# **All Wales Licensed Premises Intervention**

Submission date 23/10/2012	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>[X] Protocol</li></ul>
<b>Registration date</b> 22/11/2012	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 18/09/2015	<b>Condition category</b> Other	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 mooresc2@cardiff.ac.uk

# **Contact information**

**Type(s)** Scientific

**Contact name** Dr Simon Moore

### **Contact details**

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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 alcoholrelated 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

 On-license premises that are cafes, restaurants and entertainment venues such as sports facilities and concert halls
 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
<u>Results article</u>	results	01/09/2015		Yes	No