

Time Course of Cigarette Withdrawal Symptoms while Using Nicotine Patch during Ramadan

(Masa Perubatan Gejala Sarak semasa Menggunakan Tampalan Nikotin dalam Bulan Ramadan)

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ABSTRACT

Previous studies explain the time course of withdrawal symptoms among smokers pre and post quit attempt, either with or without the help of medication. Studies showed that male Muslim smokers could quit smoking during Ramadan since fasting relate to the changes in psychosomatic, daily activities and nicotine withdrawal symptoms. This study aimed to investigate the time course of withdrawal symptoms among smokers who used nicotine patch to quit smoking during fasting in Ramadan. A total of 40 eligible Muslim males who tried to quit smoking was selected and provided with smoking cessation counseling for the duration of 8 to 10 weeks while on nicotine patch. Participants level of withdrawal symptoms was recorded by using nine items of Minnesota Nicotine Withdrawal Scale over a period of 60 days. Participant's carbon monoxide reading and body weight were measured within six months including pre and post-Ramadan fasting. Over four weeks of the fasting month, the measured withdrawal symptoms such as urge to smoke ($P \leq 0.001$), depressed mood ($P \leq 0.001$), irritability/frustration or anger ($P \leq 0.05$), anxiety ($P \leq 0.05$), difficulty concentrating ($P \leq 0.001$), restlessness ($P \leq 0.001$), difficulty going to sleep ($P \leq 0.001$) and impatient ($P \leq 0.05$) significantly decreased except appetite by the end of week 4. Time course analyses demonstrated that all outcome measures showed good effects during cessation in fasting month. The point prevalence abstinence at first month of quitting was 67.5% which is higher in fasting month. This has shown positive clinical implications in managing smoking cessation program during Ramadan with the aid of nicotine patch.

Keywords: Withdrawal symptoms; smoking cessation; fasting; Ramadan; nicotine patch

ABSTRAK

Kajian terdahulu menerangkan masa perubatan bagi gejala sarak dalam kalangan perokok sebelum dan selepas percubaan berhenti merokok, sama ada dengan atau tanpa bantuan ubat. Kajian menunjukkan bahawa perokok lelaki beragama Islam boleh berhenti merokok semasa bulan Ramadan. Puasa berkaitan dengan perubahan psikosomatik, aktiviti harian dan gejala sarak nikotin. Kajian ini bertujuan untuk menyiasat masa perubatan gejala sarak dalam kalangan perokok yang menggunakan tampalan nikotin untuk berhenti merokok semasa berpuasa di bulan Ramadan. Sejumlah 40 orang lelaki Islam yang ingin berhenti merokok telah dipilih dan diberikan kaunseling berhenti merokok untuk tempoh 8 hingga 10 minggu semasa menggunakan tampalan nikotin. Tahap gejala sarak peserta dicatatkan dengan menggunakan sembilan item Minnesota Nicotine Withdrawal Scale dalam tempoh 60 hari. Bacaan karbon monoksida dan berat badan peserta diukur dalam tempoh enam bulan termasuklah sebelum dan selepas puasa. Dalam tempoh empat minggu dalam bulan puasa, gejala sarak yang diukur seperti keinginan merokok ($P \leq 0.001$), murung ($P \leq 0.001$), iritabiliti atau kemarahan ($P \leq 0.05$), kebimbangan ($P \leq 0.05$) ($P \leq 0.001$), kegelisahan ($P \leq 0.001$), kesukaran tidur ($P \leq 0.001$) dan tidak sabar ($P \leq 0.05$) ketara menurun kecuali selera makan pada akhir minggu 4. Analisis masa perubatan menunjukkan bahawa semua gejala sarak menghasilkan kesan yang baik semasa berhenti pada bulan puasa. Abstinens prevalens titik pada bulan pertama berhenti merokok adalah 67.5% iaitu tertinggi pada bulan puasa. Ini menunjukkan implikasi klinikal yang positif dalam menguruskan program berhenti merokok semasa Ramadan dengan bantuan tampalan nikotin.

Kata kunci: Gejala sarak; berhenti merokok; puasa; Ramadan; tampalan nikotin

INTRODUCTION

Ramadan is the holy month in the Islamic calendar whereby healthy adult Muslims are obligated to fast during the daylight throughout the month. A fasting person is required to abstain from food, drinks, smoking, certain medications, sexual activities and doing any evil deeds to increase the devotion to God and to learn about good morals, self-discipline and sacrifice (Ahmad et al. 2012; Anne Yee et

al. 2011). Published studies have shown that fasting during Ramadan is a healthy non-pharmacological approach in improving individual health through physiological or psychological effects (Ahmad et al. 2012; Rouhani and Azadbakht 2014; Meo and Hassan 2015). These effects are crucial in the maintenance phase and to avoid relapse to smoking among smokers who have the intention to quit.

A study found that the encouragement to quit smoking among male Muslim smokers during the fasting month is a

great advantage to be nicotine-free (Suriani et al. 2015). A cross-sectional study conducted during Ramadan in 2002 found that, majority of Malaysian Muslims agreed that giving up smoking is easy during this month (Abu Bakar et al. 2002). The fasting month could help smokers to reduce the number of cigarettes. Indirectly, it may become a kick-start for the smokers to quit entirely.

Malaysian Muslims will fast for about thirteen hours from dawn till dusk. Therefore, smokers would restrain from smoking throughout this period. However, the remaining time especially after the breaking of fast provides an opportunity for them to continue smoking at night to restore their nicotine dependency. This might be happening due to absence of food intake during the daytime which may increase smokers' nicotine hunger (Cheskin et al. 2005; Kendzor et al. 2008). Thus, providing support via behavioural approach and pharmacotherapy is needed to control their smoking habit after breaking the fast. In addition, a person's behaviour and lifestyle would change during Ramadan fasting (Waterhouse et al. 2009; South et al. 2013).

Studies have demonstrated the negative effects of mood, mental performance, alertness, irritability, tiredness, being unwilling to work and headache with sleep deprivation during fasting (Karaagaoglu and Yucecan 2000; Kendzor et al. 2008; Waterhouse et al. 2009). Conversely, a study reported that fasting has been helpful in minimising emotional level such as stress, anxiety and depression (Koushali et al. 2013). This psychosomatic alteration is crucial to be discussed when a smoker has an intention to quit during Ramadan fasting.

Earlier studies had characterised the valid physical and psychological symptoms caused by smoking reduction or cessation such as craving, irritability, anger, restlessness, impatience, insomnia, increased appetite, increased body weight and difficulty in concentrating (Hatsukami et al. 1984; Hughes 1986; Hatsukami et al. 1987; Hughes 1992; Hughes 2007). Most of these unpleasant symptoms are the reasons for relapse among Malaysian smokers (Wee et al. 2011) and smokers would be thinking of the difficulty in quit attempt (Jorenby et al. 1996; West and Shiffman 2001). Previous studies have shown that these symptoms rise strongly in the first week of quit attempt, before reverting slowly to a level as the same or lower than the baseline level (Hughes 1992). Thus, most relapse in smoking may occur within the first weeks of quit attempt. Study has demonstrated that withdrawal symptoms could predict failure in quitting (McCarthy et al. 2006). In order to avoid subsequent relapse, Ramadan fasting may facilitate Muslim smokers to break the habit easily. Total fasting could reduce excess hunger and rapid weight loss (Ahmad et al. 2012; Norouzy et al. 2013). In addition, nicotine patch has been proven to be effective in reducing the withdrawal symptom events (Jorenby et al. 1996). Nicotine patch is the most appropriate medication that could be used during Ramadan as oral medication is not allowed during daylight.

Previous studies have examined the time course of tobacco withdrawal symptoms over time and their relation to lapse among smokers. To the best of our knowledge, studies on the benefits of using nicotine patch during Ramadan in controlling the withdrawal symptoms are limited. Thus, our objective is to investigate the time course of nicotine withdrawal symptoms among smokers who used nicotine patch to quit smoking during Ramadan fasting.

MATERIALS AND METHODS

PARTICIPANT RECRUITMENT

This was a prospective study conducted in the workplace in Universiti Kebangsaan Malaysia (UKM). A total sample size of 60 was calculated using the quit rate (21.7%) from a previous study (Fiore et al. 2008) using a confidence interval of 95% and power of 80%. Estimating a drop out rate of 20%, the targeted sample size was 72. Purposive sampling was conducted which includes Muslim male staffs who were regular smokers and interested to quit smoking during Ramadan fasting. Women were not included because of disruptions of fasting during menstrual period, which might obscure the effects of sustained fasting. Recruitment was promoted by distributing posters, e-mails and invitation letters through the Head of Department in UKM, Bangi and Kuala Lumpur Campus. Talks and by face-to-face approach was also used to promote recruitment. Participants with any cognitive disorders, hearing or speech problem, current or past history on chronic disease such as asthma, cardiovascular disease event, mental disorders, cancer, HIV, serious liver or renal disease or history of transplantation, current use of any quit smoking medications, developed allergy to any components of medication were excluded from this study.

Eligible participants were given a set of self-administered questionnaire regarding their smoking habit profile. Those who fulfilled the inclusion criteria were selected for enrolment and then they were asked to provide their informed consent. This study was approved by the Registrar of UKM and UKM Medical Centre Research Ethics Committee with reference number (UKM 1.5.3.5/244/NF-017-14). At the end of the therapy session they were given the UKMS' continuous training point as a token of appreciation for their participation and time allocated.

SETTING AND SMOKING CESSATION PROGRAM

This study was conducted from March to July 2015. A temporary smoking cessation corner in UKM Health Centre, Bangi and UKM Community Pharmacy, Kuala Lumpur Campus was set up. The smoking cessation program consisted of both pharmacotherapy (Niquitin patch, GSK) and behavioural therapy. The session was handled by a trained pharmacist who undergone smoking cessation

training. Each participant received the minimum of five counseling sessions within the first three months of quit smoking with the pharmacist during working hours. The treatment was conducted during Ramadan to encourage the staffs to quit smoking.

During the first appointment, participants were informed about the details of the program and were counseled regarding the usage of nicotine patch, withdrawal symptoms and 4Ds (Delay, Deep breath, Drink, Distract) practice. These education points were also provided to participants through self-help pamphlets. Nicotine dependence level was assessed using the Malay version of the Fagerstrom Test for Nicotine Dependency (Anne Yee et al. 2011). Participants smoking status was determined by measuring the level of carbon monoxide (CO) using CO analyser (Mirco, UK) in an exhaled air sample.

Seven days prior to the quit date (18th Jun 2015, first day of Ramadan), participants were allowed to smoke and record the amount of cigarettes they smoked. They were also advised to reduce the quantity of cigarette sticks within this period. Nicotine patch was given biweekly for one month to the participants a week before quit date depending on the number of cigarettes smoked per day before quitting. Participants who smoke ten cigarettes per day or less was given 14 mg nicotine patch for six weeks and then the dosage was lowered to 7 mg for two weeks. Participants who smoke more than ten cigarettes per day was given 21 mg nicotine patch for six weeks. Then the dosage was lowered to 14 mg for two weeks followed by 7 mg for two weeks. Participants should comply on the usage of patches for eight or ten weeks to achieve optimum results.

They were required to use the patch on the proposed quit date which is the first day of Ramadan as a quit date. Patches were worn for 24 hours by the participants. Participants were counseled on the usage of the new patch every morning to a clean, non-irritated portion of the torso or arms, below the neck and above the waist. Each participant was given a daily diary which contained (i) a table to record the daily cigarette smoked, (ii) withdrawal symptoms score sheets and (iii) a table to record the CO reading. They were advised to complete their diaries every day. Participants were followed up biweekly for the first three months to determine their smoking status and pattern of changes in their withdrawal symptoms.

OUTCOME MEASURES

Participants' Socio-demographic Information, Smoking Characteristics and Abstinence Rate were measured. Demographic profile included age, educational level, marital status, household monthly income and occupational status. A smoking history questionnaire was developed for this study and it includes age of started smoking, number of cigarettes smoked per day, nicotine dependence and previous quit attempts. Smoking cessation was assessed via a smoking diary and CO concentration values were measured at post Ramadan. Participants' body weight

was assessed at pre and post Ramadan. The abstinence rate was calculated based on self-report and presented with repeated point prevalence abstinence. Repeated point prevalence was monitored in the first, third and sixth month of quitting.

We used nine items of validated Malay version of Minnesota Nicotine Withdrawal Scale (Blebil et al. 2014). The original scale was developed in 1986 to assess nicotine withdrawal symptoms (Hughes and Hatsukami 1986). It is concise (Etter and Hughes 2006) and most frequently used instrument (Shiffman et al. 2004; Hughes 2007b) contained urge to smoke/craving for cigarettes, depressed mood, irritability/frustration or anger, anxiety, difficulty concentrating, restlessness, increased appetite, difficulty going to sleep and impatient. These nine symptoms are valid withdrawal symptoms and include items that cover all symptoms of the smoking withdrawal syndrome as listed in Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV). Although craving is not one of the DSM-IV criteria, it is considered to be a crucial specific symptom of the nicotine withdrawal (Hughes et al. 1994; Sayette et al. 2000) and was included in the daily assessments. The validity and psychometric profile have been described in several studies (West et al. 2001; Etter and Hughes 2006). The participants were required to rate the withdrawal symptom events based on 'how they feel' or 'what they have noticed' before and after Ramadan. The nine items were rated on a 5 point Likert scale ranging from 0-not present to 4-severe. The higher the score, the higher the level of withdrawal symptoms.

ANALYSIS

The results were analyzed using SPSS version 21.0. Patients' socio-demographic, smoking characteristics, CO and body weight reading were presented using frequency counts, means and standard deviation. Impact of smoking withdrawal was computed as the difference between baseline value and post-quit follow up value (day 1, days 7, week 4). In order to determine the time course of smoking withdrawal symptoms, the mean value for every measure of smoking withdrawal was plotted for each day and week throughout Ramadan fasting. To test the statistical significance of all measures withdrawal symptoms, the change between the baseline and post-quit for each participant on each measure was computed using a one sample paired t-test. A paired t-test on the baseline to withdrawal differences was used to compare the greater changes of withdrawal symptoms.

RESULTS

PARTICIPATION, SMOKING CHARACTERISTICS AND ABSTINENCE RATE

The response rate was good with 124 eligible participants fulfilled the inclusion criteria. However, only 55

participants who were interested to quit smoking during Ramadan fasting were enrolled in this study. The other participants were uncontactable and not interested to quit smoking within the next 30 days. Out of 55 participants, only 40 participants completed the treatment within six months. All participants answered the questionnaire on socio-demographic prior to the pharmacotherapy treatment. The characteristic of study participants is shown in Table 1. All participants were found to be well tolerated with nicotine patch. The average number of cigarettes smoked

per day was 15 cigarettes. There were highly significant differences in mean exhaled CO between baseline, second and fourth week of quitting. Meanwhile, there was no significant difference in mean body weight between baseline and fourth weeks of quitting. More than half of the participants adhered to the application of nicotine patches. Repeated point prevalence abstinence at the first month of quitting was 67.5%, followed by 52.5% and 32.5% at the third and sixth month of quitting. Results showed that the abstinence rate was higher during fasting month.

TABLE 1. Characteristics of study participants

Socio- demographic and smoking characteristic	Frequency (%) n = 36	Mean (SD)
Age (years)	-	38.11 (9.74)
FTND	-	1.86 (1.35)
Low	23 (64)	-
Moderate	3 (8)	-
High	10 (28)	-
Cigarettes per day		15.28 (6.04)
<10	12 (33)	-
>10	24 (67)	-
Smoking within 30 min of waking previous quit attempt	18 (50)	-
0	6 (18)	-
≥ 1	27 (82)	-
Carbon monoxide in exhaled breath (ppm)		
Baseline	-	14.58 (7.25)
Post-2 week	-	4.06 (3.37)*
Post-4 week	-	4.64 (3.19)*
Body weight (kg)		
Baseline	-	75.86 (11.13)
Post-4 week	-	75.33 (11.02)

*p ≤ 0.001

CHANGE OVER TIME IN WITHDRAWAL SYMPTOMS

Figure 1 illustrates the time course of mean in withdrawal symptoms over four weeks of abstinence during Ramadan fasting. The results showed that the effects of withdrawal occur within 30 days for all of the outcome measures. During the first 2 weeks of Ramadan fasting, almost all the symptoms showed a sharp and steady decline and leveled out by third and fourth week of Ramadan. Although the symptoms increased slightly on day 11 and day 12, the level is still below the baseline. Thus, after a marked decline in the first week, all the withdrawal symptoms become increasingly less yielding. All symptoms had declined below baseline by the end of day 28.

The outcome measures that changed significantly were decreased in urge to smoke at day 7 and week 4 ($P \leq 0.001$ and $P \leq 0.000$, respectively), depressed mood in week 4 ($P \leq 0.001$), irritability, frustration or anger at day 7 and week 4 ($P \leq 0.05$ and $P \leq 0.05$, respectively), anxiety in week 4 ($P \leq 0.05$), difficulty in concentrating at day 7 and week

4 ($P \leq 0.001$ and $P \leq 0.000$, respectively), restlessness at day 7 and week 4 ($P \leq 0.05$ and $P \leq 0.000$, respectively), difficulty in going to sleep at day 1, day 7 and week 4 ($P \leq 0.05$, $P \leq 0.001$ and $P \leq 0.000$, respectively) and impatient at week 4 ($P \leq 0.05$) (Table 2). Increased appetite symptoms showed a slight drop pattern over the four weeks (Table 1). However, no significant difference at day 1, day 7 and week 4 compared to the baseline value was noted (Table 2).

There were significantly greater changes in urge to smoke at day 7 compared to the baseline ($t = 8.73$, $P \leq 0.001$), urge to smoke at week 4 compared to the baseline ($t = 8.27$, $P \leq 0.001$), restlessness at week 4 compared to the baseline ($t = 6.32$, $P \leq 0.001$) and difficulty going to sleep at day 1 ($t = 6.19$, $P \leq 0.001$), day 7 ($t = 6.04$, $P \leq 0.001$) and week 4 ($t = 6.18$, $P \leq 0.001$) compared to the baseline. There was a significant difference in the baseline and day 1, 7 and week 4 post Ramadan for increased appetite ($P \leq 0.001$).

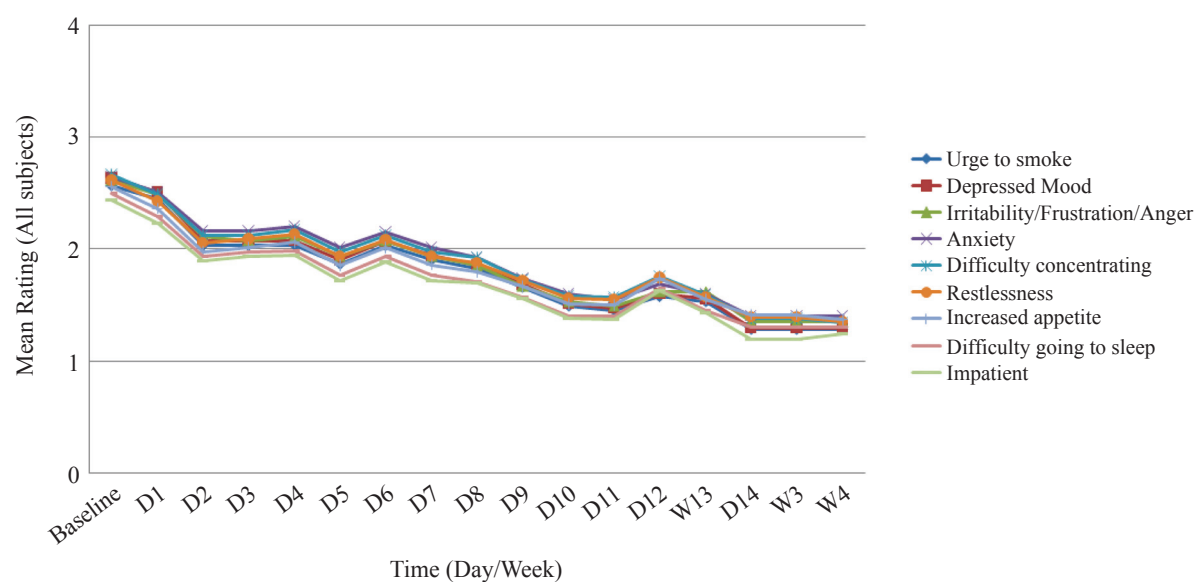


FIGURE 1. Time course of mean rating of participants' withdrawal symptoms over four weeks during Ramadan fasting

DISCUSSION

Ramadan fasting offers the opportunity for the smokers to quit smoking even for a temporary abstinence. Fasting relate to the changes in psychosomatic, daily activities and nicotine withdrawal symptoms. Application of NRT has been shown to alleviate the nicotine withdrawal symptoms among quitters (Jorenby et al. 1996). Therefore, this study is important to investigate the time course of the common nine withdrawal symptoms among smokers using nicotine patch specifically during Ramadan fasting.

The result of this study showed significant changes in withdrawal symptoms during smoking cessation. Time course analyses demonstrated that all measures showed good effects during cessation. In general, only eight withdrawal effects were found to change significantly in this study; urge to smoke, depressed mood, irritability, anxiety, difficulty in concentrating, restlessness, difficulty in going to sleep and impatient. The withdrawal symptoms declined over time on the first day of cessation until week two and almost faded away in week three and four post-smoking cessation (Figure 1). The time course over time for withdrawal effects could be best described by a declining linear slope. Regardless of the number of mean withdrawal ratings, parameters in our study were almost similar to the previous studies (Hughes et al. 1992; Van Zundert et al. 2009). In the previous study, parameters of withdrawal effects such as anxiety, difficulty concentrating, irritability and hunger showed peak on day 2 to 3, however, no peak of withdrawal effects were noted in the present study. A study revealed the course over time of study on tobacco withdrawal symptoms using trans-dermal nicotine shows quadratic trend for several symptoms (Jorenby et al. 1996). However, this study showed that majority of the smokers experienced relief from total withdrawal symptoms a week

earlier when they use the nicotine patch and the symptoms decline steadily below the baseline levels in two to three week post-cessation.

Comparing to a non-fasting condition, the duration of nicotine withdrawal could last for two to four weeks of abstinence except hunger and craving (Hughes 1992; Hughes 2007a) which persists for more than six months (Hughes et al. 1994). An explanatory study is needed to investigate the changes in the pattern of craving and increased appetite of participants until sixth month. Meanwhile, most nicotine withdrawal has an onset of 2 to 12 hours after cessation and peak in 1 to 3 days (Hughes 1992; Hughes et al. 1994).

Urge to smoke is a main notable effect of withdrawal symptoms (Piasecki 2006; Bagot et al. 2007). Increased urge to smoke is associated with the amount of nicotine intake (Hatsukami et al. 1987). The daily cigarette intakes in fasting month was less compared to normal days as smoking is prohibited during daylight. Perhaps the urge to smoke was reduced by low or no intake of cigarettes, and in addition of application of slow release of nicotine patch. On the other hand, previous studies (Alsene et al. 2003; Kendzor et al. 2008; Leeman et al. 2010) found that food deprivation or calorie restriction increases the craving towards cigarettes, and another study commented that this event could be hard for Muslim smokers to stop smoking abruptly in Ramadan (Aveyard et al. 2011). Nicotine patch application during prolonged fasting could avert this event from happening as self-reports of craving was statistically significant and declined gradually over time from first week till fourth week of cessation. A similar study using nicotine patch and same outcome measures determined that self-reports on craving were significantly increased in the immediate post-cessation period and later decreased gradually (Jorenby et al. 1996). The comparison is made

TABLE 2. The mean difference of smoking withdrawal symptoms at 1-, 7-, 14-, 21-, and 28-Day follow up than at pre-cessation among participants (n = 40)

Symptoms	Mean rating difference (SD)			Mean rating difference (SD)			Mean rating difference (SD)			Mean rating difference (SD)					
	Baseline – day 1 post Ramadan	t	P value	Baseline – day 7 post Ramadan	t	P value	Baseline – day 14 post Ramadan	t	P value	Baseline – day 21 post Ramadan	t	P value	Baseline – day 28 post Ramadan	t	P value
1. Urge to smoke/	0.06 (0.61)	0.57	0.57	0.58 (0.94)	3.53	0.001***	1.06 (1.27)	4.79	0.000***	1.06 (1.27)	4.79	0.000***	1.06 (1.27)	4.78	0.000***
2. Depressed mood	0.06 (0.66)	0.53	0.60	0.36 (1.11)	1.88	0.07	0.69 (1.21)	3.30	0.002**	0.81 (1.23)	3.80	0.001***	0.91 (1.38)	3.79	0.001***
3. Irritability/ frustration or anger	0.06 (0.70)	0.49	0.62	0.42 (1.22)	1.98	0.05*	0.76 (1.34)	3.23	0.003**	0.76 (1.34)	3.23	0.003**	0.79 (1.39)	3.26	0.003**
4. Anxiety	-0.15 (0.76)	-1.15	0.25	0.24 (1.06)	1.31	0.19	0.52 (1.09)	2.71	0.01**	0.52 (1.09)	2.71	0.01**	0.60 (1.22)	2.84	0.008**
5. Difficulty concentrating	-0.00 (0.79)	-0.00	1.00	0.58 (0.90)	3.66	0.001***	0.82 (1.26)	3.73	0.001***	0.82 (1.26)	3.73	0.001***	0.88 (1.21)	4.14	0.000***
6. Restlessness	0.15 (0.62)	1.41	0.16	0.58 (1.12)	2.96	0.006**	0.94 (1.20)	4.51	0.000***	0.94 (1.20)	4.51	0.000***	1.03 (1.21)	4.89	0.000***
7. Increased appetite	-0.03 (0.17)	-1.00	0.32	0.03 (0.59)	0.29	0.76	-0.09 (1.01)	-0.52	0.61	-0.09 (1.01)	-0.52	0.61	0.03 (1.16)	0.15	0.88
8. Difficulty going to sleep	0.21 (0.55)	2.23	0.03*	0.55 (0.87)	3.60	0.001***	1.03 (1.16)	5.11	0.000***	1.03 (1.16)	5.11	0.000***	1.06 (1.17)	5.20	0.000***
9. Impatient	0.03 (0.59)	0.29	0.768	-0.21 (0.96)	-1.26	0.214	0.69 (1.33)	3.00	0.005**	0.69 (1.33)	3.00	0.005**	-0.76 (1.37)	-3.17	0.003**

*p ≤ 0.05, **p ≤ 0.01, *** Paired t-test p ≤ 0.001

to the present study where self-reports on craving were significantly declined over time. Perhaps this dissimilarity has occurred because of the presence of Ramadan itself.

Prior studies demonstrate the negative affect seems to drop over time to the level lower than previous reports before quitting among successful quitters, and to continue at the same level or even elevated among failed smokers (Hughes 1992; Van Zundert et al. 2009; Etter et al. 2012). These negative affect such as depressed mood, irritability/anger, anxiety, restlessness and impatient is a core withdrawal symptoms. During Ramadan, the level of irritability and anxiety symptoms were higher among both smokers and non-smokers especially towards the end of Ramadan (Kadri et al. 2000). However, in contrary with our study, a declining trend was seen in self-ratings of all negative affect symptoms till the end of Ramadan. Indeed, the usage of nicotine patch during Ramadan most likely reduced these negative affect. However, these circumstances is different to the study (Jorenby et al. 1996) which showed the peak of symptoms occurred on day 1 to 3 of abstinence within the duration of 2 to 4 weeks.

Smoking cessation would worsen sleep and it is associated with depression and other sleep abnormalities (Hughes 2007). During Ramadan, the total amount of sleep may be affected due to late night prayers and major shift in the timing of meals. This would increase the frequency of sleep during the day to compensate (Kadri et al. 2000; South et al. 2013; Farooq et al. 2015). The difficulty in sleeping was almost hardly applicable in this study as the data shows significant declined and remained stable. Detailed research is needed to explore more effective ways of measuring insomnia including rapid eye movement and sleep fragmentation.

Previous studies have shown increased appetite and body weight after tobacco cessation among smokers (Hatsukami et al. 1987; Hughes 1992). This study showed lower self-rating of appetite and less changes in body weight at week 4. However, the result was found to be non significant (Table 2). These could happen due to fasting. In addition, nicotine patch itself could reduce feeling of hunger and delay weight gain among successful quitter (Jorenby et al. 1996). Quitting smoking upon fasting month could prevent fear of weight gain due to cessation among Muslim smokers.

The time course of withdrawal symptoms presented in this study may have notable, practical or clinical implications in managing smoking cessation program during Ramadan with the aid of nicotine patch. This study has shown that most smokers would have lesser effect of withdrawal symptoms throughout Ramadan fasting if they use the nicotine patch. All the symptoms declined steadily to below the baseline levels within two week post-cessation and leveled out in third and fourth week. In addition, the effectiveness of nicotine patch therapy in reducing nicotine withdrawal symptoms and information on the time course of these symptoms could be utilised in pre-

cessation counseling prior to Ramadan. Indirectly, this may encourage smokers to quit and reduce relapse especially in fasting environment. In fact, compared to the first week of using patches, participants reported less craving, less depressed mood, less anger/frustration/irritability, less anxiety, less difficulty in concentrating, less restlessness, less difficulty in going to sleep and less impatience than they reported earlier before quitting. Although the results are statistically insignificant, the application of nicotine patch during Ramadan has shown reduced appetite and weight gain among successful participants. Fear of weight gain could be prevented by doing so.

There are several limitations of this study that should be focused on future research, which are small sample size and the sample population which did not include women. Thus, future research should be based on a representative sample of the general population and taking into account other issues such as psychological impairments during Ramadan. Furthermore, research is needed to explore more effective ways to measure craving and other withdrawal symptoms.

CONCLUSION

Time course analyses demonstrated that all outcome measures showed good effects during cessation in fasting month. This has shown positive clinical implications in managing smoking cessation program during Ramadan with the aid of nicotine patch.

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