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PROTOCOL

A QUALITATIVE EXPLORATION OF SMOKER'S PERCEPTIONS OF SLEEP, FATIGUE AND COGNITIVE BEHAVIOURAL THERAPY FOR INSOMNIA TO INFORM A DUAL-ACTION DIGITAL SLEEP INTERVENTION TO AID SMOKING CESSATION

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Background

Smoking continues to be the leading cause of death and morbidity worldwide (Reitsma et al., 2017). Despite the negative health consequences over 1.3 billion individuals smoke globally (WHO, 2020). Only one in twenty smokers who engage in a quit attempt will remain smoke free (Hughes et al., 2004) and 80% quit attempts will end in relapse within six months (Zhou et al., 2009). Therefore there is a need to explore new strategies and mechanisms to aid individuals quitting smoking.

Poor sleep quality, both pre and post cessation, increases the risk of relapse during a quit attempt (Patterson et al., 2019). Consequently, sleep may be a modifiable target to aid smoking cessation. At the time of writing, few studies have targeted sleep in quitting smokers. Those that have employ Cognitive Behavioural Therapy for Insomnia (CBT-I), or components of, to improve sleep outcomes in quitting smokers have reported mixed results (Fucito et al., 2014; Patterson et al., 2020).

Despite evidence supporting a link between sleep and smoking and the use of CBT-I as an intervention to aid cessation, there has been little research on smoker's perceptions of sleep quality in relation to their smoking behaviour, sleep quality during a quit attempt or CBT-I as an intervention for quitting smokers. Without understanding smoker's experiences of sleep and potential barriers to engaging with CBT-I interventions, the effectiveness of such interventions is likely to be compromised by failure to engage with user-centred development frameworks (Yardley et al., 2016). The person-based approach (PBA) is one such framework that has in depth qualitative research at its core (Yardley et al., 2015). PBA can improve the acceptability of interventions and the feasibility of implementing them, by understanding the experiences, needs and goals of the target user. This study will recruit current smokers and recently quit or quitting smokers explore their perspectives on their current sleep quality, fatigue and daytime

sleepiness in relation to smoking (vs. abstinence) and the acceptability/ feasibility of traditional CBT-I components.

Aims and Objectives

The primary aim is to explore how a CBT-I intervention may be adapted for quitting smokers. To do this we will explore smoker's or ex-smoker's views (i.e., perceived feasibility, effectiveness, barriers of use) of traditional CBT-I components. To better understand the context in which an intervention would be delivered, we will also explore smoker's and ex-smoker's perceptions and experiences of the link between smoking and sleep, their current sleep quality (including facilitators and barriers to good sleep) and how this may have changed as a function of smoking/smoking abstinence, and any past or current use of sleep hygiene practices.

To achieve this we will conduct semi-structured interviews with current smokers that have previously engaged in a quit attempt and recently quit (<12 months)/currently quitting. The research aims that will guide the semi-structured interviews are outlined below; however, the interview guide will be used to explore specific areas in more depth.

1. Understand smokers current sleep behaviour, including sleep hygiene practices and barriers and facilitators to sleep.
2. Understand smokers / ex-smokers perceived impact of a cigarette abstinence on sleep quality, fatigue and daytime sleepiness.
3. Understand smokers / ex-smokers perceived impact of sleep quality, fatigue and daytime sleepiness on smoking behaviour and quit attempt outcome.
4. Explore potential barriers and facilitators to engagement in traditional CBT-I components to facilitate intervention development.
5. Identify potential additions smokers and ex-smokers would like to see to existing CBT-I frameworks.

Study Site

Interviews will take place online using Bristol University approved video conferencing software (Zoom).

Participants and Recruitment

The study will be advertised through existing Tobacco and Alcohol Research Group (TARG) networks. These include Stop Smoking Services (North Somerset, South Gloucestershire), as well as via the TARG Twitter feed, project website and Facebook page. The study will also be advertised locally, for example, in local public houses, cafes, children's centres, GP surgeries and job centres and using online forums (e.g., Facebook).

Study adverts will invite potential participants to contact the research team if they are interested in taking part. Interested participants will receive a recruitment email and information sheet and be given the lead researchers contact details if they wish to ask any questions. If participants want to take part in the study a date and time for the interview will be scheduled and the researcher will re-iterate the inclusion criteria.

Inclusion criteria (all self-report)

- Aged 18 years or older
- Regular smoker (≥5 cigarettes per day for at least 3 months) that has previously engaged in a quit attempt or recently quit/quitting smoker (<12 months)
- English as a first language or similar level of fluency

Participants that complete the interview will be reimbursed with a £10 shopping voucher for their time. We will aim to recruit 20 eligible participants or until data saturation has been reached, whichever occurs first.

Procedure

At the beginning of each interview, participants will be given a verbal description of the aims of the study. They will receive a link which will provide an opportunity to read the participant information sheet again, or confirm they have read the information sheet and ask any questions about the study. They will be reminded that there is no obligation to take part, answer all questions and they may pause or leave at any time. It will be explained that everything the participant says will be kept confidential until interview transcription where any identifiable information will be removed. If participants that are happy to continue, the researcher will send a link with a short survey of screening questions to confirm eligibility. If participants are eligible, they will be asked to press 'next' on the link, where digital informed consent will then be obtained. If consent is completed participants will again be asked to click 'next' and complete the short survey to collect descriptive measures (see below). If participants select 'no' to any of the questions on the consent page, the survey will not allow participants to move on to the short survey. The researcher will explain that the participant will not be able to continue in the study and will be thanked for their time.

At the start of the interview participants will be instructed the recording is about to start. The interviewer will then use the interview guide to facilitate discussion. In section 3 of the interview guide the interviewer will use a combination of CBT-I materials and videos to provide information to each participant on each CBT-I component to facilitate the discussion. At the end of each interview, the participant will be de-briefed, asked if they would be happy to be contacted about taking part in a follow up research and thanked for their time.

Each interview will take approximately 45- 60 minutes, participants will be reimbursed via email after their interview. At the end of the interview participants will be informed that they may be contacted for a follow up interview after initial analysis has taken place. This follow up interview would be to further explore themes and topics that emerge within initial interviews. Participants will be given the option to decline this additional interview and their contact details will be deleted.

Descriptive Measures

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), current

smoking status , smoking history, quit-attempt history, e-cigarette use, medication during quit attempts and cigarettes smoked per day will be recorded.
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).

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).

Analysis Plan

Interviews will be recorded using an encrypted smart phone, tablet or laptop, which is line with the University's Information Security policy: http://www.bris.ac.uk/infosec/uobdata/transcription/. Files will be exported in MP3 or FLV, anonymised and transcribed verbatim and in full by a University approved transcription service, e.g., Bristol Transcription Services. We will follow University guidelines for the secure transfer of audio files if a transcription service is used, as outlined in the Information Security policy outlined above. Once transcripts have been received MP3 files will be deleted, transcripts will then be entered into NVivo 12 (Qualitative analysis software) to facilitate analysis.

Using the framework method (Gale et al., 2013), thematic content analysis will be conducted by the research team on a subset of interviews (n=tbc) enabling themes to develop inductively utilising the personal experiences and views of the participants. The data analysis process will be comprised of several stages: data familiarisation, thematic coding, framework development, framework application and assimilation. The familiarisation stage will consist of members of the study team independently reading and re-reading transcripts, immersing themselves within in the data and individually identifying emerging themes. The research team will then meet to reduce the data into themes and sub themes and after constant comparison and refinement, a thematic framework will be developed. This framework will then be applied to the rest of the interview transcripts, with regular whole team discussions to ensure coding accuracy, consistency, and necessary refinement. Direct quotations may be used in subsequent reports or dissemination activities but any personal identifying information will have already been removed to ensure participants are anonymous.

SPSS 26 will be used to provide descriptive statistics for study sample.

Ethics

Ethics approval has been granted by the School of Psychological Science Research Ethics Committee at the University of Bristol (9130).

Safety

We do not foresee any risks to participation.

Data Management

All aspects of the General Data Protection Regulation (GDPR) and the Data Protection Act (DPA) 2018 will be adhered to. Contact details of participants that wish to be contacted for future interviews will be treated as confidential and stored separately from study data.

Anonymised study data

Each participant will be randomly allocated a Participant ID and any personal identifiable information that is revealed during the interviews will be removed or made anonymous during transcription. Therefore, if individual quotations are used in the reporting of this study, they will not identify participants as scripts will have been anonymised.

Long term data storage

Audio recordings will be given a unique code and dated. Audio recordings will only be kept until the full interview has been transcribed. After this, the recording will be destroyed. Anonymised transcription files will be backed up on a secured University of Bristol network drive. At the end of the study, electronic transcripts and quantitative data 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 transcripts we be locked and made open using the University of Bristol Research Data Repository.

Screening documents and participant contact details

Participants will be assigned a unique identifier code by the research team. Screening information will only be used determine an individual's eligibility for participation. Participant contact details will be taken and stored on an encrypted file on an encrypted device with no link with interview transcripts. Participants will be informed of this and will have the option to revoke their contact details after their interview, if they do not wish to be contacted for a follow up interview. Any participant contact details will be deleted after study completion.

Open data

At the appropriate time, anonymised transcripts will be locked and made open using the University of Bristol Data Repository and/ or Open Science Framework.

Revoked data

Participants will be able to revoke their data until interviews are transcribed, after this point it will be impossible to link their personal information (name and email address) with their interview transcripts and quantitative data. Participants will be informed of this in the participant information sheet and consent form. Participants who no longer wish to continue with the study during the interview, will be informed that the recording will be deleted immediately after study termination.

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 known conflicts of interest to declare.

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