

Evaluation of new UK drinking guidelines

Submission date 01/02/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/02/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/01/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Alcohol is a major public health problem. In the UK, there were 8,416 deaths and over a million hospital admissions due to alcohol in 2013. Treating alcohol-related problems costs the NHS approximately £3.5 billion a year. Internationally, a common approach to reducing alcohol consumption is to publish low risk drinking guidelines (DG). These aim to tell the public about the risks of drinking above a particular amount of alcohol and encourage more sensible drinking behaviour. DG are promoted in various ways including TV advertising campaigns, putting information on bottle labels and by doctors discussing drinking with their patients. Despite their widespread use, little is known about whether promoting DG affects people's behaviour or how they think about alcohol. The aim of this study is to evaluate the impact of promoting new DG has on the alcohol consumption of adults living in England.

Who can participate?

Anyone aged 16 or over who lives in a private household in England.

What does the study involve?

All participants complete questionnaires online in their own home once a month for 22 months. The questions in the questionnaires vary slightly each month but all include questions about alcohol consumption, knowledge about current drinking guidelines and the motivation and opportunity to use drinking guidelines in their own lives. Throughout the study, government and hospital records are reviewed so that the amount of alcohol related problems and injuries can be recorded.

What are the possible benefits and risks of participating?

There are no direct benefits or risks of taking part in this study.

Where is the study run from?

1. University of Sheffield (UK)
2. University College London (UK)
3. University of Nottingham (UK)

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

February 2015 to October 2018

Who is funding the study?
NIHR Public Health Research programme (UK)

Who is the main contact?
Dr John Holmes (scientific)

Contact information

Type(s)
Scientific

Contact name
Dr John Holmes

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The effectiveness of promotional campaigns associated with revised UK drinking guidelines: An evaluation of a prospective natural experiment

Study objectives

Research Questions:

1. What is the timing, audience and content for major promotional activity following publication of revised drinking guidelines?
2. Does promotion of drinking guidelines lead to changes in trends in alcohol consumption behaviour (primary outcome), individuals' capability, opportunity and motivation to change behaviour and alcohol-related hospital admissions (secondary outcomes)?

3. Are there any variations in effects across subgroups of the population defined by gender, age, and socioeconomic status?
4. Are there any variations in effects between those reporting recent exposure to the drinking guidelines and those not reporting recent exposure?
5. Are any changes in alcohol consumption behaviour preceded by changes in capability, opportunity and motivation to change behaviour?
6. Given the observed relationship between promotional activity and alcohol consumption behaviour, is the promotion of revised drinking guidelines a cost-effective intervention?

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Sheffield School of Health and Related Research ethics committee, 18/11/2015, ref: 006373

Study design

Prospective observational longitudinal study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

No patient information sheet available and the study is surveying members of the general public

Health condition(s) or problem(s) studied

Alcohol consumption

Interventions

Once a month for 22 months, participants complete questionnaires in their own homes via computer-assisted interviews conducted by Ipsos Mori interviewers. The questionnaire is an Ipsos Mori Omnibus study which we have bought questions within and therefore the full content of the questionnaire varies each month. However, it always includes sociodemographic questions and questions specific to this study which pertain to alcohol consumption, knowledge of drinking guidelines and capability, motivation and opportunity to use drinking guidelines in their own lives.

Intervention Type

Behavioural

Primary outcome measure

Alcohol consumption behaviour measured on a monthly basis via AUDIT-C scores collected in repeat cross-sectional surveys throughout the study period between January 2016 and October 2017, and compared to a combination of data collected in this study between November and December 2015 and data previously collected between March 2014 and October 2015.

Secondary outcome measures

1. Alternative alcohol consumption measures, specifically:
 - 1.1. Mean weekly consumption measured on a monthly basis using graduated frequency questions in repeat cross-sectional surveys between November 2015 and October 2017
 - 1.2. Monthly consumption measured using alcohol cleared for UK sales as recorded by HMRC
 - 1.3. Hazardous drinking measured using full AUDIT score collected as with AUDIT-C scores
2. Behavioural antecedents of alcohol consumption, specifically capability, opportunity and motivation to change behaviour as measured by questions informed by the COM-B model of behaviour change in repeat cross-sectional surveys between November 2015 and October 2017
3. Alcohol-related harm is measured using Hospital Episode Statistics monthly
 - 3.1. Admissions to hospital for alcohol poisoning (ICD-10: T51.0, T51.1 and T51.9)
 - 3.2. Admissions to hospital for assaults (ICD-10: X85-Y09)

Overall study start date

01/02/2015

Completion date

31/10/2018

Eligibility

Key inclusion criteria

1. Aged 16 years and over
2. Living in private households in England

Participant type(s)

All

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

77,400 (43 month samples of n=1,800)

Total final enrolment

74388

Key exclusion criteria

Aged under 16 years of age.

Date of first enrolment

01/03/2014

Date of final enrolment

31/10/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Sheffield

School of Health and Related Research

30 Regent Street

Sheffield

United Kingdom

S1 4DA

Study participating centre

University College London

HBRC

1-19 Torrington Place

London

United Kingdom

WC1E 7HB

Study participating centre

University of Nottingham

Clinical Sciences Building

Nottingham City Hospital

Hucknall Road

Nottingham

United Kingdom

NG5 1PB

Sponsor information

Organisation

University of Sheffield

Sponsor details

Western Bank
Sheffield
England
United Kingdom
S10 2TN

Sponsor type

University/education

ROR

<https://ror.org/05krs5044>

Funder(s)**Funder type**

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications**Publication and dissemination plan**

The results of the study will be communicated to a wide range of people by publishing papers in scientific journals and presenting to national and international conferences attended by different groups who may be interested (including the general public).

Intention to publish date

31/03/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2020	26/01/2021	Yes	No