Beck Depression Inventory – II (BDI-II)	17.7 (13.0)	17.0 (12.6)
Global Assessment of Functioning (GAF)	51.6 (10.9)	50.6 (10.7)
SF-12 Mental Component Scale (MCS)	46.8 (8.1)	47.2 (8.8)
SF-12 Physical Component Scale (PCS)	45.8 (7.8)	45.1 (8.4)
Smoking		
Cigarettes per day	29.9 (17.9)	27.2 (11.8)
Health behaviours (Mean, SD)		
10-year CVD risk	6.6 (8.7)	8.0 (12.6)
Walking time (minutes per week)	231 (374)	232 (414)
Sitting time (minutes per week)	2855 (1646)	2965 (1768)
Overall diet score (unhealthy eating index)	5.9 (1.6)	5.9 (1.8)
Selected biomedical measures (Mean, SD)		
Waist circumference (centimetres)	104.8 (16.7)	104.4 (17.2)
Weight (kilograms)	91.7 (21.4)	90.1 (20.3)
Body Mass Index (BMI)	30.5 (6.0)	30.6 (6.6)
Total cholesterol	4.9 (1.5)	5.2 (1.7)

Table 2. Mean change from baseline (99% CI) for CVD risk and lifestyle outcomes by treatment condition, and differences between conditions at each follow-up time-point (adjusted for site).

Measure	Follow-up time	Treatment condition: Healthy Lifestyles Mean change (99% CI)	*P*	Treatment condition: Telephone Mean change (99% CI)	*P*	Difference between groups: Least square mean difference (99% CI)	Difference between groups: Group effect *P*-value
10-year CVD risk	15 weeks	-1.2 (-2.3, -0.2)	0.002	-2.0 (-3.6, -0.5)	<0.001	-0.4 (-1.9, 1.2)	0.554
	12 months	-1.2 (-2.4, 0.1)	0.014	-1.9 (-3.4, -0.3)	0.003	-0.2 (-1.8, 1.3)	0.686
	18 months	-0.9 (-2.2, 0.4)	0.070	-2.2 (-3.9, -0.5)	<0.001	-0.9 (-2.4, 0.7)	0.149
	24 months	-1.1 (-2.4, 0.2)	0.029	-1.9 (-3.5, -0.4)	0.002	-0.4 (-2.0, 1.1)	0.488
	30 months	-0.7 (-2.0, 0.7)	0.180	-1.6 (-3.2, 0.0)	0.010	-0.5 (-2.1, 1.1)	0.411
	36 months	-0.9 (-2.1, 0.4)	0.070	-1.4 (-2.8, -0.1)	0.007	-0.1 (-1.7, 1.5)	0.855
Walking time (minutes per week)	15 weeks	39.61 (-173.2, 252.4)	0.624	-10.1 (-159.3, 139.2)	0.860	-71.0 (-221.2, 79.2)	0.223
	12 months	100.5 (-111.7, 312.8)	0.213	-41.1 (-179.3, 97.1)	0.433	-148.6 (-314.4, 17.3)	0.021
	18 months	-60.8 (-236.3, 114.6)	0.360	15.5 (-90.6, 121.6)	0.699	52.2 (-121.5, 225.8)	0.438
	24 months	72.1 (-95.4, 239.6)	0.257	75.5 (-21.6, 172.7)	0.043	-26.7 (-199.7, 146.3)	0.690
	30 months	-23.2 (-160.8, 114.5)	0.655	-33.3 (-176.5, 109.9)	0.538	-7.4 (-183.6, 168.7)	0.913
	36 months	-48.8 (-222.8, 125.3)	0.459	13.7 (-161.4, 188.8)	0.836	46.3 (-120.4, 212.9)	0.473
Sitting time (minutes per week)	15 weeks	-294.4 (-842.9, 254.2)	0.160	-62.0 (-576.9, 452.9)	0.752	278.4 (-338.7, 895.4)	0.244
	12 months	-18.7 (-629.0, 591.7)	0.936	-216.3 (-781.2, 348.7)	0.313	-49.4 (-712.9, 614.1)	0.847
	18 months	417.4 (-186.7, 1021.5)	0.071	175.8 (-478.4, 830.1)	0.477	126.7 (-568.8, 822.2)	0.638
	24 months	-16.1 (-645.2, 613.0)	0.946	122.6 (-547.6, 792.8)	0.627	202.3 (-498.3, 902.8)	0.456
	30 months	405.6 (-353.8, 1165.0)	0.160	281.9 (-307.7, 871.5)	0.209	-147.8 (-841.2, 545.5)	0.582
	36 months	549.1 (-150.6, 1248.7)	0.041	-61.8 (-803.0, 679.4)	0.826	-312.0 (-977.9, 353.9)	0.226
Overall diet score	15 weeks	-0.1 (-0.8, 0.5)	0.645	-0.2 (-0.7, 0.4)	0.380	-0.0 (-0.7, 0.7)	0.960
	12 months	-0.3 (-1.0, 0.3)	0.190	-0.1 (-0.7, 0.5)	0.571	0.1 (-0.7, 0.8)	0.814
	18 months	-0.6 (-1.2, 0.1)	0.021	-0.5 (-1.2, 0.3)	0.105	-0.1 (-0.8, 0.7)	0.864
	24 months	-0.4 (-1.0, 0.2)	0.100	0.3 (-0.5, 1.0)	0.345	0.6 (-0.2, 1.3)	0.049
	30 months	-0.4 (-1.1, 0.3)	0.108	0.1 (-0.7, 0.9)	0.836	0.4 (-0.3, 1.2)	0.144
	36 months	0.0 (-0.6, 0.6)	1.000	-0.4 (-1.1, 0.3)	0.109	-0.5 (-1.2, 0.3)	0.101
Waist circumference (cm)	15 weeks	-0.4 (-2.6, 1.9)	0.651	-0.6 (-2.4, 1.2)	0.373	-0.3 (-3.6, 2.9)	0.783
	12 months	-0.8 (-3.8, 2.2)	0.498	-1.5 (-4.7, 1.6)	0.192	-0.9 (-4.5, 2.8)	0.540
	18 months	-0.7 (-3.8, 2.4)	0.557	0.4 (-2.6, 3.4)	0.744	-0.1 (-3.8, 3.5)	0.923
	24 months	1.1 (-2.1, 4.3)	0.359	-0.3 (-3.4, 2.8)	0.813	-1.6 (-5.3, 2.1)	0.267
	30 months	0.7 (-3.1, 4.4)	0.635	0.1 (-3.0, 3.3)	0.911	-0.6 (-4.3, 3.1)	0.675
	36 months	-0.8 (-4.6, 2.9)	0.553	0.7 (-2.9, 4.2)	0.618	0.9 (-2.8, 4.6)	0.531

Table 3. Smoking outcomes at each follow-up timepoint by treatment condition (adjusted for site).

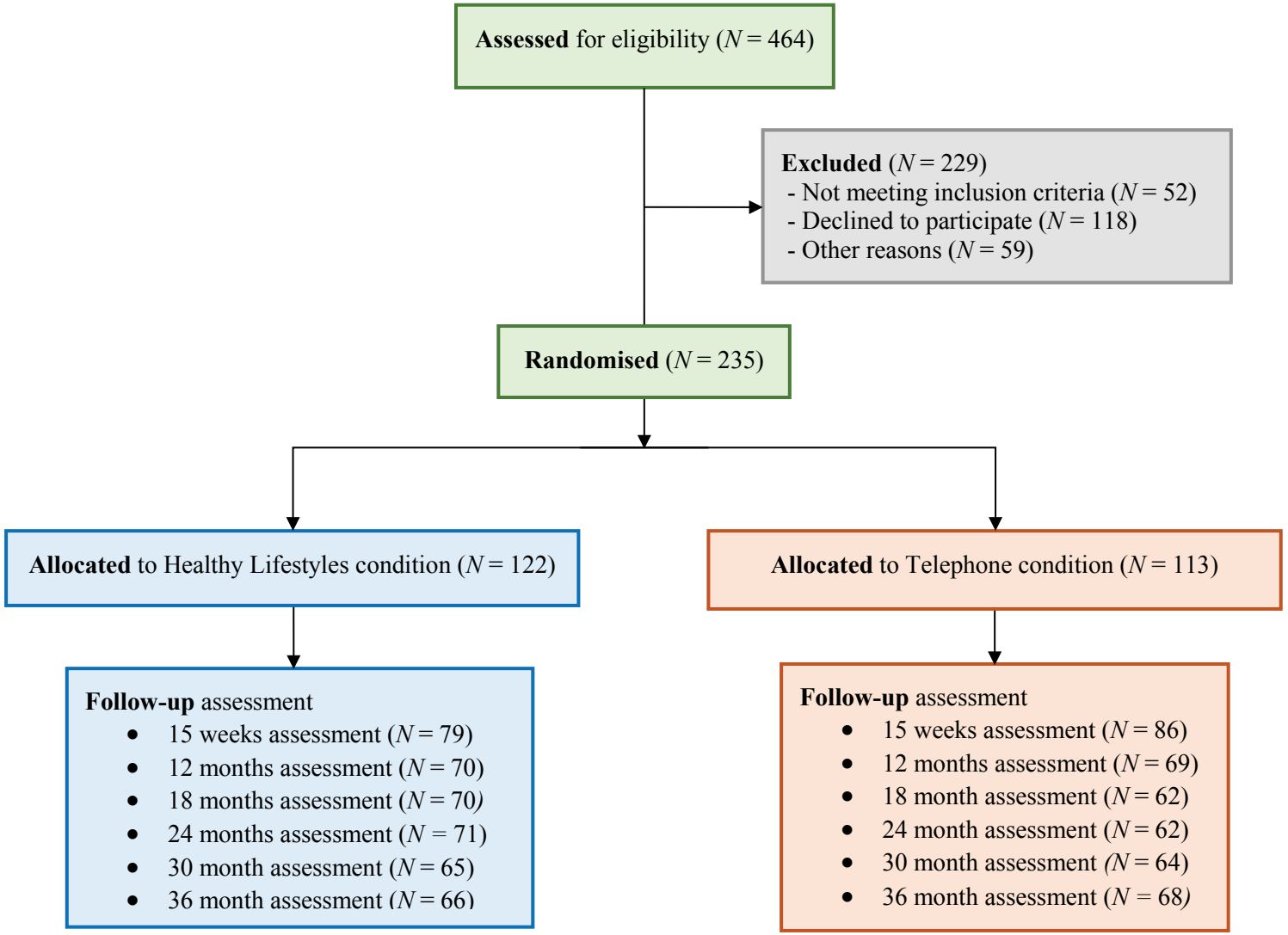
Measure	Follow-up time	Treatment condition		Group ratio /Difference between groups	
		Healthy Lifestyles	Telephone	Odds ratio (99% CI)	Group effect *P*-value
Confirmed point prevalence abstinence	15 weeks	13 (11%)	13 (12%)	0.90 (0.31, 2.66)	0.805
	12 months	8 (6.6%)	7 (6.2%)	1.05 (0.26, 4.22)	0.921
	18 months	11 (9.0%)	9 (8.0%)	1.13 (0.33, 3.83)	0.792
	24 months	11 (9.0%)	9 (8.0%)	1.13 (0.33, 3.83)	0.792
	30 months	13 (11%)	14 (12%)	0.83 (0.29, 2.40)	0.646
	36 months	13 (11%)	9 (8.0%)	1.36 (0.42, 4.44)	0.497
Cigarettes reduced by 50% or greater relative to baseline	15 weeks	38 (31%)	47 (42%)	0.64 (0.31, 1.31)	0.107
	12 months	19 (16%)	21 (19%)	0.81 (0.33, 2.01)	0.553
	18 months	20 (16%)	22 (19%)	0.81 (0.33, 1.99)	0.553
	24 months	19 (16%)	18 (16%)	0.98 (0.38, 2.49)	0.951
	30 months	24 (20%)	27 (24%)	0.78 (0.34, 1.80)	0.449
	36 months	27 (22%)	26 (23%)	0.96 (0.42, 2.16)	0.889
				Least square mean difference (99% CI)	Group effect *P*-value
Cigarettes per day - mean change from baseline (99% CI)	15 weeks	-14.8 (-21.4, -8.2)**	-13.7 (-17.1, -10.3)**	-2.4 (-8.0, 3.3)	0.286
	12 months	-8.4 (-12.7, -4.1)**	-8.8 (-13.1, -4.6)**	-2.2 (-8.5, 4.1)	0.368
	18 months	-7.5 (-11.5, -3.4)**	-6.7 (-14.3, 0.8)	-0.7 (-6.9, 5.5)	0.776
	24 months	-8.4 (-14.7, -2.1)**	-7.8 (-11.9, -3.8)**	-3.2 (-9.4, 3.1)	0.192
	30 months	-10.5 (-17.7, -3.3)**	-10.8 (-15.3, -6.3)**	-3.5 (-9.9, 2.8)	0.149
	36 months	-9.7 (-17.1, -2.4)**	-7.9 (-13.7, -2.2)**	0.3 (-5.9, 6.5)	0.899

**$P < 0.001$ from baseline

Table 4. Mean change from baseline (99% CI) for psychiatric symptomatology and quality of life outcomes by treatment condition, and differences between conditions at each follow-up timepoint (adjusted for site).

Measure	Follow-up time	Treatment condition: Healthy Lifestyles		Treatment condition: Telephone		Difference between groups	
		Mean change (99% CI)	*P*	Mean change (99% CI)	*P*	Least square mean difference (99% CI)	Group effect *P*-value
Brief Psychiatric Rating Scale (BPRS-24)	15 weeks	0.6 (-2.6, 3.7)	0.632	-2.3 (-5.0, 0.5)	0.032	-1.9 (-5.8, 2.0)	0.210
	12 months	-0.5 (-4.5, 3.5)	0.758	-5.0 (-9.1, -0.9)	0.002	-2.7 (-7.1, 1.7)	0.119
	18 months	1.0 (-2.5, 4.6)	0.442	-2.0 (-6.5, 2.5)	0.238	-1.7 (-6.1, 2.7)	0.322
	24 months	-0.7 (-4.9, 3.6)	0.687	-3.0 (-6.7, 0.7)	0.037	-1.2 (-5.6, 3.1)	0.460
	30 months	-2.4 (-6.9, 2.1)	0.164	-2.5 (-6.4, 1.5)	0.103	0.7 (-3.7, 5.0)	0.696
	36 months	0.4 (-4.1, 5.0)	0.794	-4.9 (-8.4, -1.5)	<0.001	-4.1 (-8.4, 0.1)	0.011
Beck Depression Inventory – II (BDI-II)	15 weeks	-3.0 (-7.0, 0.9)	0.046	-2.9 (-6.0, 0.3)	0.018	0.0 (-3.9, 3.8)	0.981
	12 months	-3.5 (-6.8, -0.2)	0.006	-3.9 (-8.1, 0.2)	0.014	-0.4 (-4.7, 3.9)	0.807
	18 months	-2.0 (-5.7, 1.7)	0.154	-3.2 (-7.0, 0.5)	0.025	-1.4 (-5.9, 3.1)	0.424
	24 months	-4.0 (-7.4, -0.6)	0.003	-3.8 (-7.5, -0.1)	0.008	0.2 (-4.2, 4.6)	0.892
	30 months	-4.0 (-8.2, 0.2)	0.014	-4.3 (-7.6, -0.9)	0.001	-0.1 (-4.5, 4.4)	0.975
	36 months	-2.8 (-6.1, 0.5)	0.028	-6.7 (-9.8, -3.5)	<0.001	-3.4 (-7.6, 0.9)	0.040
Global Assessment of Functioning (GAF)	15 weeks	3.9 (0.6, 7.1)	0.002	5.3 (1.6, 9.1)	<0.001	2.0 (-2.9, 6.9)	0.284
	12 months	7.8 (4.2, 11.3)	<0.001	7.5 (2.7, 12.2)	<0.001	1.1 (-4.3, 6.4)	0.603
	18 months	5.7 (1.9, 9.5)	<0.001	6.3 (1.7, 10.9)	<0.001	-0.1 (-5.6, 5.3)	0.953
	24 months	4.3 (-0.6, 9.1)	0.023	6.9 (2.9, 10.9)	<0.001	1.6 (-3.8, 7.0)	0.436
	30 months	3.9 (-1.6, 9.3)	0.063	4.1 (-0.2, 8.5)	0.015	0.9 (-4.6, 6.3)	0.684
	36 months	-1.1 (-5.7, 3.6)	0.539	0.6 (-4.2, 5.4)	0.728	1.9 (-3.4, 7.2)	0.359
SF-12 Mental Component Scale (MCS)	15 weeks	0.7 (-3.2, 4.6)	0.625	1.4 (-2.2, 5.1)	0.308	1.2 (-3.4, 5.8)	0.496
	12 months	1.9 (-1.9, 5.7)	0.182	2.3 (-2.6, 7.1)	0.217	0.6 (-4.6, 5.8)	0.756
	18 months	0.5 (-4.2, 5.1)	0.798	1.6 (-3.1, 6.3)	0.368	1.7 (-3.8, 7.1)	0.429
	24 months	2.9 (-1.7, 7.5)	0.098	3.3 (-0.9, 7.4)	0.040	0.1 (-5.0, 5.1)	0.973
	30 months	4.6 (-0.3, 9.5)	0.015	1.5 (-3.1, 6.1)	0.388	-2.5 (-7.5, 2.6)	0.211
	36 months	3.5 (-1.2, 8.3)	0.051	4.2 (0.3, 8.1)	0.006	0.2 (-4.7, 5.1)	0.916
SF-12 Physical Component Scale (PCS)	15 weeks	0.2 (-2.6, 3.0)	0.866	1.6 (-1.2, 4.4)	0.136	1.0 (-2.8, 4.9)	0.480
	12 months	0.6 (-3.5, 4.8)	0.675	1.4 (-2.6, 5.4)	0.356	0.6 (-3.7, 5.0)	0.700
	18 months	-0.9 (-3.9, 2.2)	0.445	-0.5 (-5.3, 4.3)	0.786	0.5 (-4.0, 5.1)	0.756
	24 months	3.0 (-0.6, 6.6)	0.030	2.0 (-2.5, 6.5)	0.238	-1.3 (-5.6, 2.9)	0.410
	30 months	2.9 (-0.0, 5.7)	0.010	-0.7 (-5.0, 3.7)	0.681	-3.3 (-7.5, 1.0)	0.048
	36 months	3.7 (0.1, 7.3)	0.009	2.6 (-1.9, 7.1)	0.129	-0.9 (-5.0, 3.2)	0.578

Figure 1. Recruitment and attrition profiles for the Healthy Lifestyles project (CONSORT diagram).



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Supplementary Table S1. Assessment measures by domain type across the baseline, 15 weeks, 12-, 18-, 24-, 30-, and 36-month assessments.

Domain	Measures	Reference(s)	Selected scoring or other details
Cardiovascular Disease (CVD) risk (10-year 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**)	(ASSIGN score; Woodward et al., 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. Blood pressure was assessed using an 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	(OTI; Darke et al., 1992)	Using direct questioning about quantity and frequency, and the Opiate Treatment Index (OTI)
	Confirmed 7-day point prevalence abstinence (**Primary Outcome**)	(Carmody et al., 2012)	Seven-day point prevalence abstinence rate refers to the proportion who had been abstinent for the seven days preceding the follow-up assessment. 'Abstinence' was confirmed using breathe levels of expired carbon monoxide (CO), as measured by the Micro 11 Smokerlyser. 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.
	Continuous abstinence		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.
	Smoking reduction status	(Carmody et al., 2012)	Smoking reduction status was based on an assessment of whether or not the participant had reduced their daily consumption of cigarettes by 50% or greater (including abstinence) relative to baseline.
	Fagerstrom test for nicotine dependence (FTND) (*Not used in current analysis*)	(FTND; Heatherton et al., 1991)	
	Readiness and Motivation to quit smoking (RQM) (*Not used in current analysis*)	(RQM; Crittenden et al., 1998)	
	Additional questions on smoking history		
Psychiatric symptomatology and quality of life	Diagnosis was determined using the MINI neuropsychiatric examination	(Sheehan et al., 1998)	
	Brief Psychiatric Rating Scale (BPRS-24)	(BPRS-24; Ventura et al., 2000)	Higher scores indicate more symptoms (clinician/interviewer rated).
	Beck Depression Inventory (BDI-II)	(BDI-II; Beck et al., 1988)	Higher scores indicate greater depression (self-reported).

Domain	Measures	Reference(s)	Selected scoring or other details
	Global Assessment of Functioning (GAF) scale	(GAF; American Psychiatric Association, 1994)	Higher scores indicate better functioning (clinician/interviewer rated).
	12 item Short Form survey (SF-12)	(SF-12; Ware et al., 1996)	The SF-12 produces Mental Component Scores (MCS) and Physical Component Scores (PCS), with lower scores indicating greater disability.
	Recent hospital admissions (*Not used in current analysis*)		Number of hospital admissions in the past 12 months.
	Impact of Weight On Quality Of Life (IWOQOL-lite) scale (*Not used in current analysis*)	(IWOQOL-lite; Abraham, 2003)	
Health behaviours	International Physical Activity Questionnaire (IPAQ) - walking time - sitting time	(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).
	Number of daily servings (of vegetable, fruit, or combined) (*Not used in current analysis*)		Diet and nutrition were assessed using 24 hour eating habits recall – see below for items covered.
	Overall diet score - Unhealthy eating index		An overall unhealthy eating index was 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.
Selected biomedical measures	Weight (Kg), Body Mass Index (BMI), Waist and hip circumference (cm), and waist to hip ratio	(Janssen et al., 2002)	Using Seca 770 digital scales. Waist circumference (in centimetres) was the main measure.
Alcohol, cannabis and substance use	Opiate Treatment Index (OTI) Daily caffeine intake (*Not used in current analysis*)	(OTI; Darke et al., 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 expressed as standard drinks per day. Participants were also asked to report their usual daily caffeine intake.
Other measures	"Social discomfort" score/category	See Supplementary Table S4 for further details about the latent class analysis.	Latent class analysis was used to derive a baseline "social discomfort" score/category for each participant. Variables used in this analysis included: BPRS-24 (Ventura et al., 2000) symptom constructs potentially related to social impairment (anxiety, elevated mood, grandiosity, suspiciousness, uncooperativeness, excitement, motor hyperactivity); the Rosenberg Self Esteem scale (GrayLittle et al., 1997); and a Social Disability Index score (derived from self-reported difficulties in interpersonal relationships, overall socialising, and social withdrawal in the 12 months prior to baseline; as per the Diagnostic Interview for Psychosis (DIP; Castle et al., 2006).

Supplementary Table S2. Content of Healthy Lifestyles face-to-face sessions.

Session	Content
1	***Assessment Feedback***
	MI
90 mins	Case formulation
	Goal setting /Treatment contract
(weekly)	Provision of NRT
	Measure weight; CO
	Monitoring (cigarettes, standard drinks, fruit and vegetables per day; withdrawal symptoms; adverse side-effects of medication)
	Information on contingent reinforcement
	Provide pedometer
	Set homework
2	***Title: Preparing to Quit Smoking***
	Monitoring & measures as per above & NRT use*
	Set agenda for session*
	Review homework*
	Coping with cravings
	Identifying a support person
	Review of smoking goals
	Contingency management based on CO reading*
	Summary*
	Set homework*
3	***Title: Review Quit Attempt***
	* as above
	Meet support person
	High risk situations
	Craving plan
	Identifying interests
	Coping with residual symptoms of psychosis
4	***Title: Becoming More Active***
	* as above
	Activity scheduling
	Increasing motivation and participation in physical activity
	Increasing walking
	Barriers to exercise
5	***Title: Thought Monitoring & Progressive Muscle Relaxation***
	* as above
	Identifying unhelpful thoughts
	Thought monitoring
	Progressive muscle relaxation
6	***Title: Cognitive Restructuring***
	* as above
	Changing negative thought patterns
	Progressive muscle relaxation

7	***Title: Problem Solving & Healthy Eating*** * as above Problem solving Healthy eating Progressive muscle relaxation
8	***Title: Barriers to Healthy eating, Food Planning & Goal Setting*** * as above Stoplight food plan Barriers to healthy eating Goals for healthy eating Progressive muscle relaxation
(2 weekly)	
9	***Title: Healthy Eating and Effective Refusal Skills*** * as above Review healthy eating progress Smoking refusal skills Progressive muscle relaxation
10	***Title: Decision Traps and Emergency Cravings Plan*** * as above Decision traps Devising an emergency cravings plan Progressive muscle relaxation
11	***Title: Relapse Prevention and Relapse Management*** * as above Relapse management plan Progressive muscle relaxation
(monthly)	
12 to 17	***Booster Sessions*** * as above Reviewing progress Tapering NRT

MI: motivational interviewing
CO: carbon monoxide
NRT: nicotine replacement therapy
Mins: minutes

Supplementary Table S3. Content of Telephone-based sessions.

Session	Content
1	***Assessment Feedback***
	MI
90 mins	Case formulation
	Goal setting / Treatment contract
	Provision of NRT
	Measure weight; CO
	Monitoring (cigarettes, standard drinks, fruit and vegetables per day; withdrawal symptoms; adverse side-effects of medication)
2 to 8	
(weekly); 10 mins	Weekly monitoring sheet (NRT use, cigarettes per day, Minnesota Withdrawal Scale, quit attempts, physical activity [vigorous, moderate], change in medication, adverse side-effects of medication, dietary intake yesterday [include water, caffeinated drinks, soft drinks and alcohol])
4 & 8	
30 mins	As above, but face-to-face to allow dispensing of NRT; measurement of weight and CO
9 to 11	
(2 weekly); 10 mins	As per sessions 2 to 8
12 to 17	
(monthly); 10 mins	As per sessions 2 to 8

MI: motivational interviewing
CO: carbon monoxide
NRT: nicotine replacement therapy
Mins: minutes

Supplementary Table S4. 'Social Discomfort' categorization using selected baseline measures: Probability of having each symptom/diagnosis for each latent class.

Symptoms/diagnoses	Level	Class/group	
		Class 1 (Social discomfort)	**Class 2 (Low social discomfort)**
		55.4%	**44.6%**
Anxiety (BPRS-24 item)	Not present	0.014	**0.552**
	Very mild	0.056	0.224
	Mild	0.256	0.098
	Moderate	0.221	0.060
	Moderately severe	0.218	0.064
	Severe/Extremely Severe	0.235	0.001
Mania (Four BPRS-24 items)	No	0.396	**0.797**
	Yes	**0.604**	0.203
Self Esteem (Rosenberg)	Poor self esteem	**0.860**	0.396
	Good self esteem	0.140	**0.604**
Social Disability Index (Three DIP items)	No Dysfunction	0.214	**0.631**
	Obvious Dysfunction	**0.661**	0.294
	Severe Dysfunction	0.125	0.075
Suspicion (BPRS-24 item)	Not present	0.294	**0.761**
	Very mild	0.237	0.162
	Mild	0.164	0.039
	Moderate	0.171	0.001
	Moderately severe/Severe	0.134	0.037
Uncooperative (BPRS-24 item)	No	**0.740**	**0.882**
	Yes	0.260	0.118

Note: BPRS-24, Brief Psychiatric Rating Scale (24 items) (Ventura et al., 2000); Rosenberg Self-esteem scale (GrayLittle et al., 1997); DIP, Diagnostic Interview for Psychosis (Castle et al., 2006)

Supplementary Table S5. Characterisation of client-level outcomes from 12 to 36 months: Minimal Clinically Important Difference (MCID) analysis.

Measure	Threshold for MCID Improvement – relative to baseline	Included in MCID analysis: Baseline criteria (N_A)	Included in MCID analysis: Plus: ≥ 1 follow-up (12-36 months) [N_B]	Number of follow-up phases (12-36 months) with evidence of MCID Improvement: None *N* (%N_A, N_B)	1 *N* (%N_A, N_B)	2-3 *N* (%N_A, N_B)	4-5 *N* (%N_A, N_B)	MCID Improvement in ≥ 2 follow-up phases: *N* (%N_A, N_B)
Smoking								
Cigarettes per day	≥ 50% decrease	≥ 15 (235)	[180]	55 + 84 (59.1, 46.7)	36 (15.3, 20.0)	39 (16.6, 21.7)	21 (8.9, 11.7)	60 (25.5, 33.3)
CVD risk								
10-year CVD risk	≥ 25% decrease	≥ 1.333 (168)	[134]	32 + 46 (47.6, 34.3)	36 (21.4, 26.9)	37 (22.0, 27.6)	15 (8.9, 11.2)	52 (31.0, 38.8)
Lifestyle outcomes								
Walking time (minutes per week)	≥ 25% increase	< 420 (181)	[137]	44 + 46 (49.7, 33.6)	33 (18.2, 24.1)	44 (24.3, 32.1)	14 (7.7, 10.2)	58 (32.0, 42.3)
Sitting time (minutes per week)	≥ 25% decrease	> 840 (191)	[152]	39 + 65 (54.4, 42.8)	40 (20.9, 26.3)	36 (18.8, 23.7)	11 (5.8, 7.2)	47 (24.6, 30.9)
Overall diet score	≥ 25% decrease	≥ 4 (205)	[160]	45 + 62 (52.2, 38.8)	48 (23.4, 30.0)	44 (21.5, 27.5)	6 (2.9, 3.8)	50 (24.4, 31.3)
Waist circumference (cm)	≥ 25% comparative decrease - towards 90 (M) or 76 (F) cm	M: > 94, F: > 80 (187)	[143]	44 + 80 (66.3, 55.9)	29 (15.5, 20.3)	22 (11.8, 15.4)	12 (6.4, 8.4)	34 (18.2, 23.8)
Psychiatric symptomatology								
Brief Psychiatric Rating Scale (BPRS-24)	≥ 25% decrease	≥ 36 (145)	[112]	33 + 54 (60.0, 48.2)	22 (15.2, 19.6)	29 (20.0, 25.9)	7 (4.8, 6.3)	36 (24.8, 32.1)
Beck Depression Inventory (BDI-II)	≥ 25% decrease	≥ 14 (127)	[103]	24 + 17 (32.3, 16.5)	26 (20.5, 25.2)	41 (32.3, 39.8)	19 (15.0, 18.4)	60 (47.2, 58.3)
Global Assessment of Functioning (GAF)	≥ 25% increase	≤ 70 (226)	[174]	52 + 83 (59.7, 47.7)	36 (15.9, 20.7)	42 (18.6, 24.1)	13 (5.8, 7.5)	55 (24.3, 31.6)

Measure	Threshold for MCID Improvement – relative to baseline	Included in MCID analysis: Baseline criteria (N_A)	Plus: ≥ 1 follow-up (12-36 months) [N_B]	Number of follow-up phases (12-36 months) with evidence of MCID Improvement: None *N* (%N_A, N_B)	1 *N* (%N_A, N_B)	2-3 *N* (%N_A, N_B)	4-5 *N* (%N_A, N_B)	MCID Improvement in ≥ 2 follow-up phases: *N* (%N_A, N_B)
Quality of life								
SF-12 Mental Component Scale (MCS)	≥ 25% increase	≤ 60 (208)	[161]	47 + 93 (67.3, 57.8)	22 (10.6, 13.7)	32 (15.4, 19.9)	14 (6.7, 8.7)	46 (22.1, 28.6)
SF-12 Physical Component Scale (PCS)	≥ 25% increase	≤ 60 (210)	[164]	46 + 102 (70.5, 62.2)	28 (13.3, 17.1)	26 (12.4, 15.9)	8 (3.8, 4.9)	34 (16.2, 20.7)
Any of the 11 measures	(See above)	(235)	[180]	55 + 7 (26.4, 3.9)	22 (9.4, 12.2)	54 (23.0, 30.0)	97 (41.3, 53.9)	151 (64.3, 83.9)

Note: As noted previously (Andrews et al., 2016), MCID estimates need to take account of initial severity and are probably best expressed on ratio scales (Button et al., 2015). Consequently, only participants meeting the baseline clinical cut-off specified in the third column were included in each analysis (e.g., at least mild depression – BDI-II ≥ 14); with improvement rates expressed relative to both the baseline sample size (N_A, third column) and the subset who completed at least one (12-36 months) follow-up (N_B, fourth column). On average, participants were included in 8.86 (SD = 2.09) MCID analyses (out of 11).

For the current sample, which was not acutely unwell, 25% improvement (or comparative improvement) from baseline was selected as the MCID threshold (cf., Andrews et al., 2016; Leucht et al., 2005); with a 50% improvement required for cigarette consumption (an often-used threshold within tobacco research).

Evidence of clinical improvement at two or more follow-up phases (last column) was viewed as the key MCID index for this study, which ranged from 16.2% to 47.2% across the outcome measures (or 20.7% to 58.3% based on participants who completed at least one follow-up). For the whole sample, the mean number of measures (out of 11) with MCID improvement at two or more follow-up phases was 2.26 (SD = 2.39), which was comparable across the treatment conditions: Healthy Lifestyles condition, 2.12 (SD = 2.37); Telephone condition, 2.42 (SD = 2.42).

For the whole sample, two-thirds (64.3%) of participants experienced MCID improvement (on any of the measures) at multiple follow-up phases.

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