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All Wales Licensed Premises Intervention

Submission date
23/10/2012

Recruitment status
No longer recruiting

Registration date
22/11/2012

Overall study status
Completed

Last Edited
18/09/2015

Condition category
Other

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

Plain English summary of protocol

Background and study aims
About 7 in 10 of A&E admissions are alcohol related at peak times. Urban centres typically produce a substantial share of all alcohol-related violence, and are particularly associated with severe intoxication and violent injury. Recent studies have shown that environment-specific risk factors and recognition that premises-level (PL) programs (interventions) that address such risks can lead to a reduction in alcohol-related violence. Interventions that address these risk factors are therefore urgently required to reduce the burden of harm to health services. By reducing known risk factors within premises and their immediate environment, the aim is to directly or indirectly reduce alcohol misuse and/or injury.

Who can participate?
Premises are eligible for the trial if they are on-licence premises that are: based within the 22 local authorities (LAs) in Wales, are a public house, night club, or hotel, and have recorded one or more violent incidents (including Section 18/20, Section 47, common assault, affray, assault of a police officer) in the previous twelve months.

What does the study involve?
The study is being delivered by Environmental Health Officers (EHOs) in Wales. The intervention itself is made up of three components. First, EHOs will audit premises to identify areas where premises operation might increase the risk of violence (e.g. inappropriate alcohol promotions, which are associated with violence). Second, based on the outcome of the audit, EHOs will take one of four possible steps: 1) take no further action if there are no risks; 2) advise premises to make changes; 3) formally require premises to make changes; 4) refer premises to police and Local Authority (LA) licensing officers (who are able to place conditions on premises licenses). Finally, EHOs will conduct a second audit in premises where further action is required to assess whether the required changes have been made (they will enforce as required). Depending upon the severity of the risk identified in the initial audit, the second audit will take place either one month or three months later. The control group premises will receive the usual contact that premises receive from EHOs, which does not routinely involve interventions for violence. Following the audit, we will provide premises staff with training and instructional materials designed to engage them in harm reduction practice, and will be tailored to the areas of risk identified on a per-premises basis.

What are the possible benefits and risks of participating?
If this intervention succeeds in reducing violence then there will be substantial benefits such as reducing fear of crime and the psychological impact of victimisation. Due to the nature of the trial we don't foresee any risks over and above those usually associated with licensed premises.

Where is the study run from?
The trial is being run from Cardiff University Dental School

When is the study starting and how long is it expected to run for?
January 2013 to April 2014.

Who is funding the study?
National Institute for Health Research (NIHR) Public Health Research (PHR).

Who is the main contact?
Dr Simon Moore
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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
NIHR PHR ref: 10/3010/21

Study information

Scientific Title
Randomised controlled trial of All-Wales Licensed Premises Intervention to reduce alcohol-related violence

Acronym
AWLPI

Study objectives
Primary objective
To determine the impact of Safety Management in Licensed Premises (SMILE) on police recorded violence

Secondary objectives
1. To assess whether intervention impacts change over time
2. To identify the costs associated with SMILE and the extent to which it can be regarded as an efficient use of public funds
3. To assess whether the integrity of SMILE is maintained across LAs
4. To determine the optimal format of the risk-led PL intervention for delivery by EHOs
5. To develop a revised logic model of the intervention
6. To consider the relationship between outcomes and intervention reach, dose and receipt

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dental School Research Ethics Committee, 07/09/2012, ref: 12/08

Study design
Randomised controlled effectiveness trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Public Health Research

Interventions

1. An evaluation of the Safety Management in Licensed Premises (SMILE) intervention
2. The control group premises will receive the usual contact that premises receive from EHOs, which does not routinely involve interventions for violence.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Difference in police-recorded violence between intervention and control premises over a 12 month follow-up period

Secondary outcome measures
The trial will incorporate an embedded Process Evaluation (PE) to examine how the trial is implemented and to facilitate interpretation of outcome effects.

The PE will examine the following issues:
1. Trial arm implementation and context
2. Trial arm fidelity
3. Participation, reach and dose delivered
4. Reception and responsiveness

The trial will also include an embedded economic evaluation to determine the cost of delivering the intervention.

Overall study start date
02/04/2012

Completion date
08/09/2014

Eligibility

Key inclusion criteria
1. On-licence premises that are based within the 22 LAs in Wales
2. On-license premises that are a public house, night club, or hotel
3. On-license premises that have had recorded one or more violent incidents (including Section 18/20, Section 47, common assault, affray, assault of a police officer) in the preceding twelve months

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
600 premises (300 intervention; 300 control)

Key exclusion criteria
1. On-license premises that are cafes, restaurants and entertainment venues such as sports facilities and concert halls
2. Premises that have recorded other offences such as criminal damage, drug use and theft

Date of first enrolment
02/04/2012

Date of final enrolment
08/09/2014

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University
Cardiff
United Kingdom
CF14 4XY

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
Research and Commercial Division
7th Floor
30-36 Newport Road
Cardiff
Wales
United Kingdom
CF24 0DE

Sponsor type
University/education

Website
http://www.cardiff.ac.uk/

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) - Public Health Research Programme (UK) ref: 10 /3010/21

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?
Protocol article	protocol	10/01/2014		Yes	No
Results article	results	01/09/2015		Yes	No