Evaluating and responding to the public health impact of no and low alcohol drinks:

A multi-method study of a complex intervention in a complex system

Research Register registration no: 7968 (2nd June 2022)

Protocol version: 2.1 (20th June 2022)

NIHR reference no: NIHR135310

University of Sheffield reference no: 177134

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List of abbreviations

ABV: Alcohol by volume

AG: Advisory Group

ARIMA: Auto-regressive integrate moving average

ATS: Alcohol Toolkit Study

AUDIT-C: Alcohol use disorder identification test – consumption

CMO: Context-Mechanism-Outcome

DHSC: Department of Health and Social Care

DMP: Data Management Plan

HES: Hospital Episode Statistics

HSE: Health Survey for England

KCL: Kings College London

KWP: Kantar World Panel

LCFS: Living Costs and Food Survey

MUP: Minimum unit pricing

No/lo: No- or low-alcohol

OHID: Office for Health Improvement and Disparities

ONS: Office for National Statistics

PHEDS: Public Health Economics and Decision Science

PMG: Project Management Group

SEM: Structural equation modelling

SAPM: Sheffield Alcohol Policy Model

SKU: Stock-keeping unit

ToC: Theory of change

TPB: Theory of planned behaviour

WP: Work package

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1. Background

This project will investigate the public health impact of ongoing efforts by government, industry and other stakeholders to increase the availability and consumption of no- and low-alcohol drinks (no/lo drinks) in Great Britain. It will provide insights and actionable evidence for policy-makers in three key areas: (i) shifts related to no/lo drinks within alcohol production, retail, marketing and business strategies; (ii) positive and negative impacts of increased no/lo availability and consumption on a wide-range of outcomes, including alcohol consumption, alcohol-related harm and health inequalities and (iii) the potential impact of policy options and interventions prioritised by stakeholders.

No/lo drinks are typically defined as beers, ciders, wines and spirits containing less than 1.2% alcohol by volume (ABV).[1] This definition excludes '*lower*-strength' alcohol products with an ABV up to 3.5% and also soft drinks marketed to adults as alcohol substitutes. We do however discuss these related products where appropriate in this proposal. Throughout the proposal, we refer to drinks other than no/lo or *lower*-strength products as 'standard alcoholic drinks'.

1.1. Alcohol and the alcohol industry as an evolving public health problem

Alcohol is a leading contributor to Great Britain's burden of disease.[2] In England, it caused 20,468 deaths in 2020 and 1.0m hospital admissions in 2019/20,[3] with alcohol-specific mortality rising sharply during the COVID-19 pandemic.[4] The harms caused by alcohol include liver disease, cardiovascular disease, seven types of cancer, and injuries associated with falls, violence, road traffic accidents and self-harm.[5] Alcohol also causes wide-ranging social harms through problems including alcohol dependence, foetal alcohol spectrum disorders, crime and antisocial behaviour, drink-driving, intimate partner violence, child abuse, workplace absenteeism and presenteeism, and unemployment.[2] Estimates of the overall cost of these health and social harms to UK society vary, but £21bn per year in England is the most commonly cited figure, including £3bn in NHS costs.[2]

Alcohol-related harm is distributed unevenly across society, with alcohol-specific mortality rates 5.5 times higher in the most deprived areas of the UK when compared to the least deprived areas. Similar disparities are seen for alcohol-related violence victimisation.[6] This is despite people living in more deprived areas being less likely to drink alcohol and drinking less on average if they do so.[7]

The alcohol industry is a key contributor to alcohol-related harm.[8] In addition to producing, marketing and retailing alcohol, a growing body of research describes how industry actors prevent effective regulation of their activities and hinder communication of health messages.[9,10] For example, companies, trade bodies and social aspect organisations use multi-component strategies to frame public debate around alcohol, restrict policy options under consideration, and prevent, delay or undermine proposed policies.[11] Central to these strategies is ensuring a continuous and influential role for industry as partners in Government policy-making.[10] The policies arising from such partnerships typically include self-regulatory systems and health promotion activities, often involving industry partners, that have little evidence of effectiveness.

Despite these concerns, the nature and extent of alcohol problems are changing. Alcohol consumption among young people in Britain declined sharply over the last 20 years,[12] causing concern about the future viability of alcohol businesses.[13] Concurrently, alcohol consumption among middle-aged and older drinkers is stable or increasing.[14] This has prompted a shift in policy debate away from the need to curtail public binge drinking and towards managing excess consumption in the home, particularly after alcohol consumption increased among many higher risk drinkers during the COVID-19 pandemic.[15] Industry actors are actively responding to these trends and seeking to capitalise on a perceived shift in public sensibilities that favours an increased focus on health, well-being and authenticity.[16] Central to this industry response are no/lo drinks.

1.2. The growing prominence of no- and low-alcohol drinks

The no/lo drinks market has expanded rapidly over recent years. However, detailed estimates of market size and growth are unavailable as the only public data sources are incomplete information within news reports, while key academic sources unhelpfully group together all products ≤3.5% ABV products.[17-19] The following figures are therefore calculations from the limited available data.

Beer dominates the British no/lo market, and the volume of no/lo beer sold in the off-trade (e.g. shops) increased threefold between 2009 and 2019,[20,21] and by a further 22% in 2020.[22] We estimate

no/lo beer now accounts for c1.5% of all off-trade sales by value. Sales of no/lo spirits, ciders and wines are also increasingly rapidly, with the value of no/lo spirits sales doubling in 2019 due to increased purchasing in the on-trade (e.g. pubs, restaurants).[22,23] Overall, no/lo drinks now account for c0.5% of total alcohol sales by value, following a 22% increase in 2020. Market researchers anticipate persistent strong growth due to continued investment by large producers.[22] If current trends continue, we estimate no/lo drinks could account for 10% of total alcohol sales value by 2030.

The no/lo drinks market is complex, evolving and radically different from previous decades, where a few small brands dominated.[1] Most large alcohol producers now have no/lo versions of their major brands (e.g. Beck's Blue, Heineken 0.0, Gordon's Alcohol Free). Smaller producers have distinct non-alcoholic brands (e.g. Brewdog Nanny State), while start-ups emphasise 'craft' credentials or produce only no/lo products (e.g. Big Drop). Some of these have major investment from large producers (e.g. Seedlip, whose majority shareholder is Diageo). No/lo producers also compete with producers of premium soft drinks that are marketed to adults as alcohol substitutes (e.g. Fever Tree). To create a mass-market, no/lo products are now promoted via high-profile marketing campaigns (e.g. the 'Now you can' campaign for Heineken 0.0 was prominent across most media channels and pitch-side adverts for the same product were visible throughout the Euro 2020 football tournament). Market researchers also advise retailers to provide substantial shelf-space for no/lo products.[24]

1.3. No- and low-alcohol drinks as a public health intervention

The UK Government's green paper, *Advancing our health: prevention in the 2020s*, committed to working with industry to deliver a significant increase in the availability of alcohol-free and low-alcohol products by 2025. The Department of Health and Social Care (DHSC) is now developing further actions to meet this aim in consultation with researchers, industry and public health practitioners, and requires evidence to inform decision-making, implementation and evaluation of the policy. We developed this project in consultation with DHSC and other stakeholders (see letters of support) to support policy-making via key insights into off- and on-trade sales of no/lo products, as well as impacts on consumer behaviour, alcohol-related harm, health inequalities and unintended outcomes.

This UK Government's commitment follows previous related activity by government, industry and some third sector organisations. The Government introduced a lower tax rate for beers ≤2.8% ABV in 2011 and proposed raising this threshold to <3.5% in its 2021 Alcohol Duty Review.[25] It also secured industry commitments to grow the no/lo market via the Public Health Responsibility Deal in 2014, although some researchers argue this allowed industry actors to present decisions they had already made for commercial reasons as new commitments to corporate social responsibility.[26] Beyond government, prominent organisations such as Alcohol Change UK and Club Soda use their highest profile activities (e.g. Dry January and mindful drinking festivals) to promote no/lo products to the public as key aids to cutting down on drinking. No/lo drinks are also highly visible in media debate around reducing drinking and this is reflected in perceptions among drinkers. For example, one-third of recent no/lo consumers say they chose the product to help them reduce their alcohol consumption.[1] Other alcohol charities and public health bodies remain cautious or sceptical, often citing a lack of relevant evidence to inform policy positions and activities (see letters of support).

In addition to their commercial activity, industry actors present no/lo drinks as a solution to alcohol harm and some include objectives to increase no/lo sales in their corporate social responsibility strategies.[26] For example, the multinational brewer AB InBev's Global Smart Drinking Goals include ensuring no/lo beers comprise at least 20% of their global sales volume by the end of 2025.[27] AB InBev have also engaged public health researchers in developing and evaluating this goal via stakeholder workshops and substantial contributions-in-kind to research by Anderson et al.[18,19,28-31]

The rapid emergence and growth of no/lo products means these actions could have a transformative impact on public health if people drink no/lo products instead of standard alcoholic drinks. For example, if no/lo drinks displaced 5% of alcohol sales by volume, this could have a similar impact on population alcohol consumption to interventions public health actors argue to be highly effective, such as a £0.50 minimum unit price (MUP).[32] There could be further benefits if people substitute no/lo drinks for standard alcoholic drinks in high-risk contexts, such as when driving or pregnant.

However, there are large uncertainties and the potential for unintended negative affects to co-exist alongside positive ones. Any public health benefit depends on who buys no/lo drinks and whether purchases substitute for, or add to, existing alcohol consumption. Some stakeholders argue that no/lo drinks may increase alcohol-related harm by normalising alcohol use in new contexts (e.g. workplaces, mornings), introducing young people to alcohol tastes, brands or products early, or

triggering cravings in people recovering from alcohol dependence. No/lo products can also facilitate 'alibi marketing' of standard alcoholic drinks (i.e. marketing no/lo drinks with the same or similar branding to known alcoholic products). This may circumvent alcohol marketing restrictions in general and specifically in contexts where alcohol would not otherwise be marketed.[1,33] Alibi marketing is a particular concern of the Scottish Government, and will form part of its consultation on alcohol marketing restrictions in 2021. Other concerns include no/lo drinks potentially reducing overall alcohol-related harm but widening health inequalities if they are consumed mainly by socially advantaged groups. Finally, successful growth of the no/lo drinks market may enable greater industry influence over wider alcohol policy by allowing industry actors to present themselves as effective contributors to reducing alcohol-related harm, as with tobacco industry involvement in e-cigarettes.[34]

1.4. Literature review

A recent scoping review of the literature on production, consumption and potential public health impacts of no/lo products identified 70 relevant studies published between 2010 and 2021.[35] We used the MEDLINE and PsycInfo databases to identify any additional papers by combining terms related to 'low-strength alcohol', 'low-alcohol', 'alcohol-free', 'non-alcoholic', and 'consumption'. We also used backwards and forwards citation checking of identified papers to check for further sources. Although the scoping review identified 70 studies, the authors concur with previous studies that the evidence-base is too disparate and scant to adequately inform policy.[36] We agree and note that many studies relate to *lower*-strength products (e.g. 3.5% ABV beers and 8.0% ABV wines) rather than no/lo drinks (<1.2% ABV). This includes a series of prominent studies of British household purchasing data by Anderson et al., which we discuss below. The literature falls into five main areas:

Experimental studies of labelling, purchasing and consumption: A 2017 systematic review found little evidence on the effects of no/lo product labelling and uncertainty about the effects of comparable food and tobacco labelling.[37] Since 2017, experimental studies have examined consumer responses to products labelled as no/lo or *lower*-strength options. Vasiljevic et al. found labels suggesting lower alcohol content make products less appealing to consumers, although including an ABV above 0.0% can mitigate this.[38] Consumers also perceive products labelled as low- or very low-strength to be more than 1.2% ABV.[39] Varying the descriptor (e.g. low, light, reduced) and qualifier (e.g. very, super, extra) did not substantially affect perceptions. Such labels may prompt drinkers to consume more *liquid* for no/lo drinks, with less consistent results for lower-strength products.[40-42] However, one of these studies and two additional low-quality experiments conducted in real-world settings in the 1990s suggest drinkers may still consume less *alcohol* when served lower-ABV drinks.[42-44] Finally, an experiment found that higher *relative* availability of no/lo products vs. standard alcoholic drinks increased purchasing, but higher *absolute* availability did not.[45]

Consumer attitudes, perceptions and discrimination of alcoholic strength: Several studies have explored consumer attitudes and views relating to no/lo and *lower*-strength drinks, and their ability to identify these drinks in taste tests.[35] Substantial variation in the quality and ABV of products studied mean our synthesis is cautious. Consumers generally have negative attitudes towards no/lo and *lower*-strength beers and wines, perceiving them as lower quality and functional alternatives to alcohol with neutral or negative connotations.[46-48] Consumers also regard these drinks as for women, pregnant women, dieters, drivers, sportspeople and underage drinkers.[48,49] However, consumers also see no/lo and *lower*-strength drinks as cheaper, healthier and helpful for managing weight.[48,50-52] Experimental studies find drinkers cannot discriminate consistently between ABVs in blind taste tests, suggesting product quality differences may not be discernible.[53-56] Raising public expectations of no/lo drinks may therefore increase use by changing perceptions of intended consumers.[46]

No/lo marketing: One marketing study suggests no/lo products promote additional drinking occasions rather than replacing normal alcoholic drinks within existing occasions.[57] This echoes studies of e-cigarettes and diet soft drinks, which suggest producers use 'lower risk' products to broaden consumption settings, forestall regulation and/or preserve revenues in declining markets.[34,58] It also echoes findings on 'healthier' alcoholic drinks, which include no/lo products.[16]

British household purchasing studies: A series of analyses by Anderson et al. supported by a substantial in-kind contribution by AB InBev[19] address questions analogous to this project and use similar data,[18,19,29-31] but the results have limited validity to our questions because: (i) They primarily examine *lower*-strength beers up to 3.5% ABV (equivalent to standard bitters) rather than no/lo drinks below 1.2% ABV; (ii) a single 3.5% ABV product manufactured by AB InBev dominates one analysis of the impact of *lower*-strength beer on alcohol consumption, as it accounts for 68% of all lower-strength beer purchased;[18] (iii) Two time series analyses of no/lo purchasing exclude

households at each data point if they did not purchase any alcohol at that time.[19,29] Although this provides insights into changes in the average shopping basket, it does not provide robust estimates of changes in overall purchasing by households, as changes in zero-purchasing days are excluded from the analysis. The results will therefore be biased in unpredictable ways; (iv) Most analyses aggregate the longitudinal household panel data into a population-level time series, and therefore discard substantial information on within-household change. The Anderson et al. studies should therefore be interpreted with caution in relation to no/lo drinks. They suggest that launching new *lower*-strength beers may reduce overall alcohol purchasing,[30] and that increasing the volume of *lower*-strength beer in household purchases is associated with a reduced number of units of alcohol within the average shopping basket (but not necessarily reduced overall alcohol purchasing by households).[18,19] Households that buy more alcohol and where the main shopper is aged 35-44 are more likely to buy zero alcohol and *lower*-stength beer, but those in higher socioeconomic groups are only more likely to buy zero alcohol beer, suggesting uncertain impacts on health inequalities.[31] Lower-strength beers are also cheaper than standard beers, but less likely to be on promotion.[29,30]

Health outcomes: The scoping review identifies several studies of the impact of no/lo consumption on specific health outcomes. However, these provide little relevant evidence as they typically focus on single outcomes in narrow population groups (e.g. insulin resistance among diabetic patients with high BMI), rely on short-term follow-up (i.e. <12 months) and have small samples (i.e. N≤60).[35] One 1989 experimental study of abstinent patients with alcohol use disorder found a no/lo tasting session increased alcohol cravings relatives to a soft drink control, but most participants rated the no/lo drinks favourably, did not believe they would contribute to relapse, and half intended to use them in future.[59]

***Summary*:** In summary, the public health evidence-base on no/lo drinks is small, concentrated in certain areas (e.g. labelling) or affected by substantial conflicts of interest. There are significant research gaps around basic public health questions including time-trends, social patterning, drinking practices, use in attempts to reduce drinking and health outcomes. There are also few qualitative studies, analyses of key policy areas (e.g. pricing, marketing) or studies of corporate strategy.

1.5. Contribution and value of this project

This project offers new and valuable evidence for the following reasons.

Evaluation of a major public health intervention: Increasing the availability and consumption of no/lo drinks is a key component of the UK Government's prevention strategy, is supported by some public health stakeholders, and appears both a commercial and political priority for industry actors. However, current evidence provides little information on the public health benefits or risks of this policy or of the specific actions taken by government, industry or others. Given the potentially transformative impact on public health and the uncertainties around impact, it is important that an independent evaluation, focused on the products of greatest potential benefit (i.e. <1.2% ABV) examines whether and how this rapidly evolving intervention impacts public health outcomes.

Wide-ranging evidence on a complex intervention in a complex system: As described below, this study conceptualises efforts to increase the availability and consumption of no/lo drinks as an ongoing complex intervention delivered by multiple actors within a complex and evolving alcohol consumption system. In addition to providing evidence on key outcomes, such as alcohol consumption and alcohol-related harm, it will characterise the multiple intervention components, including commercial and social marketing activity, regulatory policies and key no/lo product categories. Further, it will examine how the intervention adapts over time to consumer behaviour, the evolving market and the regulatory environment. It will also explore wider and potentially adverse effects across the alcohol consumption system, including changes in the alcohol market, corporate political activity, and changing drinking practices among underage drinkers, those in recovery and pregnant women. Finally, it will estimate impacts on health inequalities by comparing impacts *across* and *within* population subgroups defined by gender, socioeconomic status, alcohol consumption level and legally protected characteristics to the extent permitted by data available.

Value to stakeholders: We consulted extensively with stakeholders in preparing this proposal (see letters of support), and received particular input from DHSC, who influenced key aspects of the project design (e.g. focus group participants, responsive policy appraisals, focus on health inequalities). These stakeholders require evidence detailing whether and how no/lo drinks improve public health and avoid unintended harms to inform policy-making, shape advocacy strategies, and provide appropriate public guidance for reducing alcohol consumption. Stakeholders also require comprehensive and detailed statistical surveillance data on the no/lo market to support effective

decision-making. This project will provide outputs addressing these needs through our evaluation research and annual monitoring reports on no/lo-related trends (see WP2a).

Responding flexibly to a changing environment and evolving stakeholder needs: We have built substantial flexibility into the research plan to allow the project to respond to an evolving intervention and intervention context, as well as emerging stakeholder needs. This flexibility includes quarterly meetings of a stakeholder panel to share findings and identify priorities, staggered data collection and analysis points to permit ongoing adaptation of research questions or methods, and capacity for responsive model-based appraisals of stakeholders' preferred policy options.

A platform for future research: The datasets and evidence generated by this project will provide a platform for future research on no/lo drinks and related topics. We will identify research needs around major or emerging commercial and behavioural trends, policy areas requiring effective interventions, and vulnerable groups requiring targeted support. The market research datasets purchased through the project will also support wider alcohol epidemiological, econometric and policy analyses, including our high impact programmes of alcohol pricing, licensing and marketing research.

2. Aim and research questions

Aim: This project aims to characterise, monitor and evaluate the public health impact of efforts to increase the availability and consumption of no/lo drinks among adult alcohol drinkers in Great Britain from 2011 to 2025. It will examine these efforts as a complex intervention within a complex system. The project has ten research questions across four work packages (WPs):

WP1: Characterising the intervention:

1. What are the main pathways by which increased no/lo availability and consumption may produce positive and negative public health impacts?
2. What actions have industry actors, governments, and other key stakeholders taken to increase availability and consumption of no/lo drinks, how have these actions emerged, adapted to the changing intervention context or responded to feedback (e.g. consumer behaviour) between 2011 and 2025, and what pathways to positive or negative public health impacts do they support?
3. How have industry actors' market and corporate political strategies produced, adapted to or emerged from the increased availability and consumption of no/lo drinks and their wider impacts, and what pathways to positive or negative public health impacts do these support?

WP2: Monitoring and evaluating the intervention's impact on alcohol consumption:

4. What impact have the intervention and specific intervention components had on no/lo consumption and total alcohol consumption across the population and in population subgroups?
5. Does increased purchasing of no/lo drinks lead to reduced purchasing of alcohol at the population- and household-level (substitution vs. addition)?

WP3: Understanding changes in alcohol consumption and unintended outcomes:

6. How is no/lo consumption associated with cutting down on alcohol and how are no/lo-related beliefs and sociodemographic factors associated with no/lo consumption?
7. How do intervention components interact with emerging no/lo drinking practices, how do key population groups adapt their drinking and non-drinking practices in response to no/lo drinks, and what pathways to positive or negative public health impacts do these changes support?

WP4: Evaluating intervention impacts on alcohol harm and appraising policy responses:

8. What policies are used internationally to govern the availability and consumption of no/lo drinks?
9. What will be the health, health economic and health inequality impact of changes in alcohol consumption arising from increased availability and consumption of no/lo drinks, and how might these health impacts be affected by indirect or unintended positive and negative consequences?
10. What would be the impact on no/lo and alcohol consumption, and on health, health economic and health inequality outcomes, of additional policies related to no/lo drinks proposed by key stakeholders, including DHSC and the Scottish Government?

3. Research Plan and Methods

3.1. The intervention

Efforts to increase the availability and consumption of no/lo drinks are part of an **ongoing complex intervention within a complex system**. They build on actions taken from c2011 onwards by industry, government and other stakeholders. As such, the intervention as a whole involves **multiple intervention components delivered by multiple actors at multiple time-points**. Industry actors deliver the primary components, including new products, marketing and retail practices. The UK and devolved governments and other stakeholders deliver further components, including preferential taxation, labelling rules and social marketing. They also shape future intervention activity (e.g. by creating opportunities for new products or marketing campaigns). This activity is **continuous and evolving** in response to feedback effects from consumer behaviour, market changes and regulatory activity. Therefore, the intervention has **no stable form** and **no single implementation time point**.

The intervention components shape a **complex alcohol consumption system** that is also evolving continuously and includes many interlinked actors and processes, including production, marketing, retail, consumption, regulatory policy, social marketing and healthcare. The contribution of single intervention components to changes within this system **may emerge in the short- and long-term** and **may be contingent on the introduction of other intervention components**. Therefore, the project will seek to understand whether and how the overall intervention and specific intervention components contribute to observed changes within the consumption system. It will address components from 2011 onwards, but focus on 2019-2025 where feasible, as this is the period covered by the UK Government's current prevention strategy commitment to supporting no/lo drinks.

3.2. Research Design

The project draws on guidance for evaluating complex interventions in complex systems.[60-63] It will use logic models, observational and qualitative designs, natural experiment evaluation methods and mathematical modelling, to understand the contribution made by the intervention and its components to changes in proximal, intermediate and distal processes and outcomes at all points within the alcohol consumption system. Across its multicomponent and multimethod design, it will pay particular attention to adaptive responses (e.g. new business strategies, purchasing behaviour and alcohol drinking practices), emergent phenomena (e.g. no/lo drinking practices and use of no/lo drinks in attempts to reduce alcohol consumption), system feedback (e.g. marketing strategies that respond to consumer behaviour) and the 'dark logic' that drives unintended and adverse outcomes.[64] The project also will take a long-term perspective and includes iterative research to capture the evolving intervention components, changes in their effects, and changes in other relationships within the alcohol consumption system over time. Table 1 summarises the overall structure of the project.

Scope, population and setting: The project focuses on no/lo beers, ciders, wines and spirits below 1.2% ABV. It will consider additional products, including higher ABV drinks and premium soft drinks if they emerge as important in our data or to stakeholders. Our geographic focus is Great Britain (Northern Ireland data are unavailable in key datasets). We provide evidence relevant to Scotland and Wales where possible, but some components focus solely on England due to DHSC's particular interest in and support for the project, and resource limitations that prevent separate analyses for each country. We will work closely with stakeholders in Scotland and Wales to explore further funding opportunities that can generate additional evidence relevant to their needs. The primary population of interest is adults (18+) in the general population and particularly adult drinkers (variously defined). Components of WP1 and WP3 additionally focus on underage drinkers, people in recovery from alcohol dependence and other specific population subgroups.

3.3. WP1: Characterising the intervention.

WP1 will use multiple sources to characterise the intervention and its components. This includes drawing on WP2-3 findings to identify components that emerge from or adapt to the wider intervention and its impacts over time. WP1 will enable critical analysis of whether and how potential beneficial and harmful impacts of the intervention emerge across the alcohol consumption system, including interrelationships between intervention components, and other elements of the system.

Table 1: Overall structure of the project

Objective	Primary methods summary	Months	Draws on		Feeds into	
1a: Develop an intervention theory of change.	Stakeholder co-production workshops.	1-3, 42-45	1b-d	2a-c	1b-d	2a-c
			3a,b	4a-d	3a,b	4a-d
1b: Establish a timeline of intervention activity.	Charting of information from market research datasets, trade reports and desk-based scoping exercises.	1-18, 37-41	1a	2a,b	1c-e	1a,b
			3b		3b	4a-d
1c: Characterise industry actors' market and corporate political strategies.	Case studies of 10-15 industry bodies based on industry documents, market research and public consultation responses.	7-18, 37-41	1b,d	2a	1d,e	2b
					3b	4a,b,d
1d: Conduct case studies of no/lo marketing and positioning.	Case studies of 8-10 no/lo brands based on advertising spend and content, point of sale observations, online product listings, packaging and labelling, and other relevant WP1 data.	19-32, 37-41	1b,c,d	2a		2b
			3b			4a,b,d
1e: Develop a no/lo product taxonomy.	Narrative synthesis of relevant project findings	19-24, 37-41	1a-d	2a	1d	2b
			3b			4a,b,d
2a: Describe and monitor trends in no/lo availability, sales and purchasing.	Descriptive analysis of Nielsen off-trade sales data, CGA on-trade sales data, Kantar World Panel (KWP) household purchasing data and Alcohol Toolkit Study individual survey data.	1-36	1b		1b-d	2b,c
					3b	4a,b,d
2b: Evaluate the impact of intervention activity on no/lo and alcohol consumption.	Univariate, bivariate and interrupted time series analyses and panel data analyses of Nielsen, CGA and KWP datasets.	7-42	1a-e	2a	1b	2c
			3b		3b	4a,b,d
2c: Assess whether increasing no/lo consumption reduces alcohol consumption.	Bivariate time series analysis and panel data analysis of Nielsen, CGA and KWP datasets.	13-24, 34-39		2a,b		
					3b	4a,b,d
3a: Understand how no/lo drinks support individual attempts to reduce drinking.	Regression and structural equation modelling of individual data on no/lo consumption and beliefs from the Alcohol Toolkit Study.	13-24				
					3b	4b,d
3b: Explore how people embed no/lo drinks in everyday practices.	Focus groups interviews with 13-17 year-olds, parents of 13-17 year-olds, young adults, pregnant women and recent mothers, high risk drinkers aiming to cut down, and people in recovery.	13-36	1a-e	2a-c	1d	2b
			3a			4b,d
4a: Summarise international policies related to no/lo drinks.	Desk-based policy review	13-24	1a,b			
						4d
4b: Adapt the Sheffield Alcohol Policy Model (SAPM) to allow analyses of no/lo drinks.	Model coding and data preparation.	25-36		2a-c		
						4c,d
4c: Estimate the health, health inequality and health economic impact of the intervention.	Mathematical modelling using SAPM, an established policy analysis tool.	7-18	1a-e	2a-c		
			3a-e	4b		4d
4d: Define and appraise the potential impact of no/lo policy options.	Mathematical modelling using SAPM, supported by desk-based scoping and expert consensus exercises as required.	25-48	1a-e	2a-c		
			3a-e	4a-c		

Note: 'Draws on' and 'Feeds into' describe WP interdependencies. Each cell refers to the WP of the same colour and the WP objective noted.

Objective 1a: Co-produce an intervention theory of change (ToC):

Aim*:* To map potential intervention components, interactions within and between these components and the alcohol consumption system, and the multiple direct and indirect mechanisms by which these interactions may produce beneficial and harmful outcomes.

Rationale: The ToC will inform analysis and interpretation throughout the study regarding the contribution of different intervention components to observed changes in outcomes, how those changes connect together across the consumption system, how they are shaped by wider changes in the system, and how outcomes may drive different actors to further develop the intervention. ***Methods:*** Team discussions of prior literature to inform development of skeleton logic models followed by a one-day co-production workshop to populate the ToC in Year 1 and a second workshop in Year 4 to update the ToC based on project findings.

Participants: 15-20 stakeholders including policy-makers, alcohol NGOs, public health practitioners, academics and members of our public involvement groups.

Outputs and deliverables: Initial (Year 1) and updated (Year 4) ToCs comprising logic models that map key intervention and system interactions that create pathways to positive or negative intervention outcomes. One journal article (see Section 9, Research Timetable).

Objective 1b: Establish a timeline of intervention activity

Aim: To establish the nature and timing of industry, government and stakeholder activities that comprise the evolving multi-component intervention from 2011 to 2025.

Rationale: The timeline will permit understanding of the actions taken by stakeholders over time to increase the availability and consumption of no/lo drinks. It will also capture how wider shifts in the alcohol consumption identified in WP2 and WP3 (e.g. consumer trends, emerging consumption practices) shape adaptations in the intervention over time. Alongside the ToC, the timeline will provide the primary bases for developing hypotheses for WP2b time series analyses and WP3b focus group design and methods. It will also inform selection of WP1c and WP1d case studies.

Data Sources: (i) *Market research data:* No/lo sales, purchasing and advertising expenditure data from Nielsen, CGA and KWP (see WP2); (ii) *Trade reports*: We will examine commercial market intelligence reports (e.g. Mintel, EuroMonitor) and trade press publications accessed via existing subscriptions to identify leading or emerging brands, products and producers; (iii) *Desk-based scoping:* We will identify annual shareholder reports, government and stakeholder reports, and relevant press releases, announcements or strategy documents.

Data analysis: WP2a and additional WP1 analyses will provide summary statistics on no/lo sales, purchasing and marketing that describe key time-trends and patterns for specific brands, market segments and the overall market. We will extract, chart and cross-reference data from trade reports and desk-based scoping with market research data to capture the timing and details of relevant activities and contextualise them within the wider market. Key data will examine product launches, sales milestones, changes in marketing, distribution, and strategic partnerships, mergers or buyouts. Beyond industry, key data will include government and stakeholder actions, initiatives or interventions (e.g. duty changes, MUP, revised drink-driving limits) and campaigns (e.g. Dry January). Qualitative data will be summarised using thematic or content analysis with a principle focus on change over time (e.g. type of activity, key dates, stakeholder[s] involved, products or brands, reported or proposed impact). The initial timeline will be constructed inductively using the data and cover 2011 to 2022. Emerging data from WP2 and WP3 capturing important changes in the market and consumer behaviour (e.g. major product launches or shifts in marketing strategies) will be logged and time-stamped. These will then inform updated and final timelines, to be produced in Years 4 and 5 respectively, drawing on deductive analysis of new market research reports as well as WP2 findings.

Outputs and deliverables: An initial (Year 2), updated (Year 4) and final (Year 5) viewable timeline of intervention activity charting key market shifts, government and stakeholders interventions, and consumer responses from 2011 to 2022 (then 2024 and 2025). One journal article (see Section 9, Research Timetable).

Objective 1c: Characterise industry actors' market and corporate political strategies

Aim: To characterise how the market and corporate political strategies of alcohol industry bodies contribute to, emerge from and adapt to the intervention, and the potential public health implications.

Rationale: Producers of unhealthy commodities often launch and promote 'safer' or reformulated products in response to new competition, falling sales or public health restrictions (e.g. controls on pricing, availability or product design).[58,65] These products include e-cigarettes, diet soft drinks and, potentially, no/lo drinks. Such actions are often presented as self-regulation to deter government intervention and protect or rehabilitate industries' reputation and political influence. This allows industries to frame themselves as part of the 'solution' to public health problems rather than the cause. Such activities are less well studied for alcohol companies than for tobacco, food and soft drink counterparts,[66] with key gaps around how individual company strategies reflect their market position, product portfolios and priority brands, and how individual strategies translate into shared goals within trade and social aspect organisations.[67] Addressing these gaps in this project will further understanding of the intervention's system-wide impact and, particularly, the diverse market and corporate political strategies that have contributed to, emerged from or adapted to the intervention.

Data Sources: Industry and market research documents from WP1b and industry responses to three key policy consultations in the UK between 2011-2022. We will select consultations based on their relevance, timing and whether there are responses from the cause study organisations. Consultation of potential interest include the 2016 Drinking Guidelines consultation, 2021 Alcohol Duty Review consultation, and a forthcoming consultation on Scottish alcohol marketing restrictions***.***

Sample: Case studies of 10-15 alcohol industry actors (e.g. producers, retailers, trade bodies) reflecting key dimensions of interest (e.g. size of businesses, product types, marketing strategy).

Data analysis: We will extract and thematically code relevant business strategy data from all sources in NVivo. Data will include direct discussion of market or corporate political strategies in reports and references to no/lo products within consultation responses that may illustrate corporate political strategies. Previous relevant research on market and corporate political strategies of the alcohol and related unhealthy commodity industries that produce safer or reformulated products will inform development of coding frameworks and facilitate comparative analysis analyses.[58,68,69]

Outputs and deliverables: A critical account of whether and how the increased availability and consumption of No/Lo products features in the market and corporate political strategies of commercial actors. Two journal articles (see Section 9, Research Timetable).

Objective 1d: Conduct case studies of no/lo marketing

Aim: To identify and understand how no/lo brands and products are positioned and marketed to consumers, taking account of design, pricing, promotion, placement, positioning and targeting.

Rationale: Analysis of no/lo product marketing will develop understanding of the intervention via critical assessment of the intended use of products (e.g. target consumers and drinking practices), analysis of specific brand strategies, and comparison with business strategies from WP1c. It also allows for analysis of how marketing shapes and is shaped by consumer behaviour (WP2, WP3b).

Sample: WP1b and WP1c will inform purposive selection of 8-10 case study brands that reflect key dimensions of interest (e.g. sales volumes, product/producer type, target market, business strategy).

Data sources: We will use six data types for each case study: (i) *Advertising spend* from Nielson/CGA*,* see WP1b; (ii) *Advertising content:* Samples of creatives for key media channels (e.g. print, broadcast, direct mail) purchased from Nielsen or sampled from company social media accounts; (iii) *Point of sale observations*: Researchers will visit 20 stores in England and Scotland, sampled for diversity in size, ownership, type and location, to complete a structured observational protocol capturing case study brands' availability, placement, pricing, promotions and advertising. Where feasible, we will conduct brief interviews with retailers alongside observations. The interviews will provide insight into their communication with wholesalers and producers (e.g. marketing, deals, bonuses), and perceptions of case study brands' customer base. Sampling will focus on small retailers as our previous work suggests this provides valuable data on diverse communities, particularly those with high levels of deprivation or mixed ethnicities;[70,71] (iv) *Online product listings* sourced manually from leading supermarket and wholesale websites; (v) *Packaging and labelling:* Product samples will be purchased and coded for packaging style (e.g. shape, materials) and labelling (e.g. size, colour); (vi) *Relevant WP1 data* (e.g. trade and shareholder reports).

Data analysis: We will analyse each case study brand separately using basic summary statistics for quantitative data and content analysis for qualitative data. Narrative synthesis of data will provide a multi-faceted account of marketing for each brand. Analyses will particularly address: (i) brand or product design, pricing, promotion, placement; (ii) positioning within (non-)drinking practices informed by WP3b; (iii) portrayals of health or other benefits; (iv) targeting or appeal to particular consumer groups, drawing on WP2 purchasing data; (v) positioning relative to other alcoholic, no/lo and soft drinks, including alibi marketing and (vi) compliance with relevant UK advertising codes.

Output and deliverables: Illustrative case studies capturing the nature of producer and retailer marketing for no/lo products, including traditional, point of sale, business-to-business, online and social media advertising or marketing. One journal article (see Section 9, Research Timetable).

Objective 1e: Develop a taxonomy of no/lo products

Aim: To develop a taxonomy identifying the main categories of no/lo products within and, where appropriate, outside our primary definition (i.e. beers, wines, ciders, spirits <1.2% ABV).

Rationale: Current research approaches to no/lo products are informed by standard alcoholic beverage categories (e.g. beer, wine) and clear distinctions between alcoholic and soft drinks. However, the no/lo market may breakdown these categories in ways that are relevant to public health. For example, Corfe et al. argue no/lo products compete with premium soft drinks in a way that alcoholic drinks do not.[1] Understanding which products to include in public health analyses of no/lo drinks is therefore important for understanding the changing alcohol consumption system.

Data analysis: We will narratively synthesise relevant findings from WP1-3 to identify established and emerging dimensions that differentiate and link no/lo products (e.g. alcohol fermentation and strength-control procedures, associated drinking practices, consumer profiles) as well as how different industry actors and consumers define product categories using these or other dimensions.

Outputs and deliverables: An initial (Year 2) and updated (Year 4) summary report presenting the taxonomy of no/lo products.

3.4. WP2: Monitoring and evaluating the intervention's impact on alcohol consumption.

WP2 will monitor and evaluate the impact of the intervention and specific intervention components on no/lo and standard alcohol availability and purchasing at the population and household-level. With WP3, it will provide detailed analyses of how the intervention is reshaping alcohol consumption and purchasing, the potential benefits and harms to public health, and the potential impacts on health inequalities. WP2 also provides the key inputs for WP4 harm and policy modelling. WP2 uses four key datasets, including market research data purchased for this project and a long-running survey.

Nielsen, CGA and Kantar market research datasets and the Alcohol Toolkit Study

Nielsen will provide weekly, population-level data on off-trade sales values and volumes (in ml of product and alcohol units) for no/lo and standard alcohol drinks. The highly detailed data are disaggregated into stock-keeping units (SKUs: i.e. distinct items for sale, such as 6 x 275ml Becks Blue) and split by geographic region (Scotland, English regions, Wales & South-West). Nielsen only sell data from the previous three years, so the project will purchase the weekly data for 2019-2021 at start-up and then 2022-2025 data at annual intervals. See Thorpe et al. for Nielsen's methods.[72]

CGA will provide analogous weekly, population-level data on on-trade sales values and volumes (ml of product and alcohol units) for no/lo and all standard alcohol beverage types. The data can be split by England, Scotland and Wales but, to manage costs, we will only purchase no/lo data at SKU level. CGA will also provide weekly data on the number of on-trade outlets selling each no/lo SKU. CGA's service provides data from October 2016 onwards, so the project will purchase the weekly data for 2016-2021 data at start-up followed by 2022-2025 annually. Methods are similar to Nielsen.

Kantar World Panel (KWP) is a longitudinal, household-level panel dataset comprising N≈30,000 households who scan barcodes of all purchased items brought into the home each day while they are panel members. The sample is representative of British households, with continuous replenishment for attrition. KWP data for the last five years include 4.5m alcohol purchases of which 55,000 (1.2%) are no/lo purchases. The project will purchase a dataset comprising the price-paid, volume (ml of product and alcohol units) and SKU of all no/lo and standard alcoholic drinks purchased by each household. The cost of data decreases with age, so the project will purchase

2018-2021 data at start-up and 2022-2024 data in 2025, and 2025 data in 2026. See Anderson et al. for KWP methods.[19]

The ***Alcohol Toolkit Study (ATS)*** is a monthly cross-sectional survey of N≈1,700 adults in Great Britain and includes questions related to alcohol consumption.[73] We will purchase four new questions in each quarter each year asking how often people consume no/lo drinks overall, alongside standard alcoholic drinks, in the off-trade and in the on-trade. Questions will be co-produced with our public involvement groups. WP3a will purchase further no/lo-related questions (see below).

Nielsen, CGA, KWP and ATS data are key resources for the WP1b timeline, WP2 monitoring and evaluation, WP3 analyses of reduction attempts and WP4 modelling. Each has been used previously for policy evaluation and appraisal.[74-76] They are the best available data sources for trends in alcohol sales, purchasing and consumption,[72,77] and are the only sources to provide detailed data on no/lo drinks. The ATS is the best available survey for purchasing new questions, given its high frequency, rapid data delivery (i.e. one month) and accompanying questions on wider alcohol use. With regard to other potential data sources, there is no household-level equivalent to KWP covering the on-trade and HMRC alcohol duty data are unsuitable as no duty is paid on no/lo drinks. Public Health Scotland hold aggregated (i.e. non-SKU) Nielsen data for 2009 onwards and we have agreed to explore options for joint analyses of this longer time series, subject to their contract with Nielsen.

Objective 2a: Describe and monitor trends in no/lo availability, sales and purchasing.

Aim: To describe and monitor trends in availability, sales and purchasing of no/lo products across the population and within population subgroups, and to respond flexibly to stakeholders' data needs.

Rationale: Stakeholders require more surveillance data on no/lo-related trends to inform their work, including ongoing policy development. WP1b-d and WP4 also require this data to inform the intervention timeline, case studies of marketing and business strategies, and model inputs.

Measures: We will develop and update annually a key outcome set for descriptive trend analyses of the Nielsen, CGA, KWP and ATS datasets in consultation with our advisory group. Primary outcomes may include: (i) Total weekly sales volume in ml of product for no/lo and standard alcoholic drinks; (ii) Proportion of weekly total alcoholic drink sales volume in ml of product accounted for by no/lo drinks; (iii) Proportion of households purchasing no/lo products per week and (iv) Number of outlets selling no/lo products per week. Each outcome will be split where feasible by beverage type, on/off-trade sector and household characteristics (e.g. size, social grade, alcohol purchasing vs. non-alcohol purchasing). Secondary outcomes may address price per ml of product, frequency of purchasing and ranking of leading SKUs or brands by sales volume and value.

Data analysis: We will use descriptive analyses to produce data visualisations and tables of summary statistics (e.g. means, SDs, rankings) over time and by population subgroup. We anticipate using weekly or monthly data points on graphs and quarterly or annual data points in tables.

Output and deliverables: Four publicly available annual reports summarising key trends in no/lo availability, sales and purchasing. One journal article (see Section 9, Research Timetable).

Objective 2b: Evaluate the impact of intervention activity on no/lo and alcohol consumption.

Aim: To evaluate the impact of the intervention and its components on retail availability, sales and purchasing of no/lo and standard alcoholic drinks, across the population and population subgroups.

Rationale: WP1b will identify the timing, nature and scope of key intervention components, including product launches, commercial and social marketing campaigns, and business acquisitions. These components may affect broad outcomes (e.g. total no/lo sales) or narrow ones (e.g. single product sales or purchasing by specific subgroups). The effect may also be immediate, progressive or lagged, and independent of, cumulative with, or contingent on other intervention components. A broad, flexible and iterative series of analyses is therefore required to support evaluation of how the intervention as a whole and individual intervention components impact on outcomes and, importantly, produce system feedback that shapes ongoing or future intervention components.

Hypotheses: We will draw on our theory of change (WP1a), timeline of intervention activity (WP1b) and advisory group to design and prioritise hypotheses for formal statistical testing. These will specify the intervention components of interest, the anticipated timing of effects, and any interactions with other intervention components. Example hypotheses include: H_1: Heineken's 'Now you can' campaign for Heineken 0.0 and advertising of Heineken 0.0 during the Euro 2020 football

championships led to an immediate increase in no/lo beer sales volume in general, Heineken 0.0 sales volume in particular, and also sales of standard Heineken. *H_2*: Dry January and associated promotion of no/lo drinks leads to an immediate and partially sustained increase in no/lo sales volume and proportion of total alcohol sales accounted for by no/lo drinks each year. This effect is larger in affluent and higher purchasing households; *H_3*: Increased on-trade availability of no/lo drinks is associated with gradual and sustained increases in no/lo sales volume. *H_4*: Changes in real-terms alcohol taxation are associated with immediate increases in prices and reductions in sales volumes for standard alcoholic drinks, and increases in the proportion of alcohol sales that are no/lo.

Data analysis: We will test hypotheses primarily using univariate, bivariate and interrupted times series models (Nielsen and CGA). Time series models will typically use autoregressive integrated moving average (ARIMA) methods.[78] For example, for *H_1*, we would use an interrupted time series design, with two intervention points (campaign start and Euro 2020 start), a specification to capture immediate (step) changes and ongoing (slope) effects, and adjust each model for autocorrelation in the outcomes. For *H_3*, we would use a dynamic regression model with tests for lagged predictors to estimate the association between the intervention (availability) and outcome (sales) time series. We would include standard ARIMA controls so that sales are a function of both current and past availability, capturing the assumption that consumers will move gradually to a new product. The model fitting process will examine patterns of autocorrelation using (partial) autocorrelation function plots to select initial AR, I, and MA specifications. It will then use an iterative process of examining model residuals and fit statistics to select appropriate final specifications and assess whether the resulting residuals resemble white noise. Where feasible, we will also use fixed effects panel regression models in KWP to explore moderating effects of household characteristics on intervention impacts. We will iteratively update some analyses as new data or WP1 findings become available.

Output and deliverables: Quantified estimates of the effects of the intervention and intervention components prioritised by stakeholders on key outcomes, including no/lo and alcohol consumption. Four journal articles reporting results for specific hypotheses (see Section 9, Research Timetable).

Objective 2c: Evaluate whether increasing no/lo consumption reduces alcohol consumption.

Aim: To evaluate whether increased sales or purchasing of no/lo drinks leads to reduced sales or purchasing of standard alcoholic drinks at the population- and household-level.

Rationale: The primary mechanism by which no/lo drinks may improve public health is through drinkers reducing their alcohol consumption by substituting no/lo drinks for standard alcoholic drinks.[41] This substitution mechanism may be general or specific to brands (e.g. Heineken and Heineken 0.0) or beverage types (e.g. beer and no/lo beer). It may also change over time as the market develops and vary between population groups (e.g. by socioeconomic status), with implications for the intervention's long-term effectiveness and impact on health inequalities.

Data analysis: The population-level analysis will use bivariate time series analyses of off-trade (Nielsen), on-trade (CGA) and pooled (both) datasets. We will use the same dynamic regression model with tests for lagged predictors as proposed for *H_3* in WP2c. The household-level analysis will use the KWP data in a fixed-effects instrumental variable regression approach, using two-stage least squares models. First, for each geographic region we will create indices of: (i) no/lo availability – number of unique SKUs purchased per region; (ii) no/lo price by beverage type (e.g. price per ml of product for no/lo beer) and (iii) standard alcoholic drink price – price per unit of alcohol. Second, we will compare the indices to the Nielsen data to assess comparability of the datasets and draw on WP2a-b results to understand how no/lo purchasing varies with standard alcohol purchasing. Third, we will run the first-stage regression to link households' no/lo purchasing to the three regional indices (either from KWP or Nielsen). The second-stage regression will then use the estimates of no/lo consumption generated by the first-stage as instruments, and will generate our main results by regressing standard alcohol purchasing against these instruments and a set of potentially time-varying control variables (e.g. household size, income, age of main shopper). In secondary analyses, we will explore the feasibility of estimating substitution effects for beverage types and specific brands. We will also test for moderating effects of household characteristics (e.g. socioeconomic status, baseline purchasing) and will update our analyses using new data in Year 3-4, adding 'year' as a moderator to test whether substitution effects change over time as the intervention evolves.

Outputs and deliverables: Substitution elasticities capturing the impact of an increase in volume of no/lo drinks purchased (e.g. +1L) on the number of units of alcohol purchased (e.g. -1.8 units). Two journal articles (see Section 9, Research Timetable).

3.5. WP3: Understanding changes in alcohol consumption and unintended outcomes.

WP3 will draw on primary research and WP2 results to understand how individuals' attempts to reduce their alcohol consumption are adapting to include use of no/lo drinks, the emergence of new no/lo drinking practices and how people are adapting existing drinking and non-drinking practices to integrate no/lo products. In doing so, it will explore potential unintended benefits and risks of the intervention and its components for the general population and key vulnerable groups. It will also examine how no/lo-related marketing, beliefs and consumption practices shape and reshape each other. This will provide evidence to support further characterisation of the intervention in WP1 and contribute to developing additional scenarios for analysis of health-related outcomes in WP4.

Objective 3a: Understand how no/lo drinks support individual attempts to reduce drinking

Aim: To use the theory of planned behaviour (TPB)[79] to understand the role of no/lo consumption and beliefs in attempts by adult drinkers to reduce their alcohol consumption, and the moderating role of individuals' sociodemographic characteristics.

Rationale: One-third of recent no/lo consumers used no/lo drinks to help reduce their alcohol consumption,[1] and the perception that no/lo drinks support reduction attempts also underpins their promotion through Dry January and the mindful drinking movement. However, no study has explored the role of no/lo consumption in reduction attempts or how personal characteristics and beliefs influence no/lo consumption. This matters as WP2c substitution effects may be higher if no/lo drinks support reduction attempts. Similarly, intervention components identified in WP1 may shape no/lo beliefs in ways that support or undermine its use to reduce alcohol consumption.

Data: We will use pooled cross-sectional data from the Alcohol Toolkit Study (ATS, see WP2). The project will purchase five new questions in four consecutive quarterly ATS waves across Years 1 and 2. We will co-produce and pilot these questions with our public involvement groups. The questions will measure participants': (i) success in their most recent attempt to restrict consumption; (ii) attitudes towards no/lo consumption; (iii) perceived behavioural control over no/lo consumption; (iv) perceived injunctive social norms regarding no/lo consumption and (v) intentions to consume no/lo drinks. We will also extend existing ATS questions on motives for recent reduction attempts, and tools used in attempts, to all drinkers (currently only risky drinkers answer these questions).[73]

***Power calculation*:** We calculated the number of months required for a sufficient sample using Stata's *powerlog* package. Assuming 25% of participants attempting to restrict their consumption are successful,[80] we need 996 participants who have made a reduction attempt to detect a five percentage point increase in the success rate among no/lo consumers vs. non-consumers in a logistic regression. N≈250 ATS participants per month report a serious reduction attempt, meaning we need four survey waves. We anticipate N≈1,600 no/lo consumers across four waves,[1] which is sufficient to detect weak indirect effects in a structural equation model restricted to this group.[81]

Data analysis: We will undertake two analyses. First, a *logistic regression* will test the association between successful alcohol consumption reduction attempts (dependent variable) and no/lo consumption, use of no/lo drinks to reduce consumption (independent variables), sociodemographic characteristics and scores on the short-form Alcohol Use Disorders Identification Test (AUDIT-C[82], control variables). Second, a *pathway analysis using structural equation modelling* (SEM) will first test mechanisms through which alcohol consumption, motivation to reduce consumption, no/lo-related beliefs and intention to cut down are associated with at least monthly no/lo consumption in the whole sample. We will then extend this model to investigate how the same mechanisms explain whether those who attempted to restrict consumption were successful in doing so. The TPB informs the measures and structure of the SEM and we will fit a covariate-controlled model that includes direct pathways between sociodemographic characteristics (e.g. sex, age and socioeconomic status) and all other modelled variables.[83] Key goodness of fit measures will be RMSEA, AIC, BIC, CIF, TLI. Sensitivity analyses will: (i) use at least weekly rather than at least monthly no/lo consumption as the outcome and (ii) restrict the analytical sample to no/lo consumers to assess how much pathways are driven by non-consumers of no/lo drinks.

***Output and deliverables*:** Relationships between alcohol and no/lo consumption, TPB constructs, and successful reduction attempts. Two journal articles (see Section 9, Research Timetable).

Objective 3b: Explore how people embed no/lo drinks in everyday practices.

Aims: To understand how intervention components interact with emerging no/lo drinking practices and adaptations of existing drinking and non-drinking practices. To explore differences in these processes across key populations and how they generate potential benefits, risks or opportunities.

Rationale: Our previous work demonstrates how ideas from social practice theory can support analyses of the dynamic, interactive relationships between public health interventions, everyday activities and the ways and contexts in which those activities are performed.[84,85] In particular, our work emphasises examination of the role played in the emergence, evolution and decay of drinking and non-drinking practices by materials, such as no/lo drinks, and shared social meanings associated with those materials (e.g. generated by marketing). We will combine these insights with potential pathways to positive or negative effects from no/lo drinks (WP1a) and identified intervention activity and no/lo marketing (WP1b, WP1d) to understand how processes of embedding no/lo drinks in everyday practices may generate benefits, risks or opportunities for particular population groups. We will also consider how these processes contribute to reshaping intervention components.

Design: Cross-sectional qualitative focus group research. We will collect data in two waves across Year 2 and Year 3 to allow the work to respond flexibly to stakeholders' changing evidence needs.

Sample: The advisory group will determine the sample composition at each wave based on their evidence needs. We initially propose recruiting from six target groups to provide diverse perspectives: (i) 13-17 year-olds – friendship group interviews; (ii) parents of 13-17 year-olds; (iii) young adults aged 18-25; (iv) pregnant women and recent mothers; (v) high risk drinkers aiming to reduce their alcohol consumption and (vi) people in recovery from alcohol dependence. Where appropriate, topic guides will address questions to participants as members of the general adult population as well as members of target groups. We initially propose conducting four friendship group interviews with 13-17 year-olds and two focus groups with each of remaining target groups in England (Sheffield) to support DHSC policy development. We will also conduct four additional focus groups in Scotland (Central Belt) with participants selected according to stakeholder priorities. Each group will aim to include 4-8 participants for a total sample of N≈108 participants across 18 groups.

Recruitment: We will recruit most participants via a market research agency. For those in recovery, we will recruit through established relationships with practitioners. All groups will aim for diversity with regard to gender, age, ethnicity and socioeconomic status. Participants will be given a £40 shopping voucher (£25 for 13-17 year-olds) in recognition of their time and any travel expenses.

Data collection*:* Topic guides will be co-produced with public involvement groups with reference to the WP1a theory of change, social practice theory concepts, relevant literature and emerging project findings, particularly WP1d case studies of advertising. All topic guides will explore participants' perceptions, beliefs and experiences of whether, why and how no/lo drinks are (or are not) embedded into everyday practice. This includes exploring: (i) understandings and perceptions of different no/lo drinks; (ii) how and why people do and do not consume no/lo drinks, drawing on WP1d marketing examples; (iii) experimentation with no/lo drinks, including motivations and influences on drink choice; (iv) the types of no/lo drinks (not) consumed in different contexts and why; (v) perceived changes in participants' and others no/lo-related behaviours over time and (vi) perceived benefits or risks of no/lo drinks. Topics will be adapted and expanded to each of the target groups as appropriate (e.g. parents of 13-17 year-olds will explore parenting practices around alcohol). Given limited prior research, topic guides will also be updated within and between data collection waves based on emerging findings. Groups will last 60-90 minutes, be audio recorded and transcribed for analysis.

Data analysis: Transcripts will be imported into NVIVO, read and re-read to ensure familiarity before coding. We will then use a deductive approach to derive a thematic coding structure based on social practice theory and the WP1a ToC. Hughes and O'Donnell will work in a team-based approach to develop an initial coding frame, including deductive codes informed by theory and inductive codes grounded in the data.[86,87] Codes will be reviewed and emerging concepts used to develop additional themes during analysis. A constant comparative method will support further refinement, whereby researchers compare each interpretation and finding with existing findings.[88] We will compare data within each target group and also between groups to identify common and divergent themes.

Outputs and deliverables**:** A report summarising and highlighting new no/lo consumption practices, adaptations to existing practice, pathways to beneficial or harmful effects, and interactions with marketing and other intervention activity. Two journal articles (see Section 9, Research Timetable).

WP4: Evaluating the intervention's impact on harm and appraising policy responses.

WP4 will draw on WP1-3 findings to adapt an established policy analysis tool, the Sheffield Alcohol Policy Model (SAPM),[74] to evaluate the impact of the intervention on alcohol-related harm, health inequalities and health economic outcomes. Analyses will consider direct impacts of increased no/lo consumption on individuals' alcohol consumption, but also the impact of wider positive and negative effects seen in WP1-3. WP4 will also provide policy appraisals in response to stakeholders' evidence needs and a review of international approaches to regulating the marketing and sale of no/lo drinks.

Objective 4a: Summarise international policies related to no/lo drinks.

Aim: To summarise international policies relating to the marketing, sale or consumption of no/lo drinks, including definitions, restrictions or promotion.

Method: A desk-based policy review of jurisdictions in English-speaking OECD countries (i.e. US, Canada, UK, Ireland, Australia, New Zealand) and selected European countries guided by our advisory group (e.g. Norway, France, Germany, Russia). Policies will be identified via online searches and by drawing on our extensive international networks. We will synthesise identified information for each element of policies identified as potentially relevant for public health regulation.

***Output and deliverables*:** A summary of international policies related to no/lo products, including regulation and government initiatives. These policies will subsequently be discussed in deliberative activities by our public involvement groups. One journal article (see Section 9, Research Timetable).

Objective 4b: Adapt the Sheffield Alcohol Policy Model to allow analysis of no/lo drinks.

Aim: To adapt SAPM to incorporate the most recent data on no/lo consumption and purchasing and develop a new SAPM-no/lo for England that permits economic evaluation and policy appraisal.

Rationale: Model-based evaluations can estimate the impact of observed proximal intervention outcomes (e.g. alcohol consumption) on unobserved distal outcomes (e.g. alcohol-attributable mortality). SAPM is an established policy analysis tool, developed by the research team, that we have used in previous alcohol policy evaluations and appraisals, and for projecting future alcohol consumption and harm scenarios.[74,89,90] It permits estimation of multiple health and health economic outcomes (e.g. mortality, hospitalisation, NHS costs) for given distributions of alcohol consumption within subgroups defined by gender, age, socioeconomic status and consumption level, alongside aggregated estimates for the population. SAPM consists of two distinct modules: (i) an individual econometric simulation that estimates the impact of a policy on alcohol purchasing and consumption by simulated adults in England for ten beverage categories (e.g. off-trade beer, on-trade wine); (ii) an epidemiological cohort model that estimates the impact of changes in alcohol consumption on alcohol-related mortality and hospitalisations for 45 acute and chronic health conditions, resulting changes in the demographic structure of the population, and associated NHS costs. SAPM is stratified throughout by age, gender, socioeconomic status and level of drinking to account for substantial variation across these groups in alcohol consumption, spending and related health risks.

Data sources: SAPM-no/lo will require updated data from key sources to provide its baseline scenario: Health Survey for England (HSE, alcohol consumption), Living Costs and Food Survey (LCSF, alcohol purchasing and prices), Hospital Episodes Statistics (HES, hospitalisations) and ONS mortality data (alcohol-attributable and other causes). WP2 will provide evidence on consumption trends and substitution elasticities between no/lo and standard alcoholic drinks.

Model adaptation: We will update the SAPM infrastructure to produce two adaptations that permit appraisal of new no/lo beverage categories. The first adaptation will incorporate a new front-end to SAPM that enables inputting of changes in no/lo consumption and uses the substitution elasticities to obtain interim outputs in terms of changes in alcohol units consumed. The second adaptation will incorporate two new beverage categories: off-trade no/lo and on-trade no/lo, both measured in ml of liquid not units of alcohol. We also considered adaptation to additional no/lo beverage categories (e.g. off-trade no/lo beer), but our data exploration to date suggests that purchasing volumes may be insufficient to allow robust modelling of these product types in each population subgroup.

Outputs and deliverables: A model adaptation, SAPM-no/lo, allowing evaluation and appraisal of no/lo-related policies. One journal article (see Section 9, Research Timetable).

Objective 4c: Estimate the health, inequality and health economic impact of the intervention.

Aim: To use the adapted SAPM-no/lo to estimate the impact of increased availability and consumption of no/lo drinks on alcohol-related mortality, hospitalisations, health inequalities across socioeconomic groups, healthcare costs and Quality Adjusted Life Year (QALY) losses.

Modelling methods: First, we will use WP2 data and analyses to estimate current levels of no/lo purchasing and consumption, and assign this to individuals in SAPM-no/lo. We will compare two methods for assigning the KWP household-level purchasing data to individuals as consumption: (i) Using ATS data on individuals' no/lo consumption and sociodemographics to generate an assignment method and (ii) Using methods and assumption we have used previously to combine LCFS household purchasing data with HSE individual consumption data.[91] Second, we will use the WP2c substitution elasticities to generate a counterfactual for each individual in SAPM that describes their standard alcohol consumption if they did not consume no/lo drinks. This leads to two main analyses. Analysis 1: Aggregate substitution elasticities from Nielsen/CGA: We will use off-trade substitution elasticities from Nielsen to calculate the impact on each individual's total alcohol consumption of reducing their off-trade no/lo consumption to zero. We will then further reduce individuals' total consumption based on their on-trade no/lo consumption and on-trade substitution elasticities from CGA. Analysis 2: Household-level substitution elasticities from KWP: We will draw on WP2c analyses of KWP data showing how substitutions elasticities vary across population subgroups (e.g. socioeconomic status). The basecase analysis will use the same approach as Analysis 1, but adjust Nielsen and CGA substitution elasticities using KWP estimates of variation across subgroups. A sensitivity analysis will then replace the population-level Nielsen substitution elasticities with the household-level equivalents from KWP. Within each analysis, the existing epidemiological module of SAPM will estimate the health and health economic outcomes associated with current alcohol consumption (with no/lo) and compare this to outcomes in the counterfactual scenario (without no/lo) to give the overall estimated health impact of increased no/lo consumption. SAPM automatically reports results by population subgroups, providing insights into health inequalities. Further scenario analyses will model wider beneficial or harmful intervention effects informed by WP1-3 findings (e.g. no/lo increases underage drinking and thus increases future adult consumption or marketing primarily targets low risk drinkers). Scenarios will be modelled as substitution elasticities with delayed effects of affecting specific subgroups. These can be incorporated using SAPM's existing infrastructure (e.g. as used for incremental modelling of pricing policies[92]). We will prioritise scenarios in consultation with the advisory group and, where quantified estimates are unavailable, develop these through expert elicitation (see WP4d).

Outputs and deliverables: Estimates of the direct and wider intervention impact on health, health inequalities and health economic outcomes. Two journal articles (see Section 9, Research Timetable)

Objective 4d: Define and appraise the potential impact of no/lo policy options.

Aim: To work with key stakeholders, including DHSC and Scottish Government, to define and appraise using SAPM-no/lo the potential impact of up to four specific no/lo policies on alcohol consumption, alcohol-related harm, health inequalities and health economic outcomes.

Rationale: As described in Section 1.3, DHSC are currently consulting with stakeholders on policy options for further increasing the availability and consumption of no/lo drinks. The Scottish Government may also propose policies relating to no/lo drinks following their review of alcohol marketing. We will undertake up to four policy appraisals specified and agreed by key stakeholders during Years 3 and 4, after completing WP1b model adaptations.

Modelling methods: Parameters describing the changes in no/lo consumption associated with new policies will be based on evidence where available. If no direct UK or international evidence is available, we will use formal expert elicitation of effects, including uncertainty.[93,94] The composition of expert groups will depend on the policies selected. We will provide participants with a briefing on the proposed policy and implementation plan, and then ask them to estimate how much additional no/lo consumption would increase over time. Potential policies appraised could include: (i) changes in the proportion of shelf-space allocated to no/lo drinks based on experimental data;[45] (ii) requiring display of no/lo products in pubs based on expert elicitation; (iii) health promotion or social marketing campaigns, potentially drawing on WP2 findings and (iv) giving advice on no/lo consumption during alcohol brief interventions by different professionals based on expert elicitation. We do not currently plan to include analysis of alcohol taxation policies in policy appraisals for this project as this will be the subject of a separate grant applications following on from the NIHR-funded SYNTAX project.

Outputs and deliverables: Summary reports of four appraisals of no/lo policies requested by stakeholders. One journal article (see Section 9, Research Timetable).

4. Synthesis of project findings

We will integrate and synthesise findings from across the WPs to develop a coherent and overarching interpretation of the contribution made by intervention components to evolving outcomes and processes across the alcohol consumption system.[63] The synthesis will draw on the principles of realist evaluation, and specifically the ideas of programme theory and Context-Mechanism-Outcome (CMO) configurations.[95] The WP1a theory of change will underpin the synthesis by providing a basic description of our programme theory capturing how, and in which contexts, the increased availability of no/lo products will lead to particular outcomes. We will use this programme theory to develop a set of specific questions that the synthesis seeks to answer, thus narrowing the scope of each synthesis task and the extent of complexity that each task must address. The questions will be agreed and refined in consultation with our Advisory Group. For each question, we will identify and tabulate relevant evidence from across the project to develop one or more CMO configurations, describing the context in which the intervention produced particular outcomes and the mechanism(s) driving those outcomes. The tabulated evidence will include statements of evidence from each WP referenced to research outputs to ensure transparent reasoning. We will then construct narrative descriptions of the findings for each synthesis question and use these descriptions to develop overall conclusions on the impact of the intervention. We anticipate this realist approach will support both unpacking of the multiple system-wide outcomes of interest and also description of the complexity within that system.[96] As such, it will allow us to provide the strongest possible basis for drawing causal inferences regarding the direction and magnitude of intervention effects, and the pathways and mechanisms to beneficial or harmful outcomes the findings support.[97] It will involve triangulation of qualitative and quantitative evidence, as well as interpretation of convergent or divergent findings.

The project design supports successful synthesis by: (i) co-producing with stakeholders a comprehensive theory of change in Year 1 that will underpin appraisal of findings across WPs; (ii) monthly Project Management Group meetings to maintain an overview of emerging data, research questions and findings, which will then enable layering and testing of insights across the study; (iii) quarterly Advisory Group meetings to provide independent expert and public input, reduce risks of group-think in the research team, and ground emerging findings in stakeholder experiences and priorities; (iv) annual full team meetings, potentially including stakeholders, with a mini-conference format to discuss, reflect on and critically assess interpretations of emerging findings and ensure later data collection and analyses reduces uncertainties; (v) peer review of methods through submission of journal articles and (vi) a Year 4 workshop to facilitate deeper stakeholder input into interpretation of findings and implications for the theory of change.

Although realist evaluation is a well-established methodology, its application to natural experiments using a ‘complex intervention in complex system’ perspective remains novel and synthesis methods in this area are generally in their infancy.[98] We will therefore draw on emerging guidance and practice to optimise our approach and are well-placed to do this. Fitzgerald is an advisor to the group currently revising MRC guidance on using natural experiment to evaluate public health interventions and will have early insight into emerging principles and methods.

5. Dissemination, outputs and anticipated impact

The outputs for each WP are described above and in the Research Timetable in Section 9. The primary beneficiaries of these outputs will be UK and devolved government policy-makers, who will receive actionable evidence to support ongoing policy development, implementation and evaluation. This includes the UK Government, which has committed to increasing the availability and consumption of no/lo drinks by 2025, and the Scottish Government, which is developing a new alcohol marketing strategy that will address no/lo drinks. Other beneficiaries include (i) public agencies (e.g. Office for Health Improvement and Disparities [OHID], Public Health Scotland, Public Health Wales, local governments), who require evidence on no/lo drinks to inform surveillance functions, policy analyses and health promotion activities; (ii) alcohol and public health charities, who require evidence on the public health impact of no/lo products to inform health promotion activities and advocacy strategies; (iii) the public who want to know whether no/lo drinks can help them drink less alcohol and if there are risks for some population groups; (iv) health professionals who may wish to recommend no/lo drinks to patients drinking at risky levels; (vi) international public health

stakeholders who require evidence similar to UK counterparts; and (vii) academics in public health and related disciplines who require evidence to identify priority research questions.

Central to the project's dissemination approach is our Advisory Group (AG), which will meet online each quarter throughout the project. The AG will include 15-20 members, with representation from key UK stakeholders who provided letters of support to the project (e.g. DHSC, Scottish Government, OHID, Public Health Scotland, Alcohol Focus Scotland, Alcohol Change UK). It will also include three members of the public (see Public Involvement) and academics with relevant expertise. The AG will immerse and engage key project beneficiaries in the work throughout the study, provide opportunities to shape the research (e.g. WP1 Theory of Change, WP2 key outcome set and hypotheses, WP3 target focus group participants and topic guides, WP4 responsive policy appraisal), discuss relevant developments in research, public or policy spheres and offer early access to findings. AG will also generate engagement opportunities with individual stakeholders.

Beyond the AG, we will develop a formal dissemination plan, which we anticipate including engagement of professional and academic stakeholders via: (i) annual webinars showcasing findings and other outputs; (ii) annual reports summarising WP2a monitoring data for the key outcome set; (iii) policy briefings in parallel with AG meetings; (iv) presentations at practitioner and NGO conferences and (v) academic publications, reports and conference presentations. We will engage public stakeholders via: (vi) press releases and associated media interviews for key findings; (vii) social media activity via personal, project and institutional accounts; (viii) a project website providing background information, project activity, summaries of findings and links to outputs; (ix) and organising events with public engagement experts (e.g. Pint of Science, ESRC Festival of Social Science). The research team are well-equipped to deliver these activities given their excellent, international academic, policy and practitioner networks and extensive public and professional dissemination experience across wide-ranging formats established through previous high impact policy research programmes (e.g. MUP, low-risk drinking guidelines, plain packaging for tobacco).

We anticipate the main impact of the dissemination programme may include: (i) direct informing of policy decisions by the UK and devolved Governments; (ii) shaping alcohol and public health charities' policy positions and activities related to no/lo drinks; (iii) informing of public and policy debate internationally around no/lo drinks; (iv) improved understanding across all public and professional stakeholders of the emerging no/lo drinks market, the associated consumption behaviours and their public health impact; (v) more effective attempts to reduce alcohol consumption among members of the public, and avoidance of risks associated with no/lo drinks; and (vi) generation of new research projects in this and related areas within and beyond the research team.

The background intellectual property used in the project is held by (i) Nielsen, from whom we will purchase off-trade sales data under a contract that allows unrestricted and free right to use the data; (ii) CGA, from whom we will purchase on-trade sales data under a license allowing unrestricted and free use for the purposes of this project; (iii) Kantar, who will provide the Kantar World Panel data under a non-disclosure agreement allowing unrestricted use of the data for the purposes of this project; (iv) University College London, who will permit unrestricted and free use of the Alcohol Toolkit Study data for the purposes of this project and (v) University of Sheffield, who will permit unrestricted and free use of the Sheffield Alcohol Policy Model for the purposes of this project.

6. Project management and governance

Holmes will provide overall project leadership alongside leads for WP1 (Fitzgerald & Stead), WP2 (Pryce), WP3 (Kersbergen), WP4 (Brennan) and PPI (Perman-Howe & O'Donnell). The project will have a dedicated Project Manager (non-CI Johnson) to support governance and compliance, in addition to communication and dissemination planning, and monitoring timelines, risks and budget. A project management group (PMG) including experienced research leaders (Holmes, Brennan, Fitzgerald, Stead,), early career researchers (Kersbergen, Pryce, Perman-Howe, O'Donnell) and a professional project manager (Johnson) will meet monthly and the full team will meet quarterly. The PMG will agree policies on authorship, open science and data management. Perman-Howe and O'Donnell will meet fortnightly during active periods with Holmes, Johnson and relevant WP leads to ensure appropriate supervision of PPI activity. An advisory group (AG) chaired by Holmes will provide independent insight and advice to the research team (see Section 5). A subset of AG members, including public and third sector representatives will form a Study Steering Committee and meet annually throughout the project.

Primary ethical approval will be sought from the University of Sheffield and this will include a data management plan (DMP). Additional approvals will be sought from collaborator universities as appropriate. We will obtain full informed consent from all participants in primary research and anonymise all participants within interview transcripts and research outputs. There are specific ethical concerns regarding the WP3b focus groups, and particularly those with 13-17 year-olds, high risk drinkers, pregnant or recently pregnant women, and those in recovery from alcohol dependence. Hughes and O'Donnell will lead these focus groups and both have extensive experience of primary qualitative research on alcohol- and addiction-related topics (e.g. interviewing people presenting for treatment for alcohol dependence; focus groups with fathers who smoke at home). All primary and secondary data will be managed in accordance with GDPR and university procedures. As project manager, Johnson will be responsible for implementation of the DMP with support from Holmes.

7. Project and research expertise

The research team for this large, complex and methodologically diverse project comprises 18 researchers to ensure all required skillsets are available. We summarise the expertise and responsibilities of the Project Management Group here. The Justification for Costs details the full team and supervision responsibilities. **Holmes** (PI, Sheffield, 20%fte) is Prof of Alcohol Policy, Director of the Sheffield Alcohol Research Group and Director of the Wellcome Doctoral Training Centre in Public Health Economics and Decision Science (PHEDS). He has an international reputation for alcohol policy research that achieves the highest levels of scientific and policy impacts, including analyses of minimum unit pricing and low risk drinking guidelines. **Fitzgerald** (Stirling, 10%fte) is Prof of Alcohol Policy, Director of the Institute for Social Marketing and Health and Co-Director of the UKPRP SPECTRUM consortium. She currently leads two NIHR-funded mixed methods, natural experiment studies of alcohol licensing (ELEPHANT, EXILENS). Fitzgerald will co-lead WP1. **Stead** (Stirling, 5%fte) is the Deputy Director of ISMH, PI for Stirling's participation in the Public Health Policy Research Unit and led an evaluation of the impact of MUP on small retailers. Stead will also co-lead WP1. **Pryce** (Sheffield, 25%fte) is a Research Fellow with expertise in health econometrics, including modelling industry responses to alcohol taxes. He will lead WP2. **Kersbergen** (Sheffield, 50%fte) is a Research Fellow and Society for the Study of Addiction Academic Fellowship holder with expertise in mixed methods health psychology research on alcohol and food. She will lead WP3. **Brennan** (Sheffield, 5%fte) is Prof of Health Economics and Decision Modelling, co-Director of PHEDS, co-Investigator on the NIHR-School for Public Health Research and leads an internationally renowned group of 35 academics undertaking methodological and applied mathematical modelling research. Brennan will lead WP4. **Perman-Howe** (KCL, 5%fte) is a post-doctoral Research Associate with experience in researching no/lo drinks and public involvement work in the SPECTRUM consortium. She is PPI lead for the project, supported by Holmes. Non-CI **Johnson** (Sheffield, 40%fte) is an experienced project manager and will lead on project management.

8. Success criteria and barriers to proposed work

The project's key success criteria are (i) delivery of high quality research outputs, evidenced by publication and citation within journals, and invitations to speak at scientific and practitioner conferences and other dissemination forums; (ii) effective public engagement evidenced by engagement metrics for news and social media outputs; (iii) sustained stakeholder engagement, evidenced by consistent high attendance at AG meetings and two-way communication outside meetings; (iv) ability to support stakeholder needs, evidenced by co-produced research activity that informs policy and practice decisions; (v) effective public involvement, evidenced by sustained engagement of PPI participants and (vi) successful exploitation of the project's research platform, evidenced further related funding awards, including using the datasets purchased via this project. We are ideally placed to overcome the potential barriers to the proposed work as follows:

Problems with market research data (Unlikely, high impact)***:*** The Nielsen, CGA and KWP datasets are key project requirements, so delayed receipt, poor data quality or providers withdrawing from contracts are key risks. We have established relationships over 10 years with all providers and have experienced no previous problems in these areas. Other public health clients report similar experiences (e.g. Public Health Scotland). Each company has a dedicated team for supporting the distinct needs of academic research. We know from experience that dataset deliveries are often iterative to ensure specifications are met. Datasets may also require substantial preparation for analysis. The data delivery dates and project staffing are designed to accommodate this. Kantar notified us of a low risk that KWP may be replaced by an improved product during the project. This

would not affect existing data (i.e. 2018-2021) nor prevent delivery of most key project outputs (e.g. WP2c analyses of substitution), but may prevent updating of analyses in Year 4 using the 2022-2025 data. We would discuss appropriate adaptation to this with our AG and NIHR.

Changing intervention components (Very likely, Medium impact): The no/lo market, government policies and other intervention components may change across the project. This may introduce new research priorities, negate current ones and affect interpretation of findings. Key research activities therefore either allow for updates (WP1) or are long-running (WP2a-b), staggered (WP3b) or later in the project (WP4c-d) to mitigate impacts of a dynamic intervention. The project is also designed to respond flexibly to changing research priorities. We would discuss any major changes with the funder, and Johnson would lead a formal and well-documented change management process.

Low stakeholder engagement (Unlikely, High impact)**:** Ensuring high stakeholder engagement is central to our dissemination and impact plan. We have sought to ensure this through engaging stakeholders in project development (see letters of support) and proposing the AG to support frequent, sustained engagement and two-way information sharing. The AG also offers specific and general opportunities for stakeholders to co-coproduce materials and shape research to their priorities. We will supplement the AG with regular written and social media outputs.

Ineffective collaboration (Unlikely, Medium impact): The research team is large and includes four institutions, with Sheffield and Stirling critical to project delivery. Senior research team members (e.g. Holmes, Brennan, Angus. Fitzgerald, Stead, Brown) have worked together extensively over a 10-year period and regular PMG meetings will promote effective teamworking and problem resolution. Perman-Howe, as PPI lead, will receive support from Holmes and other key team members.

Loss of staff (Unlikely, Low impact): Departures of key team members are not a major project risk as both key institutions (i.e. Sheffield and Stirling) have large and experienced alcohol research teams, with substantial ability to address unforeseen staffing challenges.

9. Research timetable

	2022		2023				2024				2025				2026			
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
	Year 1				Year 2				Year 3				Year 4				Year 5	
WP1																		
WP1a: Theory of change	M1	O1,P1													M24	O10		
WP1b: Intervention timeline						O3,P3								O8			O13	
WP1c: Industry strategy			M3		M8	P4,P5												
WP1d: Marketing case studies							M13		M16	P13								
WP1e: Product taxonomy								O4						O9				
WP2																		
WP2a: Monitoring no/lo trends	M2		M4,M5	P2,O2			M14	O5			M21	O7				O11		
WP2b: Impact on consumption					M9			P8		P14	M22	P15		P18				
WP2c: Substitution effects								P9,P10										
WP3																		
WP3a: Reduction attempts					M10	P6		P11										
WP3b: Drinking practices					M11	M12		P12	M17	M19		P16						
WP4																		
WP4a: International policies			M6			P7												
WP4b: Adapting SAPM								O6										
WP4c: Modelling harms										M20		P17						P20
WP4d: Policy appraisal									M18							O12,P19		
Project management																		
Evidence synthesis				M7				M15				M23				M25		M26
Steering committee meetings																		
Stakeholder advisory group meetings																		

Milestones	
M1: First theory of change workshop. M2: First delivery of market research data. M3: Selection of initial industry case studies. M4: Agree key outcome set with AG. M5: Second delivery of market research data. M6: Agree protocol for desk-based policy review. M7: Annual team meeting (evidence synthesis). M8: Selection of final industry case studies. M9: Agree initial evaluation hypotheses with AG. M10: Main ATS data delivered. M11: Agree first wave of focus groups with AG. M12: First wave of focus groups completed.	M13: Select initial case studies of no/lo marketing. M14: Third delivery of market research data. M15: Annual team meeting (evidence synthesis). M16: Selection of final case studies of no/lo marketing. M17: Agree second wave of focus groups with AG. M18: Agree policy appraisal plan with AG. M19: Second wave of focus groups completed. M20: All key inputs to SAPM available. M21: Final delivery of market research data. M22: Agree updated evaluation hypotheses with AG. M23: Annual team meeting (evidence synthesis). M24: Second theory of change workshop. M25: Annual team meeting (evidence synthesis). M26: Delivery final report to funder.
Outputs	
O1: First co-produced theory of change. O2: First report on trends in key outcome set. O3: Viewable timeline of intervention activity. O4: Summary report on product taxonomy. O5: Second report on trends in key outcome set. O6: Adapted SAPM for no/lo analysis.	O7: Third report on trends in key outcome set. O8: Updated timeline of intervention activity. O9: Updated report on product taxonomy. O10: Updated co-produced theory of change. O11: Fourth report on trends in key outcome set O12: Summary report on policy appraisals 1-4. O13: Updated timeline of intervention activity.
Journal articles	
P1: Theory of change for the system-wide impact of no/lo drinks on public health. P2: Trends and social patterning in no/lo drink purchasing and sales in Great Britain. P3: Timeline of actions to promote availability and consumption of no/lo drinks in Great Britain P4: Alcohol industry use of no/lo drinks in responses to public consultations on wider alcohol policies. P5: Characterising the role of no/lo drinks in alcohol industry market and corporate political strategies. P6: Association between no/lo drink consumption and the success of consumption reduction attempts. P7: International regulation of no/lo drinks. P8: Intervention impact on no/lo purchasing/sales #1.	P9: Substitution between no/lo and standard alcohol sales at the population-level. P10: Substitution between no/lo and standard alcohol sales and the household-level.P11: Pathways linking no/lo beliefs and consumption. P12: No/lo consumption practices in key groups. P13: Case study analysis of no/lo marketing. P14: Intervention impact on no/lo purchasing/sales #2 P15: Intervention impact on no/lo purchasing/sales #3 P16: Potential beneficial and harmful effects of no/lo drinks within drinking and non-drinking practices. P17: Intervention impact on health outcomes. P18: Intervention impact on no/lo purchasing/sales #4 P19: Comparative appraisal of no/lo policies. P20: Further intervention impact on health outcomes

10. References

1. Corfe S, et al. Alcohol-free and low-strength drinks: Understanding their role in reducing alcohol-related harms. London: Social Market Foundation, 2020.
2. Public Health England. The public health burden of alcohol and the effectiveness and cost-effectiveness of alcohol control policies: An evidence review. London: Public Health England, 2016.
3. Public Health England. Local Alcohol Profiles for England. 2021. https://fingertips.phe.org.uk/profile/local-alcohol-profiles/data (accessed 16th December 2021).
4. ONS. Alcohol-specific deaths in the UK: registered in 2020. 2021. https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/causesofdeath/bulletins/alcoholrelateddeathsintheunitedkingdom/registeredin2020 (accessed 16th December 2021).
5. Rehm J, et al. The relationship between different dimensions of alcohol use and the burden of disease—an update. *Addiction* 2017; **112**(6): 968-1001.
6. Bryant L, et al. The socioeconomic distribution of alcohol-related violence in England and Wales. *PLoS One* 2021; **16**(2): e0243206.
7. Boyd J, et al. Causal mechanisms proposed for the alcohol harm paradox—a systematic review. *Addiction* 2022; **117**(1): 33-56.
8. Jahiel RI, et al. Industrial epidemics, public health advocacy and the alcohol industry: lessons from other fields. *Addiction* 2007; **102**(9): 1335-9.
9. Petticrew M, et al. How alcohol industry organisations mislead the public about alcohol and cancer. *Drug Alcohol Rev* 2018; **37**(3): 293-303.
10. Hawkins B, et al. 'Water dripping on stone'? Industry lobbying and UK alcohol policy. *Policy & Politics* 2014; **42**(1):
11. McCambridge J, et al. Alcohol industry involvement in policymaking: a systematic review. *Addiction* 2018; **113**(9): 1571-84.
12. Oldham M, et al. Youth Drinking in Decline. Sheffield: ScHARR, University of Sheffield, 2018. Available at https://doi.org/10.15131/shef.data.7178333 accessed 16th December 2021.
13. BBC News. The challenges facing the alcohol industry in catering for Generation Z. 2019. https://www.bbc.co.uk/news/uk-scotland-scotland-business-50194900 (accessed 4th December 2021).
14. Holmes J, et al. The collectivity of British alcohol consumption trends across different temporal processes: a quantile age–period–cohort analysis. *Addiction* 2019; **114**(11): 1970-80.
15. Jackson SE, et al. Association of the COVID-19 lockdown with smoking, drinking and attempts to quit in England: an analysis of 2019–20 data. *Addiction* 2021; **116**(5): 1233-44.
16. Keric D, et al. Proliferation of 'healthy'alcohol products in Australia: implications for policy. *Public health research & practice* 2019; **29**(3): 1-6.
17. Anderson P, et al. Impact of minimum unit pricing on alcohol purchases in Scotland and Wales: controlled interrupted time series analyses. *The Lancet Public Health* 2021; **8**(6): e557-e65.
18. Anderson P, et al. Impact of low and no alcohol beers on purchases of alcohol: interrupted time series analysis of British household shopping data, 2015–2018. *BMJ Open* 2020; **10**(10): e036371.
19. Anderson P, et al. Impact of minimum unit pricing on shifting purchases from higher to lower strength beers in Scotland: Controlled interrupted time series analyses, 2015–2020. *Drug Alcohol Rev*; DOI: https://doi.org/10.1111/dar.13408:
20. Public Health Scotland. MESAS monitoring report 2021. 2021. https://www.publichealthscotland.scot/publications/mesas-monitoring-report-2021/ (accessed 12th November 2021).
21. Giles L, et al. Monitoring and Evaluating Scotland's Alcohol Stategy (MESAS): Monitoring Report 2017. Glasgow: NHS Health Scotland, 2017.
22. The Grocer. The new puritans: low & no alcohol category report 2021. 2021. https://www.thegrocer.co.uk/category-reports/the-new-puritans-low-and-no-alcohol-category-report-2021/654978.article (accessed 4th November 2021).
23. Harpers.co.uk. Low and no sales on the rise. 2020. https://harpers.co.uk/news/fullstory.php/aid/27712/Low_and_no_sales_on_the_rise.html (accessed 17th February 2021).
24. Westons Cider Makers. Westons cider report 2021. Ledbury: H. Weston & Sons Ltd, 2021.

25. HM Treasury. The new alcohol duty system: consultation. 2021. https://www.gov.uk/government/consultations/the-new-alcohol-duty-system-consultation (accessed 4th November 2021).
26. Holmes J, et al. UK alcohol industry's "billion units pledge": interim evaluation flawed. *BMJ* 2015; **350**: h1301.
27. Anderson P, et al. Evaluating Alcohol Industry Action to Reduce the Harmful Use of Alcohol. *Alcohol Alcohol* 2016; **51**(4): 383-7.
28. Imperial College Business School. Reducing alcohol content in beverages. 2018. https://www.imperial.ac.uk/business-school/news/reducing-alcohol-content-beverages/ (accessed 4th December 2021).
29. Llopis EJ, et al. Impact of price promotion, price, and minimum unit price on household purchases of low and no alcohol beers and ciders: Descriptive analyses and interrupted time series analysis of purchase data from 70, 303 British households, 2015–2018 and first half of 2020. *Soc Sci Med* 2021; **270**: 113690.
30. Anderson P, et al. Evaluation of Alcohol Industry Action to Reduce the Harmful Use of Alcohol: Case Study from Great Britain. *Alcohol Alcohol* 2020; **55**(4): 424-32.
31. Anderson P, et al. Is Buying and Drinking Zero and Low Alcohol Beer a Higher Socio-Economic Phenomenon? Analysis of British Survey Data, 2015–2018 and Household Purchase Data 2015–2020. *Int J Environ Res Public Health* 2021; **18**(19): 10347.
32. Meier PS, et al. Estimated Effects of Different Alcohol Taxation and Price Policies on Health Inequalities: A Mathematical Modelling Study. *PLoS Med* 2016; **13**(2): e1001963.
33. Miller M, et al. Zero-alcohol beverages: Harm-minimisation tool or gateway drink? *Drug Alcohol Rev*; DOI: https://doi.org/10.1111/dar.13359:
34. Peeters S, et al. Understanding the emergence of the tobacco industry's use of the term tobacco harm reduction in order to inform public health policy. *Tob Control* 2015; **24**(2): 182-9.
35. Anderson P, et al. Production, Consumption, and Potential Public Health Impact of Low- and No-Alcohol Products: Results of a Scoping Review. *Nutrients* 2021; **13**(9): 3153.
36. Knai C, et al. Are the Public Health Responsibility Deal alcohol pledges likely to improve public health? An evidence synthesis. *Addiction* 2015; **110**(8): 1232-46.
37. Shemilt I, et al. What do we know about the effects of exposure to 'Low alcohol' and equivalent product labelling on the amounts of alcohol, food and tobacco people select and consume? A systematic review. *BMC Public Health* 2017; **17**(1): 29-.
38. Vasiljevic M, et al. Impact on product appeal of labeling wine and beer with (a) lower strength alcohol verbal descriptors and (b) percent alcohol by volume (%ABV): An experimental study. *Psychology of addictive behaviors : journal of the Society of Psychologists in Addictive Behaviors* 2018; **32**(7): 779-91.
39. Vasiljevic M, et al. Impact of low alcohol verbal descriptors on perceived strength: An experimental study. *Br J Health Psychol* 2018; **23**(1): 38-67.
40. Vasiljevic M, et al. Do alcohol product labels stating lower strength verbal description, percentage alcohol-by-volume, or their combination affect wine consumption? A bar laboratory adaptive randomised controlled trial. *Addiction* 2021; **116**(9): 2339-47.
41. Vasiljevic M, et al. Impact of lower strength alcohol labeling on consumption: A randomized controlled trial. *Health Psychol* 2018; **37**(7): 658-67.
42. Bucher T, et al. Consumer perception and behaviour related to low-alcohol wine: do people overcompensate? *Public Health Nutr* 2020; **23**(11): 1939-47.
43. van Houten R, et al. The Effects of Low Alcohol Beverages on Alcohol Consumption and Impairment. *Behav Modif* 1994; **18**(4): 505-13.
44. Geller ES, et al. Beer versus mixed-drink consumption at fraternity parties: a time and place for low-alcohol alternatives. *J Stud Alcohol* 1991; **52**(3): 197-204.
45. Blackwell AK, et al. The impact on selection of non-alcoholic vs alcoholic drink availability: an online experiment. *BMC Public Health* 2020; **20**: 1-9.
46. Bucher T, et al. Low-Alcohol Wine: A Narrative Review on Consumer Perception and Behaviour. *Beverages* 2018; **4**(4): 82.
47. Silva AP, et al. Functional or emotional? How Dutch and Portuguese conceptualise beer, wine and non-alcoholic beer consumption. *Food Qual Prefer* 2016; **49**: 54-65.

48. Chrysochou P. Drink to get drunk or stay healthy? Exploring consumers' perceptions, motives and preferences for light beer. *Food Qual Prefer* 2014; **31**: 156-63.
49. Vasiljevic M, et al. What are the perceived target groups and occasions for wines and beers labelled with verbal and numerical descriptors of lower alcohol strength? An experimental study. *BMJ Open* 2019; **9**(6): e024412.
50. Bruwer J, et al. Lower alcohol wines in the UK market: some baseline consumer behaviour metrics. *British Food Journal* 2014; **116**(7): 1143-61.
51. Johnson CD, et al. You're Not A Teetotaler, are You? A Framework of Nonalcoholic Wine Consumption Motives and Outcomes. *Journal of Food Products Marketing* 2020; **26**(5): 372-83.
52. Saliba AJ, et al. Consumer demand for low-alcohol wine in an Australian sample. *International Journal of Wine Research* 2013; **5**: 1-8.
53. Lachenmeier DW, et al. Alcoholic Beverage Strength Discrimination by Taste May Have an Upper Threshold. *Alcohol Clin Exp Res* 2014; **38**(9): 2460-7.
54. Naspetti S, et al. Effect of information on consumer preferences and willingness-to-pay for sparkling mock wines. *British Food Journal* 2019; **122**(8): 2621-38.
55. Lachenmeier DW, et al. Alcohol-free spirits as novel alcohol placebo—A viable approach to reduce alcohol-related harms? *International Journal of Drug Policy* 2016; **32**: 1-2.
56. Smeets PA, et al. Brain Responses to Anticipation and Consumption of Beer with and without Alcohol. *Chem Senses* 2019; **44**(1): 51-60.
57. Vasiljevic M, et al. Marketing messages accompanying online selling of low/er and regular strength wine and beer products in the UK: a content analysis. *BMC Public Health* 2018; **18**(1): 147.
58. Scott C, et al. Food and beverage product reformulation as a corporate political strategy. *Soc Sci Med* 2017; **172**: 37-45.
59. Long CG, et al. Low alcohol beers and wines: attitudes of problem drinkers to their use and their effect on craving. *Br J Addict* 1989; **84**(7): 777-83.
60. Moore GF, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* 2015; **350**:
61. Sanderson I. Evaluation in complex policy systems. *Evaluation* 2000; **6**(4): 433-54.
62. Hawe P. Lessons from complex interventions to improve health. *Annu Rev Public Health* 2015; **36**: 307-23.
63. Rutter H, et al. The need for a complex systems model of evidence for public health. *Lancet* 2017; **390**(10112): 2602-4.
64. Bonell C, et al. 'Dark logic': theorising the harmful consequences of public health interventions. *J Epidemiol Community Health* 2015; **69**(1): 95-8.
65. Peeters S, et al. Transnational Tobacco Company Interests in Smokeless Tobacco in Europe: Analysis of Internal Industry Documents and Contemporary Industry Materials. *PLoS Med* 2013; **10**(9): e1001506.
66. Douglas N, et al. How the food, beverage and alcohol industries presented the Public Health Responsibility Deal in UK print and online media reports. *Critical Public Health* 2018; **28**(4): 377-87.
67. Holden C, et al. Cleavages and co-operation in the UK alcohol industry: a qualitative study. *BMC Public Health* 2012; **12**(1): 1-11.
68. Savell E, et al. How does the alcohol industry attempt to influence marketing regulations? A systematic review. *Addiction* 2016; **111**(1): 18-32.
69. Ikegwuonu T, et al. Understanding commercial actors' engagement in policy debates on proposed e-cigarette regulation in Scotland. *Tob Control* 2021; DOI: 10.1136/tobaccocontrol-2020-056084: tobaccocontrol-2020-056084.
70. Stead M, et al. Tobacco companies' use of retailer incentives after a ban on point-of-sale tobacco displays in Scotland. *Tob Control* 2018; **27**(4): 414-9.
71. Eadie D, et al. E-cigarette marketing in UK stores: an observational audit and retailers' views. *BMJ Open* 2015; **5**(9): e008547.
72. Thorpe R, et al. Monitoring and Evaluating Scotland' Alcohol Strategy: A review of the validity and reliability of alcohol retail sales data for the purpose of Monitoring and Evaluating Scotland's Alcohol Strategy. Edinburgh, 2012.
73. Beard E, et al. Protocol for a national monthly survey of alcohol use in England with 6-month follow-up: 'The Alcohol Toolkit Study'. *BMC Public Health* 2015; **15**(230):

74. Holmes J, et al. Effects of minimum unit pricing for alcohol on different income and socioeconomic groups: a modelling study. *Lancet* 2014; **383**(9929): 1655-64.
75. Nakamura R, et al. Impact on alcohol purchasing of a ban on multi-buy promotions: a quasi-experimental evaluation comparing Scotland with England and Wales. *Addiction* 2014; **109**(4): 558-67.
76. Robinson M, et al. Evaluating the impact of minimum unit pricing (MUP) on off-trade alcohol sales in Scotland: an interrupted time–series study. *Addiction* 2021; **116**(10): 2697-707.
77. Robinson M, et al. A Review of the Validity and Reliability of Alcohol Retail Sales Data for Monitoring Population Levels of Alcohol Consumption: A Scottish Perspective. *Alcohol Alcohol* 2012; **48**(2): 231-40.
78. Beard E, et al. Understanding and using time series analyses in addiction research. *Addiction* 2019; **114**(10): 1866-84.
79. Ajzen I. The theory of planned behavior. *Organ Behav Hum Decis Process* 1991; **50**(2): 179-211.
80. Weisner C, et al. How important is treatment? One-year outcomes of treated and untreated alcohol-dependent individuals. *Addiction* 2003; **98**(7): 901-11.
81. Wolf EJ, et al. Sample Size Requirements for Structural Equation Models:An Evaluation of Power, Bias, and Solution Propriety. *Educ Psychol Meas* 2013; **73**(6): 913-34.
82. Bush K, et al. The AUDIT alcohol consumption questions (AUDIT-C): An effective brief screening test for problem drinking. *Arch Intern Med* 1998; **158**(16): 1789-95.
83. Hagger MS, et al. Effects of socio-structural variables in the theory of planned behavior: a mediation model in multiple samples and behaviors. *Psychol Health* 2021; **36**(3): 307-33.
84. Meier PS, et al. All drinking is not equal: how a social practice theory lens could enhance public health research on alcohol and other health behaviours. *Addiction* 2017; **113**(2): 203-13.
85. Ally A, et al. Developing a social practice-based typology of British drinking culture in 2009-2011: Implications for alcohol policy analysis. *Addiction* 2016; **111**(9): 1568-79.
86. Corbin J, et al. Basics of qualitative research: Techniques and procedures for developing grounded theory: Sage; 2015.
87. Berends L, et al. Using multiple coders to enhance qualitative analysis: The case of interviews with consumers of drug treatment. *Addiction Research & Theory* 2005; **13**(4): 373-81.
88. Silverman D. Doing Qualitative Research. 4th edition ed. London: Sage Publications; 2013.
89. Angus C, et al. Alcohol and cancer trends: Intervention scenarios. Sheffield and London: ScHARR, University of Sheffield and Cancer Research UK, 2016.
90. Purshouse RC, et al. Modelling the cost-effectiveness of alcohol screening and brief interventions in primary care in England. *Alcohol Alcohol* 2013; **48**(2): 180-8.
91. Purshouse RC, et al. Modelling to assess the effectiveness and cost-effectiveness of public health related strategies and interventions to reduce alcohol attributable harm in England using the Sheffield Alcohol Policy Model version 2.0: Report to the NICE Public Health Programme Development Group. Sheffield: University of Sheffield, 2009. Available at http://www.nice.org.uk/guidance/index.jsp?action=download&o=45668 accessed 14th January 2015.
92. Angus C, et al. Modelling the impact of alcohol duty policies since 2012 in England and Scotland. Sheffield: ScHARR, University of Sheffield, 2019. Available at https://www.sheffield.ac.uk/media/13068/download accessed 16th December 2021.
93. Morris DE, et al. A web-based tool for eliciting probability distributions from experts. *Environmental Modelling & Software* 2014; **52**: 1-4.
94. Gosling J. SHELF: The Sheffield Elicitation Framework. In: Dias L, Morton A, Quigley J, eds. Elicitation International Series in Operations Research & Management Science: Springer, Cham; 2018.
95. Pawson R, et al. Realist review - a new method of systematic review designed for complex policy interventions. *J Health Serv Res Policy* 2005; **10**(1_suppl): 21-34.
96. Paparini S, et al. Evaluating complex interventions in context: systematic, meta-narrative review of case study approaches. *BMC Med Res Methodol* 2021; **21**(1): 1-22.
97. Ogilvie D, et al. Using natural experimental studies to guide public health action: turning the evidence-based medicine paradigm on its head. *J Epidemiol Community Health* 2020; **74**(2): 203-8.
98. White M, et al. Different scientific approaches are needed to generate stronger evidence for population health improvement. *PLoS Med* 2018; **15**(8): e1002639.