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STUDY PROTOCOL

Investigating the effects of self-reported sleep quality and fatigue severity in smokers

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Background

Smoking continues to carry a large negative burden on population health and is the most important modifiable behaviour influencing premature death. Despite many smokers reporting wanting to quit, many fail to do so (Zhou et al., 2009). It is therefore important to understand factors influencing smoking behaviour and contributing to relapse.

Poor sleep is associated with a plethora of negative affective, cognitive and physical outcomes. Furthermore, sleep is reported to differ among smokers, and poorer sleep quality (SQ) (indexed by factors such as onset latency, efficiency, disturbance and duration) may be a mechanism promoting relapse (Zhou et al., 2009). Therefore, sleep quality could predict smoking relapse both prior to and during smoking abstinence (Patterson et al., 2019).

In addition to general measures of self-reported sleep quality, self-reported daytime fatigue may be an easily measurable predictor of smoking relapse. Fatigue reflects the experience of lacking energy, tiredness and feeling exhausted (Shen et al., 2006). Previous work has hypothesised that fatigue may increase the risk of smoking relapse as smokers know, from previous behaviour, that stimulation from nicotine counteracts fatigue (Hamidovic & de Wit, 2009).

This online study will explore the relationship between both self-reported sleep quality and fatigue severity on multiple smoking relapse predictor variables. The findings of this study will inform future intervention development and contribute to a current gap in the literature.

Study Objectives and Hypotheses

The primary objective of this study is to investigate the relationship between self-reported SQ and fatigue severity on multiple smoking relapse predictor variables and smoking-related beliefs in smokers.

H1. Self-reported SQ (acute [primary exposure] and habitual [secondary exposure]) and fatigue severity will be positively associated with relapse predictor variables (abstinence self-efficacy, delay discounting, smoking urges), lower perceived benefits and greater perceived risk of cessation, and greater perceived barriers for quitting.

In addition, we will explore the value of adding self-reported fatigue to a model investigating the relationship between SQ and the smoking-related outcomes. This will inform interventions by identifying whether more variance is explained by the inclusion of both measures.

Study Design

This will be a cross-sectional observational design, utilising survey responses to explore the relationship between self-reported SQ and fatigue severity, on multiple smoking relapse predictor variables and smoking related beliefs in smokers.

Study Site

This study will be conducted online, designed and hosted on the Qualtrics online survey platform (http://www.qualtrics.com/). The study will be administered via the School of Psychological Science at the University of Bristol.

Participants and Recruitment

440 adults who smoke ($\geq$ 5 cigarettes per day for at least 3 months) will be recruited through the Prolific crowdsourcing platform (https://www.prolific.ac/). Screening questions will be used so that the study is only advertised to members who meet the inclusion criteria, which are outlined below. Participants who are interested in taking part will read an information statement and will be given the opportunity to contact the researcher if they have any questions, before giving their consent to participate.

Participation is expected to take approximately 30 minutes to complete and participants will be reimbursed £3.75 on completion (based Prolific's recommended reimbursement rate of £7.50/hour). Participants who begin the experiment but do not complete it will not be reimbursed. In addition, those who do not meet the inclusion criteria will not be reimbursed. These participants will be replaced. Participants will be informed of this in the information displayed at the start of the study.

Inclusion criteria (all self-report)

- Aged 18 years of age or over
- Regular smoker (at least 5 cigarettes per day for at least 3 months)
- English as a first language or similar level of fluency

Exclusion criteria (all self-report)

- Pregnancy or breast-feeding
- Current drug use disorder
- Diagnosed with medical disorder which disrupts sleep or causes fatigue (including diagnosis of mental health disorder)
- Currently taking medication which listed side effects include drowsiness, tiredness or fatigue as side effect

Sample size determination

A sample size calculation was completed using GPower 3.1, for a fixed model linear regression model, with a power of 0.95 and an alpha of 0.01. An ΔR^2 value of 0.03 and residual variance of 0.68 was chosen from (Zvolensky et al., 2019). This gave a total sample size estimate of 408 participants. To account for post-hoc removal of outliers/attention check failures, we will recruit 440 participants.

Measures and Materials

Demographics

Age, sex, country of residence, and highest qualification attained (with the options: 'Higher Education or professional / vocational equivalents', 'A levels or vocational level 3 or equivalents', GCSE / O Level grade A*-C or vocational level 2 or equivalents', 'Qualifications at level 1 and below', 'Other qualifications: level unknown', or 'No qualifications'), Nicotine Dependence (Fagerstrom Test of Nicotine Dependence), e-cigarette user status, 12 month quit-attempt history and cigarettes smoked per day will be recorded.

Independent variables

Pittsburgh Sleep Quality Index (PSQI): The PSQI (Buysse et al., 1989) has been widely used in the context of sleep and behavioural research. Nineteen items generate a global sleep quality score and provides scores on subjective sleep efficiency, quality, onset latency, disturbances, duration, medication and daytime dysfunction. Validity and reliability of this instrument are reported elsewhere (Buysse et al., 1989; Carpenter & Andrykowski, 1998).

The above instrument will be adapted to measure the previous night's sleep. This will create two measures of sleep quality: acute sleep quality (primary exposure) and habitual sleep quality (secondary exposure).

Fatigue Severity Scale (FSS): The FSS (Krupp et al., 1989) is a well validated 9-item scale of fatigue severity. Questionnaire items are rated by a 7-point Likert scale (1 to 7 (no impairment- severe impairment)). Scores >5 indicate clinically significant levels of fatigue (Bakshi et al., 1999).

Dependent variables

Readiness to Quit Ladder: The Readiness to Quit Ladder is single item continuous measure of motivation to change smoking behaviour that uses a 10-point scale with responses ranging from 1 = "I have decided to continue smoking" to 10 = "I have already quit smoking." This instrument performs well when predicting smoking rate, quit attempts and cessation, and is associated with cognitive and behavioural indicators of readiness to consider smoking abstinence (Biener & Abrams, 1991; Prochaska & DiClemente, 1983).

The Barriers to Smoking Cessation Scale (BCS): The BCS (Macnee & Talsma, 1995) is a four-point Likert type scale of 19 items describing general circumstances or specific perceived barriers that may interfere with a quit attempt. It has been shown to be a reliable measure of perceived barriers and is related to several affective and smoking processes that may interfere with smoking cessation (Garey et al., 2017).

Perceived Risks and Benefits Questionnaire (PRBQ): PRBQ (McKee et al., 2005) is a 40-item instrument assessing perceived risks (e.g. weight gain) and benefits (e.g. social approval) of smoking cessation on a 7 point Likert scale (1 = no chance, 7 = certain to happen). This instrument has demonstrated superior reliability and validity when compared to other self-reported measures of personal health risk (McKee et al., 2005).

Abstinence Self-efficacy: Abstinence self-efficacy will be measured by a two 'If you were to quit smoking today, how confident are you that you would not smoke within the next 24 hours' and 'If you were quit smoking today, how confident are you that you would remain abstinent?'. Responses will be measured on a 100-point visual analogue scale from 'not confident' to 'very confident'.

Questionnaire of Smoking Urges (QSU-brief): Smoking Urges will be measured by the QSU-brief (Clausius et al., 2012), a 10-item questionnaire which measures overall smoking urges and two factors: Factor 1 - a strong desire and intention to smoke, with smoking perceived as rewarding and Factor 2 - an urgent desire to smoke in anticipation of relief from negative affect (Clausius et al., 2012). Items for the QSU-brief are assessed using a Likert scale ranging from 0 to 7 (strongly disagree to strongly agree).

Delay Discounting: Delay discounting is a widely used 27-item measure. Participants will be presented with a hypothetical choice between two sums of money, one sum immediately and a larger sum after a varying amount of time (Kirby et al., 1999). For example, participants could be asked to answer if they would prefer £10 immediately or £15 in 1 month.

Attention checks

Given concerns regarding participants' attention in unsupervised research settings, one attention check will be hidden within the questions. *'When was the last time you flew to mars?' ('never'; 'a few days ago'; 'weeks ago'; 'months ago').* Only never responses will be considered satisfactory. The following information will be provided at the start of the study:

'Important –data quality!!!
Data quality is of the utmost importance for this task, please be aware that there are simple test questions that are there to check you are paying due care and attention to answering all the questions. Please note that if you answer these simple questions incorrectly, we will not be able to use your data.'

Procedures

Participants will be recruited using the Prolific online crowdsourcing platform, which provides participants with a link to the study on the Qualtrics platform. Participants will be shown an information statement explaining the study and what they will be required to do. Participants will be informed that they are able to withdraw from the study by closing their browser.

Before commencing the study, participants will complete a tick-box consent page, where they will be given the opportunity to contact the researcher if they have any questions. Participants will then complete the screening, questions will be based on inclusion and exclusion criteria. Individuals who are not eligible will be taken to the end of the experiment and will not be reimbursed. Eligible participants will complete some demographic questions and then complete a battery of measures detailed above.

Finally, participants will be presented with a debriefing screen including information about how they can find more about the study as well as contact details of the researchers if they wish to contact them.

Statistical Plan

Linear regression analyses will be used to assess the association between independent (IV) and dependent variables (DV) for our two primary questions. We will use this model to independently investigate the association between acute SQ (primary question) and smoking outcomes (all DVs), the association between fatigue (primary question) and smoking outcomes (all DVs), and the association between habitual SQ (secondary question) and smoking outcomes (all DVs).

We will use hierarchical regression to explore the secondary question of whether there is an independent effect of fatigue after account for the effects of SQ (acute).

Co-variates will be entered at the first stage of each model and will include (age, sex, education, nicotine dependence, cigarettes per day). These co-variates have been selected based on prior research (Zvolensky et al., 2019). Initial analyses will be run on the full sample, but we will conduct secondary sensitivity analyses removing participants who fail the attention check.

We will also explore the sub-components (i.e., sub-scales on the SQ) on outcomes to determine if some are more influential than others. These are exploratory analyses to inform (i.e., generate hypotheses) for future studies. In particularly they may provide insight into whether certain aspects of sleep should be targeted in intervention development.

Ethical Considerations and Informed Consent

Ethics approval from the School of Psychological Science Research Ethics Committee at the University of Bristol has been granted (reference: 117349). The study will be conducted according to the revised Declaration of Helsinki (2013) and the 1996 ICH Guidelines for Good Clinical Practice E6(R1). The participant will access the information sheet electronically, explaining the nature, purpose, and risks of the study to the participant. There will be no time restriction on how long participants take to complete the survey, with the exception that participants who engage with survey after all study places have been filled will not be able to take part in the study. Therefore, participants will be given sufficient time to read the information and consider any implications, and to raise any questions with the investigators prior to making a decision to participate. Participants will be informed that they are free to withdraw at any time by simply closing the web page.

Data management

All aspects of the General Data Protection Regulation (GDPR) and the Data Protection Act (DPA) 2018 will be adhered to.

Anonymised study data

Limited demographic data will be collected, and this will not enable participants to be identified. Prolific IDs will only be used during the running of the study (for reimbursement purposes) and will be removed from resulting data files. All study data will therefore be anonymised by a unique numeric identifier at the point of collection.

Study data will be stored on an encrypted cloud server. The data may only be accessed via a secure website which requires log-in credentials. Only study personnel will have access to this data at this point (although data will be later shared openly – see below).

Long-term data storage

Electronic data files will be backed up on a secured University of Bristol network drive. At the end of the study, electronic study data (including finalised data sheet) will be transferred to a designated University of Bristol Research Data Storage Facility for long-term archiving. Study data will be kept for a minimum of 15 years. At the appropriate time the data sheet will be locked and made open using the University of Bristol Research Data Repository.

Screening documents and participant contact details

Participants will not be identifiable by the data they provide. Participants will be assigned a unique identifier code from Prolific and we will not collect any contact/personal details. Screening information will only be used by Prolific to determine an individual's eligibility for participation. We will only collect and store research data.

Open data

At the appropriate time the data sheet will be made open using the University of Bristol Data Repository and/or Open Science Framework.

Revoked data

Participants will be unable to revoke their anonymised data once it has been submitted on the final webpage. Participants will be informed of this in the participant information sheet and consent form and reminded on the final webpage prior to submitting. Participants who no longer wish to continue with the study can exit without submitting their data. Incomplete data sets will not be analysed or made open access.

Quality Control and Quality Assurance

The investigators will be responsible for data quality. After approximately 10% of data collection has been completed, the study will undergo a quality assessment. During this monitoring process, the online data stores will be checked to ensure complete recordings of participant data.

Insurance

As this is an online study, we do not foresee any risks to participants. The University of Bristol holds appropriate liability insurance for research studies involving human participants. If required further information can be found at the link below:
http://www.bristol.ac.uk/secretary/insurance/liability-insurance/#employers

Publication Policy

The findings from this research study may be published in an appropriate scientific journal (and made available open access), and/or presented at an appropriate meeting. Study data will be collected and held by the study investigators. The data will be made available for sharing via a University of Bristol online data repository and/or Open Science Framework.

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Conflicts of Interest

The study investigators have no conflicts of interest to declare.

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