CHAPTER 4

STUDY 1: EXPLORATION OF THE SYNERGISTIC EFFECT OF NICOTINE REPLACEMENT THERAPY AND A GUIDED BODY SCAN ON CIGARETTE CRAVINGS AND NICOTINE WITHDRAWAL

4.1 Introduction

The aim of Nicotine replacement therapy (NRT) is to temporarily replace much of the nicotine from cigarettes, thereby reducing the motivation to smoke by moderating many of the associated physiological and psychomotor withdrawal symptoms (Fant, Owen & Henningfield, 1999). It is also well accepted and recommended as an effective treatment for people seeking pharmacological help to quit smoking (Cahill et al, 2013), with a systematic review of 117 trials by Stead et al (2012) finding that NRT alone returned a pooled estimate for abstinence of RR 1.60 (95% CI 1.51 - 1.68). However whilst a high dose treatment regimen of NRT patches has been shown to almost completely eliminate cravings and withdrawal symptoms, and improve abstinence rates over a placebo, substantial relapse rates of between 30 – 59% still occur (e.g. Dale, Hurt, Offord, Lawson, Croghan & Schroeder, 1995; Shiffman, Ferguson, Gwaltney, Balabanis & Shadel, 2006; Stead et al, 2012).

Reasons for this relatively high rate of relapse have centred on the possibility that patches simply eliminate underlying background symptoms without protecting the smoker from acute reactivity to situational cues (Shiffman, Paty, Gnys, Kassel & Hickcox, 1996). For example, a study by Tiffany, Sanderson-Cox and Elash (2000) examined the impact of nicotine patches on cue-elicited cravings in abstinent smokers,

and report that while the NRT effectively reduced abstinence induced cravings, it had no significant impact on cravings generated by smoking related cues. They conclude that cravings originating from nicotine abstinence and those that stem from smoking related cues appear to make independent contributions to overall levels of cigarette cravings in smokers.

As discussed in chapter 2, mindfulness-based interventions have been proposed as a potentially useful tool in helping smokers to quit via the promotion of flexibility of awareness and reduced reactivity to smoking cues during emotionally challenging situations (e.g. Bowen, Witkiewitz, Dillworth & Marlatt, 2007; Breslin, Zack & McMain, 2002; Chambers, Lo & Allen, 2008; Lutz, Slagter, Rawlings, Francis, Greischar & Davidson, 2009; Chiesa, Serretti & Jakobsen, 2013). In other words, mindfulness practice may reduce emotional volatility to smoking related cues during high-risk situations and consequently counteract the impulsive behaviour that would normally lead to a smoking relapse. Furthermore, a recent review by Stead, Koilpillai, Fanshawe and Lancaster (2016) found that combining pharmacotherapy with behavioural interventions (such as mindfulness) increased the chances of successful smoking cessation compared with usual care, with meta-analysis indicating an RR of 1.83 (95% CI 1.68 - 1.98). This suggests that while the NRT element of an intervention may counteract the negative consequences of nicotine abstinence, the added behavioural element may improve efficacy further by negating the negative impact of smoking related cues on cigarette cravings.

Building on the work of Cropley et al (2007) and Ussher et al (2009), which both found that a brief guided body scan had the ability to significantly reduce cigarette

cravings and nicotine withdrawal symptoms, the current study aims to explore the effect of combining NRT transdermal patches with a 10 minute audio guided body scan on cravings and withdrawal symptoms in temporarily abstinent smokers. It is hypothesised that there will be a synergistic effect when NRT is combined with the guided body scan, and that this condition will result in a significantly greater reduction in ratings of craving and withdrawal symptoms compared with the administration of a placebo patch or listening to a control audio.

4.2 Methodology

4.2.1 Participants

A G-power calculation indicated that a sample size of 72 participants was needed for a power of 95% (Cohen, 1988), with a significance level of .05 and an effect size of .30. Opportunity sampling was used to select the participants for the study, who consisted of 72 smokers (n = 38 male, 34 female), aged between 18 and 63 years (M = 26.8, SD = 9.6) who smoke at least 10 cigarettes a day (M = 13.1, SD = 3.2), and who have smoked for at least three consecutive years (M = 10.8, SD = 9.1). They were recruited using posters advertising the study (appendix 3) placed in private companies around the Maidenhead and Slough areas, and on the University of Surrey campus. Participants were paid £10 on completion of the experiment for their involvement in the study.

4.2.2 Design

The aim of this randomised controlled trial (RCT) was to explore whether combining a 10 minute guided body scan with NRT could produce a synergistic effect in reducing cigarette cravings and tobacco withdrawal symptoms. The placebo

controlled study design consisted of two levels of independent variable: i) the administration of an active nicotine patch or a placebo nicotine patch, and ii) completing either the 10 minute guided body scan or listening to 10 minutes of the control text reading. The dependent variable was participants' ratings of desire to smoke and tobacco withdrawal symptoms given immediately after the task, and at 5, 10, 20 and 30 minutes post-task.

4.2.3 Interventions

The guided body scan

After receiving brief verbal instructions about what the guided body scan would entail (e.g. "the aim of this recording is to increase awareness of your body and mind, of your whole self"), participants were guided through a 10 minute audio recording of a seated body scan routine based on that used originally by Cropley et al (2007). They were instructed to focus on their breathing by concentrating their attention on the abdominal area and to become aware of the way they are breathing and the sensations associated with breathing (e.g. "feel the breath that enters your body by your nostrils or by your mouth"). This focus of awareness was gradually moved to other areas of the body, before attention was brought back into the room in which the participant was sat to gently bring them back to being conscious of their surroundings (see appendix 4 for full verbatim narrative).

Control audio

The control audio condition involved participants listening to a 10 minute recorded extract of a natural history text (White, 1997). The extract narrative centres on the geographical and geological features of Selborne in Hampshire, England, has been

used previously by Cropley et al (2007), who report that those who listened to the recording found it to be a neutral yet relaxing passage.

Nicotine replacement therapy

Nicotine replacement was delivered via a NiQuitin® 21mg transdermal patch (GlaxoSmithKline Plc.), with each 22cm^2 patch containing 114mg of nicotine, equivalent to 5.1 mg/cm^2 of nicotine. This is the recommended dosage for individuals smoking more than 10 cigarettes per day (as specified by the eligibility requirements of the study). Following transdermal application, the skin rapidly absorbs nicotine released initially from the patch adhesive. The plasma concentrations of nicotine reach a plateau within 2 hours after initial application (Berner & John, 1994), with relatively constant plasma concentrations persisting for 24 hours or until the patch is removed. The placebo patches were identical in appearance to the active nicotine patches, but delivered no nicotine to the wearer at any time.

4.2.4 Measures

Fagerström Test for Nicotine Dependence (FTND; Heatherton et al, 1991)

The FTND is a 6-item self-report measure (appendix 5) of dependency on nicotine that is closely related to biochemical indices of heaviness of smoking. The reliability of the questionnaire has been investigated using a sample of students, academic and administrative staff by Etter, Vu Duc and Perneger (1999), who report an internal consistency alpha of .70, test re-test reliability of .85 ($p > 0.001$), and a single factor structure accounting for 41.4% of total variance. In terms of predictive validity, they found that the number of cigarettes smoked per day successfully predicted abstinence at follow up, although the odds of quitting decreased by 5% for each additional

cigarette smoked per day. Cross validation also showed that all variables were strongly associated with saliva cotinine levels, with a relative validity of 95% of variance explained by the items on the FTND. The FTND was administered to participants in the present study to establish their background level of tobacco dependency and explore whether this had any impact on the effect of the interventions.

Mood and Physical Symptoms Scale (MPSS; West & Hajek, 2004)

The MPSS (appendix 6) is specifically designed to assess self-rated levels of the nicotine withdrawal symptoms of irritability, tension, depression, restlessness, difficulty concentrating and stress. Each is rated on a seven-point scale, for example "how tense do you feel right now?" (1 = not at all, 4 = somewhat, 7 = extremely) with the additional question of "how strong is your desire to smoke right now?" added for the purposes of the present study. West and Hajek (2004) report factor loadings for each scale on the MPSS to be high (with the exception for 'hunger' which was not included in the analysis of the present investigation), and a coefficient alpha of .78 indicating a high degree of overall coherence and reliability.

4.2.5 Procedure

Upon expressing interest in taking part in the study, and prior to abstinence, participants were screened via e-mail to check their eligibility status by confirming that they were within the correct age range (18 – 65), had been smoking long enough (more than 3 consecutive years), and smoked an average of more than 10 cigarettes per day. They were also required to be able to read and write in English, not be receiving treatment for mental health problems, not pregnant or currently trying to conceive.

Once eligibility was established, smoking status was verified via an expired carbon monoxide (CO) concentration of ≥15ppm (Middleton & Morice, 2000). They were then given a participant information sheet to read (appendix 7), a consent form to sign (appendix 8), and an opportunity to ask any questions. They then completed the Fagerström Test for Nicotine Dependence (FTND; Heatherton et al, 1991), and were asked to provide further demographic information on age, gender, ethnic group, marital status, occupation, whether they would like to give up smoking, how long they have been smoking, and how many serious quit attempts they have made in the last year (appendix 9). Participants were then requested to abstain from smoking cigarettes from 10pm that evening, and to attend a second session at 10am the next day to take part in the actual intervention (after approximately 12 hours of abstinence). Once overnight abstinence was established with an exhaled CO reading of < 10ppm, and the exact length of abstinence was ascertained, participants were allocated to one of four conditions based on a random number generated in advance of their arrival. The four conditions were:

a) Active nicotine patch plus:

(i) Guided body scan

(ii) Control audio

b) Placebo nicotine patch plus:

(iii) Guided body scan

(iv) Control audio

Participants were given a palmtop computer (PalmOne, Tungsten E2) to record their baseline ratings for strength of desire to smoke and withdrawal symptoms using the Mood and Physical Symptoms Scale (MPSS; West & Hajek, 2004), and administered

either an active or placebo nicotine patch by the researcher in accordance with their allocated condition. Participants were blind to their allocated condition until debriefing, and were informed that there was an equal chance of receiving an active nicotine or placebo patch, and that they were unlikely to suffer any noticeable side effects from either. They were then given an mp3 player (Mikomi FM6611 512mb) containing the appropriate audio recording, which for the importance of consistency, was made by the same person and edited to include approximately the same number of pauses at the same time points. Finally, participants were asked not to consume alcohol, take vigorous exercise or do anything beyond their normal routine whilst participating in the study.

Once the participant left the laboratory, the palmtop computer sounded an alarm an hour after the baseline ratings were given (approximately 11am), automatically turned itself on, and prompt them to make another set of desire to smoke and withdrawal symptom ratings. Once this was complete, they were to turn the palmtop off again and continue with their normal routine. Two hours after the initial baseline ratings were given (approximately 12pm), the palmtop sounded another alarm and turned itself back on, and asked the participant to make a further set of MPSS ratings before listening to the 10 minute audio recording on the mp3 player. Once this had finished, the palmtop asked them to make further ratings immediately after the intervention, and then again at 5, 10, 20 and 30 minutes following the intervention. Participants were given an information sheet detailing the intervals at which the palmtop would prompt them to make ratings and listen to the audio intervention (appendix 10):

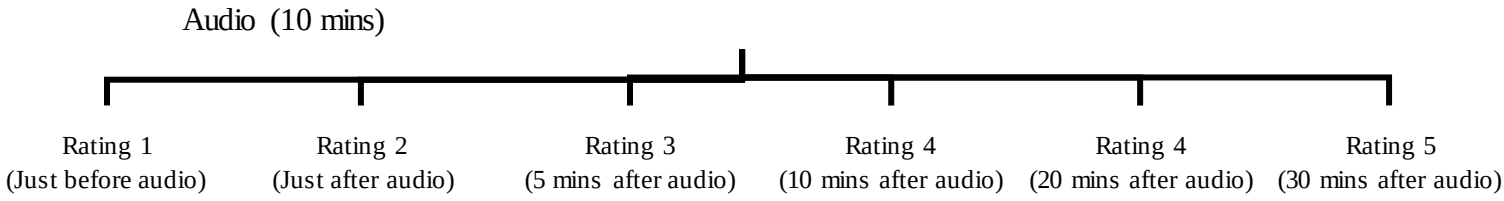

Figure 4.1 Rating schedule for MPSS items immediately before and after audio intervention

On returning to the laboratory, participants were asked to complete a final questionnaire regarding the perceived effectiveness of the intervention (appendix 11), and then debriefed on their allocated condition. The palmtop computer and mp3 player were returned to the researcher, and once abstinence was confirmed with a final CO reading of < 10ppm, participants were paid £10.00 for taking part, and were free to take the active/placebo patch off and smoke again if they wished. The researcher then pointed out the details of a number of useful quit support websites and the free phone numbers of NHS local and national smoking helplines on the ratings interval sheet, which was retained by participants.

4.3 Results

4.3.1 Baseline comparisons

A series of one way analyses of variance (ANOVAs) were used to compare the baseline characteristics of the four groups (body scan plus NRT, control audio plus NRT, body scan plus placebo, and control audio plus placebo), and indicated that there were no significant differences between the groups for any of the demographic or smoking related characteristics: Age, $F(3,68) = 0.66$, $p = .58$ (*ns*); Cigarettes smoked per day, $F(3,68) = 1.19$, $p = .32$ (*ns*); Years smoking, $F(3,68) = 1.08$, $p = .37$ (*ns*); FTND, $F(3,68) = 0.97$, $p = .41$ (*ns*); Post-abstinence ECO, $F(3,68) = 0.75$, $p = .52$ (*ns*); Time since last cigarette, $F(3,68) = 0.39$, $p = .76$ (*ns*). The means and standard deviation for each can be seen in table 4.1.

Table 4.1

Mean ± SD of demographic and smoking characteristics by group

	NRT & body scan *(n = 18)*	Placebo & body scan *(n = 18)*	NRT & control audio *(n = 18)*	Placebo & control audio *(n = 18)*
Age	24.3 ± 6.1	27.7 ± 11.2	26.8 ± 10.4	28.7 ± 10.1
Cigarettes per day	12.3 ± 2.3	13.1 ± 3.2	14.2 ± 4.1	12.8 ± 2.7
Years smoking	7.7 ± 4.3	11.4 ± 10.2	11.1 ± 10.7	12.9 ± 9.6
FTND	3.7 ± 1.6	3.9 ± 1.5	4.2 ± 1.9	3.3. ± 1.5
Post-abstinence ECO	4.9 ± 2.0	4.1 ± 2.5	5.3 ± 2.9	4.5 ± 2.4
Hours since last cigarette	12.4 ± 0.9	12.7 ± 1.6	12.8 ± 2.1	12.4 ± 0.8

FTND = Fagerström Test for Nicotine Dependence; ECO = Expired Carbon Monoxide

Chi-squared analysis indicated that there were also no significant differences between the groups for: marital status, $\chi^2 = 11.39$, $df = 12$, $p = .49$ (*ns*); occupation, $\chi^2 = 13.04$, $df = 15$, $p = .59$ (*ns*); ethnicity $\chi^2 = 24.99$, $df = 21$, $p = .25$ (*ns*); desire to give up, $\chi^2 =$

1.16, df = 3, p = .76 (*ns*). There was however a significant difference in the gender ratios between the groups; $\chi^2 = 7.80$, df = 3, $p < 0.05$, with significantly more males in the NRT plus body scan group, and significantly more females in the placebo plus control audio group. As a result and where necessary, gender was entered as a covariate during data analysis to control for any potentially confounding effects. The percentage split for each factor for each group can be seen in table 4.2.

Table 4.2

Percentages for gender, marital status, occupation, ethnicity & desire to give up smoking by group

	NRT & body scan *(n = 18)*	Placebo & body scan *(n = 18)*	NRT & control audio *(n = 18)*	Placebo & control audio *(n = 18)*
Men	72.2*	50.0	61.1	27.8*
Single	77.8	77.8	72.2	77.8
Married	5.6	5.6	11.1	22.2
Professional/Manager	27.8	27.8	33.3	33.3
Student	66.7	50.0	66.7	50.0
Caucasian	94.4	77.8	83.3	88.9
Want to give up smoking	66.7	72.2	66.7	55.6

* Percentage difference is significant at the .05 level

A further series of one way ANOVAs were used to compare the 10.00am baseline levels of strength of desire to smoke and six withdrawal symptoms measured by the MPSS for the four groups before they were allocated to a patch condition: Strength of desire to smoke; F(3,68) = 0.32, (*ns*); Irritability, F(3,68) = 0.20 (*ns*); Tension, F(3,68) = 2.64 (*ns*); Restlessness, F(3,68) = 1.40 (*ns*); Difficulty concentrating, F(3,68) = 2.32 (*ns*); Stress, F(3,68) = 1.33 (*ns*); Depression, F(3,68) = 2.77, $p < .05$. Post-hoc analysis indicated that there was a significant difference in baseline depression ratings

given by the NRT plus body scan group and placebo plus control audio group, however because depression had a low baseline rating across all four groups, it was excluded from any further analysis. The means and standard deviations for each item by group can be seen in table 4.3.

Table 4.3.

Mean ± SD of desire to smoke and MPSS withdrawal items by group

	NRT & Body scan *(n = 18)*	Placebo & Body scan *(n = 18)*	NRT & Control *(n = 18)*	Placebo & Control *(n = 18)*
Strength of desire to smoke	4.61 ± 1.54	4.78 ± 1.40	5.06 ± 1.47	4.67 ± 1.53
Irritability	3.56 ± 1.75	3.72 ± 1.56	3.50 ± 1.76	3.28 ± 1.87
Depression	2.78 ± 1.83*	2.50 ± 1.34	2.50 ± 1.34	1.56 ± 0.70*
Tension	4.00 ± 1.61	3.56 ± 1.42	4.06 ± 1.59	2.83 ± 1.25
Restlessness	4.11 ± 1.41	3.94 ± 1.30	4.39 ± 1.72	3.33 ± 1.91
Difficulty Concentrating	3.56 ± 1.58	3.33 ± 1.57	4.06 ± 1.47	2.67 ± 1.78
Stress	3.39 ± 1.79	3.50 ± 1.65	3.67 ± 1.68	2.67 ± 1.33

* Mean difference is significant at the .05 level

In terms of baseline correlations, those who scored higher on the FTND also gave higher baseline rating for strength of desire to smoke ($r = .49$, $p < 0.001$), irritability ($r = .52$, $p < 0.001$), tension ($r = .54$, $p < 0.001$), restlessness ($r = .48$, $p < 0.001$), difficulty concentrating ($r = .52$, $p < 0.001$) and stress ($r = .47$, $p < 0.001$). This is in line with expectation, as the higher an individual's level of nicotine dependence, the higher their desire to smoke and withdrawal symptoms would be in response to an acute period of abstinence. Additionally, there were significant correlations between all baseline MPSS ratings and the number of cigarettes a person reported smoking per day: strength of desire to smoke ($r = .21$, $p < 0.05$), irritability ($r = .31$, $p < 0.01$), tension ($r = .34$, $p < 0.01$), restlessness ($r = .28$, $p < 0.01$), difficulty concentrating (r

= .35, $p < 0.01$) and stress ($r = .32$, $p < 0.01$). There were no significant correlations between any of the MPSS baseline ratings and age, post-abstinence ECO, years smoking or hours of abstinence.

4.3.2 Data screening

Data screening was conducted in order to highlight any participants who reported a very low desire to smoke at baseline. In other words, those who reported their desire for a cigarette at 10.00am as either 1 (not at all) or 2 (slightly) were excluded from the dataset. This excluded six participants: two from the NRT plus body scan group, one from the placebo plus body scan group, one from the NRT plus control audio group, and two from the placebo plus control audio group. Furthermore, reliability analysis of the five remaining MPSS items showed high inter-item correlations and a high level of internal consistency, $\alpha = .90$, so for all further analyses they were grouped together and treated as a single item labelled 'withdrawal symptoms'.

4.3.3 Changes in desire to smoke and withdrawal symptoms pre-audio intervention

Plasma concentrations of nicotine (i.e. changes in blood levels and tissue distribution of nicotine) reach a plateau within 2 hours of initial patch application (Berner & John, 1994), meaning that participants should have been receiving optimum relief from nicotine cravings and withdrawal symptoms at this point. A preliminary analysis between the NRT and placebo patch conditions was therefore conducted looking at the change in ratings of desire to smoke in the two-hour time period following patch application but prior to the audio intervention. As per the method used by Cropley et al (2007), for both desire to smoke and composite withdrawal symptoms, 10am baseline ratings were subtracted from ratings given at 11.00am and 12.00pm, and the change scores analysed using a series of group (NRT & placebo) by time (11.00am &

12.00pm) repeated-measures analysis of variance (ANOVA). The results indicated that there was no significant main effect of patch condition $F(1,64) = 3.43$, $p = .07$ (*ns*), or time $F(1,63) = 0.01$, $p = .92$ (*ns*), and is contrary to expectations as it suggests that neither patch type had a significant impact on ratings of desire to smoke in the two hours prior to the audio intervention. Furthermore, (albeit non-significant) the placebo patch resulted in a greater reduction in desire to smoke than the NRT patch (see figure 4.2).

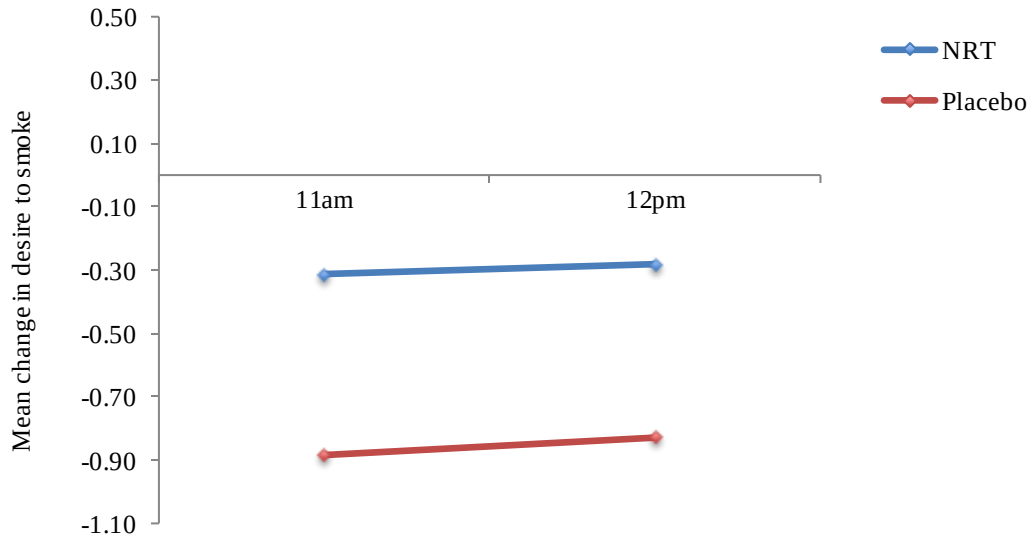

Figure 4.2 Changes in pre-audio intervention ratings of desire to smoke by patch

The same analysis was then conducted looking at changes in withdrawal symptom ratings in the two hours prior to taking part in the audio intervention (but after receiving a patch), between those wearing an NRT and a placebo patch. The results indicated that again there was no significant main effect of group $F(1,64) = 1.06$, $p = .31$ (*ns*) or time $F(1,64) = 0.01$, $p = .92$ (*ns*), and contrary to expectations suggests that neither the nicotine or placebo patch had a significant impact on withdrawal symptom ratings prior to the audio intervention. Furthermore, mean ratings of

withdrawal symptoms actually increased in the NRT group after receiving the nicotine patch (see figure 4.3).

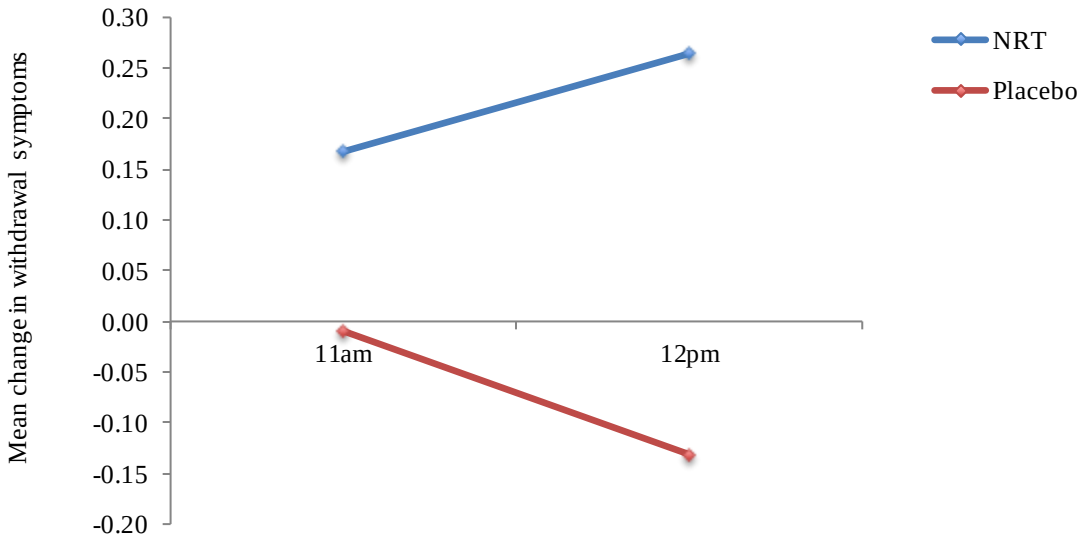

Figure 4.3 Change in pre-audio intervention ratings for withdrawal symptoms by patch

To summarise, there does not appear to be any significant difference in ratings of desire to smoke or tobacco withdrawal symptoms between those wearing an active NRT or placebo patch. This suggests that the groups were relatively equal in terms of the reported levels of craving and withdrawal symptoms prior to receiving the audio intervention two hours after the patches were initially applied.

4.3.4 Changes in desire to smoke and withdrawal symptoms post-audio intervention

Again, for both desire to smoke and composite withdrawal symptoms, pre-audio baseline ratings were subtracted from ratings given immediately after the interventions and at 10, 20 and 30-minutes post-intervention. This change score data was analysed using a series of group (NRT & body scan / NRT & placebo / placebo & body scan / placebo & control) by time (0, 10, 20, 30 minutes post-intervention)

repeated-measures ANOVAs. Due to the significant difference in the male to female ratio between two of the groups (NRT plus body scan and placebo plus control audio), gender was also used as a covariate to control for any potentially confounding effects. The results indicated that for ratings of desire to smoke, while there was no significant interaction effect $F(9,186) = 1.37$, $p = .21$ (*ns*) or main effect for group $F(3,62) = 1.75$, $p = .17$ (*ns*), there was a significant main effect of time $F(3,186) = 1.63$, $p < .01$, $\eta_p^2 = .09$. This suggests that irrespective of intervention type, there was a significant change in ratings of desire to smoke over the course of the time points measured. Furthermore, post-hoc analysis confirmed that the mean strength of desire to smoke rating was significantly reduced both immediately ($t = 3.99$, $df = 71$, $p < .001$) and at 10-minutes post-intervention ($t = 3.14$, $df = 71$, $p < .01$). There were no significant reductions after this point (see figure 4.4), however it does give an indication of the duration of the intervention's efficacy.

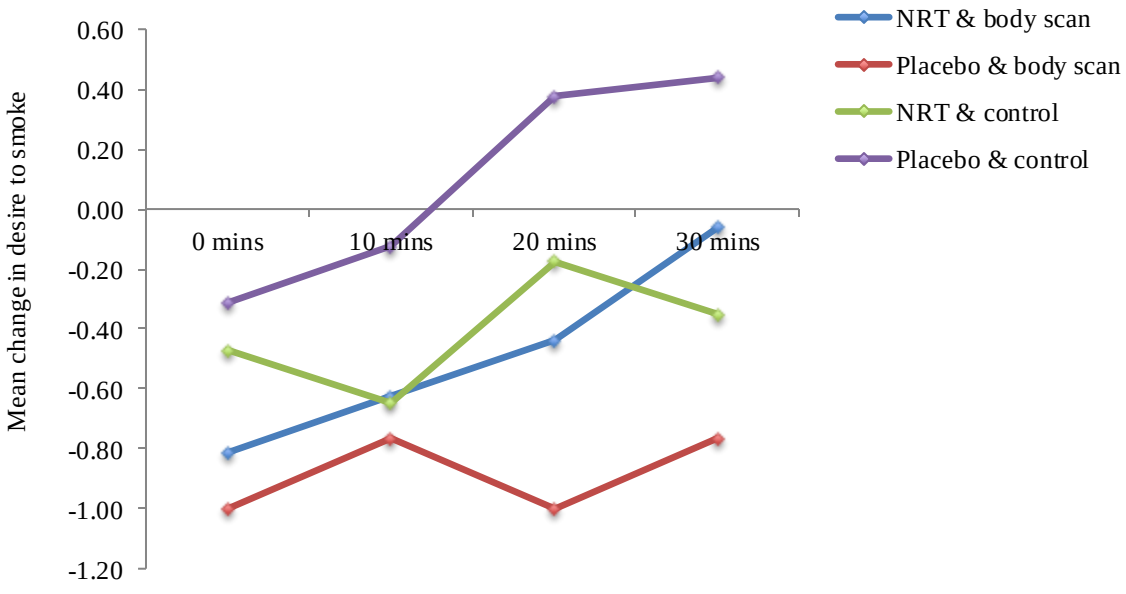

Figure 4.4 Mean changes in desire to smoke ratings by group

The same analysis was then conducted for the composite rating of tobacco withdrawal symptoms, with the results again indicating that while there was no significant interaction effect $F(9,186) = 1.92$, $p = .06$ (*ns*), or main effect of group $F(3,62) = 0.24$, $p = .87$ (*ns*), there was a significant main effect of time $F(3,186) = 4.69$, $p < .01$, $\eta_p^2 = .09$. This again suggests that irrespective of intervention type, there was a significant change in ratings of withdrawal symptoms over the course of the time points measured. Post-hoc analysis further confirmed that relative to baseline ratings, the mean withdrawal symptom rating was significantly reduced at all time points: immediately ($t = 5.07$, $df = 71$, $p < .001$), 10-minutes post-intervention ($t = 3.54$, $df = 71$, $p < .01$), 20-minutes ($t = 2.68$, $df = 71$, $p < .01$), and 30-minutes ($t = 2.92$, $df = 71$, $p < .01$). Figure 4.5 shows how ratings remain below baseline levels throughout the experiment, and indicate that the interventions were still effective in reducing withdrawal symptoms up to 30 minutes after the audio listening task.

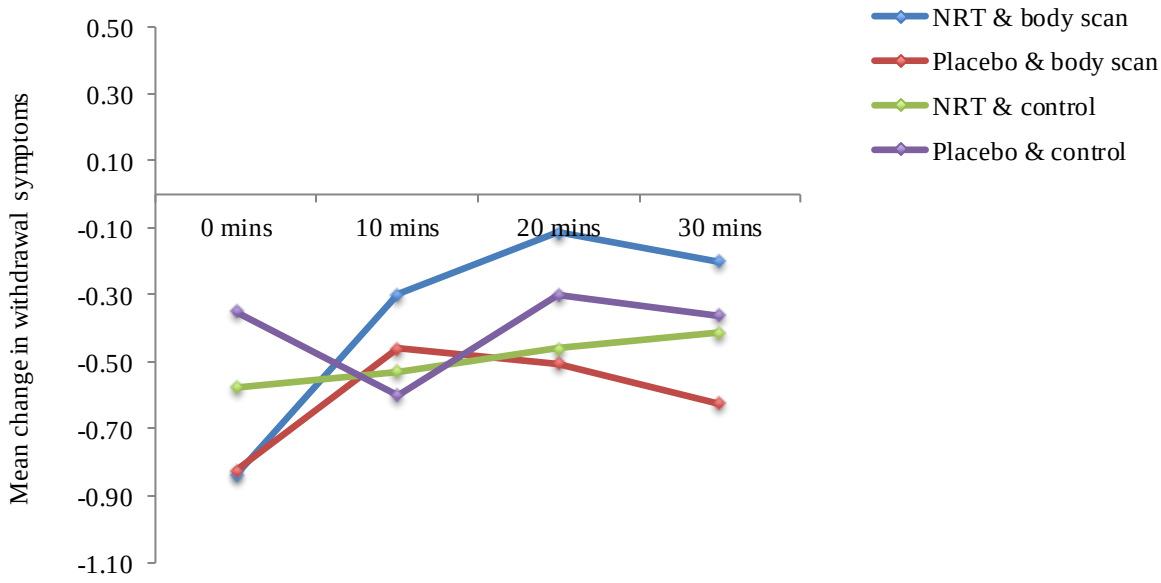

Figure 4.5 Mean changes in withdrawal symptom ratings by group

To summarise, while there was no significant difference between baseline and post-intervention desire to smoke or tobacco withdrawal symptoms rating according to experimental group, there was an overall effect of the interventions over time. This suggests that irrespective of patch type or audio task, the intervention had a significant impact on ratings. This does however lead to the rejection of the hypothesis that there would be a synergy between the NRT patch and body scan intervention, as there was no significant difference between the ratings given for this group compared with the other groups.

4.3.5 Credibility of interventions

If audio interventions combined with pharmaceuticals (NRT) are realistically to be used as an aid to quitting smoking, it is important to explore how the participants in this study perceived them. In light of this, measures of perceived credibility were added in order to determine how useful and effective participants believed the interventions to be, and whether they would recommend them as a strategy to others. Analysis indicated that in terms of usefulness, the two body scan conditions were rated as most useful: NRT plus body scan (M = 2.83, SD = 1.15); Placebo plus body scan (M = 2.83, SD = 1.04), followed by NRT plus control (M = 2.44, SD = 1.29) and then placebo plus control (M = 2.28, SD = 1.18). As for recommending the interventions to other smokers trying to quit, the two body scan conditions again were rated highest; Placebo plus body scan (M = 3.28, SD = 1.07); NRT plus body scan (M = 3.22, SD = 1.06), followed by NRT plus control (M = 2.83, SD = 1.47) and then placebo plus control (M = 2.50, SD = 1.10). The final question asked how effective interventions would be for most smokers, and again the two body scan conditions were rated highest; Placebo plus body scan (M = 2.89, SD = 0.76); NRT plus body

scan (*M* = 2.61, *SD* = 1.14), followed by NRT plus control (*M* = 2.28, *SD* = 1.13) and then placebo plus control (*M* = 2.17, *SD* = 1.04). This suggests that the body scan interventions were rated as more credible than the control audio interventions, however mean ratings only actually translated as "Slightly" or "Moderately" useful.

Despite this, ANOVAs were performed in order to compare the four conditions for any significant differences in credibility rating, with the results unsurprisingly indicating that there was no significant difference in how useful participants found the interventions for relieving their desire to smoke ($F(3,68) = 1.04$, $p = .38$, *ns*), recommending the interventions to other smokers ($F(3,68) = 1.69$, $p = .18$, *ns*), or how effective they the interventions would be for most smokers ($F(3,68) = 1.83$, $p = .15$, *ns*).

4.4 Discussion

This study found that contrary to the hypothesis that there would be a synergistic effect of combining NRT and a guided body scan on desire to smoke and withdrawal symptoms, there was no significant difference between any of the groups across the course of the time points measured. One potentially confounding factor that may have diminished the significance of the results was that despite the process of randomisation, there was a significant difference in gender ratio between two of the groups. This is especially noteworthy in light of research examining gender differences in the placebo response during smoking cessation trials using Bupropion by Collins, Wileyto, Patterson, Rukstalis, Audrain-McGovern, Kaufmann, Pinto, Hawk, Niaura, Epstein and Lerman (2004). They found that while women had comparable abstinence rates to men whilst using Bupropion, they tended to respond

more poorly than men to placebo. In the current study, there were significantly more women than men in the placebo plus control arm of the study, and this may have resulted in a skewed response to the placebo intervention in this group.

Irrespective of a potential gender effect, according to a review by Perkins, Sayette, Conklin and Caggiula (2002), several important factors are thought to influence the strength of the placebo effect in nicotine and tobacco based studies. Proximal environmental stimuli in the form of salient cues or verbal instructions concerning the drug content (or effect) determine the participant's stimulus expectancy, and this consequently elicits a pre-existing response expectancy regarding the likely effects of consumption. In other words, if participants are given a placebo patch but receive relevant instructions along with salient cues that they are wearing a nicotine patch, this should prompt a stimulus expectancy in which they believe they are receiving nicotine. This activates their response expectancy about the effect nicotine is likely to have on them thereby producing a placebo effect, i.e. reduced cravings and withdrawal symptoms in the absence of nicotine replacement. The opposite phenomenon, the antiplacebo effect, occurs when participants are given a nicotine patch with instructions to the contrary, with the resulting stimulus expectancy that they believe they are not receiving nicotine. Their response expectancies regarding the effects an inactive patch would have on them (no effect), can reduce or prevent normal responses to receiving nicotine, i.e. no reduction in cravings and withdrawal symptoms (see figure 4.6).

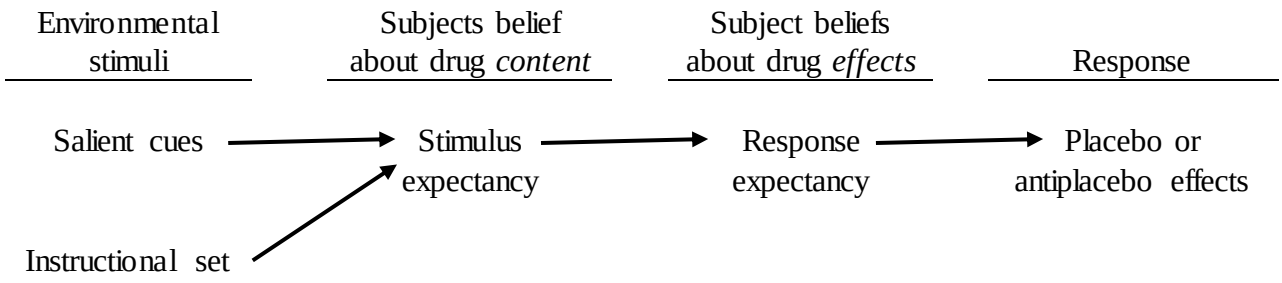

Figure 4.6 Non-pharmacological influences on responses to substance use (Perkins et al, 2002)

According to Dar, Stronguin and Etter (2005) however, a balanced placebo design makes the assumption that instructions fully control participants' beliefs about their assigned drug condition, and without verification of this assumption, the validity of the design is at risk. This is especially a problem in studies using NRT due to the easily recognisable effects of nicotine that cannot be accurately reproduced by a placebo, and limits the ability to fully assess the placebo effect of NRT products. Whilst every effort was made to maintain participant naivety in the current study by informing them of their equal chance of being allocated to either patch condition and that there should be no noticeable side effects, participants were not formally asked prior to taking part whether they had used NRT patches before. Having previous experience of using NRT patches may have had an effect on participants' response expectancy, and as a result may be responsible for the antiplacebo response in the experimental arm of the study.

Despite not being expected, and contrary to the findings of a number of existing studies comparing NRT and placebo (e.g. Tonnesen, Norregaard, Simonsen & Säwe, 1991; Shiffman, Khayrallah & Nowak, 2000; Shiffman, Ferguson, Gwaltney, Balabanis & Shadel, 2006), the results from the current study have still been

supported in previous research. For example, a study by Teneggi, Tiffany, Squassante, Milleri, Ziviani and Bye (2002) compared free smoking with NRT and a placebo, and report that while withdrawal symptoms were significantly lower for those in the free smoking group compared to either the NRT or placebo, there was no difference in the withdrawal symptom levels between those on the NRT patches and placebos. A review by Dar & Frenk (2004) looking at self-administration of pure nicotine also found that neither smokers nor non-smokers showed a preference for nicotine over placebo in any of the studies reviewed. This casts doubt onto the widely held belief that nicotine is the primary agent motivating tobacco smoking, and the main obstacle facing smokers during a quit attempt. These studies suggest that traditional NRT fails to moderate the non-pharmaceutical factors that maintain the negative consequences of tobacco abstinence, and it is possible that when these factors were combined with expectations associated with a placebo effect in the current study, any positive impact of the nicotine replacement therapy was negated.

In terms of exploring the therapeutic benefits of the guided body scan, the results of the current study found that while there were no differences in efficacy between the body scan and control audio on desire to smoke or withdrawal symptoms (irrespective of patch condition), there were differences in the ratings given for both interventions over time. This suggests that irrespective of audio intervention type, both had an impact on ratings over the course of the study. Previous research using the same audio interventions by Cropley, Ussher and Charitou (2007) and Ussher et al (2009) both found that the guided body scan produced significantly lower ratings of desire to smoke and some MPSS withdrawal symptoms compared to the control audio. However, the effect was shown to diminish outside of a laboratory environment in the

Ussher et al (2009) study, and as participants in the current study also used the audio intervention in their normal (non-lab) environment, uncontrolled environmental factors may have contributed to their level of engagement with the body scan instructions and consequently lessened it's impact. Nevertheless, the results show that both audio interventions had a significant impact on desire to smoke and withdrawal symptoms, and prompts the need to explore why this result has occurred.

Despite the difference in content between the audio files, the common factor shared by both is that the 'intervention' consisted of listening to a 10-minute audio delivered experience. One potential theory is that they both functioned as a cognitive distractor from cravings and withdrawal symptoms, and the act of simply 'taking their mind off' the negative consequences of tobacco abstinence was enough to temporarily reduce ratings. The idea of using distraction tasks in the reduction of cravings and withdrawal symptoms does not appear to have been well tested in the field of tobacco addiction, with literature searches returning only two studies looking directly at distraction as a strategy for supressing cravings for a cigarette: following smoking cue exposure, participants in a study by Versland and Rosenberg (2007) were randomly assigned to listen one of three beach themed imagery interventions (olfactory, visual, olfactory plus visual) or a distracting cognitive task (serial 7's) and rate their craving levels. They found that cravings during the intervention were significantly lower in all three imagery conditions compared to the distraction task, and suggest that this type of task holds the ability to interrupt cue induced cravings – even if temporarily. A later study by May, Andrade, Panabokke and Kavanagh (2010) asked abstinent and non-abstinent participants to create either auditory or visual mental images based on cues such as 'a telephone ringing' (auditory) or 'cows grazing' (visual) and rate their

craving strength and mood before and after. They found that while the visual imagery task reduced cravings in the abstinent smoker the auditory task did not, and go on to argue that visual imagery supports tobacco cravings, and that competing tasks reduce cravings by loading the limited-capacity working memory. Building on this limited research, and as a result of the findings of the current study, the theory that the guided body scan is simply an effective form of cognitive distraction is explored and tested in the next two chapters of this thesis.