

All-Wales Licensed Premises Intervention (AWLPI): a randomised controlled trial of an intervention to reduce alcohol-related violence

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Scientific summary

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Scientific summary

Background

Alcohol-related violence (ARV) continues to place a burden on public services, including the NHS. Research suggests that interventions that address environment-specific risk factors in premises licensed for the on-site sale and consumption of alcohol may help to reduce ARV; there is currently a lack of evidence in the UK from trials that evaluate premises-level risk-management interventions. The All-Wales Licensed Premises Intervention (AWLPI) project builds on the available literature and an earlier feasibility study to develop and evaluate the Safety Management in Licensed Environments (SMILE) intervention.

Aims

Primary aim

To determine the impact of SMILE on police-recorded violence.

Secondary aims

1. To translate existing knowledge into an intervention suitable for use within environmental health practitioners' (EHPs') remit for intervention in licensed premises.
2. To assess whether or not the impact of the intervention changes over time (intervention wane).
3. To identify the costs associated with SMILE and the extent to which it can be regarded as an efficient use of public funds.
4. To assess whether or not the integrity of SMILE is maintained across local authorities (LAs).
5. To determine the optimal format of the risk-led premises-level intervention for delivery by EHPs.
6. To develop a revised logic model (a detailed description of intervention development and delivery) of the intervention.
7. To consider the relationship between outcomes and intervention reach, fidelity, dose and receipt.

Intervention

The SMILE intervention involved an initial visit and risk audit by EHPs to identify known risks of violence and a follow-up audit scheduled to enforce changes in premises where serious risks had been identified. Structured advice was administered by EHPs on how risks could be addressed in premises and supported by online materials that provided educational videos and related material to premises staff.

The risk audit tool was based on results of an earlier feasibility trial and systematic review evidence. Materials were coproduced and adapted to conform to EHPs' usual practice and then piloted by senior EHPs. The online materials were developed by a project advisory group with the help of a design company.

Methods

A trans-disciplinary action research (TDAR) approach was used to develop SMILE and implement it within normal environmental health working practices. Normalisation process theory was used to assess the effectiveness of TDAR in promoting intervention adoption, reach, fidelity, receipt and sustainability.

The evaluation involved a randomised controlled trial, with licensed premises drawn from all 22 LAs in Wales as the unit of allocation. Eligible premises ($n = 837$) that had previously experienced violence were randomised into an intervention group, which received SMILE, and a control group, which received usual practice. Primary analysis was by intention to treat (ITT) with additional sensitivity testing. An embedded process evaluation examined intervention implementation, reach, fidelity, reception and premises responsiveness. An economic evaluation compared costs of the intervention with benefits from a societal perspective.

Trial population and eligibility criteria

A minimum sample size of 274 licensed premises per arm was required, randomly selected from the eligible population. Eligible premises ($n = 837$) were public houses, nightclubs or hotels with a public bar operational at the time of intervention that had been identified in police-recorded violence data as having experienced violence. Cafes, restaurants and entertainment venues such as sports facilities and concert halls were excluded. Eligible premises ($n = 606$) were available for study and randomly allocated to control ($n = 300$) or intervention ($n = 300$) groups. Of these, however, only 453 were available for analysis, mainly as a result of closures during the time available for intervention delivery. Thus, the trial was underpowered.

The sample available for analysis included the ITT group (control group, $n = 208$; intervention group, $n = 245$) on which primary analyses were conducted, and two further groups on which sensitivity analyses were conducted (per-protocol: control $n = 208$, intervention $n = 238$; non-randomised group where spare premises not initially allocated were included: control $n = 321$, intervention $n = 285$).

Randomisation

Within each LA, premises were allocated randomly to intervention or control groups. Premises were optimally balanced by LA: number of violent incidents in baseline data and opening hours (coded into two groups: open up to 11 p.m. and open after 11 p.m.). Optimal allocation was used to carry out the randomisation where a balancing algorithm minimised the imbalance between treatment groups across the prespecified balancing factors on a block (LA) basis. This ensured that overall balance was maintained within blocks, and also between blocks by conditioning on the previous block allocation. Randomisation was carried out by an independent statistician within the South East Wales Trials Unit to conceal allocation from the trial team.

Outcome measures

The primary outcome was difference in police-recorded violence between intervention and control premises over the 455-day follow-up period (from 1 January 2013, the first day when intervention premises were eligible to receive the intervention). The trial incorporated an embedded process evaluation that was used to examine how the trial was implemented and to facilitate interpretation of outcome effects. The cost of the intervention (including any implementation costs) and the estimated differences in cost-generating events as a result of violence were secondary outcomes.

Statistical analyses

The primary analysis was an ITT analysis of police-recorded violence between intervention and control premises over the follow-up period, with time-zero being the time of randomisation. The analytic approach used the Andersen–Gill model, where sessions (where each temporal unit was from 12 p.m. to 12 p.m. the following day) were marked with a binary fail indicator such that if one or more violent offences occurred during that session it was marked as being in a state of failure. This approach facilitated the inclusion of time-varying covariates and censoring. Additional sensitivity analyses were conducted on the per-protocol and the non-randomised populations. A secondary analysis was undertaken to assess the hypothesised intervention wane over the follow-up period. An embedded process evaluation examined intervention implementation, reach, fidelity, reception and premises responsiveness. In line with the main statistical analysis, the cost-effectiveness analysis was carried out on premises in the ITT sample, with a secondary exploratory analysis investigating the cost-effectiveness of the intervention where it included a follow-up visit.

Results

Trial results

Almost all premises (98%) eligible to receive the initial intervention received it. The intervention was associated with an increase in police-recorded violence [hazard ratio (HR) = 1.34, 95% confidence interval 1.20 to 1.51]. This effect was constant across the follow-up period. Fewer than expected premises ($n = 16$ in ITT group, $n = 18$ overall) received a follow-up visit from EHPs and these premises yielded a modest reduction in recorded violence (HR = 0.43, $p < 0.001$), although analyses were underpowered.

Process evaluation results

Study findings suggest that researchers and EHPs were able to draw on their expertise and knowledge to shape an intervention that could be successfully integrated into routine practice. Consequently, SMILE achieved high levels of fidelity and reach owing to the statutory powers of EHPs. However, a similar intervention dose was delivered regardless of premises risk factors, with EHPs less confident in using enforcement options in what was a new area of work. There were also some questions regarding whether or not police data were adequately targeting violent premises and could be used to assess effectiveness. Overall, premises responded positively to the use of a statutory intervention, although smaller independent premises were more likely to perceive the intervention as an imposition and a burden.

Economic evaluation results

The total cost of the SMILE intervention (training 70 EHPs, auditing 281 premises with further follow-up audit to 18 premises with higher risks of violence) was £35,196, or £125 per premises. The intervention was shown to be less effective and more costly than normal practice and hence not cost-effective. Despite the uncertainty due to small numbers of follow-up visits, a sensitivity analysis capturing joint uncertainty in costs and effects suggests that the probability of a follow-up visit being cost-effective may be almost 100%.

Conclusions

The SMILE intervention was acceptable to EHPs, consistent with their usual working practice and delivered with high levels of fidelity and reach. However, EHPs rarely enforced their recommendations with follow-up visits, and so premises received a similar intervention regardless of their level of violent incidents or risk factors. This represents implementation failure of what was seen as a key mechanism of action. Indeed, the modest findings associated with follow-up visits may suggest that they are necessary in order to yield a positive reduction in violence. Given this, the SMILE intervention as delivered was found to be ineffective and associated with increased levels of violence, compared with normal practice. To be effective, any future intervention may require a longer implementation period to develop EHP confidence in using enforcement approaches in this area and a multiagency approach including the police. Results are further complicated by concerns regarding whether or not police data were adequate in identifying the most risky premises and assessing effectiveness, and the possibility that the audit of intervention premises might have resulted in increased police vigilance and recording of violence at follow-up, compared with control premises.

Implications

Environmental health practitioners can play an important role in delivering harm-reduction measures to premises licensed for the on-site sale and consumption of alcohol.

Recommendations for research

Further work is required to develop the accuracy and reach of data needed to understand the harm associated with ARV. This will require more objective measures of alcohol-related harm such as those available from NHS services, which are less prone to recording biases. In addition, data are lacking on the activities that different premises are licensed for, and this requires urgent attention if researchers and responsible authorities are to make positive contributions to ARV. The cost of alcohol-related harm is poorly understood. Work needs to be undertaken to better understand both the tangible cost to services of ARV and the intangible victim costs.

Attention should be given to the nature of the relationship between authorities whose remits overlap in tackling ARV. There currently appears to be a mismatch between skills available in some authorities and the intended effect of their involvement in this area, given the evidence showing that changes within premises can bring about reductions in violence. Further work is required to better understand the role of follow-up visits in this context, in particular whether or not they are necessary to enforce change in premises.

Trial registration

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