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Evaluating possible intended and unintended consequences of the implementation of Minimum Unit Pricing of Alcohol in Scotland: a natural experiment

Submission date
24/04/2018

Recruitment status
No longer recruiting

Registration date
16/05/2018

Overall study status
Completed

Last Edited
31/10/2022

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Minimum unit pricing of alcohol is a new public health policy that aims to reduce alcohol-related harms and health inequalities. It sets a minimum price (based on alcohol content) below which alcohol cannot be sold and it is designed to impact those at greatest risk of experiencing alcohol-related harms. A comprehensive set of evaluations is being coordinated by NHS Health Scotland, which this study contributes to. This study aims to investigate the impact of the introduction of minimum unit pricing of alcohol in Scotland on alcohol-related attendances to Emergency Departments and sexual health clinics.

Who can participate?
Patients over 16 years of age who attend the participating Emergency Departments or sexual health clinics

What does the study involve?
Data is collected from four Emergency Departments in Scotland and North England to see if there is a difference in the rates of alcohol attendees before and after the legislation is in place. Data is also collected from six sexual health clinics in Scotland and North England. Questionnaires are provided to all attendees at the clinics for self-completion, seeking information on alcohol consumption, drug use and the source of any alcohol consumed. Differences in the outcomes between Scotland and North England are measured to see if there have been any potential negative effects caused by the introduction of the legislation.

What are the possible benefits and risks of participating?
Participants have the opportunity to contribute to the evaluation of a national health policy. Risks are negligible.

Where is the study run from?
1. Glasgow Royal Infirmary (UK)

2. Sheffield Teaching Hospital (UK)
3. Royal Liverpool University Hospital (UK)
4. Royal Infirmary of Edinburgh (UK)
5. Sandyford Clinic (UK)
6. Sexual Health Lothian (UK)
7. Sexual Health Manchester (UK)
8. The Centre for Sexual Health - Leeds (UK)
9. Royal Hallamshire Hospital (UK)
10. Sexual Health Tayside (UK)

When is the study starting and how long is it expected to run for?
September 2017 to September 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ross Forsyth

Contact information

Type(s)
Scientific

Contact name
Mr Ross Forsyth

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11/3005/40

Study information

Scientific Title

Evaluating possible intended and unintended consequences of the implementation of Minimum Unit Pricing of Alcohol in Scotland: a natural experiment

Study objectives
This study aims to investigate the impact of the introduction of minimum unit pricing (MUP) of alcohol in Scotland on alcohol-related attendances to Emergency Departments and potentially unanticipated negative impacts of the introduction of minimum unit pricing (MUP) of alcohol in Scotland.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scotland A Research Ethics Committee, original approval 14/08/2012, latest ethical review 17/01/2018, REC ref: 12/SS/0120 for the Emergency Dept arm and 12/SS/0121 for the Sexual Health arm

Study design
Observational cross sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Alcohol-related A&E attendances, and Sexual Health Clinic attendances

Interventions
This research is a natural experiment study of the impact of introducing MUP in Scotland. The methods involve a repeated cross-sectional audit of all alcohol-related attendances at EDs in two Scottish hospitals and two North England geographical control hospitals at three timepoints. On each occasion, data collection will involve a face-to-face survey administered by research nurses to ED patients over selected times during a three week time period.

The sexual health arm of the study will compare self-completed questionnaires at three sexual health clinics in Scotland with three sexual health clinics in North England at three different time points.

Each wave of data collection for the main study will last three weeks. The first wave is planned for prior to the introduction of MUP in Scotland with two follow-up waves of data collection at approximately 6 months after and 12 months after.

Intervention Type
Other

Primary outcome measure
The primary outcome for the ED arm:
Absolute numbers of alcohol-related attendances as defined by any one of:
1. Patient self-reports attendance is alcohol-related
2. Patient reports alcohol consumption in past 24 hours >=8 units in men, >=6 units in women
3. Patient not approached because too intoxicated with alcohol
Compared between intervention and control areas, adjusted for baseline attendances
Measured by questionnaire administered by research nurses at the Emergency Departments:
Wave 1 – February 2018, Wave 2 - October 2018 and Wave 3 – February 2019

The primary outcome for the sexual health arm:
Rates of higher/lower risk drinking, as measured by FAST score, compared between intervention and control areas, adjusted for baseline attendances. Data will be collected at baseline (February 18), 6 month follow up (October 18) and 1 year follow up (February 19)

Secondary outcome measures
Secondary outcomes for the ED arm:
1. Changes in absolute number of alcohol-related attendances by age/sex/deprivation
2. Changes in problematic alcohol use, as defined by the Fast Alcohol Screening Test (FAST)
3. Changes in mean FAST score
4. Changes in prevalence of binge drinking in the past week
5. Changes in reason for attendance, coded by ICD-10
Measured by questionnaire administered by research nurses at the Emergency Departments:
Wave 1 – February 2018, Wave 2 - October 2018 and Wave 3 – February 2019

The secondary outcome for the sexual health arm:
Self-reported binge-drinking with analyses for differential impact by age/sex/deprivation. Data will be collected at baseline (February 18), 6 month follow up (October 18) and 1 year follow up (February 19)

Overall study start date
01/09/2017

Completion date
30/09/2020

Eligibility

Key inclusion criteria
For the Emergency Department arm of the study, the target population for the study is all patients over 16 years age who attend EDs to receive acute treatment for a health condition. For those who are approached, the inclusion criteria are:
1. >=age 16

2. able to speak English and no interpreter available
3. Is a new ED presentation
4. The patient is conscious
5. The patient is physically well enough
6. The patient is mentally well enough
7. The patient is sober enough (alcohol)
8. The patient is sober enough (drugs)
9. The patient is still in the department
10. The patient is safe for staff to approach

For the sexual health arm of the study the target population for the study is all patients of any age attending participating sexual health clinics during data collection periods. The inclusion criteria are:
1. People able to complete the questionnaire
2. People who are deemed by the clinical staff as appropriate to approach

Participant type(s)
Other

Age group
Mixed

Sex
Both

Target number of participants
Sexual Health sites: 15000; A&E sites: 5640

Key exclusion criteria
For the ED sites:
1. Patient too unwell
2. Too distressed
3. Grossly intoxicated (alcohol)
4. Grossly intoxicated (drugs)
5. Cognitive impairment
6. Police in attendance
7. Clear language barrier, and no interpreter available
8. Patient already participating
9. Routine follow-up that has been instigated by ED staff
10. Patient left dept
11. Patient admitted
12. Staff safety issue
13. End of shift
14. Dead on arrival
15. Other

For the Sexual Health sites:
1. People unable to complete the questionnaire with assistance from the research assistant
2. People who leave the department before an approach can be made
3. People who are deemed by the clinical staff as inappropriate to approach

Date of first enrolment
22/11/2017

Date of final enrolment
28/03/2019

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Glasgow Royal Infirmary
United Kingdom
G4 0SF

Study participating centre
Sheffield Teaching Hospital
United Kingdom
S10 2JF

Study participating centre
Royal Liverpool University Hospital
United Kingdom
L7 8XP

Study participating centre
Royal Infirmary of Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Sandyford Clinic
United Kingdom
G3 7NB

Study participating centre
Sexual Health Lothian
United Kingdom
EH3 9HQ

Study participating centre
Sexual Health Manchester
United Kingdom
M13 9WU

Study participating centre
The Centre for Sexual Health - Leeds
United Kingdom
LS2 8NG

Study participating centre
Royal Hallamshire Hospital
United Kingdom
S10 2JF

Study participating centre
Sexual Health Tayside
United Kingdom
DD1 9SY

Sponsor information

Organisation
NHS Greater Glasgow & Clyde

Sponsor details
Greater Glasgow Health Board
JB Russell House
Gartnaval Royal Hospital
1550 Great Western Road
Glasgow

Scotland
United Kingdom
G12 0XH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

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
Study protocol is available on the NIHR website: https://www.journalslibrary.nihr.ac.uk/programmes/phr/11300540/#/summary-of-research

Planned publication of the study results in a high-impact peer reviewed journal in 2020/21.

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as although not personal data the data are potentially sensitive. Electronically

entered data will be held on a secure computer drive at SPHSU and paper versions shelved in a locked storage room.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/06/2019	17/06/2020	Yes	No
Results article		01/10/2021	31/10/2022	Yes	No