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Decision-making in alcohol consumers

Submission date
31/08/2023

Recruitment status
No longer recruiting

Registration date
12/09/2023

Overall study status
Ongoing

Last Edited
12/09/2024

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The mechanisms through which alcohol addiction affects decision making are largely unknown. Therefore, there is a need for neuroscience-informed methods that can characterise the internal processes that determine choice for alcohol, and demonstrate how those processes are implicated in the persistence of alcohol use disorder, recovery, and treatment response.

To better understand the role of alcohol craving in making decisions about alcohol, we will conduct a laboratory study in which we will experimentally increase desire for alcohol in regular alcohol consumers before analysing their decision-making and recording how much alcohol they voluntarily consume. This will tell us how decision making changes during craving episodes, and which specific aspects of decision-making are predictive of alcohol consumption.

Who can participate?
Anyone over the age of 21 who consumes over 28 UK units of alcohol per week may participate, as long as they have no medical conditions that are affected by alcohol and have not been previously diagnosed with, or treated for alcohol use disorder.

What does the study involve?
Participants will attend the Solly Street building on the University of Sheffield campus on two separate occasions, ideally within 10 days. Each session will take around an hour and a half (3 hours in total).

During the sessions participants will complete some questionnaires which will contain questions about their alcohol consumption, engagement with activities and hobbies, values and personality. They will also be asked to talk about two positive life experiences (one that involved drinking alcohol, and one that did not). Additionally, participants will complete some computer-based tests, where they will be asked to think about the pleasantness of pictures of alcoholic and non-alcoholic drinks, and other types of pictures, before subsequently choosing between the pictures as quickly as possible.

At the end of the second testing session, participants will be asked to sip and taste two alcoholic drinks. The maximum amount of alcohol that participants will be able to consume is two units (equivalent to about a pint of beer, or a medium glass of wine, or a double measure of spirits). Participants are under no obligation to drink all of the alcohol provided.

What are the possible benefits and risks of participating?
Whilst there are no immediate benefits for people who participate in the project, it is hoped that this work will contribute to tailoring treatments and advice for people who want to reduce their alcohol consumption.

Answering some of the questions may cause participants to become concerned about their drinking, and recalling positive memories associated with alcohol may cause intense emotions. There is also a risk that participants may become slightly intoxicated (drunk) after taking part in the second testing session of the study where they will be asked to sip and taste alcoholic drinks.

Where is the study run from?
The University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
October 2022 to September 2025

Who is funding the study?
The Medical Research Council (UK)

Who is the main contact?
Professor Matt Field, matt.field@sheffield.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Matt Field

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
329884

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56670, MR/W028476/1, IRAS 329884

Study information

Scientific Title
Value based decision-making in alcohol consumers

Study objectives
We will identify how value based decision making (VBDM) changes during craving episodes, and which VBDM parameters are predictive of drinking behaviour.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/02/2023, Department of Psychology Research Ethics Committee (Department of Psychology, University of Sheffield, Sheffield, S1 1LT, United Kingdom; -; psy-ethics@sheffield.ac.uk), ref: 050755

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Laboratory

Study type(s)
Other

Participant information sheet
https://bit.ly/AlcoholStudyPIS

Health condition(s) or problem(s) studied
Value based decision-making in alcohol consumers

Interventions
Intervention arm: "Alcohol-specific episodic memory and cue exposure”. Description: participants listen to an audio recording of their own vivid positive alcohol-related memory and they are instructed to sniff and allow their preferred alcoholic drink to touch their lips, but to refrain from drinking it.

Control arm: "Non-alcohol episodic memory and cue exposure". Description: participants listen to an audio recording of their own vivid non-alcohol related memory and they are instructed to sniff and allow their preferred non-alcohol drink to touch their lips, but to refrain from drinking it.

Total duration of both treatments: approximately five minutes

Total duration of follow-up for both treatments: approximately 45 minutes.

Details of randomisation process: online tool (Google Sheets built-in randomisation function), with group allocation hidden from view until participants are enrolled into the study and have completed their first session.

Intervention Type
Behavioural

Primary outcome measure
1. Drift rates and response thresholds when making alcohol-related decisions and non-alcohol decisions. These outcomes are derived from the value-based decision-making (VBDM) task administered at baseline and immediately after the intervention.
2. Percent choice of alcohol over the alcohol-free alternative reward. This outcome is derived from the concurrent choice task administered at baseline and immediately after the intervention.

Secondary outcome measures
1. Volume of alcohol consumed during the ad-libitum taste-test (measured immediately after the intervention)
2. Indices of self-reported demand for alcohol, derived from the alcohol purchase task. This task is administered at baseline and immediately after the intervention

Overall study start date
01/10/2022

Completion date
30/09/2025

Eligibility

Key inclusion criteria
Participants must consume over 28 UK units of alcohol per week and be aged 21 years or over.

Participant type(s)
Other

Age group
Adult

Lower age limit
21 Years

Sex

Both

Target number of participants
126

Total final enrolment
129

Key exclusion criteria
1. Any conditions or medications that are affected by alcohol.
2. Diagnosis of AUD within the last 10 years.

Date of first enrolment
01/03/2023

Date of final enrolment
12/09/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sheffield
Western Bank
Sheffield
United Kingdom
S10 2TN

Sponsor information

Organisation
Medical Research Council

Sponsor details
Polaris House
North Star Avenue
Swindon
England
United Kingdom

SN2 1ET
-
international@mrc.ukri.org

Sponsor type
Research council

Website
https://mrc.ukri.org/

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/09/2025

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be stored in a publicly available repository.
Upon publication of results from this study in a peer-reviewed journal, or before the 30th

September 2025 (whichever is sooner), aggregated, anonymised data selected for long-term preservation and sharing will be deposited in the UK Data Service. The UK Data Service is openly accessible and searchable and will guarantee preservation of these data for ten years or more. Metadata records describing these data will also be stored in ORDA, the University of Sheffield research data registry and repository. The anonymised data may also be uploaded to other publicly accessible repositories such as ResearchBox or the Open Science Framework.
Governance of access: Data will be made available through shared research platforms (UK Data Archive and ORDA) with the relevant permissions in place.
The study team's exclusive use of the data: The project group (including Project Partners) will have exclusive use of the data until the main research findings are published.
Regulation of responsibilities of users: External users will be bound by data sharing agreements as specified by the MRC Data Sharing Policy. These will include provisions that data are not shared with third parties without permission, and that credit is given to the research group that produced the data. Anybody who wishes to access the data from the UK Data Service will be required to sign a license agreement that permits the UKDS to perform its curatorial functions and make the data available via a Creative Commons Licence.
Participants provided their informed consent for sharing of their anonymised data.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			11/09/2023	No	Yes
Protocol file			11/09/2023	No	No