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A study to assess the Breezing Med™ metabolic device following stimulant use

Submission date	Recruitment status	[X] Prospectively registered
02/07/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/07/2021	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/07/2022	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and aims
The Breezing Med™ device is a portable device that can be used to determine the Resting Metabolic Rate (RMR) - the total number of calories burned when the body is completely at rest. The portability and accessibility of the device mean it has great potential as a research tool for metabolic assessment studies. This is an exploratory study with the aim to assess the effectiveness of the Breezing Med™ device and to assess if the device could be used to support future research.
Typically, metabolism and more specifically RMR have been assessed with traditional indirect calorimetry. Whilst this is an effective and reliable measure, this approach requires large and expensive equipment. This study will evaluate the Breezing Med™ device. Breezing Med™ consists of a reusable section (containing a rechargeable battery and an activation button), and disposable sensors, head straps, and silicone masks.
Smoking is known to have a range of effects on the body, including effects on body weight. Scientific evidence suggests that smoking combustible cigarettes containing nicotine can affect some elements of body weight maintenance, including (but not limited to) metabolism. Whilst combustible cigarettes have been shown to increase energy expenditure over a 24-hour period, the exact role of nicotine is not well understood. The ability of nicotine delivered by electronic cigarettes to affect metabolism has not been widely researched and may be an important aspect of the acceptability of these products to existing smokers. Increases in body weight are common after quitting smoking (with a typical increase in body weight of 4-5 kg) and may be a barrier to smoking cessation. By replicating the effects of the nicotine delivered in a combustible cigarette, it is anticipated that smokers who would otherwise continue to smoke can be encouraged to switch to potentially reduced risk products such as electronic cigarettes.
This study complements another study in progress (https://www.isrctn.com/ISRCTN72435551). The study will evaluate aspects of appetite via calorie consumption, subjective appetite, and hormones to help build a better understanding of the effect of nicotine on metabolism.

Who can participate?
Healthy adults, aged 25-35 years, who smoke at least 10 cigarettes per day and are familiar with e-cigarette products.

What does the study involve?
Screening will occur within 28 days of the first testing session. Eligible participants will be asked to attend a total of four testing sessions.
The first testing session is a familiarisation visit. Eligible participants will be shown how to correctly use (and subsequently test) the two study products and also trial the Breezing MedTM device, completing four readings on the device over a 1-hour period. Eligible participants will be provided with the e-cigarette study product (and two associated cartridges) to familiarise themselves with the study product prior to the first study session.
At least 48 hours after the familiarization session, participants will attend the first study session. Before the session, participants will be required to abstain from nicotine, alcohol and caffeine for 12 hours and refrain from high-intensity exercise (24 hours). On the morning of the study sessions, participants should refrain from consuming water within 1 hour of the study session start time. Upon arrival, cigarette abstinence will be confirmed with an exhaled carbon monoxide (eCO) breath test.
Upon completion of the eCO, participants will be seated in a dimly lit room and undertake a 30-minute relaxation period. Two metabolic readings will be taken. Participants will then have a 5-minute product (or no product) use period and use one of the associated study products (e-cigarette use, consume a caffeinated fruit drink, or no product use). Only one study product is to be tested at each session. At specific intervals over the next 1-hour and 10 minute period, participants will have their metabolic readings taken repeatedly.
Participants will repeat three study sessions, each using both study products and observing a no product use session. The order in which the study products are used by each participant will be fully randomised.

What are the possible benefits and risks of participating?
There are no direct benefits to participants. The main risks are the side effects of using nicotine products (such as headache, dizziness, palpitations, and mouth and throat irritation); participants should be familiar with these side effects as a result of being regular users of these products.

Where is the study run from?
British American Tobacco (UK)

When is the study starting and how long is it expected to run for?
January 2021 to September 2021

Who is funding the study?
British American Tobacco (UK)

Who is the main contact?
Harry Green
harry_green@bat.com

Study website
https://www.bat-science.com

Contact information

Type(s)
Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
BAT_NSHS_2021_007

Study information

Scientific Title
An exploratory, crossover study to assess changes in metabolism in healthy adult volunteers following stimulant use using the Breezing Med™ metabolic device

Study objectives
1. The Breezing Med™ metabolic device is capable of determining differences in the resting metabolic rate of participants following caffeine administration, subsequent to a period of caffeine abstinence
2. Acute nicotine delivery (delivered via an e-cigarette) will influence the resting metabolic rate of participants subsequent to a period of nicotine abstinence, assessed via the Breezing Med™metabolic device

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/05/2021, Reading Independent Ethics Committee (93 Reading Road, Woodley, Reading, RG5 3AE, UK; +44 (0)484303842/+44 (0)1189691022; berkshireb.rec@hra.nhs.uk), ref: NSHS-2021-007

Study design
Single-centre interventional randomized three-period crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Metabolic assessment

Interventions
The order of the Investigational Product use will be randomised for this three-period crossover study. The Investigational Products in this study are as follows:
1. No Product Use (Control 1)
2. LIQD_RAB_RP001_C200 (Control 2)
3. EPEN3.0_VGT18 (Intervention 1)

Each participant will use the e-cigarette for 5 minutes of ad-libitum puffing (puffing as participants feel necessary for 5 min). Participants will use one Investigational Product per study session. There will be at least 7 days between the administrations of each study session.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Resting metabolic rate (RMR) assessed via the Breezing Med™ device at set timepoints over a 1 hour and 10 minute timeframe (0-10 min, 15-25 min, 30-40 min, 45-55 min, 60-70 min)

Secondary outcome measures
1. RQ (respiratory quotient) assessed via the Breezing Med™ device at set timepoints over a 1 hour and 10 minute timeframe (0-10 min, 15-25 min, 30-40 min, 45-55 min, 60-70 min)
2. VCO_2 ml/min assessed via the Breezing Med™ device at set timepoints over a 1 hour and 10 minute timeframe (0-10 min, 15-25 min, 30-40 min, 45-55 min, 60-70 min)
3. VO_2 ml/min assessed via the Breezing Med™ device at set timepoints over a 1 hour and 10 minute timeframe (0-10 min, 15-25 min, 30-40 min, 45-55 min, 60-70 min)
4. Breath frequency/min assessed via the Breezing Med™ device at set timepoints over a 1 hour and 10 minute timeframe (0-10 min, 15-25 min, 30-40 min, 45-55 min, 60-70 min)

5. Tidal volume ml assessed via the Breezing Med™ device at set timepoints over a 1 hour and 10 minute timeframe (0-10 min, 15-25 min, 30-40 min, 45-55 min, 60-70 min)

Overall study start date
04/01/2021

Completion date
24/09/2021

Reason abandoned (if study stopped)
Technical issues

Eligibility

Key inclusion criteria
1. Healthy male or female subjects, between 25 and 35 years of age, inclusive. An effort will be made to recruit an even split of subjects by gender, with an even distribution around the mean age of participants also
2. Subjects with a body mass index (BMI) of 18.5-24.9 kg/m²
3. Subjects who are current daily users of conventional factory-made cigarettes and/or roll your own cigarettes (10 cigarettes per day) and who have done so for at least 3 years. Subjects should also be familiar with using e-cigarettes (i.e. have used e-cigarettes over a period of greater than 1 month within the last 2 years)
4. Subjects who are regular caffeine consumers of the equivalent of >1 and ≤5 cups/day of coffee /tea/energy drink
5. Subjects who are willing to comply with the study protocol
6. Subjects must be available to complete the study
7. Subjects must provide written informed consent to participate in the study

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
25 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
35

Key exclusion criteria
1. Subjects who self-report to have an acute illness (e.g. upper respiratory tract infection, viral infection, etc) requiring treatment within 4 weeks prior to Screening or on admission

2. Subjects who self-report to have any clinically significant abnormalities or underlying health conditions
3. Subjects who are self-reported non-inhalers (smokers/vapers who draw smoke/aerosol from the cigarette/e-cigarette into the mouth and throat but who do not inhale)
4. Female subjects who are pregnant and breastfeeding or lactating
5. Subjects who, prior to enrolment, are planning to quit/alter smoking/vaping within the duration of the study (to follow-up telephone call). All subjects will be informed that they are free to quit smoking/vaping and withdraw from the study at any time.
6. Self-reported evidence of metabolic dysfunction
7. A self-reported significant history of drug or alcohol abuse [defined as the consumption of more than 14 units for male and female subjects of alcohol a week] within the past 2 years
8. Inability to communicate well with the Investigators (i.e., language problem, poor mental development or impaired cerebral function)

Date of first enrolment
05/07/2021

Date of final enrolment
19/07/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Walnut Unlimited
St. Swithun's House
1a St. Cross Road
Winchester
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Sponsor information

Organisation
British American Tobacco (United Kingdom)

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Sponsor type
Industry

Website
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ROR
https://ror.org/01znsh139

Funder(s)

Funder type
Industry

Funder Name
British American Tobacco

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The full study protocol, informed consent form and study report will be available. Results from this study will be published in peer-reviewed scientific journals.

Intention to publish date
27/09/2022

Individual participant data (IPD) sharing plan
Deidentified participant-level data will be available on request from Harry Green (harry_green@bat.com) for at least 5 years. This data will be available immediately following publication. Data will be available to anyone who wishes to access the data and for any purpose subject to request. Requestors must sign a data access agreement.

IPD sharing plan summary

Available on request