

Effects of sleep deprivation and low blood alcohol on driving capacities in young people

Submission date
31/01/2014

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
10/02/2014

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
12/02/2021

Condition category
Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Background and study aims

Driving while sleep deprived and after alcohol consumption are frequently suspected in road traffic crashes among young drivers. The effects of sleep deprivation on driving can be increased even at low legal levels of blood alcohol. This study aims to clarify how and to what degree sleep deprivation combined with low, legal levels of alcohol consumption influences driving in young drivers.

Who can participate?

Male and female drivers aged 18-25 years and 30-34 years.

What does the study involve?

The effects of combined sleep deprivation and low legal alcohol levels on simulated driving performance will be compared to either of these conditions alone.

Participants are randomly allocated to one of four groups:

1. No alcohol intake, no partial sleep deprivation
2. Alcohol intake, no partial sleep deprivation
3. No alcohol intake, partial sleep deprivation (1 hour less of sleep/night over a one-week period)
4. Alcohol intake, partial sleep deprivation (1 hour less of sleep/night over a one-week period)

What are the possible benefits and risks of participating?

Participants receive a maximum compensation of 250 Canadian dollars for their time and transport.

About 5% of participants may suffer simulation sickness that includes dizziness, nausea and vomiting. We screen for simulation sickness during a driving simulation practice session lasting about 10 minutes. We advise participants to reduce or avoid driving during their participation. To avoid any risks following alcohol administration, participants are advised to leave the laboratory only after their blood alcohol drops to 0%. Taxis are made available to participants if they feel fatigued following the experimental sessions.

Where is the study run from?

Douglas Mental Health University Institute Research Centre in Montreal, Canada.

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

The study will start recruiting participants in February 2014 and will run until March 2016.

Who is funding the study?

Canadian Institutes of Health Research (CIHR) and a consortium made up of Quebec Society & Culture Research Foundation (Fonds de Recherche du Québec Société et Culture - FQRSC), Quebec Motorcar Insurance Company (Société de l'Assurance Automobile de Québec - SAAQ) and Quebec Health Research Foundation (Fonds de Recherche du Québec Santé - FRSQ), Canada.

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Canadian Institutes of Health Research MOP-123346

Study information

Scientific Title

Effects of sleep deprivation and low blood alcohol on executive functions in young drivers: a randomized controlled trial

Study objectives

To compare the effects of cumulative sleep deprivation and legal blood alcohol levels on the safe driving capacities of young people.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Douglas Mental Health University Institute Review Ethics Board, 17/01/2014, ref. REB#12/18

Study design

Randomized controlled trial - double blinded for sleep deprivation induction and alcohol dose

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Diagnostic

Participant information sheet

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

Health condition(s) or problem(s) studied

Injury prevention, driving while impaired by alcohol and/or sleep deprived

Interventions

The participants are randomised to one of four conditions.

1. No alcohol intake, no partial sleep deprivation
2. Alcohol intake [blood alcohol concentration (BAC) = 0.03%], no partial sleep deprivation
3. No alcohol, partial sleep deprivation (1 hour less of sleep/night over a one week period)
4. Alcohol (BAC = 0.03%), partial sleep deprivation (1 hour less of sleep/night over a one week period)

One follow-up session is involved for measurement of simulated driving performance.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Driving performance on the driving simulator measured at intake and one week following randomization to condition and the partial sleep deprivation induction protocol.

Secondary outcome measures

Performance on neuropsychological executive function tasks

Overall study start date

01/02/2014

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Male and female drivers aged 18-25 years and 30-34 years, having drunk alcohol in the past 6 months
2. Having driven in the past 3 months
3. Medication-free (except contraceptives for females)
4. Usually sleeps during regular night-time hours

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

34 Years

Sex

Both

Target number of participants

300

Total final enrolment

93

Key exclusion criteria

1. Attention-deficit hyperactivity disorder diagnosis
2. Signs of alcohol dependence
3. Signs of drug dependence
4. Sleep problems
5. Pregnancy or breastfeeding

Date of first enrolment

01/02/2014

Date of final enrolment

31/03/2016

Locations

Countries of recruitment

Canada

Study participating centre

Douglas Mental Health University Institute Research Centre

Montreal

Canada

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Sponsor information

Organisation

Douglas Mental Health University Institute Research Centre (Canada)

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.douglas.qc.ca/page/administration>

ROR

<https://ror.org/05dk2r620>

Funder(s)

Funder type

Government

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada)

Alternative Name(s)

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR),
CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Funder Name

Consortium made up of Quebec Society & Culture Research Foundation (Fonds de Recherche du Québec Société et Culture - FQRSC) + Quebec Motorcar Insurance Company (Société de l'Assurance Automobile de Québec - SAAQ) + Quebec Health Research Foundation (Fonds de Recherche du Québec Santé - FRSQ) (Canada)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019	12/02/2021	Yes	No