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Cognitive mechanisms of an intervention to reduce heavy drinking

Submission date
13/12/2018

Recruitment status
No longer recruiting

Registration date
18/01/2019

Overall study status
Completed

Last Edited
27/09/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This in an exploratory research study investigating the styles of thinking and brain changes that are related to alcohol consumption. The study is designed to improve our understanding on alcohol consumption and aspects of psychological functioning, including cognitive process. The study is also interested in whether we can use these processes to change levels of alcohol consumption.

Who can participate?
People aged between 18 and 65 who drink more than 20 units per week if they are female or 30 units per week if they are male, and are interested in reducing their drinking

What does the study involve?
The study involves an appointment at the University of Manchester for a session that lasts up to 4 hours in total. The appointment involves:
1. Giving a breath test and urine sample to ensure no presence of drugs or alcohol that day. A minimum list of drugs that are screened for includes amphetamines, barbiturates, cocaine, opiates, cannabinoids and benzodiazepines. Positive results would only exclude them from taking part that day and rescheduling would be dependent on the time needed to gain a negative result. This initial appointment can only be rescheduled once following positive results and positive results at the rescheduled appointment would result in full study exclusion.
2. Being asked about drug and alcohol use, as well as briefly about mental and physical health
3. Filling-in some questionnaires to assess personality
4. Doing some computer tests that provide information about how people react and think in particular ways
5. Completing some questionnaires online
Participants are randomly allocated to either receive a brief paper-based intervention aimed at reducing alcohol intake at the initial appointment, or to be offered the intervention at the end of study. The researchers do not know who received the intervention at the initial appointment until the end of the final appointment. One month later there is another appointment to return and record alcohol consumption, give another breath test and urine sample, and complete some further questionnaires and computer tests which should take up to an hour. All urine samples are immediately destroyed after testing.

What are the possible benefits and risks of participating?
There are no direct benefits of taking part. There are indirect benefits of improving knowledge around alcohol use and potentially informing future research. There are also no direct risks pertaining to the measures used that would not be encountered in everyday life.

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

When is the study starting and how long is it expected to run for?
May 2015 to December 2017

Who is funding the study?
Investigator PhD initiated and funded

Who is the main contact?
Elly McGrath

Contact information

Type(s)
Scientific

Contact name
Ms Elly McGrath

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M139PT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15/LO/0835

Study information

Scientific Title

Cognitive mechanisms of an intervention to reduce heavy drinking: a randomised controlled trial

Study objectives
H1: Participants randomised to form implementation intentions will show significant reductions in alcohol consumption at one month follow-up compared to those undertaking a control intervention.
H2: Participants randomised to form implementation intentions will show significantly improved performance on all neuropsychological tasks compared to those undertaking a control intervention at immediate and one month follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS South East Coast – Brighton and Sussex Research Ethics Committee, 26/05/2015, ref: 15/LO/0835

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Excessive alcohol consumption

Interventions
Participants were randomised using the simple randomisation technique of a random number table. Participants attended the University of Manchester, and following consent, an alcohol breath test and drug urine screen will be obtained. Demographic information was collected and an assessment of drug and alcohol history, including the SCID (Structured Clinical Interview for Depression) for dependence history, was conducted. They then completed a maximum 4 hour session comprising personality measures and neuropsychological testing. All measures were computerised and participants performed the tests in a designated quiet testing room, with comfort breaks as required. The intervention and control conditions received near identical paper sheets during the intervention/control element of the study. These packs were created and numbered prior to randomisation and the researcher was blind as to which numbers relate to which condition. Both intervention and control packs contained some examples of alcohol

units and a list of "situations" and "solutions". The intervention group were instructed to link specific situations with specific solutions. The control group were asked to tick all that apply to themselves in both columns. After completion of the implementation intentions helpsheet, all neuropsychological tasks were repeated by all participants as an immediate follow-up. Participants were then given a link at initial appointment and be asked to complete some sub-clinical and personality questionnaires in their own time over the following week. One month after this appointment, participants will completed another 28 day Timeline Followback as well as all questionnaires and neuropsychological tasks once more.

Intervention Type
Behavioural

Primary outcome measure
Alcohol consumption was measured using a 28-day Timeline Followback at baseline and one month follow-up

Secondary outcome measures
Cognition was measured using reaction times and errors on the Stop-Signal, Alcohol Stop-Signal, Alcohol Stroop, Approach Avoidance, Delay Discounting and Sternberg tasks. These were measured at baseline, post-intervention and one month follow-up

Overall study start date
22/05/2015

Completion date
01/12/2017

Eligibility

Key inclusion criteria
1. Aged 18+
2. The participant is capable of giving written informed consent, which includes compliance with the requirements and restrictions listed in the consent form
3. The participant is able to read, comprehend and record information written in English
4. A signed and dated written informed consent is obtained from the participant
5. The participant has expressed an interest in reducing current alcohol consumption
6. Consumption of 30 or more units of alcohol per week for men, and 20 or more units per week for women (1.5 times the UK Government guidelines of 2-3 drinks per day for women and 3-4 drinks per day for men with two nights off a week)but not meet SCID criteria for dependence

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
116

Total final enrolment
92

Key exclusion criteria
1. Participants must not meet criteria for alcohol dependence as per the Structured Clinical Interview for Depression (SCID) (as assessed at online screening and during baseline interview)
2. Positive drug/alcohol screens on testing visits. A minimum list of drugs that will be screened for include amphetamines, barbiturates, cocaine, opiates, cannabinoids and benzodiazepines. Positive results for cannabinoids will be allowed given the long halflife of cannabinoid metabolites. This exclusion criteria would exclude a subject from completing the study on that day only and not the study as a whole, at the discretion of the research team
3. High dosage use of regular psychoactive prescription medications such as those with antidepressant or anxiolytic properties
4. History or presence of a neurological diagnosis (not limited to but including, for example, stroke, epilepsy, space occupying lesions, multiple sclerosis, Parkinson's disease, vascular dementia, transient ischemic attack, that may influence the outcome of any cognitive testing
5. Clinically significant head injury (e.g., requiring medical or surgical intervention)
6. Unwillingness or inability to follow the procedures outlined in the protocol
7. Significant current or past psychiatric history, including Major Depression, Generalised Anxiety Disorders, or anything that involves referral to secondary services and/or significant functional impairment
8. Neuroendocrine disorder, including impaired thyroid function and steroid use
9. Female participants who are, or may be, pregnant

Date of first enrolment
01/07/2015

Date of final enrolment
01/12/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PT

Sponsor information

Organisation
University of Manchester

Sponsor details
Oxford Road
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M139PT

Sponsor type
University/education

Website
www.manchester.ac.uk

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Other

Funder Name
Investigator PhD initiated and funded

Results and Publications

Publication and dissemination plan
To submit to publish in peer reviewed journal in 2019.

Intention to publish date
01/04/2019

Individual participant data (IPD) sharing plan
Confidentiality: Each participant will be identified by an individual anonymised code number that will be used throughout the duration of the study. Participant names, addresses, and other contact details will be stored securely (in a locked filing cabinet) and kept completely separate from all their data. Only fully anonymised data will be stored on laptop computers which cannot

be traced to individuals without study codes filed separately and only accessible to the research team. Computerised databases containing anonymised data will additionally be fully encrypted using the high level encryption software recommended by the University of Manchester. Urine samples will be identified by code number only and will be destroyed immediately after screening.
Unanonymised personal data will only be accessible to the study team. Additionally, study data and material may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, for essential monitoring and auditing purposes, and this may well include access to personal information.
Consent forms will be retained as essential documents, but items such as contact details will be deleted as soon as they are no longer needed. The University of Manchester policy on storage of data is 5 years after the last publication of the study or for 10 years, whichever is the greater.
Alcohol consumption change and cognitive tasks will be analysed using univariate and multivariate techniques from SPSS as appropriate.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2019	27/09/2019	Yes	No
HRA research summary			28/06/2023	No	No