

RISK ASSESSMENT – ACUTE NICOTINE ADMINISTRATION

School: Exp Psychol	Location: 12a Priory Road	Activity: Research	Date: 10.07.2018
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Purpose: This risk assessment is relevant to any study delivering acute doses of nicotine to smokers or non-smokers.

Note on use: All studies should refer to Table 1, which details general effects of nicotine regardless of the delivery vehicle used. After, please refer to Table 2 and identify the vehicle-specific effects of nicotine that are relevant to your study (i.e., depending on the vehicle that will be used). If you are delivering nicotine via cigarettes (smokers only), refer to Table 3. Many symptoms are common and expected (see frequency column Tables 1-3). If symptoms are mild, their presentation does not mean participants should be withdrawn from the study, although immediate delivery of nicotine should be stopped. Participants should not continue if the symptoms are considered severe or serious or if the participant wishes to withdraw.

All studies should consider the following when using this risk assessment:

- This risk assessment can only be considered when **the nicotine administration is given acutely (i.e., single doses)**. Single doses may be given on multiple occasions (e.g., once per week for three weeks), but this risk assessment should not be used for continuous nicotine delivery (i.e., more than 2 administrations per day, lasting more than 1-week).
- **The likelihood, severity and duration of adverse events is likely to be higher in non-smokers.**
- **The likelihood, severity and duration of adverse events is likely to increase as the dose of nicotine increases.**
- Unless noted otherwise, all hazards are considered non-serious and transient.
- For all entries (unless otherwise stated), we consider that only **research participants might be harmed**. There are no anticipated risks for the researcher. The exception to this are effects of second-hand smoke when delivering nicotine by cigarette (refer to Table 3).
- **Participants must be informed about the potential side effects on the Participant Information Sheet, and informed consent must be taken.**
- The staff member should stay with the participant at all times following nicotine administration (until end of study session).
- If the staff member administering the nicotine is not a first-aider, “level 2” phone support must be in place (i.e., a first aider must be available on the phone and within the Experimental Psychology buildings for the duration of each session).
- If nicotine is administered via smoking, testing must take place in designated research cubicles for indoor smoking (e.g., smoking lab., 5 Priory Road).

Study specific information

Study title:

Ethics reference:

Nicotine dose:

Vehicle:

Smoking status of participants (circle): Daily smoker / Weekly smoker / Occasional (i.e., less than weekly) smoker / non-smoker

If your dose is high and/or being administered to very infrequent smokers/non-smokers, the likelihood and severity of symptoms may be higher than suggested in tables below.

Table 1. General effects of nicotine (all methods of delivery)

Effect	Frequency	Action
Headache (mild)	Common	Upon presentation, participants will be instructed to stop all nicotine administration. The participant should sit in a quiet space until they feel better and offered a glass of water. If the issue continues then a first aider will be called (via laboratory 'phone) to assess the situation. In the case of vomiting, the participant will also be given a sick bag; once participants feel that they are able to move, they will be brought to the first aid where they can rest until they feel better. Student participants may be taken to the Student Health Service if symptoms persist. If the symptoms worsen or are very severe an ambulance should be called.
Nausea	Common	
Vomiting	Common	
Syncope (fainting)	Uncommon	Upon presentation participants will be instructed to stop all nicotine administration. A first aider will be called (via laboratory phone) to assess the situation. If the symptoms worsen or if the participant loses consciousness for longer than 1 minute, then an ambulance will be requested. At the start of the study you should assess your lab space to ensure there is appropriate facilities in case of fainting/dizziness (e.g., comfortable chair, floor space to lie down).
Mood changes	Very Uncommon	Upon presentation of symptoms (mood alterations, included heightened irritability and heightened reports of feeling 'low') the participant will be instructed to stop all nicotine administration. They will be followed up to ensure any mood change is not ongoing. Participants will be advised to seek advice from their doctor if symptoms last longer than 48 hours post cessation of nicotine.

Table 2. Vehicle-specific effects of nicotine

Vehicle	Effects	Frequency	Action
Nicotine Mouthspray	Salivary hypersecretion	Very Common	Upon presentation of symptoms the participant will be able to sit down in a quiet space until they feel better and offered a glass of water.
	Burning sensation in mouth		
	Throat tightness or numbness	Common	Upon presentation of symptoms the participant will be able to sit down in a quiet space until they feel better and offered a glass of water. If the pains/ discomfort continues then a first aider will be called (via laboratory 'phone) to assess the situation. If the symptoms worsen then an ambulance will be requested. Nicotine administration should be stopped.
	Respiratory symptoms	Very Uncommon	Upon presentation of symptoms, all nicotine administration should be stopped. The researcher will contact a trained first aider via lab phone. If symptoms persist, worsen or the participant loses consciousness further medical attention will be required (i.e., an ambulance will be called).
	Heart racing/increased heart rate / palpitations	Very Uncommon	
Hot flushes/ Increased sweating	Very Uncommon	Upon presentation of symptoms the participant will be able to sit down in a quiet space until they feel better and offered a glass of water. These are expected to be transient and non-serious unless accompanied with other respiratory / cardiovascular symptoms (see above).	
Nicotine Inhaler	Salivary hypersecretion	Very Common	Upon presentation of symptoms the participant will be able to sit down in a quiet space until they feel better and offered a glass of water.
	Burning sensation in mouth	Very Common	
Nicotine Gum	Salivary hypersecretion	Very Common	Upon presentation of symptoms, the participant, if still chewing the gum, will be asked to remove it. The participant will be able to sit down in a quiet space until they feel better and offered a glass of water.
	Burning sensation in mouth	Very Common	
	Throat tightness or numbness	Common	Upon presentation of symptoms the participant, if still chewing the gum, will be asked to remove it and will be able to sit down in a quiet space until they feel better and offered a glass of water. If the pains/ discomfort continues then a first aider will be called (via laboratory 'phone) to assess the situation. If the symptoms worsen then an ambulance will be requested. Nicotine administration should be stopped.
	Sleep disturbances / Altered sleeping patterns / Nightmares	Common	Reported cases have been transient. Upon presentation of symptoms, the participant will be asked to stop all nicotine administration.

	Heart racing/increased heart rate / palpitations	Very Uncommon	Upon presentation of symptoms, all nicotine administration should be stopped. The researcher will contact a trained first aider via laboratory 'phone. If symptoms persist, worsen or the participant loses consciousness further medical attention will be required (i.e., an ambulance will be called).
	Hot flushes/ Increased sweating	Very Uncommon	Upon presentation of symptoms the participant will be able to sit down in a quiet space until they feel better and offered a glass of water. If they are still chewing gum, they will be asked to remove it. These are expected to be transient and non-serious unless accompanied with other respiratory / cardiovascular symptoms (see above).
Nicotine Nasal Spray	Salivary hypersecretion	Very Common	Upon presentation of symptoms the participant will be able to sit down in a quiet space until they feel better and offered a glass of water.
	Burning sensation in mouth	Very Common	
	Throat tightness or numbness	Common	Upon presentation of symptoms the participant will be able to sit down in a quiet space until they feel better and offered a glass of water. If the pains/ discomfort continues then a first aider will be called (via laboratory 'phone) to assess the situation. If the symptoms worsen then an ambulance will be requested. Nicotine administration should be stopped.
	Heart racing/increased heart rate / palpitations	Very Uncommon	Upon presentation of symptoms, all nicotine administration should be stopped. The researcher will contact a trained first aider via laboratory 'phone. If symptoms persist, worsen or the participant loses consciousness further medical attention will be required (i.e., an ambulance will be called).
	Hot flushes/ Increased sweating	Very Uncommon	Upon presentation of symptoms the participant will be able to sit down in a quiet space until they feel better and offered a glass of water. These are expected to be transient and non-serious unless accompanied with other respiratory / cardiovascular symptoms (see above).
Nicotine Patch	Sleep disturbances / Altered sleeping patterns / Nightmares	Common	Upon presentation, participants will be instructed to stop all nicotine administration. They will be asked to clean the area of the skin the patch was placed on with hot water and soap to remove any residual nicotine left on the skin.
	Localised skin irritation / Hypersensitivity (including rashes, itching of the skin)	Common	Upon presentation of symptoms the patch will be removed and the participant will be instructed to clean the area with hot soapy water. If the irritation persists or fails to reduce in severity the participant will be told to seek further medical attention. Note: Irritation usually reduces significantly within the first 24 hours.

	Heart racing/increased heart rate / palpitations	Very Uncommon	Upon presentation of symptoms, the patch will be removed and the area cleaned with hot soapy water. The researcher will contact a trained first aider via laboratory 'phone. If symptoms persist, worsen or the participant loses consciousness, further medical attention will be required (i.e., an ambulance will be called).
	Hot flushes/ Increased sweating	Very Uncommon	Upon presentation of symptoms the participant will be able to sit down in a quiet space until they feel better and offered a glass of water. The patch should be removed and the skin cleaned with hot soapy water. These effects are expected to be transient and non-serious unless accompanied with other respiratory / cardiovascular symptoms (see above).
Nicotine Lozenges	Salivary hypersecretion	Very Common	Upon presentation of symptoms, the participant, if still sucking the lozenge, will be asked to remove it. The participant will be able to sit down in a quiet space until they feel better and offered a glass of water.
	Burning sensation in mouth		
	Throat tightness or numbness	Common	Upon presentation of symptoms, the participant, if still sucking the lozenge, will be asked to remove it. The participant will be able to sit down in a quiet space until they feel better and offered a glass of water. If the pains/ discomfort continues then a first aider will be called (via laboratory 'phone) to assess the situation. If the symptoms worsen then an ambulance will be requested.
	Sleep disturbances / Altered sleeping patterns / Nightmares	Common	Upon presentation participants will be instructed to stop all nicotine administration.
	Heart racing/increased heart rate / palpitations	Very Uncommon	Upon presentation of symptoms, all nicotine administration should be stopped. The researcher will contact a trained first aider via laboratory 'phone. If symptoms persist, worsen or the participant loses consciousness further medical attention will be required (i.e., an ambulance will be called).
	Hot flushes/ Increased sweating	Very Uncommon	Upon presentation of symptoms the participant will be able to sit down in a quiet space until they feel better and offered a glass of water. If the lozenge is still in the mouth, they will be asked to remove it. These effects are expected to be transient and non-serious unless accompanied with other respiratory / cardiovascular symptoms (see above).

Table 3. Delivering nicotine via cigarettes

Note: cigarettes should only be administered to smokers. Therefore, adverse effects are not expected unless cigarettes have very high nicotine yield. It is advisable to ask participants to smoke one of their own cigarettes if the study design allows.

Risk	Who?	Frequency	Action
Effects of smoke exposure, including second-hand smoke (e.g., tight chest)	Participant and researcher	Common	The risk of long-term damage is low to very limited exposure (e.g., single session). To mitigate harm, smoking should take place either outside in a designated smoking area or in the smoking laboratory ventilated cubicles (see associated risk assessment for using this laboratory).

Approvals

Reviewed and approved by (name and role)	Department/School/Unit	Date
Marcus Munafò, Professor of Biological Psychology and Director of Tobacco and Alcohol Research Group	School of Experimental Psychology	20.02.2018
Anthony Crawford, Technical Manager	School of Biological Sciences	10.07.2018