The effectiveness of promotional campaigns associated with revised UK drinking guidelines

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Project summary

Title	The effectiveness of promotional campaigns associated with revised UK drinking guidelines: A prospective evaluation	
Reference number	15/63/01	
Evaluation design	Prospective observational longitudinal study	
Participants	Adults aged 16+ living in private households in England	
Planned sample size	77,400 (43 monthly samples of n=1,800)	
Intervention date	On-going from January 2016.	
Start date of data collection	March 2014 (with additional measures collected from November 2015).	
End date of data collection	October 2017 (43 months and 24 months for additional measures).	
	Objectives	Outcome measure
Primary	Evaluate whether trends in alcohol consumption behaviour alter following publication and promotion of revised drinking guidelines	AUDIT-C score
Secondary	1. Document the timing, audience and content for major promotional activity following the publication of revised drinking guidelines No further activity planned (see Section 4 for more details) 2. Evaluate whether trends in three additional sets of outcome measures alter following publication and promotion of revised drinking guidelines 3. Evaluate whether intervention effects vary across population groups defined by age, sex and socioeconomic status. 4. Evaluate where intervention effects vary between those reporting recent and frequent exposure to drinking guidelines vs. those reporting infrequent or no recent exposure. 5. Undertake pathway analyses to validate theorised relationships between factors theorised to influence behaviour change and behaviour change itself. 6. Assess cost-effectiveness of any	1. TBC 2. Alternative alcohol consumption measures (graduated frequency, HMRC duty data, full AUDIT score). Behavioural antecedents (capability, opportunity, motivation to change behaviour). Hospital admissions (monthly admissions for alcohol poisoning and assaults). 3. AUDIT-C score (plus secondary measures above) 4. AUDIT-C score (plus secondary measures above) 5. AUDIT-C score (plus secondary measures above) 6. Mortality rate, disease prevlance, NHS costs, QALY costs.

	identified intervention effects. Not going ahead currently as, following preliminary analyses and lack of promotion, no intervention effects are expected to be identified.	

Funding and support in kind

Funder	Financial and non-financial support given
NIHR Public Health Research panel	£590,606

Roles and responsibilities

Research team

University of Sheffield:

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Sarah Lewis

Contributors to this protocol

JH conceived the study. PB, PM, AB, SM, JB EB and SL contributed to study design and are grant holders with JH. RW provided expertise in evaluation and behaviour change research. JH will lead the primary data analysis with statistical support from JB and EB. All authors contributed to development of the study protocol and approved the final manuscript.

Sponsor and funder

The sponsor has had no role in the design of this study. The funder's role in the design of the study is limited to peer-review and panel member feedback on the funding application. Neither the sponsor nor the funder will have any role in the collection, analysis, interpretation of the data or in the write-up and decision to submit results for publication.

Project Advisory Group

The project advisory group comprises two senior researchers (one of whom chairs the group), two representatives of researcher users and two members of the public. All of the above are independent of the research team and sponsor. Meetings will also be attended by project investigators.

The group will meet annually and will provide advice and oversight on all aspects of the research process and particularly on study progress, research instruments, analysis of data, interpretation of findings and dissemination and impact.

Table of Contents

The effectiveness of promotional campaigns associated with revised UK drinking guidelines: A prospective evaluation

1. Background

1.1. Context for the study

In 2012, the UK Government's Alcohol Strategy placed a strong emphasis on supporting drinkers to make healthier choices. A key mechanism for achieving this was for the Chief Medical Officer to lead a review of the country's lower risk drinking guidelines (DG).[1] That review is on-going and Department of Health have publicly stated that a decision has been taken to revise the DG. A likely realistic date for publishing new DG is March/April 2016 with a public consultation on proposals expected before the end of 2015. However, the publication of new DG is not, on its own, a public health intervention; it is the **promotional activity** that disseminates these guidelines and encourages engagement with them which the proposed project will seek to evaluate.

The promotion of public health guidance is a major strand of UK public health policy. Public Health England's (PHE) marketing plan has a stated aim of "motivating and supporting more people than ever before to improve their health".[2 p.3] Crucially, PHE have identified a "relentless focus on behaviour" (p.6) as a guiding principle for that plan, noting that previous campaigns have often succeeded in raising awareness of and motivation for healthy behaviour, but have failed to translate that into behavioural change. Therefore, the proposed study focuses on evaluating the impact of promoting DG on alcohol consumption behaviour (primary outcome) using an interrupted time series design. Alcohol consumption is difficult to measure, so a triangulation approach will be used to assess whether an extensive series of secondary analyses using alternative outcome measures (e.g. alcohol-related hospital admissions, alcohol taxation data) and analytical approaches will provide validation of the primary analysis and aid its interpretation. Health economic outcomes will also be modelled using the Sheffield Alcohol Policy Model. [3,4]

Promoting DG is a complex intervention as it is delivered in diverse forms by diverse bodies with an extended causal chain from implementation to outcome. For example, DG are not promoted by a single organisation but by a range of governmental and non-governmental bodies including PHE, the NHS, Drinkaware (an alcohol industry-funded charity), public health charities, and the news media. These bodies are likely to engage in a range of promotional activity including use of mass media campaigns, interactive social media, consultations with health professionals, product labels and point of sale advertising. Behaviour change theory suggests any resulting impacts on alcohol consumption will not be direct but mediated through changes in factors including individuals' knowledge, motivations and social context.[5] Therefore, the triangulation approach will be extended to elicit evidence on each stage of this causal chain and assess whether that evidence tells a consistent story. A logic model of the causal is provided in Appendix B and this accounts for additional complexities such as a public consultation on draft guidelines and that stigmatisation and improved knowledge may alter self-reporting biases for alcohol consumption.

1.2. Existing research

***Lack of evidence**:* DGs are promoted in most developed nations and many emerging economies but are often viewed by public health stakeholders as an ineffective distraction from more meaningful interventions.[6-9] Scientific evidence to support this perspective is lacking and reviews have repeatedly noted that there have been no rigorous evaluations of the impact of producing, revising

or promoting DG on alcohol consumption or other factors linked to behaviour change.[9-12] However, guidance on health behaviours including smoking, drink-driving, physical activity, nutrition and cancer risk awareness has been shown to produce small to moderate effects on knowledge, attitudes and behaviour.[12-16] The likelihood of positive effects is increased when attention is paid to good intervention design, including drawing on theories of behaviour change.[14,15]

***Previous studies**:* The small literature examining effects of promoting DG relies on weak research designs and generally contains little engagement with the promotional activity itself (e.g. with the media and content through which DG are promoted, demographic targeting of promotional activities and theory-based mechanisms for behaviour change). Cross-sectional analyses of public knowledge of guidelines have been undertaken in several countries. These generally conclude that large minorities of the population are aware of DG and can correctly identify guideline consumption levels, but there is little evidence that this influences drinking behaviour.[17-19] The impact of promoting guidelines on related knowledge and perceptions has been examined in Australia[20] and Denmark[21,22] via retrospective analysis of varying numbers of repeat cross-sectional surveys. Similarly, the UK ONS included occasional DG-related questions within its monthly Omnibus survey until 2009. In each country, it was concluded that promotional activity improved knowledge of guidelines and in Australia there was evidence that beliefs regarding what constituted safe drinking also changed.[20] In the UK, ONS found awareness of DG had increased from 54% in 1997 to 75% in 2009 with little variation by gender and with greater awareness among heavier drinkers.[23] However, just 33% of all men and 39% of all women were able to correctly identify the guideline for their gender (37% and 57% among heavier drinkers) with only modest increases in this proportion over time. Further, in 2009 just 13% of all drinkers and 16% of those exceeding the UK guidelines reported using units to monitor their drinking.[23] The most detailed study to date of promoting DG evaluates an Australian campaign aiming to raise awareness of DG and alcohol-related cancer risks.[24] This prospective evaluation used three small sample (N≈150-200) repeat cross-sectional surveys of women over a 15 month period. The results suggested that multiple waves of advertising led to good recognition and recollection of campaign content which, in turn, impacted on cancer awareness, DG-related knowledge and behavioural intentions among heavier drinking women in particular. However, no impacts were seen on behaviour and the authors attributed this to competition from commercial pro-alcohol marketing and pro-drinking social norms; a barrier also noted by in a major review of alcohol policy effectiveness.[9]

***Recommendations for future research**:* Several studies have made research recommendations which emphasise the need for rigorous prospective evaluations of the impact of producing, revising and promoting guidelines.[11,25] Specific recommendations have highlighted the need for evaluations with control arms where feasible, examination of the effects of different campaign messages and studies which are theory-driven and evaluate impacts on both behaviour and factors influencing behaviour change.[11,17,25]

As described in the sections below, the proposed project is designed to meet these recommendations and provide the most authoritative analysis to date of the effectiveness and cost-effectiveness of promoting DG. This is facilitated by unique features of the project including the research team being embedded in the UK guideline review process, advanced knowledge of publication and promotional timeframes which permits robust baseline data collection, a powerful existing evaluation tool (the Alcohol Toolkit Study), robust primary analyses supported by multiple

detailed secondary analyses and an interdisciplinary team of world-leaders in alcohol policy analysis, behaviour change theory and evaluation of health promotion campaigns who have worked together over several years within the NIHR School for Public Health Research and UK Centre for Tobacco and Alcohol Studies.

2. Rationale

A rare evaluation opportunity: Promoting DG is a key feature of alcohol policy debate in the UK and internationally. Successive UK governments have been reluctant to increase regulation of the alcohol market and have instead focused on promoting 'responsible' drinking with the support of vested interests within the alcohol production and retail industries.[26] Evaluating the public health consequences of such decisions is challenging as research possibilities are limited by the often small-scale nature and unpredictable timing of promotional activity. Revision of the DG presents a rare and valuable opportunity as promotional activity is likely to be at its peak and its timing can be anticipated. It is unlikely similar circumstances will arise for many years given the forthcoming revisions are the first since 1995 and a significant investment is required to update and communicate DG. The situation is comparable internationally and recent revisions to DG in Canada and Australia were implemented without rigorous evaluation of their impacts on public health. The research team are well-placed to take this once-in-a-generation opportunity as the PI is an advisory member of the Chief Medical Officers' Guideline Development Group and has detailed knowledge of the likely revisions to the DG and the planned promotional activity.

Evaluating the Government's Alcohol Strategy: In addition to providing the most robust evaluation to date of promoting DG, the proposed project will evaluate the effectiveness of the Government's Alcohol Strategy (published in 2012). The strategy initially included many evidence-based measures (e.g. minimum unit pricing, restrictions on price-based promotions, a public health licensing objective) which were later withdrawn following a public consultation.[27] However, emphasis on the need to "support individuals to make informed choices about healthier and responsible drinking";[1 p.4] was retained, with the main mechanism for achieving that aim being to review and promote the DG. Therefore, this project will evaluate the public health impact of a central element of current Government alcohol policy.

Value to policy stakeholders: UK Department of Health have voiced a strong interest in the proposed project and its outputs, while PHE have agreed in principle to stagger of rollout their campaign across the country to facilitate more robust evaluation (e.g. by using a step-wedge design). **NICE have also provided a letter of support** (see attached uploads) highlighting areas of interest to them. The monthly survey data generated by the project will be available within one month of collection, allowing for rapid provision of feedback to stakeholders on trends in outcome measures while promotional activities are on-going. International stakeholders are also likely to benefit as DG are promoted in most developed nations[28] and international convergence in guideline consumption levels has been noted,[29] meaning evidence on the effectiveness of promoting UK guidelines will have increased international relevance. In general, the evaluation will make a key contribution to international policy debate on reducing alcohol-related harm commercial actors have successfully exploited the lack of effectiveness evidence to argue education and persuasion approaches should be preferred to regulatory interventions for which the evidence-base is stronger (e.g. tax increases, restricted advertising).[9] Robust evaluation of the impacts of promoting DG will better allow policy makers to compare the effectiveness of these different approaches and respond accordingly.

***Contribution to behaviour change science**:* We have designed questions to reflect a well-supported integrative model of behaviour change (COM-B[30]) which will allow us to identify mechanisms of effect (i.e. capability, opportunity and motivations for behaviour). This will advance our understanding of how promotional activities such as mass media campaigns and product labelling impact on outcomes. It will also provide data on inequalities in effects across society and the variations in impact for different promotional activities. This, in turn, can inform the development and design of future health promotion activities.

Added value to NIHR: The proposed project will add DG-related questions to the ongoing NIHR-funded Alcohol Toolkit Study (ATS).[31] The ATS started in March 2014 and was designed to facilitate evaluation research. It comprises a monthly survey of adults living in private households in England and is modelled on the Smoking Toolkit Study (STS) which began in 2006 and sits within the same Ipsos Mori Omnibus survey. The STS has achieved high impact through successful evaluation and monitoring of a range of smoking interventions and developments leading to over 50 scientific journal articles.[32-37] Additional ATS data collected within this project will be subsequently available for analysis by other ATS users and facilitates further high value analyses related to alcohol and smoking behaviour and behavioural trends (e.g. planned evaluation of the Dry January initiative, the reasons for long-term declines in per capita alcohol consumption).

3. Objectives and outcome measures

The proposed study aims to conduct a detailed prospective evaluation of the impact of promoting revised DG on alcohol consumption behaviour. It will elicit evidence on the complex causal chain from implementation to effect including what promotional activity occurs, who is exposed to it, how it affects factors theorised to influence behaviour change and the relationship between those factors and behaviour itself. The evaluation will utilise data collected both pre- and post-publication and promotion of the revised DG.

3.1.Primary objective

To assess whether trends in alcohol consumption behaviour among adults (16+) living in private households in England alter over a 21-month period following publication and promotion of revised DG.

3.2. Secondary objective

The project has the following secondary objectives:

(1) To document the timing, audience and content for major promotional activity following the publication of revised DG. No further activity (See Section 4 for details).

(2) To assess whether trends in a series of alternative outcomes measures among adults (16+) living in private households in England change over a 21-month period following publication and promotion of revised DG. Secondary outcome measures will include additional individual and aggregate-level measures of alcohol consumption, alcohol-related hospital admissions and factors theorised to influence behaviour change.

(3) To undertake subgroup analyses to examine whether there are variations in intervention effects across groups of the population defined by age, sex and socioeconomic status.

(4) To use difference-in-difference methods to examine whether direct and frequent exposure to promotion of DG increases effects on trends in alcohol consumption behaviour. Intervention effects will be compared between those reporting recent and frequent exposure and those reporting infrequent or no recent exposure.

(5) To undertake pathway analyses to validate theorised relationships between capability, opportunity and motivation to change behaviour and behaviour itself.

(6) To assess cost-effectiveness of any identified effects on alcohol consumption using the published Sheffield Alcohol Policy Model framework.[38] Not going ahead currently as, following preliminary analyses and lack of promotion, no intervention effects are expected to be identified.

3.3. Outcome measures

The effects of promoting DG on alcohol consumption behaviour are the focus of this evaluation. Alcohol consumption is challenging to measure and survey-based studies consistently and substantially underestimate per capita consumption relative to sales or taxation data for reasons which are well-documented.[46] Of particular relevance here is that promoting DG may alter stigmatisation of heavy drinking and change knowledge so as to affect self-reporting biases related to alcohol consumption. However, UK taxation data are also problematic as (a) they do not account for the approximately 10% of alcohol consumed which is untaxed; (b) are difficult to model due to highly inconsistent seasonality (e.g. due to producers warehousing or pre-releasing alcohol ahead of duty cuts or rises); (c) may misrepresent short-term changes in consumption due to stockpiling by retailers or purchasers and (d) have been found to be subject to inconsistent coding practices.[46,47] Alcohol-related harm metrics, such as hospital admissions, offer an alternative proxy for consumption but also have limitations. These include time lags between changes in consumption and changes in harm, unobserved trends in attributable fractions (i.e. the proportion of cases attributable to alcohol) and, for many alcohol-specific conditions which are associated with very heavy drinking (e.g. liver cirrhosis), low likelihood that promoting DG will impact short-term trends to a detectable extent.

Given these challenges, analysis of the primary outcome measure will be validated via analysis of a carefully selected set of secondary outcomes. This approach reflects best practice as set out in MRC guidance on evaluating complex interventions[40] and the combined results will strengthen confidence in our findings and conclusions.

3.3.1. Primary outcome measure

The primary outcome measure will be AUDIT-C score. AUDIT-C is the short-form of the AUDIT (Alcohol Use Disorders Identification Test); a validated screening test for heavy drinking and/or active alcohol abuse or dependence.[42] It has demonstrated excellent reliability and responsiveness to short-term change.[48] The questions focus on alcohol consumption and combine measures of drinking frequency, typical quantity per occasion and frequency of drinking heavily on a single occasion and has been found to be sensitive to short-term changes in behaviour. AUDIT-C has been included within the ATS since March 2014 and thus sufficient pre-intervention data are available to detect modest effects (see Section 8.1.2. below). AUDIT-C is preferred to full AUDIT as the latter (a) includes questions with 12 month reference periods (e.g. in the last year have you…) which may prove insensitive to short-term intervention effects and (b) contains several items addressing alcohol

dependence which promoting DG would not be expected to affect directly. A further advantage of AUDIT-C is it is widely used internationally and will thus offer comparability with future studies.

3.3.2. Secondary outcome measures

Three sets of secondary outcome measures will be used:

1. Alternative alcohol consumption measures: The proposed project will fund adding **Graduated frequency** (GF) questions on alcohol consumption to the ATS for 24 months from November 2015.[49] GF questions ask (a) on how many days participants drank during the last four weeks; (b) how many units they consumed on their heaviest drinking day; (c) on how many days they drank at that level and (d) on how many days they drank at progressively decreasing levels (e.g. if the maximum was 20 units, they would then be asked on how many days they drank 15-19 units, 10-14 units, 5-9 units etc.). GF measures are a recent development and have rarely been used in the UK. However, they are used extensively in the US, within the international GENACIS project and have been recommended for use by WHO.[50] Relative to other common measures, GF performs comparably in estimation of consumption volume and in ranking drinkers by consumption level.[51-53] The greatest strength of GF is detailed measurement of drinking patterns; a property of interest in this evaluation where changing patterns may be an aim of promotional activity. A potential weakness of GF is that respondents sometimes record more drinking days across consumption categories than the total number of days provided at the outset; however this has been mainly seen with 12 month reference periods and should be a lesser problem with the four week period used here. As no other large-sample UK survey uses GF, data collection will provide opportunities to compare its performance against AUDIT-C and other measures used within UK surveys which are generally weak. **Alcohol duty data** taken from HRMC's monthly duty bulletins record alcohol released for sale in the UK and provide an aggregate-level measure of consumption not subject to self-report biases. Finally, we highly recommend analyses using **full AUDIT score.** This would provide a test of the impact of promoting DG on a broader measure of hazardous drinking which, unlike the above measures, explicitly incorporates questions on harmful outcomes and dependence symptoms. By using standard cut-off AUDIT scores, further added value can be gained by examining change in the proportion of the population within different categories, including those at highest risk of dependence who may be of special interest to policy makers.

2. Behavioural antecedents: To strengthen causal inference analyses will examine change in factors which are theorised to influence behaviour. **Questions informed by the COM-B model of behaviour change will be used** and design of these has been guided by questions found to have predictive validity in the Smoking Toolkit Study. A literature review of behaviour change theories found 83 different theories, each with a different combination of constructs playing meditational and moderating roles within the theory.[5] Many of these theories are overlapping and there is a need to develop core integrative constructs that are evident across theories. One such integrative model is COM-B which identifies Capability, Opportunity and Motivation as necessary for Behaviour to occur and also identifies the ways in which these constructs reciprocally influence each other.[54] A COM-B oriented questionnaire has been developed by the research team (Appendix A) and covers guidelines-related knowledge, perceived capability and skills required to drink within DG, social opportunity to do so and automatic and reflective motivations. These questions have been piloted internally by Ipsos Mori and will be commented on by PPI representatives ahead of a funding decision to avoid delays to starting data collection.

3. Alcohol-related harm: Trends in acute alcohol-related hospital admissions will be examined to detect short-term effects of alcohol-related harm resulting from modest consumption change. Data on **monthly admissions for alcohol poisoning (ICD-10: T51.0,T51.1,T51.9) and assaults (ICD-10: X85-Y09)** will be requested from Hospital Episode Statistics. The former proxies change in heavy episodic drinking, while the latter proxies alcohol-related violence, a key outcome for policy makers.

4. Study design

***Overall design**:* The starting point for designing the study is that promotion of DG is a complex intervention as it is delivered in diverse forms by diverse bodies with a complex causal chain from intervention to outcome. A further challenge is that no robust control population is available. MRC best practice guidelines for evaluating complex interventions and natural experiments acknowledge that in such cases an optimal methodology is unlikely to be feasible but stress that application of best available methodologies can still deliver useful results. [39,40] Therefore, the study applies a triangulation approach to assess whether evidence obtained using a variety of methods tells a consistent story. In practice this means that we aim to validate results of the primary analysis by undertaking a series of secondary analyses using alternative outcomes, research designs and analytical techniques. Similarly, we aim to elicit evidence on the progression of intervention effects through the causal chain and assess whether this evidence is consistent with the intervention causing observed changes in the outcome measures. This triangulation approach permits stronger conclusions to be drawn and enhances understanding of intervention effectiveness

The primary analysis applies an **interrupted time series design** to test for changes in alcohol consumption trends within repeat cross-sectional individual-level survey data. One set of secondary analyses will apply the same design to a series of secondary outcomes including measures of capability, opportunity and motivation to change behaviour, alcohol-related hospital admissions and a series of alternative alcohol consumption measures in recognition of challenges in measuring consumption. A further set of secondary analyses will (a) attempt to evaluate the impact of specific promotional campaigns; (b) apply a **difference-in-difference design** to compare intervention effects between those reporting and not reporting exposure to DG and (c) using pathway analysis to test theorised relationships between capability, opportunity and motivation to change behaviour and behaviour itself. Finally, a cost-effectiveness analysis will be conducted using the Sheffield Alcohol Policy Model framework.[4,38]

PHE have committed in principle to staggering roll-out of their promotional campaign across English regions or groups of regions to enable the creation of a stepped wedge design. At the time of writing, PHE have not sufficiently progressed in planning their campaign to allow us to commit to treating this design as our primary evaluation approach; however, as more detail is agreed, this may become feasible.

Promotional activity timeline: As the promotion of DG is the active component which is being evaluated, a timeline of promotional activities will be constructed and used to understand the timing and nature of the intervention. The timeline will be created using a structured tool adapted from a previous study by co-investigator Lewis.[41] Where data are available, this will document the activity timing, content (e.g. theme, style, emotional content, suggested action) and audience size and demographic. Secondary analyses will use the timeline to explore whether effects of specific large-scale promotional campaigns can be detected on primary and secondary outcome measures.

Collection of data for the timeline of promotional activity stopped in May 2018 with the support of the project advisory group. After collecting data from five major organisations via an initial survey and informal follows-up, and also drawing on communication with key stakeholders (e.g. Public Health England, Department of Health), we concluded that no significant promotional activity was taking place. Therefore, any timeline would be uninformative for the purposes of understanding intervention effects.

Replacement work is planned. This will involve a review to assess the scale and content of newspaper coverage mentioning the drinking guidelines during the study period (see Appendix 1).

The Alcohol Toolkit Study: Time series data will be collected via the Alcohol Toolkit Study (ATS). The ATS is a monthly repeat cross-sectional survey of new nationally-representative samples of approximately 1,800 adults each month living in private households in England. Data collection for the existing ATS began in March 2014 and includes the validated screening instrument AUDIT (Alcohol Use Disorders Identification Test).[42] However, detailed alcohol consumption questions and questions on exposure to DG or wider factors theorised to influence behaviour change are not included. Therefore, this project will add questions addressing these topics to the ATS for 24 consecutive months including approximately six months before publication of revised guidelines (Nov 2015 – Mar/Apr 2016) and 18 months post-publication (Apr/May 2016 – Oct 2017).

Strengths of the Alcohol Toolkit Study*:* The ATS has considerable strengths as a policy evaluation tool. The collection of monthly data provides multiple pre- and post-intervention time points within a relatively short timeframe, particularly for the primary outcome where data collection began in March 2014. This increases statistical power within population-level analyses, permits more robust subgroup analysis and allows for examination of temporal effects (e.g. how the development and decay of intervention effects aligns with the timing of specific promotional activities). The latter is particularly important for the proposed project where timing of promotional activity is unknown in advance and any effects on outcome measures may be time-limited. ATS also represents excellent value for money as collection of sociodemographic and primary outcome data are already funded by NIHR and additional data on smoking behaviour for sample members is available via the Smoking Toolkit. The budget allocated to purchase of additional ATS questions will add further value to NIHR's existing investment as data will be available for analysis by other researchers and will greatly enhance the proposed study by strengthening the causal inferences and conclusions which can be made. Neither the existing nor the additional ATS questions are present within any comparable UK dataset, nor could they be incorporated in an existing dataset to permit a comparably robust or timely evaluation.

Control population: Selecting an interrupted time series design for the primary analysis is appropriate as a robust contemporaneous control population cannot be identified given data from a comparable control country are unavailable, DG are promoted to the UK as a whole and exposure to this promotional activity is not distributed across the population in a random manner or in a way which can be predicted in advance. As a secondary analysis, a difference-in-difference approach will compare change in outcome measures between those reporting and not reporting exposure to DG.

5. Study population and recruitment

5.1. Study population

The study population are respondents to 43 monthly samples within the ATS between March 2014 and October 2017. A subsample of 24 monthly samples between November 2015 and October 2017 will be used in some secondary analysis. Each monthly sample is collected by the research agency Ipsos Mori using in-home computer-assisted interviews and contains approximately 1,800 adults aged 16+ in England. All sampled individuals are included in the study assuming they respond to the ATS section of the Omnibus survey within which it sits.

5.2. Sampling

The baseline survey uses a form of random location sampling which is a hybrid between random location sampling and simple quota sampling. England is first split into 171,356 'Output Areas', each comprising approximately 300 households. These areas are then stratified according to ACORN characteristics and geographic region. ACORN is a socioeconomic profiling tool developed by CACI (http://www.caci.co.uk/acorn), which segments postcodes into five categories (wealthy achievers, urban prosperity, comfortably off, moderate means and hard-pressed). These categories are subdivided into 17 groups and 56 types using government and consumer research data (e.g. census data and lifestyle records). Areas are then randomly allocated to interviewers who travel to their selected areas and conduct the electronic interviews with one member of the household. Interviews are conducted until quotas based upon factors influencing the probability of being at home (i.e. employment status, age, gender) are fulfilled. Morning interviews are avoided to maximise participant availability. This method of sampling is often seen as superior to conventional quota sampling as the choice of properties approached is significantly reduced by random allocation of small output areas to interviewers. However, no response rate can be calculated as interviewers still choose houses within allocated areas.

5.3. Consent procedures

After identifying themselves to ATS participants, interviewers introduce the nature of the omnibus survey to participants, providing information, the general subject of the data collection, its purpose, the likely length of the interview and an assurance that the activity is being conducted in accordance with the Market Research Society Code of Conduct.

Participants are informed by interviewers at the start of the interview that they have the right to terminate the interview at any point. They are also provided with contact details for Ipsos MORI's fieldwork team, which they can contact if they wish for their data to be withdrawn. Interviews will only take place where participants give their informed consent for the interviews to take place.

Ipsos Mori do not use written consent forms when seeking informed consent for their routine omnibus surveys. The procedure for gaining consent is that the interviewer shows them their Interviewer ID badge, which displays their MRS number, introduces the fact that Ipsos Mori is carrying out the research, the nature of the research, and their right to withdraw at any point verbally. Informed consent is then based on a participant's explicit verbal agreement and willingness to answer questions voluntarily. For participants aged 16, consent must be given by a responsible adult before they can take part, and the name of the responsible adult is recorded.

6. Planned intervention

In January 2016, the Department of Health published draft revisions to the UK's lower risk drinking guidelines. These recommended that men and women are 'safest not to drink regularly more than 14 units per week, to keep health risks from alcohol to a low level'. It was also recommended that 'if you drink as much as 14 units per week, it is best to spread this evenly over 3 days or more'. The previous guidance stated that men should not regularly consume more than 3-4 units on a single day and women should not regularly consume more than 2-3 units on a single day.

6.1. Nature of promotional activities

The purpose of this project is to evaluate the impact of activities promoting the revised drinking guidelines. The scale, nature and content of promotional activity are unknown at this stage. It is likely that they will be promoted by governmental and non-governmental organisations including the NHS, Public Health England, public health charities, Drinkaware, the alcohol industry and the news media. The proposed project will define promotional activity broadly as: any activity that increases public awareness of the DG even if this is not its main aim. Therefore, relevant activities are likely to include mass media campaigns, interactive social media applications, point of sale advertising, dissemination to the public during medical and pharmacy consultations, changes to product labels and news coverage. The latter may be particularly relevant if a consultation on draft guidelines is published as this will likely attract substantial reporting and comment within our pre-intervention period. As a likely source of large-scale campaigns, the project team has met with PHE and Department of Health and received updates on their planned activities.

6.2. Monitoring timescales

An important challenge for the evaluation will be monitoring and managing shifting timescales for publishing final revisions to the guidelines and launching any major government public information campaign. This problem is inherent to prospectively evaluating a politically sensitive intervention. The alternative of retrospective evaluation was used recently when evaluating the Scottish Alcohol Strategy and, although the project achieved some success, the strength of conclusions was limited as routinely collected alcohol data lack sufficient detail or focus to evidence clear policy effects or causal processes.

The proposed project will have robust processes to manage uncertainty. First, the research team have access to timely information due to the PI's advisory role on the Guideline Development Group and the applicant institutions' strong working relationships with Department of Health and Public Health England who are supporters of the ATS (e.g. they provide co-authorship on the ATS protocol paper [31]). Second, at the time of writing draft guidelines have been published in January 2016 and non-governmental bodies have already started to promote these meaning effects of the intervention should already be emerging. Third, stopping rules were written into the original proposal such that discontinuation of data collection would be discussed with the funder in November 2016 if: (a) Department of Health cannot confirm DG publication will occur by end of 2016 (this test has already been met); (b) No meaningful revisions to DG are agreed (this test has already been met); (c) No change in promotional activity by PHE is planned (this test has not yet been met). Allowing 12 months of data collection means a large dataset can be collected for non-evaluation analyses can be collected ensuring funds are not wasted.

7. Statistics and data analysis

7.1. Sample size calculation

As the ATS is an established module of Ipsos Mori's Omnibus survey, we have no control over the sample size of approximately 1,800 per monthly wave. Power simulations were run in R version 3.1.1. Data were simulated using a normal distribution and with 42 months of data collection, implementation of the guidelines during the 24th month, n=1800 participants sampled each month, no underlying trend over time (i.e. assuming stable levels of alcohol consumption), a significance value of $p<0.05$ for the interaction term in the time series model and no step change following the implementation of the guidelines. Simulations were set to n=1000. **Assuming a baseline AUDIT-C score of 2.9 (SD=3.02) (STS, 2014), this study would have 80% power to detect a decline in the post-guideline period of -0.18 points (6% reduction overall).**

7.2. Statistical analysis plan

7.2.1. Primary evaluation analysis

The interrupted time series will be analysed using segmented regression through the application of Generalized Additive Mixed Models (GAMM). These can account for complex autocorrelation structures and seasonality. Although to our knowledge not previously used in alcohol policy analysis, segmented regression approaches have been used within a diverse set of tobacco studies; for example to evaluate smoke-free legislation, the cessation of UK mass media campaigns, changes to licensing arranges for nicotine replacement therapy and the partial tobacco point of sale display ban, as well as to analyse whether the growth in the use of e-cigarettes was responsible for the decline in the use of licensed nicotine products.[37,55-58]

In the proposed research, three variables will be derived to model the trend in the outcome variable in the pre-intervention period, any immediate step change in the dependent variable following the intervention, and any change in the trend in the post-intervention period relative to the pre-intervention period. The first variable, time, will be measured in months from the start of the observation period to the last time point in the series. The second variable, level, will be a dummy variable taking the values 0 before the intervention and 1 after; while the third variable, slope, will be coded as 0 up to the intervention and record the number of months post-intervention months thereafter. The extent and type of autocorrelation will be assessed using the autocorrelation function and partial autocorrelation, in combination with the Durbin Watson statistic.[59]

Insofar as there is no evidence of effect in the primary analysis, secondary analyses will use linear and polynomial regression models to evaluate different potential accumulations and decays of effects in the population. This will include testing for a pulse effect in which there is short-term (e.g. 2-3 month) decline in AUDIT-C scores before a return to pre-intervention levels. In a final exploratory approach, segmented regressions will be run with unspecified breakpoints to identify points where significant changes in trends occur and the Bayesian Information Criterion will be used to select the optimal number of breakpoints. Causal inferences will be weaker here and will need substantial supporting evidence (e.g. alignment with the timeline of promotional activity or temporal sequencing of changes in COM-B and alcohol consumption measures which correspond with behaviour change theory).

Where analyses are weighted, this will use a marginal (rim) weighting technique described in the ATS protocol paper.[31]

7.2.2. Confounding

Analyses will control for three major sources of confounding. First, major changes in other **policy-related factors**. Price represents a key factor and will be controlled for using the quarterly alcohol affordability index.[60] We will monitor the policy environment to identify additional interventions potentially affecting our outcome measures and control for these using binary control variables indicating pre- and post-intervention periods. Second, alcohol consumption trends display **seasonality** with December and January representing extremes of high and low consumption. We will attempt to directly control for seasonality by (a) simulating seasonal trends in AUDIT-C scores using the available ATS data and (b) Estimating monthly seasonality effects from multiple years of alcohol consumption data within the General Household/Lifestyle Survey and the Health Survey for England. **Hot weather** and **major events (e.g. sports tournaments)** can also lead to spikes in alcohol consumption and analyses will control for monthly temperature trends. Sensitivity analyses will also test the effect of controlling for the 2016 European football championships which may lead to a spike in alcohol consumption.

7.2.3. Secondary evaluation analyses

A series of secondary analytical approaches will be used to explore and validate results from the primary analysis. These are described below:

Difference-in-difference analysis: A difference-in-difference analysis will be facilitated by collection of a graded measure of self-reported exposure to the DG for 24 months from November 2015. A brief review of the literature suggests graded measures of exposure to health promotion campaigns are uncommon as evaluations typically focus on a single campaign and ask about recollection of that campaign in detail.[24] This is not feasible here as the intervention evaluated here comprises multiple campaigns. Therefore, we will ask participants whether they have been exposed to promotional messages through each of a series of media (e.g. TV, radio, internet or social media, health professional, product label) either 0, 1-2, or 3+ times in the last month.

Evaluation of specific campaigns: Following Sims et al.[61] we will explore whether data from the timeline of promotional activity can be used to evaluate impacts of specific campaigns. Hypotheses will be generated regarding breakpoints where intervention effects would be expected to begin and, potentially, further breakpoints where an 'effect decay' segment would be expected to begin.

As the timeline of promotional activity was discontinued, analyses of specific campaigns will not take place.

Sensitivity and specificity analyses: Alternative definitions of pre- and post-intervention periods will be tested to assess the sensitivity of the findings. In particular, the effect of defining the post-intervention period as beginning when a consultation on draft guidelines is published will be tested. A specificity analysis will be conducted by repeating the primary analysis using smoking-related outcomes (e.g. quantity smoked, prevalence of quit attempts). These measures are available in the Smoking Toolkit Study which sits within the same survey as the ATS. Although there may be some cross-over effects onto smoking of alcohol health promotion campaigns, these should be markedly

smaller and, if absent, confidence in the inference that observed effects are not attributable to general improvements in health behaviour trends would be strengthened.

7.2.4. Subgroup analyses

Additional subgroup analyses will examine effects on sociodemographic groups of interest defined by age, sex and socioeconomic status. Given sharp regional variations in alcohol-related harm, it is possible promotional activity may vary substantially across the UK and, if this is the case, we will examine the feasibility of regional analyses. At the time of writing, PHE are at a very early stage of developing their promotional campaign but have agreed in principle to explore staggered rollout of promotional campaigns by region to permit a stepped wedge analytical design and also strengthen such regional analysis.

7.2.5. Consistency of results with behaviour change theory

To enhance understanding of the mechanisms by which promoting DG affects behaviour and inform design of future health promotion activity, exploratory analyses will also be undertaken to assess whether a theory-based structural equation model (SEM) of the relationship behaviour and factors influencing behaviour change can be constructed. This will be based on the COM-B integrative model (see Section 8.1.1. Secondary outcome measures) and will examine the interrelationship between measures of capability, opportunity and motivation to change behaviour and behaviour itself measured by AUDIT-C (and potentially the alternative individual-level consumption measures).

A model will be initially fitted on six months of pre-intervention data using the generalised SEM ordinal regression command in Stata. Accounting for measurement error, the model will be specified to permit testing of whether statistically significant pathways between COM-B variables correspond to those proposed by theory.[30] To assess the stability and sensitivity of identified pathways, the analysis will be repeated using data from the post-intervention period. In the absence of true longitudinal panel data, experimental analyses using pseudo-panel techniques will be used to test pathways through which change in COM-B variables predicts change in alcohol consumption. Pseudo-panel methods assume a longitudinal panel can be created where individuals are aggregated into subgroups based on shared characteristics (e.g. age, gender socioeconomic status), and these subgroups then become the unit of analysis. This approach has previously been used by the applicants to estimate alcohol price elasticities.[62]

7.2.6. Constructing a timeline of promotional activity

Promotional activity is likely to occur at multiple points and in different forms across the evaluation period. Causal inferences regarding intervention effects can be strengthened if changes in outcome measures can be shown to temporally align with promotional activities plausibly influencing those measures. To facilitate such inferences, a timeline will be constructed of the promotional activity which occurs over the evaluation period. The timeline will focus on large-scale promotional activity which the research team judge could plausibly lead to population-level effects. Cumulative effects of smaller-scale activities will be captured by the primary evaluation analysis.

Promotional activities will be identified primarily by interviews with key organisations from the public, commercial and charity sector (e.g. Public Health England, Department of Health, Drinkaware, Alcohol Concern, The Portman Group) with the research team's social media presence and monitoring of alcohol-related news used to identify further activities. Interviews will be conducted at the time of guideline publication and update interviews will be conducted at six month

intervals throughout the evaluation period to confirm activities were undertaken as planned, gather any evaluation data and identify further activities. Interviews are for fact-finding purposes only and therefore, will be recorded for checking information but will not be transcribed. Summaries of the information provided will be sent to interviewees for verification following the interview.

For mass media campaigns, we will seek audience metrics from the body responsible. Following Langley et al.[41] we will attempt to obtain *advertising creatives* specifying the desired content of the campaign and also *Gross Rating Points (GRP)* for TV and radio advertising. GRP measure the number of times an advert is seen or heard taking account of the audience size and number of broadcasts and can also be broken down to indicate audience composition.[63] We will also seek to obtain online- and social media-related data (e.g. unique views, click-through rates, app downloads and registered or active users of services) to assess audience scale and thus potential impact.

Promotional activity will be classified using a tool adapted from one used previously by co-investigator Lewis to classify tobacco mass media campaigns.[41] The tool is informed by COM-B[30] (the same integrative model we apply to examine influences on behaviour change) and focuses particular on motivation through the PRIME theory.[64] It also draws on effectiveness evidence for tobacco mass media campaign content.[65] The smoking tool classifies content by **key themes** (e.g. smoking cessation, preventing uptake), **delivery style** (e.g. acted scenes, testimonials), **call to action** (e.g. prompts for quit attempt or quitline calls) and **positive/negative emotional content**. An initial version of an equivalent alcohol tool has been developed informed by a review of promotional material available on the websites of key organisations (e.g. NHS, Drinkaware, Alcohol Concern). The tool will be iteratively developed as the guidelines and promotional activity emerge to ensure comprehensive coverage of content. In year 3, following data collection and prior to using the tool within statistical analysis or publications, both the tool and the research team's coding of materials will be validated by PPI representatives (see PPI on application form).

Data will be used to construct a timeline of major promotional activities across the evaluation period allowing for development of testable hypotheses. For example, a period with intense mass media advertising focused on changing motivations would be hypothesised to trigger a change in ATS measures of motivation.

See Section 4. This work was discontinued in May 2018 after no significant promotional activity was identified during an initial survey of key organisations or at informal follow-ups.

7.2.7. Cost-effectiveness analysis

The Sheffield Alcohol Policy Model (SAPM) has been developed to provide estimates of the effectiveness and cost-effectiveness of alcohol policies including pricing and screening and brief interventions. For a given policy-induced change in consumption, the outputs of the model provide estimates of changes in the incidence or prevalence of 47 chronic and acute health conditions which are either wholly or partially attributable to alcohol. The full model methodology is published elsewhere.[4] In brief, functions relating risks of each health condition to measures of either mean weekly or single occasion consumption are the key component. Change in consumption, and hence risk, over time is used to adjust observed mortality and morbidity rates by applying the potential impact fraction method.[66] For chronic conditions, debate exists regarding the time lag between population-level changes in exposure and changes in outcome and SAPM uses lag functions posited in a recent systematic review.[67] SAPM also provides estimates of the long-term costs associated with

alcohol-related harm including direct costs to the health service as well as a financial valuation of changes in individuals' quality of life. Analyses with the model can be carried out on population subgroups defined by age, sex, consumption level and income or socioeconomic status. This means the model is able to present results describing the impact of alcohol policies on particular subgroups of interest such as young hazardous drinkers, low income moderate drinkers or high income harmful drinking women.

We will incorporate evidence of intervention effectiveness into SAPM in order to evaluate long terms health costs and benefits. To understand the effects of the intervention on long-term outcomes, SAPM needs three pieces of evidence. First, a baseline distribution for mean weekly consumption which will be taken from the Health Survey for England (HSE) 2014. Second, a revised distribution of mean weekly consumption after promotion of DG has completed its effect and this will be simulated based on the results of the evaluation analyses, with simulation methods dependent on the results obtained. Third, an assumption regarding the counterfactual (i.e. the distribution of mean weekly consumption if the intervention had not occurred) and we will assume a steady state (i.e. that consumption remains as it is in the baseline). Our basecase analyses will examine effects in the full population and the resulting analyses will present the expected incremental effects of promoting DG in terms of mortality reductions, disease prevalence, NHS costs and quality-adjusted life years gained. Further scenario analyses will examine the effects of alternative model assumptions which will be selected based on the results of the evaluation analyses. Scenarios may include modelling health and health economic consequences of short-term effects on acute alcohol-related harms. Adaptations to SAPM's annual structure would be required in this instance. Subgroup analyses will also be undertaken for age, sex and socioeconomic groups.

The planned economic evaluation will not go ahead after discussion with the project advisory group in May 2018. This decision was taken after preliminary analyses and a lack of promotional activity suggested no intervention effects would be identified.

8. Data handling

Ipsos Mori provide ATS datasets to the research team in anonymised form on a monthly basis. At no point will the research team have access to identifiable data.

On receipt, these data are appended by JB to a longitudinal dataset which is shared with research team members and other users of the ATS in SPSS, Stata and R format via a password-protected online shared workspace. Subsequent to accessing the longitudinal dataset, it will be stored on password-protected University computers or encrypted portable media. This will include the University of Sheffield's shared drive in a folder only accessible to members of the Sheffield Alcohol Research Group (i.e. the project team and close collaborators at the University of Sheffield). Regular backup of all data stored on the shared drive are routinely performed by the University's Corporate Information and Computer Services (CICS) and regular checks will be undertaken by the research team to ensure the usability of back-ups.

JH will lead the primary data analysis with support from JB and EB. Analytical datasets will not be transferred between the research team. Instead, team members will share software code (e.g. via email) which allow data manipulation and analyses to be replicated on the master dataset.

8.1. Data access

Project data will be available to ATS collaborators outside of the project at all times on agreement that use of project-specific variables (e.g. questions relating to drinking guidelines) is agreed with JH in advance. Access to and use of the dataset beyond the collaborators on the ATS is subject to agreement by the ATS managers at UCL (JB, RW, SM).

9. Ethical considerations

Ethical approval for the evaluation has been gained from the University of Sheffield's Research Ethics Committee (Ref: 006373). Copies of all review documents are retained by JH.

10. Public and patient involvement

The project description along with the scientific and lay abstracts were shared with a member of the public who acts as a PPI representative on several of the University of Sheffield's projects. Feedback led to various improvements being made to the clarity of the proposal (e.g. revising the project aims, defining hazardous drinking, emphasising the focus on promotional activity).

Suggestions were also made to expand the scope of the project to look at a wider range of health and social outcomes (e.g. hospital admissions, alcohol-related crime) and explore in detail how different promotional activities are received by drinkers. Although not included in the original proposal, a secondary analysis examining impacts on alcohol-related hospital admission has been incorporated into this revised proposal. We have recently published qualitative research examining public reactions to the current drinking guidelines and plan to submit funding proposals for smaller linked projects to build on that work. The comments of our PPI representative will inform those proposals.

During the project, an established PPI group will be drawn on, namely the UK Centre for Tobacco and Alcohol Studies (UKCTAS) Drinkers Panel. This comprises circa 40 adults drinkers based near Stirling with diverse sociodemographic characteristics. Members were recruited in 2014 via social media and meet 2-3 times a year. A £25 voucher plus travel costs are offered for each meeting attended.

Two panel members will be asked to join the project steering group and will contribute to oversight of project direction and focus. Recruitment of these panel members at a panel meeting in August 2016 has been arranged.

The wider panel will also be asked to input on four specific areas throughout the project: (1) new questions to be added to the survey; (2) additional research needs or questions arising after revised drinking guidelines are published; (3) the comprehensiveness and application of the tool for classifying promotional material and (4) interpretation of findings and key messages.

The proposed project will fund travel and incentives for steering group members and will also fund incentives for one Drinkers Panel meeting (UKCTAS will fund the remainder).

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12. Appendix 1: Brief protocol for a review of English newspaper reports on the revised UK drinking guidelines

This review was added to the project with the agreement of the funders and following consultation with the Project Advisory Group due to the suspension of data collection on the timeline of promotional activity and the decision to not develop a cost-effectiveness model (see Sections 4, 7.2.5 and 7.2.6).

12.1. Rationale

Only a small amount of promotional activity has taken place since revised UK drinking guidelines were announced in January 2016 and confirmed in summer 2016. For example, there has been no large scale mass media campaigns and alcohol producers have not consistently updated their packaging. However, the drinking guidelines are routinely mentioned in news reports and have been the subject of commentary and discussion within newspapers. Therefore, news reports may be an important means by which the guidelines have been communicated to the public. They may also act as a proxy indicator for discussion of the guidelines by the public.

12.2. Aim

To identify the scale and content of newspaper coverage in England before and after the revised UK drinking guidelines were announced.

12.3. Objectives

1. Conduct a systematic search of a newspaper reports database to identify all reports mentioning the drinking guidelines during the study period (February 2014 to October 2017)
2. Construct a timeline showing the accumulation of newspaper reports over the study period.
3. Determine the different contexts in which newspaper reports discuss the revised drinking guidelines and the key themes addressed.

12.4. Summary of methods

We will conduct a systematic search of the Nexis UK database of newspaper reports for all reports mentioning the drinking guidelines between February 2014 and October 2017. The search will be limited to the main UK national daily and Sunday newspapers. Local and regional newspapers will not be included. Scottish newspapers and Scottish editions of UK newspapers will be excluded as the project is focused on England. A search will also be conducted of the main UK news broadcasters' websites for news reports (e.g. BBC, ITV, Channel 4, Sky News) and we will attempt to identify efficient means to search a selection of news magazines (e.g. The Economist) and popular magazines (e.g. Cosmopolitan). Mentions of either the previous or revised guidelines will be included as mentions of the former will indicate whether there was a growing interest in guidelines in the lead-up to the announcement of revisions.

All identified reports will be checked to ensure the search has not included false positives. Reports will then be placed on a timeline to allow identification of periods of high and low interest in the drinking guidelines. We anticipate identifying several periods of high interest including the initial announcement of revisions, related statements from the Chief Medical Officer for England, the publication of major scientific articles relating to the risks of alcohol and critical reports on the development of the guidelines.

We will select a random sample of reports for thematic analysis with the N to be determined after assessing the total number and timing of reports. The sample will be stratified by periods of high and low interest in the drinking guidelines and different types of newspaper (e.g. tabloid). Analyses will identify the contexts in which the guidelines are mentioned (e.g. a report focused on the guidelines, a report on alcohol-related health risks, an incidental mention in a report with a wider focus). They will also identify the themes addressed (e.g. 'nanny statism', the harmfulness of alcohol, the health of the nation). We will develop a coding frame informed by previous public health-oriented reviews of newspaper reports and our own knowledge of this topic.

12.5. Outputs

We anticipate that the analysis will lead to one journal article and may be presented at academic and/or practitioner conferences.

12.6. Proposed timeline

This work would begin in Autumn 2018 and, given existing commitments, would require a no-cost extension with a view to completion in early 2019. An initial conversation on a six-month no-cost extension has been held with NIHR.