Supporting alcohol consumers to reduce their drinking with contingency management

Submission date 08/04/2024	Recruitment status No longer recruiting	[X] Prospectively registered	
		[X] Protocol [] Statistical analysis plan	
Registration date 16/04/2024	Overall study status Completed	[] Results	
Last Edited 18/08/2025	Condition category Mental and Behavioural Disorders	 [] Individual participant data [X] Record updated in last year 	

Plain English summary of protocol

Background and study aims

Contingency management (CM) is a behaviour modification technique that rewards desired behaviours such as abstinence from alcohol by providing incentives. Systematic reviews confirm that it is effective for people with addictions including alcohol use disorders. CM may help people to reduce drinking because it will change the way that they make decisions about alcohol and about other things such as engaging in hobbies, family time, work and so on. This study aims (i) to investigate if a three-week CM intervention can help risky drinkers reduce their alcohol consumption, and (ii) to characterise the value-based decision-making mechanisms that underlie this effect.

Who can participate?

Healthy adults aged 21 years old and over who currently drink 28 or more alcohol units per week and want to cut down

What does the study involve?

This is a study in which adults who drink at a risky level will be recruited from the local community and randomly assigned to receive either daily CM or a control intervention over three weeks. Participants receiving CM will get payments according to their abstinence from alcohol (as verified by cellular breathalysers). Control participants will also receive payments but these will be "yoked" to participants assigned to CM, therefore for participants in the control group these payments will not be contingent upon their alcohol consumption. The research will measure participants' value-based decision-making immediately before and immediately after the intervention period, and at one-month follow-up.

What are the possible benefits and risks of participating?

Benefits: This work will contribute to tailoring treatments and advice for people who want to reduce their alcohol consumption. People who take part in the study will also receive shopping vouchers as a thank you. The way that payments are determined will be explained after participants have been screened and randomised to the experimental group.

Risks: People who are invited to take part in the study after initial screening are unlikely to experience serious negative side effects if they were to stop drinking. However, answering some of the questions may make them concerned about their drinking.

Where is the study run from? The University of Sheffield

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

Who is funding the study? Medical Research Council

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

Study website

https://docs.google.com/forms/d/e /1FAIpQLScEMuWBV9hk7auwDrcRHeZ2IvoyoBI0JBzKtnfMDdX0rniktg/viewform

Contact information

Type(s) Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number 338990

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

MR/W028476/1, IRAS 338990, CPMS 60386

Study information

Scientific Title

Changes in alcohol use and value-based decision-making in alcohol use disorder during and after contingency management treatment: a randomised controlled trial

Study objectives

The primary hypotheses are:

 Participants randomised to CM will have a higher percentage of abstinent days over the threeweek intervention period, compared to participants randomised to control (primary outcome 1)
 In participants randomised to CM (relative to participants randomised to control), evidence accumulation (EA) rates for alcohol-free reinforcement will increase, whereas EA rates for alcohol reinforcement will decrease, from baseline to post-intervention (primary outcome
 In participants randomised to CM (relative to participants randomised to control), response thresholds (RT) for alcohol-free reinforcement will decrease, whereas RT for alcohol reinforcement will increase, from baseline to post-intervention (primary outcome 3)
 In participants randomised to CM (relative to participants randomised to control), the percentage alcohol choice on the concurrent choice task will decrease from baseline to postintervention (primary outcome 4)

The secondary hypotheses are:

5. At one-month follow-up, participants randomised to CM will report reduced quantity (secondary outcome 1) and frequency (secondary outcome 2) of alcohol consumption, compared to participants randomised to control (secondary outcomes 1 and 2)

6. At one-month follow-up, EA for alcohol-free reinforcement will be higher, whereas EA for alcohol reinforcement will be lower, in participants randomised to CM relative to participants randomised to control (secondary outcome 3)

7. At one-month follow-up, RT for alcohol-free reinforcement will be lower, whereas RT for alcohol reinforcement will be higher, in participants randomised to CM relative to participants randomised to control (secondary outcome 4)

8. At one-month follow-up, the percentage alcohol choice on the concurrent choice task will be lower in participants randomised to CM relative to participants randomised to control (secondary outcome 5)

9. Changes in aforementioned value-based decision-making (VBDM) parameters and % alcohol choice from baseline to post-intervention will partially mediate group differences in the percentage of abstinent days over the three-week intervention period.

10. Changes in VBDM parameters and % alcohol choice from baseline to follow-up will partially mediate group differences in the quantity and frequency of alcohol consumption over the corresponding period.

11. Individual differences in VBDM parameters and % alcohol choice at baseline will moderate the effect of group assignment on the percentage of abstinent days over the three-week intervention period.

12. Individual differences in VBDM parameters and % alcohol choice at baseline will moderate the effect of group assignment on the quantity and frequency of alcohol consumption at follow-up.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 05/04/2024, Department of Psychology Research Ethics Committee (Department of Psychology, ICOSS building, University of Sheffield, 219 Portobello, Sheffield, S1 4DP, United Kingdom; +44 (0)114 222 6533; psy-ethics@sheffield.ac.uk), ref: 059456

Study design Interventional randomized controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Community, Laboratory

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Treatment of alcohol use disorder

Interventions

Contingency management: Intervention is delivered in the community. Participants breathalyse themselves with a cellular breathalyser (which takes their photo as they provide the breath sample), and they transmit the readings to the research team. They do this three times per day during the three-week intervention period. For each day of verified abstinence from alcohol, participants receive a payment. This is £5 for the first day of verified abstinence and it increases by £1 for each consecutive day of verified abstinence, up to a maximum of £15. If participants drink alcohol, the payment resets to zero on that day and then restarts at £5 on the next day of verified abstinence. Participants receive a summary of the total payment at the end of each week of the intervention period, and they receive payments in the form of shopping vouchers at the end of the intervention period.

Comparator: Intervention is delivered in the community. Each participant in the control group is "yoked" to a participant in the contingency management group. Participants breathalyse themselves with a cellular breathalyser (which takes their photo as they provide the breath sample), and they transmit the readings to the research team. They do this three times per day during the three-week intervention period. Payments are unrelated to their alcohol consumption but are instead matched to those awarded to the participant in the contingency management group to whom they are yoked. Participants receive a summary of the total payment at the end of each week of the intervention period, and they receive payments in the form of shopping vouchers at the end of the intervention period.

Intervention Type

Behavioural

Primary outcome measure

1. Percentage of abstinent days over the three-week intervention period (as verified by cellular breathalyser)

2. Evidence accumulation rates for alcohol and alcohol-free reinforcement (inferred from valuebased decision-making task) at post-intervention

3. Response thresholds for alcohol and alcohol-free reinforcement (inferred from value-based decision-making task) at post-intervention

4. Percentage alcohol choice on the concurrent choice task at post-intervention

Secondary outcome measures

 Quantity and frequency of self-reported alcohol consumption at one-month follow-up
 Evidence accumulation rates for alcohol and alcohol-free reinforcement at one-month followup

3. Response thresholds for alcohol and alcohol-free reinforcement at one-month follow-up

4. Percentage alcohol choice on the concurrent choice task at one-month follow-up

Overall study start date

01/10/2022

Completion date

08/08/2025

Eligibility

Key inclusion criteria

1. Adults aged 21 years or above

2. Currently consume 28 or more alcohol units per week

3. Want to cut down on drinking

Participant type(s)

Healthy volunteer

Age group Adult

Lower age limit 21 Years

Sex Both

Target number of participants 140

Total final enrolment 89

Key exclusion criteria

1. Drinking alcohol in a way that would increase the risk of experiencing withdrawal symptoms if were to suddenly stop drinking alcohol

2. Pregnancy or attempting to become pregnant

3. Any history of treatment for an alcohol use disorder (alcoholism) or received advice from a GP or other health professional to seek treatment

Date of first enrolment 22/04/2024

Date of final enrolment 07/08/2025

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 1FL +44 (0)1793 444164 nmhb@mrc.ukri.org **Sponsor type** Government

Website https://www.ukri.org/councils/mrc/

ROR https://ror.org/03x94j517

Funder(s)

Funder type Government

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 peer-reviewed journal

Intention to publish date 30/09/2026

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 31st December 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 the preservation of these data for ten years or more.

Metadata records describing these data will also be stored in ORDA (https://orda.shef.ac.uk/), 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 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?
<u>Protocol (other)</u>		16/04/2024	16/04/2024	No	No