## An exploratory randomised controlled trial of a premises-level intervention to reduce alcohol-related harm including violence in the United Kingdom

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## **Abstract**

BackgroundTo assess the feasibility of a randomised controlled trial of a licensed premises intervention to reduce severe intoxication and disorder; to establish effect sizes and identify appropriate approaches to the development and maintenance of a rigorous research design and intervention implementation. Methods An exploratory two-armed parallel randomised controlled trial with a nested process evaluation. An audit of risk factors and a tailored action plan for high risk premises, with three month follow up audit and feedback. Thirty-two premises that had experienced at least one assault in the year prior to the intervention were recruited, match paired and randomly allocated to control or intervention group. Police violence data and data from a street survey of study premises' customers, including measures of breath alcohol concentration and surveyor rated customer intoxication, were used to assess effect sizes for a future definitive trial. A nested process evaluation explored implementation barriers and the fidelity of the intervention with key stakeholders

and senior staff in intervention premises using semi-structured interviews. Results The process evaluation indicated implementation barriers and low fidelity, with a reluctance to implement the intervention and to submit to a formal risk audit. Power calculations suggest the intervention effect on violence and subjective intoxication would be raised to significance with a study size of 517 premises. Conclusions It is methodologically feasible to conduct randomised controlled trials where licensed premises are the unit of allocation. However, lack of enthusiasm in senior premises staff indicates the need for intervention enforcement, rather than voluntary agreements, and on-going strategies to promote sustainability.

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