ISRCTN46845361 https://doi.org/10.1186/ISRCTN46845361

Use of transdermal alcohol sensors with or without contingency management

Submission date
13/07/2023

Recruitment status
No longer recruiting

Registration date
09/10/2023

Overall study status
Completed

Last Edited
18/03/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
This study is going to evaluate the feasibility of using Transdermal Alcohol Sensor (TAS) devices with clinical population patients (patients who are currently accessing treatment from an alcohol service for their alcohol use). The participants recruited will wear the TAS for two weeks, then complete a post-wear survey and self-report their alcohol consumption. The post-wear survey will be used to explore the user experience while the self-reported alcohol consumption will be used to determine TAS accuracy (TAS versus self-report). Half of the participants will be randomised into the contingency management group (where rewards can be earned when the target behaviour occurs). The target behaviour in this study is to keep to low or no drinking (as measured by the TAS). The other half of the participants will be in the control group without any CM rewards. The study will be conducted in SLaM NHS alcohol services and will last approximately 6 months. The study will investigate how the intended population of TAS (patients receiving alcohol treatment from their alcohol service) experiences wearing it. From this, feasibility measures will be evaluated, such as recruitment rate, the willingness of participants to enrol and staff to enrol patients, follow-up rates, response rates, and device tampering and malfunction. This is important to inform future research on the application of TAS in a larger study. This is a growing field of interest and in recent years there has been an increase in the number of TAS being developed. Currently, there is no published study, to the team's knowledge, that has conducted a feasibility study with the clinical population, who have worn a TAS over an extended length of time, specifically using the BACtrack Skyn brand of TAS. The study aims to explore the feasibility, strengths, and limitations of using a TAS to monitor alcohol consumption in individuals in treatment for AUD with or without contingency management to promote abstinence or low-level alcohol consumption.

Who can participate?
Anyone who is over 18 years old and currently receiving alcohol treatment at one of the participating alcohol services

What does the study involve?
The participant will express an interest in the study and if they are eligible they will be enrolled by the researcher. At enrolment, the participant will be randomised into either contingency management or control group and trained on how to wear the TAS. They will arrange all their

meetings with the researcher. There will be seven research visits in 15 days, occurring every other weekday, for example, Monday, Wednesday, Friday, Monday, Wednesday, Friday, and Monday. This is to make sure the data is downloaded from the TAS regularly to avoid data loss. At each meeting, the researcher will download the data from the TAS and record self-reported alcohol consumption, in the last meeting a post-wear survey will be completed.

All participants (control and contingency management group) will be given a £5 voucher at each meeting they attend, a £10 voucher for TAS return at the end and travel expenses reimbursed.

The contingency management group only will also be able to earn additional rewards for achieving target behaviour (low or no drinking below our set threshold, as measured by the TAS). For every day they achieve this, they can earn another £5 voucher and additional voucher bonuses for consecutive days when behaviour is achieved. When a behaviour does not occur, no rewards will be earned.

What are the possible benefits and risks of participating?
Possible benefits are that the participant may learn more about their alcohol use and reduce their alcohol consumption by wearing the TAS and earning rewards for alcohol reduction/low drinking.

Risks of participating are that previous studies have reported side effects and skin marks from wearing the TAS, particularly in hot weather. Participants will be made aware of this possibility before enrolment.

Where is the study run from?
South London (UK)

When is the study starting and how long is it expected to run for?
May 2022 to December 2023

Who is funding the study?
National Institute for Health Research (NIHR) Applied Research Collaboration (ARC) South London (UK)

Who is the main contact?
Eileen Brobbin, eileen.brobbin@kcl.ac.uk (UK)

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
316566

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 57841, IRAS 316566

Study information

Scientific Title
Use of transdermal alcohol sensors in conjunction with contingency management to reduce alcohol consumption in people with alcohol dependence attending alcohol treatment services: Feasibility RCT

Acronym
TAMS (Transdermal Alcohol sensor with cM Study)

Study objectives
How feasible is the use of wearable transdermal alcohol sensors to monitor alcohol consumption in individuals receiving treatment for AUD with or without contingency management to promote abstinence or low alcohol consumption, and to what extent can wearable transdermal alcohol sensors be implemented in clinical settings?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 31/05/2023, Cornwall and Plymouth (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048071; cornwallandplymouth.rec@hra.nhs.uk), ref: 23/SW/0066

Study design
Interventional feasibility pilot randomised control trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Use of transdermal alcohol sensors with or without CM with AUD individuals.

Interventions
South London and Maudsley NHS Foundation Trust will aid recruitment, the study will be advertised in these services, and key workers will be informed and can pass on this information via a Participant Information Sheet to patients who meet the inclusion and exclusion criteria to see if they are willing to participate. Those who are interested to participate will be asked if they consent for the service staff to pass on their name and phone number to the research team so they can be contacted about participation. The research team will then ring the potential participant: the study procedure will be explained, what is expected of them, ensure the PIS has been provided and any questions they have will be sufficiently answered.

If they are still willing to participate and meet all inclusion criteria, a date will be arranged for the researcher to meet with the patient to collect consent, baseline data and train them on wearing the device (e.g., Monday). They will also meet with the researcher every two days for around 15 minutes to download device data, complete the Time-Line Follow Back (TLFB) for that period, and, if applicable, receive contingency management (CM) from the device data (e.g., Wednesday, Friday, Monday, Wednesday and Friday). A final meeting will be arranged for 2 weeks after the first meeting to collect the device, post-wear survey, and TLFB.

Randomisation of participants will be done remotely by an independent statistician using a sealed envelope randomisation technique. Each time a participant enrols, their group allocation will be revealed to the researcher. This randomisation will be completed by an independent statistician (Simon Colton). His role and responsibility in this study are to create the random allocation of each participant into the control or CM group (which I only will know on enrolment of a participant). He will not be involved in any other part of the data collection.

Throughout the two-week period, the participant will be free to contact the research team about any queries or device issues. They will be given the research team's contact number and told to contact them if they have any queries about the device or study between the hours of 9 am-5 pm. The device data download meetings will also allow participants to ask any queries they have about the device and allow for TLFB data to be collected, reducing the burden of recalling all alcohol consumption in the last meeting.

Baseline and demographic variables will have descriptive statistics reported. Analysis of the post-wear survey will be conducted, and the device data will be compared against the TLFB to address the secondary outcomes on device accuracy. Outcome measures will be compared between the control and CM groups.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility will be measured and defined by:
1. Enrolment measured using recruitment rate, the number of participants who are approached and who enrol, number of staff approached and refer participants at the recruitment stage
2. Participation measured using the number who complete the intervention, attendance rate, and compliance measured at each research visit (days 2, 4, 6, 8, 10, and 12) during the two-week study participation period
3. Device tampering/malfunction measured using the % of removed minutes, % of minutes of tampered data, % of minutes with missing data, reported battery issues, the number of meetings not attended and the number of additional meetings booked, and the number of devices returned measured at each research visit (days 2, 4, 6, 8, 10, and 12) during the two-week study participation period
4. TAS for CM implementation measured using CM vouchers provided at research visits in line with TAC device recorded data (days 2, 4, 6, 8, 10, and 12) during the two-week participation period

Key secondary outcome(s))
1. TAS acceptability measured using the post-wear survey at the final research visit (day 15)
2. TAS accuracy measured using TAC device recorded data and self-report data collected at each research visit (days 2, 4, 6, 8, 10, and 12) during the two-week study period

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Receiving alcohol treatment for an alcohol use disorder in one of the participating South London alcohol services
2. Over 18 years old and over
3. Speak English competently
4. Able to meet throughout the study period
5. Not currently participating in any other research trials
6. Willing to provide informed consent to participate

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
32

Key exclusion criteria
1. Current use of any illegal/addictive substances (excluding cannabis and smoking)
2. Under 18 years old
3. Cannot speak English

Date of first enrolment
05/07/2023

Date of final enrolment
15/12/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Marina House
63-65 Denmark Hill
London
United Kingdom
SE5 8RS

Study participating centre
The Pier Road Project
Health Centre
50 Pier Rd
Erith
United Kingdom
DA8 1RQ

Study participating centre
Wandsworth community drug and alcohol service
162 St John's Hill
London
United Kingdom
SW11 1SW

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Organisation
South London and Maudsley NHS Foundation Trust

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Applied Research Collaboration South London

Alternative Name(s)
NIHR Applied Research Collaboration South London, ARC South London, NIHR ARC South London, NIHR Applied Research Collaboration (ARC) South London, NIHR ARC SL

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Eileen Brobbin, Eileen.brobbin@kcl.ac.uk. Participant demographics, TLFB data, TAC data, and post-wear survey responses will be shared after publication. Data shared will be anonymous.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/03/2025	18/03/2025	Yes	No
Protocol article		31/07/2024	01/08/2024	Yes	No
Participant information sheet	version 2.0	22/05/2023	24/07/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Thesis results		01/08/2024	08/01/2025	No	No