

**The Effectiveness of an Intervention to Reduce Alcohol-Related Violence in Premises Licensed for the Sale and On-site and Consumption of Alcohol: A Randomised Controlled Trial**

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Word Count: 3,723

## Abstract

### **Background and Aims**

Premises licensed for the sale and consumption of alcohol can contribute to levels of assault-related injury through poor operational practices that, if addressed, could reduce violence. We tested the real-world effectiveness of an intervention designed to change premises operation, whether any intervention effect changed over time, the effect of intervention dose and cost effectiveness of the intervention.

### **Design**

A parallel randomised controlled trial with the unit of allocation and outcomes measured at the level of individual premises.

### **Setting**

All premises (public houses, night clubs, or hotels with a public bar) in Wales, UK.

### **Participants**

A randomly selected subsample (N = 600) of eligible premises (that had one or more violent incidents recorded in police recorded crime data; N = 837) were randomised into control and intervention groups.

### **Intervention and Comparator**

Intervention premises were audited by Environmental Health Practitioners who identified risks for violence and provided feedback by varying dose (informal, through written advice, follow-up visits) on how risks could be addressed. Control premises received usual practice.

### **Measurements**

Police data were used to derive a binary variable describing whether, on each day premises were open, one or more incidents were evident over a 455 day period following randomisation.

### **Findings**

Due to premises being unavailable at the time of intervention delivery 208 received the intervention and 245 were subject to usual practice in an intention to treat analysis. The intervention was associated with an increase in violence compared to normal practice (HR = 1.34, 95% CI 1.20 to 1.51). Exploratory analyses suggested that reduced violence was associated with greater intervention dose (follow-up visits).

### **Conclusion**

An Environmental Health Practitioner led intervention in premises licensed for the sale and on-site consumption of alcohol resulted in an increase in police recorded violence.

WORDS: 290

**Funding:** Public Health Research Programme UK National Institute for Health Research (10/3010/21). The funder (National Institute for Health Research Public Health Research Programme) of the study had no role in study design, data analysis, data interpretation, data collection, or writing of the paper. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

**Key Words:** Alcohol, Violence, Randomised Controlled Trial, Licensed Premises

**Declaration of interests:** We declare that we have no competing interests.

**Trial registration:** This trial was registered at the UK Clinical Research Network Study Portfolio ([www.ukctg.nihr.ac.uk](http://www.ukctg.nihr.ac.uk)) (14077) and the International Standard Randomised Controlled Trial Number Register ([www.isrctn.com](http://www.isrctn.com)) (78924818).

**Protocol:** Study protocol can be retrieved from [www.biomedcentral.com/1471-2458/14/21](http://www.biomedcentral.com/1471-2458/14/21) and <http://orca.cf.ac.uk/56949/>. The protocol was published before data collection had ended.

## Introduction

Premises licensed for the sale and on-site consumption of alcohol and that are characterised by disorder typically feature lax door security, late licenses, poor risk management and other poor operating practices (1-3). In England and Wales it is estimated that 211,514 people attended healthcare services in 2014 for treatment following violence (4). Alcohol is involved with 47% of all violent offences (5) and an estimated 20% of all violence occurs in or around pubs, bars or nightclubs (6). While quasi-experimental and similar studies suggest intervention in premises can reduce harm (7) there is only limited evidence from methodologically sound trials exists to inform how policy can address violence of which none have been conducted in the UK. Two systematic reviews of the international literature have been completed (8, 9). One review focussed on server training interventions and concluded that research in the context of the licensed trade should be broadened to develop interventions that address multiple risk factors across the full socio-ecological environment (9). The second (8) included a broader range of approaches but only identified five randomised controlled trials, many of which were methodologically weak (poorly defined outcomes, ad hoc follow-up periods, no consideration of intervention sustainability, inappropriate control groups, and failure to achieve random allocation). Moreover, a significant barrier to research and development in this area is the unwillingness of premises to engage. An earlier feasibility study (10) found 5% of premises invited into a voluntary harm reduction initiative engaged.

The aim of the All-Wales Licensed Premises Intervention (AWLPI) was to evaluate the effectiveness of the SMILE (Safety Management in the Licensed Environment) intervention, designed to reduce violence in licensed premises. SMILE included a risk audit to identify areas of operation associated with violence, which prompted feedback on how operations could be improved to address risks. The primary objective was to (1) compare the day by day rate of violence in premises that receive the intervention to those that received usual practice over a 455 day follow-up period. Secondary objectives included (2) analysis of change in the rate of violence over time across follow-up period, any intervention effect might take time to bed in or wane. We further sought to (3) explore intervention dose on outcomes. An embedded process evaluation assessed fidelity, reach, acceptability and dose, results from which are available elsewhere (11).

## Methods

The study was approved by the Cardiff University Dental School Research Ethics Committee (Reference 12/08). It was undertaken and reported in accordance with CONSORT (12). Details of pre-registered hypotheses, design, intervention development and logic models are available elsewhere (10, 11, 13).

### *Study design and participants*

A parallel randomised controlled trial where premises were randomised into two groups: control and intervention. Premises in the intervention group received the SMILE intervention, no contact was made with control premises who received usual practice. Police violent crime data was used to describe whether violence was present (denoting failure in premises operation) or not following randomisation and daily for 455 days. These longitudinal data were then used to determine whether there were differences in failure rates across control and intervention groups. SMILE was delivered by EHPs who are employed by LAs to protect public health by enforcing legislation and provide support. EHPs work mostly with health and safety legislation, which is applicable to all businesses whether licensed or not, and they have a violence in the workplace remit. While EHPs had little experience working with licensed premises (11) they did have regulatory powers that enabled their entry into premises, needed to overcome the expected unwillingness of premises (9), and they are trained to conduct work-place risk assessments (14). Premises were therefore not able to opt out of the study. SMILE was designed to work within EHPs' statutory remit and to translate the applicable research base to inform activity. The underlying logic of the intervention recognised that violence arises through a complex interaction between place, person and social norms (15). As perpetrators are likely intoxicated, appealing to personal control is less effective compared to modifying the premises environment (16). Our approach emphasised opportunity (e.g. perceived surveillance), guardianship (e.g. door security) and cues (e.g. the perceived acceptability of disorder) and EHPs were prompted to work with premises staff and managers to develop appropriate policy and procedures that mitigate the risk of violence.

Premises were eligible if they were licensed for the sale and onsite consumption of alcohol, were a public house, night club, or hotel with a public bar and that between the months May 2011 to April 2012 had one or more violent incidents recorded in police recorded crime data. Premises were excluded if they were cafes, restaurants or entertainment venues such as sports facilities and concert halls. The police data used to select eligible premises did not identify premises that had changed purpose (e.g. from bar to restaurant) or had ceased trading. LA business rate data (these fees are only paid by businesses that are trading) were used to cross-check all study premises and determine whether they ceased to trade in the follow-up period and when. All premises were also

telephoned by researchers to cross-check eligibility. The control group received usual practice. As EHPs only visited licensed premises for food related matters usual practice would include management by police and LA licensing teams, which both control and intervention premises were exposed to.

### **Materials**

-- Figure 1 about here --

SMILE was developed from EHP usual practice (14, 17) and used existing audits and related measures used by EHPs as a template. All intervention premises received an audit that covered 11 areas of operation [S1]. For each area a Risk Control Indicator (RCI) scale was completed. Based on the RCI EHPs determined the level of enforcement required to bring about change and this ranged from no feedback (no risk), verbal feedback, written advice to follow-up visits (RCI > 3) to enforce compliance (Figure 1). For serious infringements that placed the public at risk formal notices could be issued. These placed a legal requirement on premises' to comply and made them liable to punitive measures (e.g. fines). EHPs could also refer premises to partner agencies (police, licencing and fire) if they discovered risks that were not within their remit. EHPs' usual approach requires that they intervene proportionately to the evidence for risk, with the emphasis on dialogue to assist those they regulate achieve compliance (17).

### **Procedures**

Senior EHPs piloted the intervention in ten premises that were excluded from the main study. Minor revisions to intervention documentation were made. EHPs were trained in intervention delivery at one of three training sessions that included researchers, senior EHPs and consultants in emergency medicine who raised awareness of assault-related injury as EHPs were naïve to the extent and severity of violence in this context. EHPs initially wrote to premises advising that they were to visit. When visiting they undertook a risk audit and provided feedback to premises staff on how identified risks could be addressed. Following the audit and feedback additional materials were distributed to premises staff that included template policies and educational films.

### **Outcomes**

Our primary outcome measure was police recorded violence (including homicide, violence with injury and violence without injury), notifiable offences that are reported to and recorded by the police. These data were independently collected by the four police forces in Wales, they contained the location, time and nature (using UK Home Office crime classification codes) of all violence in Wales but were otherwise anonymous. For the baseline query eligible premises were identified through manually screening data. LA licensing teams and the premises themselves were telephoned by researchers to ensure they were operational and met eligibility criteria. Using the baseline data as a training set, automated search algorithms were designed to screen follow-up data and extract events associated with study premises. A random selection of 20% of these follow-up data were also screened manually and compared. Events were scored 1 if they appeared in both data sets, otherwise 0, the proportion in agreement was 0.97.

The primary analysis was the comparison of failure rates between intervention and control premises over the follow-up period with time-zero being 1st January 2013, the earliest date an audit could be delivered. While police recorded violence provided data for the primary outcome a derivative of these data were used. Police data record violent events but do not indicate whether they are independent. We therefore ascribed each day using a binary indicator set to one when a day yielded one or more violent offenses (indicating a failure in premises operation to prevent violence) and zero otherwise. These longitudinal data facilitate an analytical approach that can include time varying covariates and account for when premises close temporarily or permanently. The primary data set used data extracted using automated search procedures, sensitivity analyses were conducted on data manually curated using the methods used to create the baseline data. Using the date and time of violent incidents, incidents were organised into sessions. A session was defined as 12noon to 12noon the following day and took the date of the first 12 hour period. Each session was coded with a binary failure indicator: 1 if a premises had registered one or more violent incidents in a session, otherwise 0.

## **Randomisation**

The total number of premises eligible for randomisation was 837. An earlier exploratory trial used simulation on an assumed hazard rate of 0.9, based on pilot data, to estimate what overall group size (N = 274 premises) would be sufficient to provide a power of 90% to detect a relative 10% reduction in the failure rate at a significance level of 0.05 (18). This was rounded up to 600 premises to account for premises ceasing business before the trial began. Premises were randomly selected from the total eligible population for randomisation (the

remaining unallocated premises were later used in additional sensitivity analyses, Figure 2). Allocation to control and intervention groups was in a 1:1 ratio. Optimal allocation was used to carry out the randomisation where a balancing algorithm minimised the imbalance between treatment groups across the pre-specified balancing factors (opening hours: low (0-4 hours open after 11pm across Friday and Saturday evening in total) vs high; number of baseline incidents: low (1 or 2 incidents) vs high) 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 (19). LAs with greater capacity to carry out audits were not supplemented with other LA premises as EHPs do not go beyond their boundary. At the point of inclusion in the study no one knew which arm the premises would be randomised to and since randomisation occurred at a single time point independently from the trial team and EHPs, allocation concealment was ensured. Control premises were not aware of their participation and intervention premises were not allowed to exclude themselves from the study. For the unallocated sensitivity analyses, premises that were closed prior to receiving an audit were replaced with a premises randomly selected from a matched list of any remaining premises within that LA. Randomisation was carried out by an independent statistician to conceal allocation from the trial team.

### **Blinding**

EHPs were aware of the intervention premises, but blinded to control premises identities. Although it is feasible that EHPs who were aware of the premises in their LA could deduce which premises were in the control group, this is moderated by the large number of premises in Wales (approximately 2,725). Independent statisticians in the South East Wales Trials Unit undertook the primary and secondary analyses.

### **Analytic Strategy**

Violence in premises repeats over time and premises are prone to closure (temporary and permanent, otherwise known as censoring). A simple time to first event ignores the recurrent nature of these data and are therefore unlikely to reveal whether an intervention effect wanes over time. As our hypotheses were both specific to the rate of failure and the nature of any change over time, an analytical approach was selected that could test for both. An Andersen-Gill model was used to analyse failure in premises in the follow-up period (20). The intervention effect was realised as a time varying predictor for both initial and later follow-up visits. Variables used to balance randomisation were included in the analysis. Since the randomisation was stratified by LA analyses included LA as shared frailty. Frailty assumes premises within the same LA may be subject to similar influences on their risk of failure causing the LA responses to be heterogeneous. The intervention was further interacted with  $e^{-0.03t}$ , where  $t$  was analysis time, to assess any change over time. Primary analyses were conducted on the Intention to Treat groups (premises assigned to control and intervention groups, irrespective of whether they received the intervention or not) with sensitivity analyses conducted on the Per Protocol groups (premises that received the intervention) and the non-randomised groups that included additional premises that were added to the control and intervention groups after randomisation (Figure 2). Further exploratory analyses considered intervention dose in the intervention group only. All analyses were conducted using Stata 14MP.

--Figure 2 about here--

## **Results**

The initial analysis of police data identified 837 eligible premises and a total of 2,236 violent incidents across the 12 month baseline period. Most premises were open beyond 11pm and hours open past 11pm were similar on Friday and Saturday evenings (0 hours - Friday = 13.3%, Saturday = 13.3%; 0.5 to 1 hour - Friday = 12.9%, Saturday = 12.5%; 1.5 to 2 hours - Friday = 27.5%, Saturday = 27.7%; 2.5 to 3 hours - Friday = 25.9%, Saturday = 25.4%; 3.5 to 4 hours - Friday = 12.1%, Saturday = 12.3%; 4.5 to 5 hours - Friday = 5.5%, Saturday = 5.9%; 5.5 to 7 hours - Friday = 2.9%, Saturday = 2.9%), although opening hours may vary across the year as premises can close early if there are few or no customers. Of the 837 eligible premises capacity data were available for 144 from Local Authority licensing records. Capacity data were historically included as a licensing condition and was determined by fire services. Deregulation allowed premises to determine their own capacity meaning only a subset of premises licensing data included this historical data. For these 144 premises, baseline total violence was associated with capacity (Spearman's  $\rho = 0.38$ ,  $p < 0.01$ ), suggesting that stratifying on baseline violence was adequate.

For the initial audit, there were three refusals following EHPs' letter of introduction and these premises were not audited (one premises name was identical to the village in which they were situated and thus it was not possible to disambiguate the exact location of the incident in police data, another premises had recently been reviewed for licensing violations, and EHPs indicated that they did not wish to audit a third premises). There were four premises that were closed at the time of audit but reopened within the time available for EHPs to audit them and

were audited (false negatives). All remaining premises unavailable to the study were no longer trading (as indicated in business rate data).

--Table 1 about here--

All available intervention premises were eligible for auditing from 1<sup>st</sup> January 2013, 25% were audited by 11<sup>th</sup> Feb, 50% by 25<sup>th</sup> Feb, 100% by 29<sup>th</sup> April.

From the 1<sup>st</sup> January 2013 onwards a total 1,829 incidents were observed in the automatically curated data (1,762 in the manually curated data). For the intention to treat group, overall there were 891 failures with an average 1.19 (SD = 0.70) violent incidents per failure. Few premises received a second follow-up audit (N = 16; although 97 premises scored greater than three on one or more RCIs indicating 81 more premises should have received a follow-up visit), for those that did there were 17 failures, representing 19 incidents (average violence per failure = 1.12, SD = 0.49), for premises receiving an audit but no follow-up there were 512 failures representing 620 violent incidents (average violence per failure = 1.21, SD = 0.72). Ten control premises closed before the follow-up period ended, these sessions were marked as missing in the data, yielding an average follow-up period of 447.48 days (SD = 43.38) (min 76, max 455); the intervention group follow-up average was 449.78 sessions (SD = 32.61; min 162, max 455).

Referring to Figure 1, of the 245 intervention premises 24 premises received no feedback and presumably had no evident risks, 200 premises received verbal or written and verbal feedback. Of the remaining 21 premises, five received a follow-up audit but no formal notice, one received a formal notice and a follow-up audit and 15 received a follow-up audit and no notice. EHPs could also refer premises to partner agencies. There were no referrals to the police, seven premises were referred to the fire services and 22 were referred to LA licensing. Reasons for referral to LA licensing were for premises not operating according to their licensing conditions. Reasons for formal notices covered lack of safety policies and records (n = 3), inadequate staff training (n = 1), poor condition of the premises (n = 2), poor lighting (n = 1) and significant failing in respect of gas safety (n = 1). One premises received a prohibition notice for inadequate fire safety but also demonstrated failings with regard to CCTV and staff training.

### ***1. Comparison of the rate of failure in intervention and control premises***

Primary analyses indicated the intervention was associated with an increase in the rate of failure and therefore police recorded violence (Table 2, Figure 3A) for the intervention group compared to the control group, a result replicated in sensitivity analyses across both automatically extracted and manually extracted data and with the per-protocol and non-randomised groups. For all analyses the likelihood test for LA heterogeneity ( $\theta = 0$ ) yielded a robust result (chibar2 > 150 for each test), justifying the inclusion of shared frailty by LA. All models performed significantly better than the null ( $\chi^2 > 470$  for each model). Baseline characteristics were significantly associated with violence, higher historical levels of violence and longer opening hours were positively associated with failure in the follow-up period.

--Table 2 about here--

--Figure 3 about here--

### ***2. Analysis of change in the rate of violence over time across follow-up period***

Analyses examined whether the intervention effect waned over the follow-up period, however no significant interaction with time was noted.

### ***3. The effect of intervention dose on outcomes***

Additional unplanned exploratory analyses considered the effect of follow-up visits (N = 16 premises received a follow-up visit) on failure (Figure 3A) against the control group and, for the intervention group alone, whether receiving EHP feedback effected failure (Figure 3B). The net HR for the effect of a follow-up audit was determined through multiplying the audit HR (Table 2) with the follow-up audit HR (HR = 0.46, 95% CI 0.26 0.71, p < 0.01; HR = 0.57), suggesting premises that received a follow-up audit experienced fewer failures. To further explore the effect of the intervention on failure intervention premises were divided into two groups according to nature of the feedback given: premises that received no advice and premises received feedback. For the intention-to-treat group, using the automated data and controlling for violence and opening hour groups, premises receiving feedback (N = 217) yielded a lower hazard rate compared to those that did not (N = 21; HR = 0.51, 95% CI 0.42 to 0.63, p < 0.001) and controlling for baseline violence and opening hours. These

secondary analyses are problematic, however, given the low number of premises and that the effects might be attributable to regression to the mean.

## Discussion

Our findings show that, compared to usual practice, the SMILE intervention was associated with a sustained increase in police recorded violence. The large number of premises that closed before the intervention was delivered, likely attributable to the economic recession at that time, meant that a lower sample size than target was achieved and the trial was underpowered. Furthermore, the methodological approach assumed a continuous process (premises operational over time) that may or may not produce violence but only from randomisation onwards. Studies adopting similar methods may benefit from including pre-randomisation outcome data and modelling the effect of the intervention as a time varying covariate. This may identify where underlying trends emerge, whether they are due to the intervention or preceded the intervention.

The collaborative approach to the intervention aided the successful adoption, development and implementation of SMILE within EHP working practices, resulting in high levels of premises reach and the successful completion of a robust randomised controlled trial in a complex area of study. However, data presented here and confirmed in an embedded process evaluation highlight implementation failure of a key intervention mechanism of action: the expected follow-up enforcement visits were not delivered by EHPs (11). This raises questions about EHPs confidence in this new area of work. Future delivery of statutory interventions may require partnership working with more experienced partners, such as licencing officers, to overcome EHP resistance (11, 13). The earlier feasibility study that informed the current trial (10) was not conducted by EHPs, but a private organisation that was not partnered with the police and licensing. In this feasibility study all intervention premises received a follow-up audit. While EHPs overcame the barrier involved with recruiting premises it also brought about failures elsewhere.

The study would have benefitted from more objective measures of violence, such as those available in hospital unscheduled care data. Police recorded violence only include offences that have been reported to or observed by them and therefore underestimate levels due to difficulties in ascertainment, which result from fear of reprisals, poor attitudes towards police involvement, and an unwillingness to have conduct scrutinized (21). Therefore, a potential explanation of this study's results is that EHP scrutiny increased the ascertainment of violence by the police, as has happened elsewhere (22).

Violence is a burden on individuals and health services. This trial demonstrates that EHPs are able to identify risks, willing to work with premises and submit to robust evaluation methods. However, work in this new context together with revised working practices for EHPs, which emphasises a lighter approach to regulation (14, 17), blunted the opportunity to enforce change. EHPs have a public health remit and could still play an important role in assisting Health Services such as the NHS discharge their responsibilities to proactively address the causes of violence.

### *Contributors*

SCM was the chief investigator; MFA, KH, CH, SM, RP, LM, JPS, VS and David Cohen (retired) were co-applicants for funding and designed the original study protocol; CS coordinated the trial; DC led the economic evaluation; SM led the process evaluation; SCM, KH, LM, RP and CH developed the statistical analysis plan; AW collected and analysed the qualitative data; CH analysed the quantitative data; all authors contributed to interpretation of results and drafting of the final article, including critique for intellectual content.

### *Acknowledgement*

The trial is funded by the National Institute of Health Research Public Health Research (NIHR PHR) Programme (project number 10/3010/21). This paper is independent research commissioned by the National Institute of Health Research. The views and opinions expressed in this publication are those of the authors and not necessarily those of the NIHR PHR Programme or the Department of Health. The work was undertaken with the support of The Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHer), a UKCRC Public Health Research Centre of Excellence. Joint funding (MR/KO232331/1) from the British Heart Foundation, Cancer Research UK, Economic and Social Research Council, Medical Research Council, the Welsh Government and the Wellcome Trust, under the auspices of the UK Clinical Research Collaboration, is gratefully acknowledged. Thanks are due to Claire Simpson and Helen Stanton for administrative work on the project. We would also like to thank the Senior EHPs (Richard Henderson, Sarah Jones, Iwan Llewellyn, Simon Morse, Liz Vann, and Gweirydd Williams) for their help

during the development stage of the trial and their useful comments and suggestions throughout. And also to all EHPs who delivered the intervention to licensed premises in Wales.

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## Tables and Figures

**Figure 1**

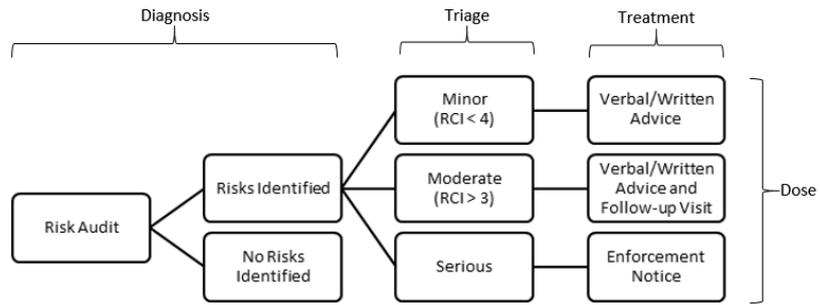


Figure 1: Intervention components, risk control indicator (RCI) scores

Figure 2

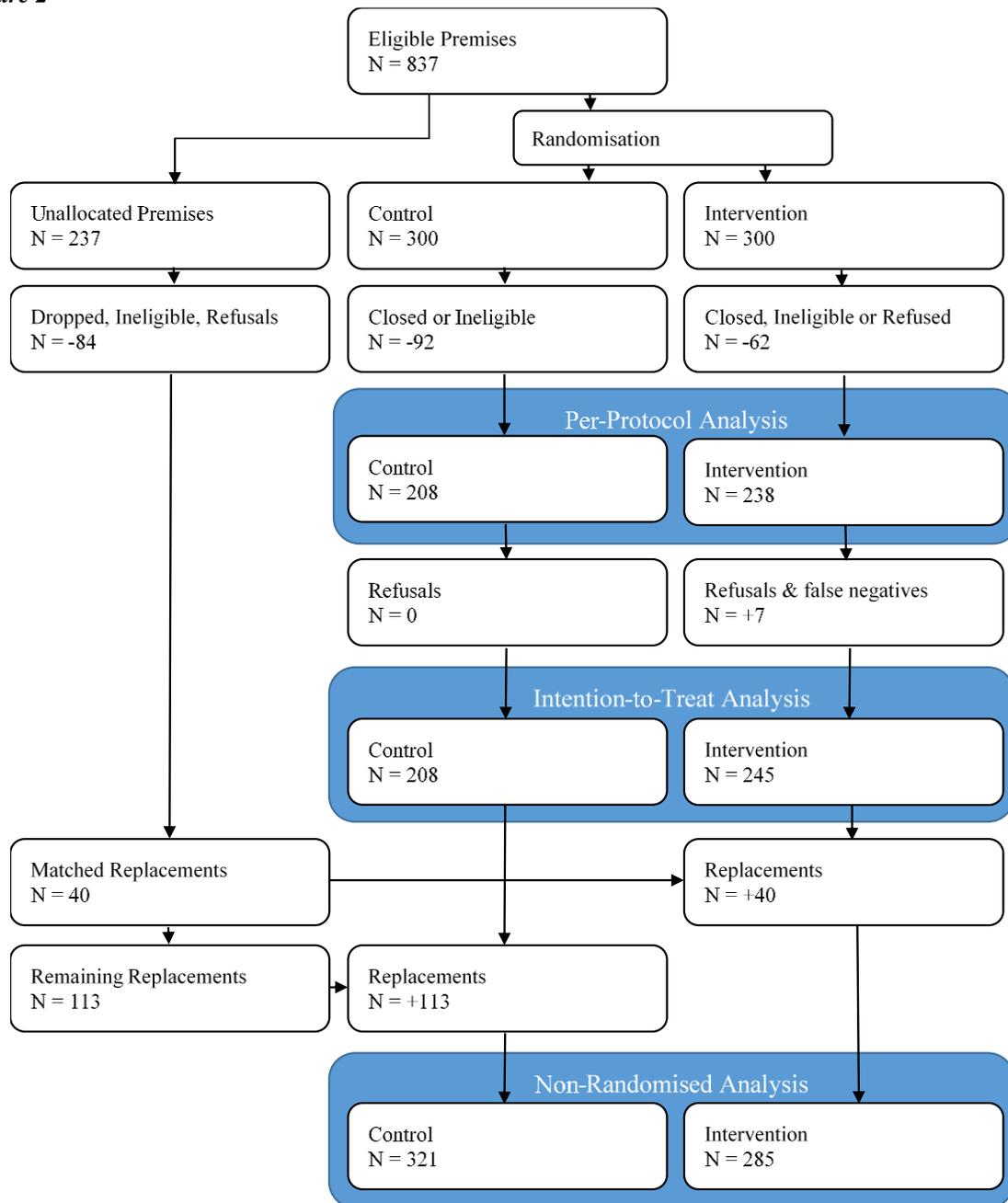


Figure 2: trial profile.

Eligible premises were randomly allocated into control and intervention groups. The premises that were available for the intervention comprise the per-protocol group. Three premises refused and four were false positives (premises that were closed at the time of audit but reopened within the time available for EHPs to audit them). In the unallocated group, premises that were not available for the intervention were replaced from the pool of remaining unallocated premises (randomly selected from the same strata of the premises being replaced, if no premises were available in that strata then no replacement was made); all remaining premises following replacement into the intervention group were added to the control group, this was done so that EHPs could meet their quota.

Figure 3

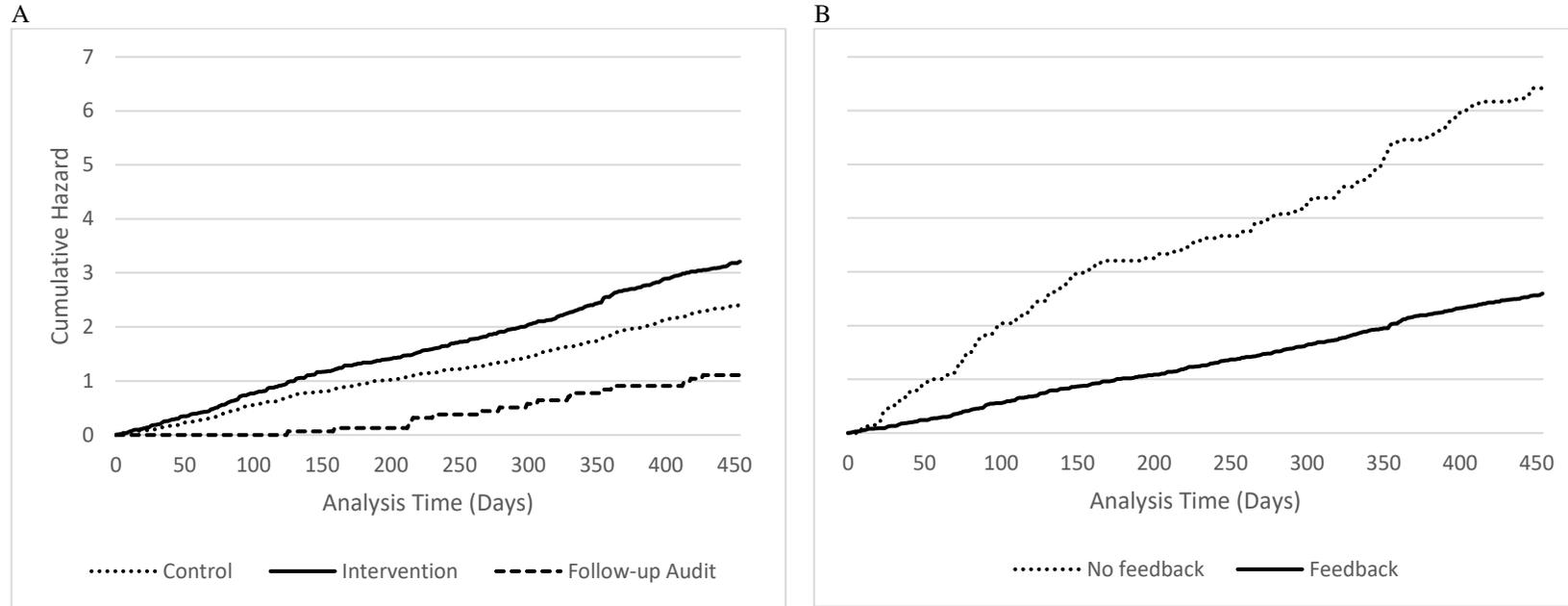


Figure 3: Nelson Aalen cumulative hazard estimate. A: For control premises against all intervention premises and intervention premises receiving a follow-up enforcement visit. B: Intervention premises only, for those premises receiving feedback (written and verbal) and those receiving no feedback.

**Table 1**

Group	Control		Intervention	
	N High	Mean (SD)	N High	Mean (SD)
Initial Allocation	(n = 300)		(n = 300)	
Violence	85	2.53 (3.16)	87	2.78 (4.39)
Opening hours	134	4.26 (2.94)	132	4.47 (3.05)
Intention to Treat	(n = 208)		(n = 238)	
Violence	54	2.41 (3.03)	73	2.93 (4.75)
Opening hours	97	4.35 (2.86)	109	4.49 (2.86)
Per-protocol	(n = 208)		(n = 245)	
Violence	54	2.41 (3.03)	72	2.92 (4.75)
Opening hours	97	4.35 (2.86)	106	4.47 (2.86)
Non-Randomised	(n = 321)		(n = 285)	
Violence	103	2.64 (4.31)	73	2.78 (4.46)
Opening hours	172	4.32 (2.75)	109	4.34 (2.80)

Table 1: Baseline characteristics for premises initially allocated, that remained in the intention to treat analysis and those in the per-protocol and non-randomised sensitivity analyses. Binary indicator variables were created and designated premises as high or low in respect of historical violence and weekend opening hours. Mean and standard deviations of raw figures are included.

**Table 2**

Group	Dataset			
	Automated		Manual	
Intention to Treat	HR	95% CI	HR	95% CI
Intervention	1.34***	1.20 1.51	1.23**	1.07 1.41
Violence group (1 = high)	2.55***	2.21 2.94	3.45***	3.00 4.01
Opening hours group (1 = high)	2.52***	2.22 2.85	2.00***	1.69 2.37
Per-protocol				
Intervention	1.35***	1.20 1.52	1.24**	1.07 1.42
Violence group (1 = high)	2.54***	2.24 2.88	3.49***	3.00 4.07
Opening hours group (1 = high)	2.51***	2.17 2.89	1.96***	1.65 2.32
Non-randomised				
Intervention	1.33***	1.20 1.48	1.15*	1.02 1.29
Violence group (1 = high)	2.78***	2.48 3.12	3.74***	3.28 2.47
Opening hours group (1 = high)	2.44***	2.15 2.77	2.13***	1.84 2.47

Table 2: Results across primary (intention-to-treat) analysis and sensitivity analyses (per-protocol and non-randomised) for both automatically extracted and manually curated datasets.

Note: \*  $p < 0.05$ , \*\*  $p < 0.01$ , \*\*\*  $p < .0001$