Protocol

Project Title

Communities In Charge of Alcohol (CICA) Programme: Evaluation of an alcohol health champions programme in Greater Manchester

Funder's Reference

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This study protocol describes the CICA Programme Evaluation and provides details about the procedures involved for study participants. Any problems that arise relating to this study should be referred to the Chief Investigator in the first instance.

This protocol has regard for the HRA guidance http://www.hra.nhs.uk/about-the-hra/consultations-calls/closed-consultations/protocol-guidance-template-use-clinical-trial-investigational-medicinal-product-ctimp-consultation-use/

Chief Investigator [CI]:
Professor Penny Cook
School of Health Sciences
L812d, Allerton Building
University of Salford
Salford M6 6PU
Tel: 0161 295 2804
Email: p.a.cook@salford.ac.uk

Sponsoring Institution:
University of Salford
Research and Enterprise Division
2.01 Joule House, Acton Square
The Crescent
University of Salford
Salford M5 4WT
Tel: 0161 295 3530

Funder
National Institute for Health Research
Evaluation, Trials and Studies Coordinating Centre
University of Southampton
Alpha House, Enterprise Road
Southampton SO16 7NS
Tel: 02380595638

Study Steering Committee (Appendix 5)
Professor Eileen Kaner (Independent Chair)
Institute of Health & Society
Newcastle University
Baddiley-Clark
Richardson Road
Newcastle upon Tyne
NE2 4AX

Study summary

Trial Title	Communities In Charge of Alcohol (CICA) Programme: Evaluation of an alcohol health champions programme in Greater Manchester	
Internal ref. no. (or short title)	CICA	
Clinical Phase	n/a	
Trial Design	Natural experiment with manipulated roll-out analysed as a stepped wedge	
Trial Participants	Area based study	
Planned Sample Size	Nine small areas, one in nine of the 10 Greater Manchester boroughs, mean pop approx. 1500 to 4500	
Treatment duration	1 year	
Follow up duration	2 years	
Planned Trial Period	5 years	
	Objectives	Outcome Measures
Primary	(i) Determine the effect on area level alcohol-related hospital admissions, A&E attendances and ambulance call outs (ii) Determine the effect on key crime indicators (street-level crime data) and key indicators of anti-social behaviour (iii) Identify set-up and running costs using a standardised costing exercise (examination of commissioning documents and contracts) (iv) Resolve costs by sector (health, ambulance and police) before, during, and after CICA setup (v) Quantify benefits due to reduced hospital admissions, ambulance call outs, emergency department	• Alcohol-related hospital admissions (narrow measure) • A&E attendances • Alcohol related call outs for ambulance services • Numbers of crimes in local area • Numbers of incidents of anti-social behaviour • Set-up and running costs for CICA

	use, crime and anti-social behaviour.	
Secondary	(i) Explore policy context and variation in licensing practice, including any impact of devolution in Greater Manchester (ii) Explore barriers/facilitators (partnerships, data sharing across partners and acceptability) (iii) Explore response to alcohol health champions training, modelling of health behaviours, perceptions of community cohesion and development (iv) Determine the numbers of trainees, brief interventions applied and community awareness events organised/participated in (v) Quantify the amount and success of community involvement in licensing issues (vi) Determine whether there is a change in composite measure of alcohol availability	• Barriers and facilitators of CICA, • Licensing practice in the nine boroughs before and after CICA • Ability to deliver the training as planned • Response to training, modelling of health behaviours, and participants' perceptions of community cohesion and development • Number of alcohol health champions trained • Number of brief interventions applied • Number of awareness events organised/participated in • Composite measure of alcohol availability in area • Community licensing activity (numbers of: • licences challenged; licence reviews requested) • Licensing outcomes (numbers of licence applications refused; existing licences revoked ;cumulative impact zones established)
Intervention	CICA is a bespoke community engagement and alcohol health champions (AHC) training programme. Following a two day training course, AHCs will (i) give alcohol-related brief advice to individuals and (ii) help communities tackle the availability of alcohol in the local environment through the licensing process. They will be supported by a local coordinator (one per each of the nine boroughs) who will manage the AHCs.	

Contents

1 Background

1.1 Existing research

Excessive alcohol consumption harms an individual's health and social relationships[1]. It also harms society more generally, as urban areas can become less pleasant and less safe to visit[2] and crime may increase[3]. Moreover, the consumption of alcohol contributes significantly to health inequalities. Those living in deprived areas drink the same average quantity of alcohol as those from more advantaged groups. However a so-called 'alcohol harm paradox' exists whereby, for a given level of alcohol consumption, alcohol harm is higher amongst those living in more deprived areas[4]. Possible reasons for this include patterning of consumption (e.g. consuming the same quantity on fewer occasions[5]) and combinations of other health risks (e.g. smoking, obesity) in individuals living in deprived areas[6]. Interventions that are effective at reducing alcohol harm have been shown to operate at the individual level (i.e. brief advice about drinking[7]), the community level (e.g. measures that control access to alcohol[1]) and national level (e.g. alcohol pricing policy[1]). This protocol describes an evaluation of an intervention, 'Communities In Charge of Alcohol' (CICA), which aims to target alcohol at two levels, by influencing individuals (through brief intervention) and communities (through reducing the availability of alcohol).

Brief interventions and brief advice have been shown in systematic reviews and metaanalyses to be effective in a variety of settings including emergency departments[8] and primary care[7]. There is relatively little evidence about training lay persons for this role, although pilot work with ex-offenders giving advice to offenders in community settings seems promising[9]. Accessibility to alcohol is a key determinant of harm[4 10 11]. Systematic review level evidence shows that high alcohol outlet density is linked to higher levels of crime and poor health[12]. A systematic review (rated high quality[13]) found that higher outlet density and greater exposure to advertising tends to be associated with higher levels of alcohol use[14]. Interventions that change the alcohol environment thus have the strongest evidence for effectiveness[1 13 15].

In England, local authorities can address public health through licensing policies. However, because 'public health' is not currently one of the licensing objectives, the extent to which this is carried out varies across the country[16]. Local people have the ability to influence the availability of alcohol via the licensing process, but do not tend to do so, due to low awareness and lack of confidence that local views will be valued[17]. Recent longitudinal, area-level analysis of UK datasets shows that, at borough level (i.e. lower tier local authorities in England) both alcohol-related hospital admissions[16] and crime[18] have reduced faster in areas where more restrictive licensing policies are in place. Using small area level data (lower super output area, LSOA, circa 1500 persons), alcohol outlet density in Wales is similarly associated with alcohol-related hospital admissions and crime data[4].

This protocol describes a study that takes an existing planned intervention, CICA, funded through nine Greater Manchester (GM) local authorities, and manipulates the roll-out to convert it to a quasi-experimental situation (i.e. a natural experiment). CICA takes an Asset Based Community Development (ABCD) approach, where a health asset is any factor which enhances the ability to create or sustain health and wellbeing[19]. Local volunteers working with the community will identify alcohol harm in their community, and will be facilitated to enable them to intervene in their community. The National Institute for Health and Care Excellence (NICE) guidance on behaviour change advocates building on existing community resources and skills[20]. The ABCD approach is promoted widely (e.g. in new NICE guidance[21]) and is attractive in terms of current fiscal challenges and cuts to services, but there is relatively little evidence for its effectiveness[22]. Therefore, this study also aims to strengthen the evidence base for this approach, and anticipates the findings will be widely relevant across a range of topics, not just interventions to reduce alcohol harm.

1.2 Risks and benefits of the study

Reviews of the effectiveness of health champions approaches do not cite any risks to taking part as a champion, and instead suggest that such individuals can be effective in increasing knowledge and awareness in their communities, improving access to services, health behaviour change and improving health and wellbeing[23]. In terms of benefits to the health champions themselves, reviews have identified benefits of volunteering in this role including improvement in health and self-esteem[23]. Benefits cited in case studies include personal development and employability[24]. Alcohol health champions will receive training and a qualification (level 2 award), which may increase employability.

No previous health champion projects with a specific focus on alcohol have been published in the literature. While the specific topic of alcohol is sensitive, it is not necessarily more so than issues such as weight management, which are the more traditional focus of health champions[23]. There is a risk that the component of the role that supports communities to address alcohol misuse in their local areas could lead alcohol health champions to become unpopular if this involves reducing the number of alcohol outlets. However, as part of the development of the study, a consultation with community members already successful in campaigning against alcohol licences did not highlight that this is as a potential risk. Evidence suggests that potential risks would be justified by the outcomes in terms of improved health and wellbeing of community members and alcohol health champions themselves[23]. Attempts have been made to calculate the monetary value of health champion activity, and these suggest the potential social return on investment would be between £0.79 and £112.42 per pound invested[25].

1.3 Rationale for current study

The CICA intervention will be rolled out across Greater Manchester (GM) from September 2017. This is the first time that GM has attempted to coordinate an approach to building health champion capacity across all 10 boroughs and all 12 Clinical Commissioning Groups and this has been made possible by the Greater Manchester Health and Social Care Strategic Partnership’s commitment to a 'Radical Upscale in Prevention' as one of the four key programmes within the 'Greater Manchester Taking Charge' Strategy. This protocol sets out independent, robust evaluation of this programme. It is critical that evaluation on this scale and nature occurs, otherwise an important opportunity for evaluating a public health intervention, with all its implications for policy, is lost.

The powers exist for local people to influence the availability of alcohol in their local area, but such action does not generally happen. Although there have been isolated success stories of community campaigns against alcohol retailers[26], the possibility of utilising ‘people power’ has not been explored but could represent a huge untapped resource. This aligns precisely to the Government’s attempts to make it easier for residents and other local agencies interested in licensing to take action[27]: it will therefore be of great interest nationally, and we will be in an ideal position to utilise the interest of key national players to drive the dissemination and impact of this research.

1.4 Socioeconomic position and inequalities

A fifth of all lower super output areas in GM are in the highest decile of deprivation nationally (ranging from only 3% in the borough of Trafford to 28% in the City of Manchester). All GM local authorities have higher than England averages for alcohol related mortality, ranging from 46.7 in Trafford to 71.9 per 100,000 in Manchester[28]. CICA explicitly aims to reduce health inequalities due to alcohol harm by focusing this community-level intervention in a geographical area of priority in terms of having high levels of alcohol related harm and significant economic and social deprivation.

This study investigates an ‘asset based’ approach to tackling alcohol harm. While an asset based approach *per se* does not tackle health inequalities, by targeting those areas most in need, the principles of the approach (i.e. allowing time for communities to realise and acknowledge their individual and collective assets and to rebuild their confidence and networks; enabling local people to take the lead; building trust with communities by demonstrating that involvement leads to change[29]) may provide support towards reducing inequalities. The approach seeks to build community networks, which are health promoting[30].

2 Research aims and objectives

The overarching aim of this research is to evaluate the effectiveness and cost consequences of a community alcohol champions programme (Communities In Charge of Alcohol—CICA). The project is divided into three distinct work packages (WP):

2.1 WP1 - Process Evaluation

Aim - to understand the context and factors that enable or hinder the intervention and obtain process measures.

Objectives

(i) Explore policy context and variation in licensing practice, including any impact of devolution in Greater Manchester
(ii) Explore barriers/facilitators at key stages of the intervention (recruitment of AHCs to initial training and cascade training, delivery of initial training and cascade training, using skills beyond the training in AHC activity; retention of AHCs)
(iii) Explore response to alcohol health champions training, modelling of health behaviours, perceptions of community cohesion and development
(iv) Determine the numbers of trainees, brief interventions applied and community awareness events organised/participated in
(v) Examine and quantify the amount and success of community involvement in licensing issues
(vi) Determine whether there is a change in composite measure of alcohol availability

2.2 WP2 - Outcome Evaluation

Aim - to evaluate the effectiveness of CICA.

Objectives

Use routinely collected quantitative data to:

(i) Determine the effect on key health performance indicators (alcohol-related hospital admissions, A&E attendances and ambulance call outs)
(ii) Determine the effect on key crime indicators (street-level crime data)
(iii) Determine the effect on key anti-social behaviour indicators

2.3 WP3 - Economic Evaluation

Aim - to carry out a cost consequences analysis of CICA

Objectives

(i) Identify set-up and running costs using a standardised costing exercise (examination of commissioning documents and contracts)
(ii) Resolve costs by sector (health, ambulance and police) before, during, and after CICA setup

(iii) Quantify benefits due to reduced hospital admissions, ambulance call outs, emergency department use, crime, anti-social behaviour.

3 Research design

CICA is a complex community-level intervention (CICA: see logic model, Appendix 1) and was already in the planning phase prior to the NIHR call for proposals. Therefore it is researcher-influenced but not researcher-controlled. Since it is not amenable to conventional randomisation (as recognised in the complex interventions guidance[31]) CICA will be evaluated as a natural experiment[32]. This fits on the 'continuum of evaluation'[33], which recognises the need for multiple methods/variants on experimental design[34]. CICA will be delivered sequentially in one location in nine of the 10 GM boroughs. Although researchers have no control over the selection of the areas, the order of roll out in the boroughs will be influenced. The researchers have had the opportunity to develop the research questions, and will use methods for testing a complex intervention[31]: process evaluation (WP1)[35]; outcome evaluation (WP2); and economic analysis (WP3).

3.1 WP1 Process Analysis

The process analysis (WP1) will use interviews with practitioners and health champions. The relationships between the organisations responsible for alcohol licensing with the broader community will be scrutinised. Alcohol Health Champion training sessions will be observed to assess the delivery (i.e. dose) and provide data on numbers and what types of people are trained, brief advice given and alcohol licences investigated/challenged (i.e. reach). The context, acceptability, facilitators and barriers to the intervention will be explored. Analyses will utilise the Framework method[36]: textual data will be 'charted' in themes relating to key research questions and scrutinised for differences and similarities within themes, keeping in mind the context in which these arise.

Normalisation Process Theory[37] will be used as a second stage within our process analysis. According to May et al, Normalisation Process Theory (NPT) is a theoretical framework that aims to help researchers to consider how complex interventions are (or are not) implemented, embedded and integrated: *normalised*. While Alcohol Health Champions take part in CICA as volunteers, driven by their own personal motivations to get involved, several aspects of the intervention are imposed upon them such as promoting the Government lower risk drinking guidelines, offering advice to drink less rather than promoting abstinence, and taking action on local licensed premises. The second stage of analysis will subsequently map the initial themes and sub-themes analysed using the Framework method against the four NPT core constructs: coherence, cognitive participation, collective action, and reflexive monitoring.

3.2 WP2 Outcome Analysis

The statistical outcome analysis (WP2) will be at the level of the small intervention area (the equivalent of one to three lower super output areas, LSOA—see 'study population'), comparing with areas where CICA has not been introduced yet. The outcome analysis will involve two distinct approaches:

(i) ***'Internal' evaluation***: We will compare trends in area-time intervention areas before and after the intervention using a stepped-wedge randomised trial design[38]. Sensitivity analyses using different lagging periods (6-24months) between introduction of the intervention and expected effects will allow for a delayed effect on output measures. If differences in the slopes of the longitudinal models are observed, the population impact will be estimated from deviation of the post-intervention slope compared to the pre-intervention slope. Randomisation will be carried out by Co-I de Vocht, and will be concealed from the rest of the investigators and the implementation team until two

months before each given area's turn in the sequence of roll out. Two months will be sufficient to recruit the potential AHCs for training (see section 6.3).

(ii) ***'External' evaluation***: Secondly, we will assess the impact of the intervention using two complementary methods: (a) we will match intervention and control areas inside the GM area by area-level deprivation, population size, age distribution and baseline alcohol-related burden by calculating propensity scores[39]. Temporal trends in each of the outcomes will be plotted graphically and analysed using hierarchical growth models (similar to de Vocht et al.[16 18]); and (b) we will use time series data from GM LSOAs to construct weighted 'synthetic control time series'[40] that mimic the 'intervention area' as close as possible prior to the introduction of CICA. Modelled and measured post-introduction time series can then be compared directly to quantitatively estimate the impact of CICA. Both methodologies (a and b) are complementary, and while the latter approach has the distinct advantage that it provides a direct comparison to the counterfactual time-series, it can be considered as less insightful than the former method because it does not compare actual areas on the ground.

The external evaluation may be affected by 'spill-over'. In other words, if as a result of the introduction of CICA it will be harder for new premises to start in the specific areas, these may decide to establish themselves in neighbouring areas (close to the border). This is a known issue, but difficult to tackle, and therefore directly neighbouring LSOAs will not be incorporated into control areas. Instead only LSOAs that are further away will be combined and matched, as outlined above, using propensity score matching or incorporated in the synthetic control time series.

3.3 WP3 Economic Analysis

The economic evaluation of the CICA programme will estimate the costs of training, delivery and support elements of the intervention. A standard costing exercise will be adopted using documents and contracts to identify resources and costs required to deliver the CICA intervention in each locality. The process outcomes (WP1) will help identify the resource consequence associated with delivery and outcomes. Standardised methods will allow comparability of costs. The economic evaluation will follow a cost-consequences analysis. Such an approach is favoured when costs and outcomes fall on a range of budget-holders and government agencies enabling cost and consequences domains to be presented in a disaggregated form, which enables decision makers to assess results using different relevant perspectives.

The key cost categories identified will be the set up cost for the intervention area, comprising of staff costs, consumables and overheads (premises). In terms of consequences, there will be an analysis of health benefits, changes in health care resource utilisation as a consequence of alcohol use (A&E attendances, hospital inpatient stays, ambulance service costs) and changes in contacts with the criminal justice system.

WP3 will build on WP2 by attributing costs to the health performance indicators collected in the previous work package. Treasury approved methods will be used for the cost-consequences analysis (CCA) published by New Economy and unit costs will be taken from the New Economy Unit Cost Database.

WP2 will use mixed-effects log-rate models and differences-in-differences models to evaluate changes relative to propensity-score-matched controls and will use Bayesian structural time series to model the synthetic control areas; both to assess and compare potential changes in the health care and criminal justice resources before and after CICA interventions. The economic component of the study will follow the statistical methods used in WP2 and apply unit costs to the resource indicators to derive costs for each domain.

These costs will be presented in a CCA framework, disaggregated in terms of costs to individual stakeholders and different cost domains.

The work will be undertaken in collaboration with New Economy, a wholly owned company of the Greater Manchester Combined Authority (GMCA), which delivers policy, strategy and research services for GM's economic growth and prosperity. New Economy has developed cost benefit analysis (CBA) tools over the past 6 years[41]. In April 2014, New Economy worked with HM Treasury and the Public Service Transformation Network to make the methodology accessible to anybody across the UK. It is now supplementary guidance to the HM Treasury Green Book – ensuring that GM's commitment to growth and reform is closely wedded to, and informed by, a best-practice method in how to appraise proposals before committing funds to a policy, programme or project. The proposed approach would be undertaken to align with GM's existing commitment to cost benefit analysis (ensuring that the research findings are translated into a form that is most familiar to local decision makers) and legible / transferrable to a national audience, which is itself adopting the New Economy model as the industry standard tool.

4 Study setting

As an intervention 'testbed', GM is a culturally and socioeconomically diverse area, making it a good model to generalise to the UK. GM has been selected by the UK Government as the testbed for the devolution of fiscal and economic responsibilities and is the prototype for putting the 'Northern Powerhouse' into practice, an initiative that aims to redress the North-South economic imbalance. One of the key sectors for decentralised responsibilities is health and social care spending. The Association for GM Authorities has already identified a focus more on preventative work in the community[42] and has agreed an Alcohol Strategy 2014-17. The lessons learnt from GM's devolution will be passed on to other urban areas and city regions, and as such a robust evaluation of the CICA intervention will be important for other urban areas and city regions in England. GM is heterogeneous in terms of its application of licensing policy: in a recent national study, only one borough was classified as having high licensing policy intensity (two boroughs were medium, five low and two passive in terms making use of cumulative impact areas and/or declining licences[16]).

CICA will be rolled out sequentially across specifically targeted areas in nine boroughs, so that it will eventually (within the timespan of a year) be delivered in all areas. In this natural experiment, each borough will decide which small area to target the intervention—this will use a consistent approach and will be an area of priority in terms of having high levels of alcohol related harm. The target areas themselves within each borough will be formed around pre-existing communities in defined geographical locations, equivalent in size to one to three LSOAs (circa 1500-4500 residents). For data analysis purposes, the one to three LSOAs that are represented by each community will be combined to make the 'intervention area' unit of analysis.

5 Inclusion criteria

5.1 Inclusion criteria for study setting

In order to ensure there is consistency for the evaluation, each local authority will use the following guiding principles as inclusion criteria for selecting an area for the intervention:

- One to three Lower Super Output Areas in size (max 6000 residents and 2,400 homes).
- An area of high alcohol related harm (defined as high within the local authority, not high in comparison to North West or England average rates).
- Alcohol harm should be considered in terms of:

- Alcohol related crime and anti-social behaviour
- Alcohol-related hospital admissions
- Weekend evening A&E attendances
- Users of local treatment services
- Hospital recording of location of violent incidents (if available)
- Density of licensed premises in the area or adjoining areas

5.2 Inclusion criteria for CICA training programme

Those individuals targeted for CICA training will be sought from the existing population of health champions. The health champion network is established to different extents in the GM area, with the borough of Wigan having the highest number of health champions. The age of those recruited to be alcohol health champions (AHCs) will be adults aged 18 years and over. Since this is a community-level intervention, the beneficiaries are anticipated to be persons of all ages.

6 Planned interventions

CICA is a bespoke community engagement and alcohol health champions (AHC) training programme tailored to the themes identified by the GM Alcohol Strategy. AHCs will (i) give alcohol-related brief advice to individuals and (ii) help communities tackle the availability of alcohol in the local environment through the licensing process. The intervention is based on the principles of asset based community development[19], and its components are based on evidence from successful interventions to reduce access and availability of alcohol[1 13 15] and alcohol brief intervention[7] (see logic model, Appendix 1).

The logic model shows the intervention's mechanisms of action and the interplay between its core components. At the heart of the CICA programme, based on ABCD principles, is the assumption that individuals and communities have strengths, motivations and skills that benefit everyone. Further, there is an assumption that the AHC training programme and infrastructure of support can help build the strengths, motivations and skills of these individuals to develop confidence to put their skills into practice. As communities take action by offering brief advice or getting involved in licensing decisions, a feedback loop illustrates how such success positively reinforces the strengths, motivations, and skills of the community. Influencing access and availability to alcohol and building a groundswell of brief advice about alcohol should, as a result, directly impact on alcohol related outcomes.

Additionally, the evaluators have also considered the possible unintended consequences of the intervention. Few public health interventions and evaluations explicitly look at unintended harms and, although logic models considering positive consequences and outcomes are common, the consideration of the potential negative outcomes (and their mechanisms of action), or a 'dark' logic model, are less common[43]. According to Bonell et al. (2015), not only is it important to produce a dark logic model ahead of the evaluation/intervention, or during it, but also the framework could be useful to evaluate the project retrospectively to see how it might have been strengthened[44]. To develop the dark logic model (see Appendix 2) we first created a matrix to hypothesise a priori the potential unintended consequences of CICA using a simple framework, adapted from Lorenc and Oliver's five categories of harm (see Table 1)[43]. Each potential harm was reflected upon using one of three approaches recommended by Bonell et al.[44]: how agencies and structures may interact in unintended ways; comparative understanding across similar interventions; and consultation with individuals/groups with insights into local contexts and how interventions might operate within them. Evidence that supports or refutes the hypothesised unintended consequences of the intervention will benefit future design and minimise the risk of future harm[44].

Table 1 CICA Unintended consequences matrix

Potential unintended consequences	How agencies and structures may interact in unintended ways	Comparative understanding across similar interventions	Consultation with individuals/groups with insights into local contexts and how interventions might operate within them (CICA Project Advisory Group)
Direct harms	None identified	Lack of depth of knowledge by lay health advisors could result in time delays or inconsistent advice for 'in-need' populations[45]	Concerns that volunteers recruited from recovering communities could be at increased risk of relapse of alcohol, drug or mental health problems
Psychological harms	None identified	Volunteers embedded within communities find it hard to 'switch off'[45]	Intervening in licensing could lead to negative reactions from local retailers
		Dissatisfaction and disillusionment of volunteers[46]	
Equity harms	Communities most in need are probably the least able to form a strong community group[47 48]	Motivated individuals becoming health champions are likely to benefit from being a champion more so than those less motivated (who need the potential positive benefits more)[45]	Individual assets within communities excluded from participation due to barriers to recruitment/participation e.g. literacy, criminal record checks, worry about impact on benefits
Group and social harms	'Communities' chosen to be in charge of alcohol set by experts (normative needs) vs. self-identified communities (felt needs)[46]	Becoming a community champion could result in lack of acceptance by own community resulting in marginalising "do gooders"[45]	None identified
		Current recovery dominated culture within alcohol service provision in UK influences the selection of volunteers from 'recovery' communities[49]	
Opportunity cost harms	Commissioners may miss opportunities to invest in alternative public health interventions[50]	Missed opportunities to identify "at-risk" populations[51] due to stereotyping those 'in need' as only the most severe drinking patterns[52]	None identified

6.1 The CICA training programme

The CICA training programme aims to give AHCs the confidence and tools to:

Day 1: Support individuals to reduce drinking and/or to guide individuals towards specialist services/organise community awareness events (how to help and support individuals; alcohol's impact on local communities; collaborative work to reduce alcohol harm; how to use a range of data sources to capture evidence of alcohol impact);

Day 2: Half day - Establish community action against alcohol harm (delivered in collaboration with the local area's alcohol licensing officers: specific local arrangements for licensing decision making; strategies to create interest and mobilise communities in becoming active in the local licensing process);

Day 2: Half day - For first generation ('seed') AHCs only, train subsequent AHCs (enable participants to prepare and set up programme material; select appropriate material relevant for delivery in their area using PTLLS 'Preparing to Teach in the Lifelong Learning Sector' approach).

Each local team is anticipated to train a further 30 individuals in their community to become AHCs. This train-the-trainer model, whereby existing Health Champions act as the lead Alcohol Health Champion Trainers with the support of professionals (local coordinators), is a cascade model of training that is viewed as the most affordable and sustainable approach in the long term and will support wider roll out.

6.2 Infrastructure

The following infrastructure is also part of the intervention:

- Local coordinators who will manage the implementation of CICA in their area and a hub approach for engaging with community assets by appointing a local operational lead to manage AHCs (whether they are already in paid roles or volunteers). The operational lead could be the same person as the local coordinator or a different person/organisation,
- A centralised point of contact so that training can be rolled out (e.g. local coordinator/local operational lead)
- A network/community council: a community-related consultee for new or amended licence applications will be available to assist local communities.

Independently of the evaluation, there is a group of local leads (one for each Local Authority) and Co-I Duffy (Public Health England) who have been working to agree and define the intervention more precisely during this co-design phase. The group has identified the key (consistent) components of the intervention, which are:

- The selected areas will be of significantly high alcohol related harm, and there will be a consistent approach to selection (see section 5.1)
- The champions will be individuals who are already embedded in their community either through their residency or their work role (i.e. they must spend the majority of their time in the target area) (see section 5.2)
- Accredited and standardised training delivered initially by the Royal Society for Public Health (RSPH) trainer and then by the local community (the training will be adapted in each local area to reflect the local context, e.g. by providing local alcohol harm information)
- Secondary recruitment of 30 additional champions in each area
- Commitment in each area from the local Director of Public Health
- A person given a role of local implementation lead (a local coordinator) and a local operational lead who provides ongoing champion support (which could be the same individual as the local lead or a different person/organisation)

- A local licensing lead who will act as a community-related consultee for new or amended licence applications and will be available to assist local communities
- Support of local leads and licensing leads in the design of intervention and delivery of training (i.e. refining it for the target area)
- Consistent qualitative role description to support recruitment and training. The role includes the need to share health harms information; provide alcohol brief advice and referral to treatment; engage with local licensing where issues arise; and supporting/organising local events about alcohol harm. The role description will specify that champions should only do whatever they are comfortable with and that the programme does not dictate where and when conversations can take place.

In addition, the group has identified the elements that are required from each local area, but that cannot be precisely stipulated:

- The mechanism of recruitment and recruitment above 50 initial seed champions (5 in each area)
- The precise nature and quality of the ongoing support
- The quantity of alcohol health champion activity and the proportion of activity spent delivering either brief advice or community action on licensing

The current health champions model utilises lay health workers from a variety of backgrounds (e.g. voluntary sector, housing, environment) to work in a voluntary capacity to offer brief advice and brief interventions alongside their other daily activities[53]. These local health champions have a varied background, including public sector staff, amateur sports clubs and local residents (total >3,000 people in the last six years). CICA participants will be primarily drawn from this existing health champion population across GM (holders of the national health champions qualification, Level 2 Understanding Health Improvement). Potential AHCs will be identified by working with existing community organisations, and will be invited to be trained in a new Level 2 award: Understanding Alcohol Misuse delivered by the Royal Society for Public Health (RSPH).

The role descriptor and a clear set of competencies for the AHC role will be agreed by RSPH, Public Health England, New Economy, academics and community partners co-designing CICA's AHC training. Support for CICA has been indicated by all of the necessary partners including the Police and Crime Commissioner, the GM Directors of Public Health and designated representatives of the Local Authority Chief Executives.

6.3 Recruitment and retention of Alcohol Health Champions

Guided by the RSPH's experience of running similar interventions, local coordinators will approach around 20 potential AHCs per area in order to recruit six or seven participants to the training. This recruitment strategy will aim to obtain the target number of five fully trained AHCs. The process of approaching AHCs will begin two months in advance of the training date. The champions will be individuals who are already embedded in their community either through their residency or their work role (i.e. they must spend the majority of their time in the target area). The qualitative role description will be used consistently across the nine local authorities to support recruitment.

7 Methods

7.1 WP1 Process analysis (WP 1)

In the evaluation of this natural experiment, the intervention will be introduced in a stepped-wedge manner, but will not be exactly the same in each locality; this depends on various local factors, such as specific skills, motivation and behaviour of the local alcohol health champions and the characteristics of the support network. Given the pragmatic approach to this intervention there is even the possibility of adapting the intervention after its introduction. The goal of WP1 analysis is to capture context and the mechanisms by which the intervention may or may not be effective[54].

7.1.1 WP1 Data collection

Data collection will be through collaboration between stakeholders (AHCs and local coordinators) and researchers. During team discussions it will be emphasised that the performance of individual AHCs will not be assessed but that data will be sought about the complex issue of how the intervention might operate in the 'real world'. Each step of the intervention is explored through relevant data capture and methods, as described below (see also 'Process Evaluation Flowchart', Appendix 3):

a. **Context** will be explored by document review and key informant interview either in person or by telephone (there are currently at least two individuals nominated as local leads for CICA (n=2 per borough=20), and will aim to discover how licensing policy was enacted prior to intervention and the on-going monitoring of the policy/practice context. A composite alcohol availability score will be calculated for each area.
b. **Existing health champions (HCs) will be identified**, by contacting local networks. Issues will be identified with regards to the process of finding the previously trained HCs and provide a baseline number of HCs.
c. **Recruitment, training and retention of AHCs** will be analysed using descriptive statistics from registers of all those attending training, and carrying out observations of training of 'second generation' Alcohol Health Champions (AHCs) carried out by first generation/seed AHCs with the support of local coordinators. Response rates, compliance rates, social patterning in uptake of AHC role and fidelity to training programme will be described.
d. **Pre- and post-training questionnaires to all participating AHCs** (n=315) will be used to collect information on knowledge and attitudes to alcohol and reasons for participating.
e. **Post-training semi-structured interviews conducted with a purposive sample of AHCs** soon after attending the CICA training (e.g. three months) with a range of motivations for getting involved in the CICA programme.
f. **One year post-training during the delivery of alcohol health champion activity**, a follow-up questionnaire will be used with all AHCs (n=315) to capture descriptive statistics on whether the training equipped them for their role, the modelling of health behaviours, the number of alcohol issues report to local licensing leads, the number of brief advice contacts (and those who maintain contact), and the number of people decreasing their self-reported alcohol consumption. Local coordinators will send out and collect these follow-up questionnaires from AHCs. During the first year, AHCs will be offered the choice of completing a monthly reflective diary to capture their observations and reflections on the process / barriers to carrying out champion activity (either their own online, paper or voice recorded diary, or via their local lead recording the information on their behalf).
g. **At one year follow-up** semi-structured interviews (n=22) will be held with a purposive sample of lead AHCs who trained further AHCs and AHCs who have not. We will interview a purposive sample of seed AHCs who participated in community action to reduce alcohol or delivered brief advice, and seed AHCs who have not. We

will carry out interviews with a purposive sample of 'second generation' AHCs who participated in community action to reduce alcohol or delivered brief advice , and 'second generation' AHCs who have not. We will interview wider stakeholders (4 public health teams in councils, 4 licensing officers, 4 members of local community groups initially identified as 'assets'). We will carry out two focus groups with people who have come into contact with AHCs.

h. **At one year follow-up**, we will review documents to validate activity around licensing. This will include Written Representations, Review Applications, Decision Notices, requests for Cumulative Impact Assessments, Statements of Licensing Policy consultations, and documented complaints submitted to Responsible Authorities. We will interview key informants to discover how licensing policy is being enacted post intervention (n=20). We will measure the composite alcohol availability scores for each area.

Interviews with key informants

There are currently at least two individuals nominated as local leads for CICA (n=2 per borough=20): a local coordinator and a local licensing lead. At baseline, the interview schedule will cover:

a. Number of baseline HCs and ability to recruit AHCs
b. Access to local data on baseline licensing activity within the chosen target area
c. To what extent the local community reports alcohol issues at baseline
d. Other public health interventions coinciding with CICA that might be relevant to the target area

At follow-up, the schedule will cover:

e. To what extent activity around licensing took place
f. Challenges/facilitators for motivating AHCs
g. Challenges/facilitators for carrying out lead's role
h. Reflections on the role of the lead

Document review

Existing licensing practices in the area will be analysed using a standard data extraction form. This will include access to local Licensing Registers which are public databases containing records of applications received and licenses issues (see outcome measures, section 8.2). This will occur at baseline, during and after the intervention across all nine areas.

Composite alcohol availability score

From the list of licensed premises, the density of outlets within the target area will be measured alongside the licensed hours for alcohol sales and where applicable, the size of the premises (on-licensed premises only). This will be repeated during follow-up phases.

AHC questionnaires

Questionnaires with AHCs will be carried out at baseline (pre- and post-training), and at one year follow-up. Baseline questionnaires will be given out at training and will be filled in at the beginning of the day. An evaluation form for the training will be completed at the end of the day. The follow-up questionnaires will be completed online (using the Bristol Online Survey Tool) or given out on paper by local coordinators and returned by post to University of Salford (prepaid envelopes).

Training event evaluation

This will involve analysis of registers and immediate feedback forms provided by the RSPH. Observations of first and second generation training events will be recorded on a standard sheet to evaluate fidelity of cascaded training.

Post-training interviews with AHCs
Within three months of attending the training, some AHCs will be invited to take part in a semi-structured interview. This purposive sample will aim to interview AHCs with a range of motivations for getting involved in the CICA programme. The following table sets out motivational groups with an aim to interview two people from each group:

Purposive sample	**n=12**
Family experiences of alcohol misuse, concerned relative	2
Cares for and values the community, wants to help people	2
Lived experience of alcohol dependence, in recovery	2
General desire to learn more about alcohol, wants alcohol awareness	2
Works in the local community	2
To gain a qualification	2

Recruitment for these new interviews will be carried out via Local Leads who will put forward people who meet our criteria, but will not tell us which person relates to which criteria. In the interview we will explore the motivations of the participant. We will ask Local Leads to invite training champions to interviews with the research team at local network meetings that are held once a month or bi-monthly following training.

Reflective Diaries
Reflective diaries will be completed by AHCs who consent, although the detail will be as much or as little as the AHC is willing to provide. The benefits of completing a reflective diary includes supporting the AHC to learn from their experiences by looking back on facilitators and barriers to the use of their skills and knowledge beyond the initial CICA training and for the evaluation team in understanding the experiences of the AHCs over the intervention period. The AHCs will have the choice of using their own online reflective diary, paper diary or a diary kept by their local lead recording the information on their behalf (a group diary).

Focus groups with recipients of brief advice
People who have come into contact with AHCs will be invited to attend a focus group. There will be two focus groups organised in central locations that aim to optimise access from across the nine local authority areas. Focus group participants will be recruited via small leaflets/flyers attached to local resources that AHCs will have available to use to support conversations at a local level. This leaflet will invite potential participants to contact the researchers directly if they are interested in taking part.

Interviews with AHCs at one year follow-up
Interviews will capture a range of experience depending on which of the CICA intervention activities the AHCs took part in: cascading training to others (first generation/seed AHCs only), giving alcohol brief advice and intervening in licensing. We aim to cover a variety of engagement with CICA. The target number is a minimum of 22, with up to two in each of the below categories:

	Possible CICA intervention activities			
Role	**Train others**	**Give alcohol brief advice**	**Intervene in licensing**	**Target number**
First generation/seed AHC	X	X	X	2
First generation/seed AHC	X	X		2
First generation/seed AHC	X		X	2
First generation/seed AHC		X	X	2
First generation/seed AHC		X		2
First generation/seed AHC			X	2
First generation/seed AHC				2
Second generation AHC	n/a	X	X	2
Second generation AHC	n/a	X		2
Second generation AHC	n/a		X	2
Second generation AHC				2

Stakeholder interviews
At one year follow-up, stakeholder interviews will be held with people wider stakeholders who may be either responsible for the chosen intervention area or those affected or interested in CICA e.g. lead commissioners in local authority public health teams, members of community groups, and licensing officers from different Responsible Authorities (n=12).

7.1.2 WP1 Analysis
Appropriate analysis techniques will be selected for each method. Documents will be analysed using content analysis, and quantitative data from documents (e.g. on numbers of licence applications) will be extracted and described. Interviews and focus groups will be digitally recorded, fully transcribed and anonymised. Analysis will utilise the Framework method[36]: textual data will be 'charted' in themes relating to key research questions and scrutinised for differences and similarities within themes, keeping in mind the context in which these arise. We will 'sense check' our emerging qualitative findings with stakeholders, who will help us with the interpretation of our themes. We will use implementation theory[55] to evaluate mechanisms of effectiveness (and of harm), and the influence of contextual factors on the implementation and effectiveness. Questionnaire data and data on numbers of licences challenged etc. will be analysed using descriptive statistics (SPSS v23). The context-mechanism-outcome (CMO) configuration will be employed to consider: "In this context, that particular action/response involving these actors, generated these outputs/outcomes." Data will be analysed to construct the most robust and plausible explanation of observed outcomes. The logic model and programme theory may be modified in light of the study findings.

7.2 Outcome analysis (WP2)
The CICA intervention will be evaluated by comparing changes in key outcomes measures in comparison with the most appropriate 'counterfactual' areas. Evaluation of CICA will be conducted using two distinct control comparisons:

(1) Between the areas in the GM boroughs where the intervention is planned as different time points and analysed as a stepped-wedge randomised trial design. Using the stepped-wedge design each of the intervention areas can be considered their own controls up until the time point that the intervention is introduced in their respective area. Because of the staggered introduction across GM, this will enable a stepped-wedge controlled design until all areas have received the intervention.

(2) By comparing the intervention areas where the intervention is located with other areas in GM, but where the intervention is not introduced. The study will employ two complementary strategies to analyse these comparisons:

a) Intervention areas (which each will comprise one to three LSOA areas) will be propensity score matched to control areas (also comprising one to three LSOAs) in the same borough (but not immediately adjacent). In order to build our control areas, the LSOA that has the highest level of alcohol harm will be used for the initial matching to a control LSOA. We will then find its most similar adjacent area(s), so that overall our constructed control and intervention areas are as similar as possible.
b) Additionally, 'synthetic control' intervention areas time series[40 56] will be constructed using Bayesian structural time series[57] based on weighting of all LSOAs to mimic the pre-intervention time trends in the intervention areas. Post-introduction of CICA, the synthetic control time series will be interpreted as 'counterfactuals' and this will enable direct comparison of temporal trends in key outcome measures to what would have happened in those control areas had CICA not been introduced.

7.2.1 WP2 Data acquisition and processing

Data are required at LSOA level, in order to build geographies for intervention areas and control areas. Each control area and intervention area will be represented by aggregating data for one to three LSOAs.

7.2.1.1 Alcohol health data

There are several routes for accessing the routine alcohol-related hospital admissions data at LSOA level. Co-I Ardern is entitled to request alcohol data for all GM LSOAs from the Local Alcohol Profiles (LAPE) team at Public Health England (PHE). Six months following the financial year end, the LAPE team process the Hospital Episodes Statistics (HES data), and will be able to release the narrow measure of alcohol-related fractions some 5-6 months after this. The follow-up period is 2019/20. Data for the financial year 2019/20 are expected to be submitted to the LAPE team in Sep 2020. These will then be made available sometime between Feb and May 2021. This is our preferred option for data access and is the basis of our timelines and milestones. As a back-up, record-level HES data are also available via application to the Health and Social Care Information Centre, and the research team can aggregate to any geography.

7.2.1.2 Crime and anti-social behaviour (ASB) data

For crime and ASB data, all the necessary data sharing arrangements are in place for GM. The GM crime and ASB data have an alcohol marker (this is not done by all police forces currently). However, the application of this marker is not consistent, therefore we propose to analyse all crimes hypothesised to have a relationship with alcohol use, namely: violent crimes, sexual offences, criminal damage and public order offences (selected from the Crime Statistics list[58]). Crimes are more likely to be recorded as being related to alcohol over a weekend[59]. The Crime Survey of England and Wales also shows that victims of violent crime are more likely to report the offender to be under the influence of alcohol at the weekend (70% of crimes are related to alcohol) compared to overall (53%)[60]. Thus, the analysis will be restricted to those crimes occurring between Friday 15:00 and Sunday 15:00.

Crime data relates to those events where a crime (in law) has occurred, and where this is included within the Home Office Counting Rules for recorded crime (i.e. a 'notifiable' crime as defined within the National Crime Recording Standard). Anti-social behaviour data relates to those events reported to the police where a crime has not occurred, but where the police receive a call for service and the recorded incident is classified by the call handler as involving personal, nuisance and/or environmental anti-social behaviour, in accordance with the 2011 National Standard for Incident Recording (NSIR). Anti-social behaviour is generally defined as any behaviour that causes people nuisance, annoyance, alarm or distress. 'Personal' ASB incidents are incidents perceived to be intentionally targeting (or impacting

on) an individual or group rather than a community. ‘Nuisance’ ASB incidents affect a local community more generally (rather than an individual or group of individuals) in which the behaviour is interfering with the community’s quality of life, health and/or safety. ‘Environmental’ ASB incidents involve individuals (or groups of individuals) impacting on the surrounding area including the built or natural environment. While specific types of ASB incident codes do not map directly onto these three call handler categories[58], we propose to analyse incidents of ASB recorded between Friday 15.00 and Sunday 15.00 that are most likely to be drink related.

7.2.2 WP2 Data analysis

See section 9.4, assessment of effectiveness, and section 11, statistical analysis.

7.3 Economic analysis (WP3)

A cost-consequences analysis (CCA) will be carried out following the methodology published by New Economy in their HM Treasury approved guidance. The costs of providing the CICA intervention will be identified and measured using documents from the contracting process and resources recorded during delivery. Costs will include training costs. Within the study, all costs are fixed as they will be constant for each area when setting up the intervention. For future scale up, most costs would have to be considered as variable as costs will increase as the intervention is rolled out to other areas in GM and beyond. For the control areas we do not anticipate any costs.

The CCA will categorise costs and consequences as health benefits, changes in health care resource utilisation as a consequence of alcohol use and changes in contacts with the criminal justice system. Health care resources and criminal justice contacts in the intervention and control areas and identified in WP2 will be costed using standard unit costs published by New Economy. These costs are based on national averages which will increase the generalisability of findings when cost-effectiveness estimates are used to inform decision making in areas outside the geographical area of the study itself.

Bayesian structural time series will be used to investigate changes in the total cost of utilisation of health care and criminal justice systems before and after the roll out of the intervention compared to the matched controls. Generalised linear models will adjust for the different observation periods.

Costs and consequences for intervention and matched control areas will be presented in a disaggregated form in a CCA framework which permits different stakeholders to identify their own budget impacts.

In this study, costs and outcomes will be presented from the perspective of:

(1) The Criminal Justice System: costs of courts, legal aid, victim services, probation and prisons.
(2) The Police and Crime Commissioner: costs of policing activity.
(3) Health: resource costs of ambulance call outs, A&E attendance and hospitalisation due to alcohol-related disease.
(4) Society: the wider perspective includes (1) to (3) above, and in addition the costs and outcomes of crime to private individuals (using the New Economy tool).

A sensitivity analysis will be undertaken to examine the cost-effectiveness estimates generated from the analysis. We will use the variability in the effectiveness rates which provide the input for WP3 as estimated from WP2 to investigate the robustness in cost-effectiveness ratios and how sensitive these ratios are to changes in parameter estimates.

8 Proposed outcome measures

8.1 Primary outcomes

The intervention is at area-level, therefore analysis is carried out at area level. Area-level routinely collected data (available at LSOA level will be combined to create the intervention and control areas) to answer the aims of the outcome analysis (WP2):

- Alcohol-related hospital admissions (narrow measure)
- A&E attendances
- Alcohol related call outs for ambulance services
- Numbers of crimes in local area (violence, sexual offences, criminal damage and public order offences) occurring between Friday and Sunday
- Number of incidents of anti-social behaviour in local area occurring between Friday and Sunday (personal, nuisance and/or environmental anti-social behaviour)

Timescales:

- Intervention rollout year 1 (2017/2018)
- Intervention embeds year 2 (2018/2019)
- Effects on A&E attendances, alcohol-related hospital admissions, ambulance call-outs, as well as crime rates and ASB for the first 9 months of year 3 (2019/2020)[1]

For the cost consequences analysis (WP3):

- Set-up and running costs for CICA
- Hospital admissions
- Ambulance call outs
- Crime/criminal justice system contact

Timescales:

- Relies on data from WP2, therefore occur during year 4-5 (2020-2022)

8.2 Secondary outcomes

Derived from the process analysis (WP1):

- Barriers and facilitators of CICA, with reference to context, governance, funding, partnerships, data sharing across partners and acceptability (year 1)
- Licensing practice in the nine boroughs before and after CICA (years 1-3)
- Ability to deliver the training as planned (year 1)
- Response to training, modelling of health behaviours, and participants' perceptions of community cohesion and development (year 1)
- Number of alcohol health champions trained (years 1-2)
- Number of brief interventions applied (year 2)
- Number of awareness events organised/participated in (year 2)
- Composite measure of alcohol availability in area (number of licenced premises/size/opening hours) (years 2-5)

Community licensing activity—numbers of:

- licences challenged (year 2)
- licence reviews requested (year 2)

[1] Follow-up was originally due to end in May 2020. In version 3.0 of this protocol, follow-up timescales have been reduced from 12 months to 9 months to remove the impact of the lockdown due to the COVID-19 pandemic (which started in March 2020). This is because the lockdown is likely to have changed the nature and type of alcohol-related harms occurring between March 2020 and May 2020.

- representations submitted (year 2)
- issues reported to local licensing authorities (year 2)
- investigations initiated (year 2)

Licensing outcomes—numbers of:
- licence applications refused (years 2-3)
- existing licences revoked (years 2-3)
- licences amended with reduced hours (years 2-3)
- licences with other amended conditions (years 2-3)
- cumulative impact zones established (year 2-3)

Timescales: Process outcomes relating to training/rolling out the intervention are collected in year 1. At the end of year 2 and during year 3, when CICA is embedded, data will be collected on process outcomes related to the expected AHC activities.

9 Assessment and follow up

9.1 Process evaluation-WP1

Baseline assessments include:
- Barriers and facilitators of CICA, governance, funding, partnerships, data sharing across partners and acceptability (stakeholder interviews);
- Licensing practice in the nine boroughs prior to CICA (document review);

Post intervention secondary outcomes (to be carried out sequentially in the nine areas as the intervention is rolled out: year 1):
- Delivery of, and response to, training (trainers/seeds'/trainees' evaluation forms, observations/interviews with trainers/trainees)
- Numbers of
    - Alcohol Health Champions (AHCs) trained (seeds) (from training registers)
    - AHCs trained by seed AHCs (registers)
    - Brief interventions applied (seeds'/trainees' questionnaires)
    - Brief advice contacts (seeds'/trainees' questionnaires)
- Community licensing activity (seeds'/trainees' questionnaires/document review)
- Licensing outcomes (document review)
- Perceived health and wellbeing (seeds'/trainees' questionnaires/interviews)
- Self-reported alcohol consumption (seeds'/trainees' evaluation forms)
- Perceptions of community cohesion and development (focus groups/interviews)

One year follow-up (sequentially, in the order in which CICA was rolled out: year 2):
- Numbers of
    - Brief interventions applied (seeds'/trainees' questionnaires)
    - Brief advice contacts (seeds'/trainees' questionnaires)
    - Events organised (seeds'/trainees' questionnaires)
- Community licensing activity (seeds'/trainees' questionnaires/document review)
- Licensing outcomes (document review)
- Composite measure of alcohol availability (seeds'/trainees' questionnaires/document review)

9.2 Outcome evaluation-WP2

Towards the end of year 2, all areas will have had 1 year for CICA to embed. Baseline data for 2015/16 will become available May 2017 and will be incorporated into baseline trend for 2012 to 2016. Follow-up data for 2019/20 (nine months) will be available in September 2020:

- Alcohol-related hospital admissions (narrow measure) (routinely collected health data)
- A&E attendances at weekend and weekdays (routinely collected health data)
- Alcohol related call outs for Ambulance services (routinely collected health data)
- Numbers of crimes (violence, sexual offences, criminal damage and public order offences) from Friday to Sunday in local area (street-level recorded crime data)
- Number of ASB incidents in local area (personal, nuisance and/or environmental, occurring between Friday and Sunday)

9.3 Cost consequences evaluation-WP3

During years 1-4, health costs are calculated. In year 5, final primary outcomes are combined with costs to generate cost consequences estimates.

- Set-up and running costs for CICA (commissioning documents and contracts)
- Hospital admissions costs
- Ambulance call out costs
- Crime costs

9.4 Assessment of effectiveness

The stepped-wedge design will provide an estimate of the effect size of the intervention comparable to that from a randomised-controlled trial. Several quantitative methods will be employed to evaluate the effectiveness of CICA introduced in those areas compared to 'controls':

1) Propensity score matching will be used to match intervention areas to the most appropriate control areas. This methodology has been used specifically within the context of alcohol-related harms in England by one of the co-investigators, and a similar methodology will be used here[39]. A priori, we will match on deprivation, size and age distribution, but we will explore the availability and usefulness of other covariates as well. Subsequently, trends in matched areas will be evaluated using mixed effects log-rate models as previously used at lower-tier local area level for alcohol-related hospital admissions[16] and alcohol-related crime rates[18] in England.
2) Comparisons will also be made to the time series in 'synthetic control areas' based on weighted inclusion of other (non-neighbouring) GM LSOA. To create the synthetic controls Bayesian structural time series methods will be used[57 61].

Both methods above provide complementary results of the impact through comparison of the time series in the intervention areas to that in either the (propensity score matched) external control intervention areas or to the counterfactual time series in the synthetic control areas. These differences should be comparable, but provide additional evidence of how robust the individual estimates are. Importantly, these will be directly compared to the estimation of efficiency from the stepped-wedge design, which should again be of comparable magnitude. This will be important for future evaluations since, if comparable, there will be no need to conduct new stepped-wedge designs, but instead the routinely collected data used in this study can be monitored further; using the methodology outlined here. These differences then, or the average thereof, will be interpreted as the efficiency and will subsequently be used as input in the economic analyses (WP3).

9.5 Assessment of harms

This is an evaluation of a natural experiment, making use of secondary data (routinely collected hospital, ambulance and crime data). The intervention is low risk. It is possible that alcohol health champions may be uncomfortable discussing alcohol issues with peers. AHCs will have support from their local coordinators, who may be able to work with them to address issues, or they may choose not to implement this aspect of the intervention. AHCs may also receive negative reaction from members of the community when intervening over

licensing issues. The researchers will be mindful of these potential harms and will record and analyse any such incidents qualitatively during WP1. Participating AHCs will have the contact details of the PI, Prof Cook, to report adverse incidents, which will be recorded and kept on file. If adverse events are attributable to the intervention, relevant participants (e.g. fellow AHCs in the same area) will be informed immediately, and if necessary, activities will be reviewed. Any illegal or threatening behaviour will be reported to the police.

10 Proposed sample size

We base our statistical power calculations on the methodology for stepped-wedge randomised trials outlined in Hussey and Hughes[38], and calculated this specifically for the primary outcome 'alcohol-related hospital admission rates' obtained from the Local Alcohol Profiles for England (LAPE) extracted for all 10 LSOA in the GM boroughs. This design can be regarded as a clustered randomised trial[62], and as such the methodology for the power calculation can, in addition to the repeated measurements within each unit, also include adjustment for clustering of time points at which areas receive the intervention; however, within this study design the intervention will be introduced in each area subsequently, so no additional adjustment for clustering was required. Similarly, in the propensity score matched analyses the controls will either be from within GM, and also do not require additional clustering other than through repeated measures.

Statistical power analyses were initially conducted on borough level rather than at the level of the intervention area (the equivalent of one to three LSOAs) because the exact areas and comparisons had not been determined yet, and this aggregated level provided indications within the stepped-wedge context. The mean standardised alcohol-related hospital admission rate in these boroughs for the year 2014 was 207 (per 100,000 people) with a maximum temporal standard deviation per site of 17.2 (range within sites 5-17) and a coefficient of variation across sites of 4.35. With 10 areas and 12 month follow-up (i.e. when all areas have received the intervention and a minimum of 1-month post-intervention follow-up), and a statistical significance level (alpha) of 5% and statistical power (beta) of 90%, the proposed study will be able to detect a 10% average difference in rates compared to baseline (or about 7% difference assuming 80% statistical power). For an intervention to be effective and cost-effective a minimal reduction in key indicators of 10% seems reasonable. With respect to the comparison with propensity matched controls and synthetic controls in which time trends will be compared within the larger area of between different areas, no additional clustering occurs. Assuming a standard comparison of independent means, 1-sided test, and significance level of 5%, changes in alcohol-related hospital admission rate in the intervention-LSOA relative to the selected comparison area yield an 84% statistical power to detect a similar 10% decrease.

For the previous version of the protocol (version 2-1), once the exact areas had been determined, the original power calculations were recalculated with one intervention area removed. With only nine local authorities in the study instead of 10, but with all other characteristics the same and using the same statistical power calculation methodology, with 90% power the study will similarly be able to detect 10% differences (or 8% with 80% statistical power). The difference between nine LAs and 10 is approximately 0.1%.

In these statistical power calculations we have not taken into account any potential 'spill-over' effects, such as described for a community action programme in Sweden[63], and which implies that the above may be an underestimation of the true statistical power (or, conversely, of the minimal detectable effect). It is unclear how these should be modelled, and therefore, as outlined above, no LSOAs immediately adjacent will be matched.

As such, these analyses indicate that the proposed study, given the assumptions outlined above, should enable detection of moderate to high impacts in the order of 10% change minimal in small area level comparisons.

11 Statistical analysis

11.1 Analysis of the stepped-wedge

At borough level, the same areas within the nine GM boroughs can be considered their own controls up until the time point at which the intervention is introduced in their respective area. Because of the staggered introduction across GM this will enable a stepped-wedge controlled design until all areas have received the intervention. The stepped-wedge design will provide an estimate of the effect size of the intervention comparable to that from a randomised-controlled trial. Statistical analyses will be done using standard mixed-effects models with an indicator of when the intervention was introduced in each area and a time component to account for the repeated measures nature of the data.

11.2 Comparison with propensity matched controls

At area level within each borough a conventional study design will be used in which intervention areas will be matched on a set of area-level statistics (for example, baseline harms, population size, area-level deprivation) following the methodology outlined by de Vocht et al.[39] and we will directly match temporal trends in key outcome measures prior to the introduction of CICA so that we can evaluate differences that may occur post-intervention period (i.e. 'differences-in-differences' models). Trends in matched areas will be evaluated using multi-level mixed effects log-rate models as previously used at lower-tier local area level for alcohol-related hospital admissions[16] and alcohol-related crime rates[18] in England.

11.3 Comparison with synthetic controls

Comparisons will also be made to the time series in 'synthetic control areas' based on weighted inclusion of other (non-neighbouring) GM LSOA. To create the synthetic controls Bayesian structural time series methods will be used[57 61].The generation and use of synthetic controls will be based on 'dynamic time warping' methodology, which can be regarded as 'nearest neighbour' propensity matching across the time series[64] (using the 'dtw' package in R statistical software). These 'synthetic areas' are based on weighted averages of other GM local areas, where the weights are chosen so the synthetic GM area most closely resembles the actual GM area before the intervention started[56]. Trends between the measured and the modelled outcomes in the synthetic controls (generated using Bayesian structural time series) can then be directly compared with the difference, providing an estimate of the intervention effect. This will be further augmented by use of new methods for analysing natural experiments that make use of Bayesian structural time series and spike-and-slab priors[65].

12 Project timetable and milestones

The project timetable sets out the key milestones for the three distinct work packages (WP):

- WP1: Process Evaluation
- WP2: Outcome Evaluation
- WP3: Economic Evaluation

Description of milestones	Start date	End date
0.1 Ethical Review, 0.2 Ethics Committee Approval	March 2017	Aug 2017

0.3 Study registration on ISRCTN registry	March 2017	Aug 2017
0.4 Submit protocol to NIHR Portfolio and journal BMC PH	March 2017	Feb 2018
0.5 Formalise project committees	March 2017	July 2017
0.6 Recruit RA1	Sept 2017	Sept 2020
0.7 Recruit RA2	March 2020	Feb 2022
0.8 Recruit RA3	March 2021	Feb 2022
1.1 Prepare process evaluation tools	March 2017	Aug 2017
1.2 Baseline policy context, licensing practice, alcohol availability, barriers/facilitators prior to CICA	Sept 2017	June 2018
1.3 Explore responses to CICA training programme	Sept 2017	Nov 2018
Progress report to NIHR (WP1)		Sept 2017
Progress report to NIHR (WP1)		March 2018
1.4 Determine the number of brief interventions applied and community events organised	Sept 2017	May 2019
1.5 Quantify the amount and success of community involvement in licensing issues	Sept 2017	May 2019
1.6 Post intervention follow-up	Sept 2018	June 2019
1.7 Process evaluation data cleaning and analysis	Sept 2018	Feb 2020
Progress report to NIHR (WP1)		Sept 2018
Progress report to NIHR (WP1)		March 2019
2.1. Obtain and collate secondary data sources	Sept 2017	Nov 2019
2.2 Compare intervention locations with matched controls locations within each borough	Dec 2019	Aug 2021
2.3 Compare intervention locations with synthetic controls	Dec 2019	Aug 2021
Progress report to NIHR (WP1 & WP2)		Sept 2019
Progress report to NIHR (WP1 & WP2)		March 2020
3.1 Estimate set-up and running costs for CICA	March 2017	May 2019
3.2 Compare costs between intervention areas and matched control areas	Jan 2020	July 2020
3.3 Generate cost consequences estimates	March 2021	Jan 2022
6 monthly progress reports to NIHR (WP1, WP2 & WP3)	Sept 2020	Sept 2021
Draft final report/papers for publication	Feb 2019	Feb 2022

Additional details on milestones are available in the Gantt chart (Appendix 4), including project management, which will be used for project monitoring purposes. Project Advisory Committee meetings and Study Steering Committee meetings will be held every six months during years 1, 2 and 5 starting July 2017 with a final meeting in December 2021.

Randomisation of areas

GM local authority	**Randomisation of areas**
Stockport	September 2017
Salford	September 2017
Rochdale	November 2017

Bury	November 2017
Wigan	January 2018
Oldham	January 2018
Bolton	March 2018
Tameside	May 2018
Manchester	May 2018

13 Ethical arrangements

Ethical approval for the study will be obtained from the University of Salford Research Ethics Committee. As part of WP1, potential participants (AHCs, key informants, stakeholders and people who have had contact with AHCs) will be invited to take part in the study, and will be provided with full information about the study. Written consent will be obtained from participants prior to completing pre- and post-training questionnaires (AHCs only). Potential participants for interviews and focus groups will be given a minimum of one week to decide whether or not to take part and written informed consent will be obtained prior to the start of the interview or focus group.

Data obtained during WP1 will be anonymised and each participant will be given a unique code, stored separately to the main datafile. Consent forms will be stored in a separate location to the main data files. Transcripts will use pseudonyms in place of real names. Data will be stored on secure University file servers, accessible only to the research team.

WP2 relies on analysis of secondary data from LAPE and/or HES and the police obtained initially at LSOA level. Police data are publically available at street level. HES data are sensitive at LSOA level, although once alcohol attributable fractions are applied to the data, they are deemed to represent a low risk of disclosure. Nevertheless, appropriate measures will be taken to ensure the security of potentially sensitive datasets, including their storage only on secure university file servers. These data will be aggregated to compile intervention areas (composed of one to three LSOAs) and their matched controls.

In line with current policy on open access to data, we will retain all suitably anonymised research data for 20 years after the end of the study to allow secondary analyses to take place, and to allow any verification of findings to take place. Data will be saved as .csv files, which can always be opened by any program. The model scripts will be provided as.txt files to accompany the data, so that results can be replicated if required.

14 Research Governance

14.1 Sponsor

The University of Salford takes the role of Sponsor for this research.

14.2 Project management group

This will be led by the PI to assist with the day-to-day management of the project. Management meetings will be quarterly throughout the project, generally by video conferencing. At least one meeting per year will be held face to face. Separately,

investigators associated with each WP will meet every 2 weeks, generally by video conferencing.

14.3 Study steering committee (SCC)

The steering committee will be established at the outset. Membership will include an independent chair, statistician and health economist, along with other members with relevant expertise, such as in alcohol policy. The SSC will also have representation from the study team (the PI). The study team will not form more than 25% of the SSC, as per NIHR guidance. The SSC will ensure that the project is conducted to the standards set out in the Department of Health's Research Governance Framework for Health and Social Care. The main role of the SSC will be to provide advice, through its Chair, to NIHR PHR, the Sponsor (host institution) and the PI on all appropriate aspects of the project; to monitor the progress of the project, the adherence to the protocol, and to consider any new information of relevance to the research question. It is not anticipated that a data monitoring and ethics committee will be needed; this will be confirmed by the SSC. See also 'SSC Terms of Reference'; Appendix 5.

14.4 Advisory panel

An advisory panel will be held twice a year during year 1, 2 and 5. Membership will include licensing practitioners, lay participants, public health teams from local authorities.

15 Expertise

Professor Penny Cook takes overall responsibility as Principal Investigator, provides expertise in alcohol harm[2 10 66 67] and leads WP1. She has significant experience of research project management (total £1.5m). Dr Suzanne Audrey contributes to WP1 with her expertise in process evaluation (she is co-author of the MRC guidance[35]). As PI of a multi-centre RCT funded by NIHR-PHR, she will support Prof Cook in leading an NIHR project. Dr Frank de Vocht leads WP2 and supervises the Bristol research assistant (RA2). He has experience with longitudinal data analyses, uses growth models to investigate the longitudinal impact of local areas' licensing policies[16 18], and is expert on propensity score methods[39]. Steve Parrot is a Reader and health economist from the University of York Centre for Health Economics and is a member of the UK Centre for Tobacco & Alcohol Studies. He leads on WP3 and supervises the York RA (RA3). Elizabeth Burns will supervise the Salford RA (RA1) for fieldwork and public involvement. Currently a Lecturer, Burns has substantial recent experience as a public health practitioner using population approaches to reducing alcohol harm. Dr Margaret Coffey is a Reader in Public Health whose focus is health improvement in deprived populations. She supervises RA1 for the qualitative analysis. Professor Kate Ardern is Director for Public Health for Wigan and lead on alcohol harm reduction for GM. She has led the introduction of health champions to GM. Paul Duffy is PHE lead for substance use, with expertise in research and policy implementation including recent work on accessing data for alcohol harm reduction through licensing. Kiran Kenth has a track record of strategic leadership, policy development and commissioning of health improvement services. She represents RSPH and advises on the training and the infrastructure. Collaborator David Ottiwell represents New Economy, an organisation that provides strategy and policy support to the GM Combined Authority. New Economy will provide networking and facilitation, support with data access and dissemination of project key findings and recommendations. Sue Hare is a lay expert in licensing interventions and sits on the Project Advisory Group.

16 Partner Collaboration

The Association of Greater Manchester Authorities (oversight of project; negotiated agreement to fund CICA), all the GM local authorities (funding the CICA programme), Wigan Borough Council (for advice on Asset Based Community Development and health champions training), New Economy (access to data sources and cost analysis resources), Royal Society for Public Health (intervention development and delivery), Public Health England (access to data, advice on Asset Based Community Development and health champions training—supporting the project financially by the in-kind contribution of co-applicant Duffy—10% FTE for 5 years), Forever Manchester (PPI, advice on Asset Based Community Development), the LGBT Foundation (public participation in the research-'Village Angels' advised on project), Fallowfield Community Guardians (advice on community action on alcohol licensing).

Support for the proposed project has been indicated by all of the necessary partners including the Police and Crime Commissioner, the nine Directors of Public Health and designated representatives of the Local Authority Chief Executives.

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18 Acronyms

Alcohol Health Champion (AHC)

Asset Based Community Development (ABCD)

Communities In Charge of Alcohol (CICA)

Cost-consequences analysis (CCA)

Greater Manchester (GM)

Hospital Episode Statistics (HES)

Local Alcohol Profiles for England (LAPE)

Lower Super Output Area (LSOA)

National Institute of Health Research (NIHR)

National Institute of Health Research Public Health Research (NIHR PHR)

Principal Investigator (PI)

Public Health England (PHE)

Research Assistant (RA)

Royal Society for Public Health (RSPH)

Study steering committee (SSC)

Work Package (WP)

Appendix 1 - Logic model
Appendix 2 - Dark logic model
Appendix 3 – Process evaluation flowchart
Appendix 4 - Gantt Chart
Appendix 5 – Study Steering Committee Terms of Reference