The effect of alcohol strength on alcohol consumption: a pilot study

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Abstract

Background

Excessive alcohol consumption can impair health, lead to intentional and non-intentional harm to the self and others and incurs a large financial burden on society. Effective interventions are required to reduce alcohol consumption and its associated harms at the population level. Replacing regular-strength alcohol with reduced-strength alcohol has the potential to reduce alcohol consumption and, therefore, mitigate alcohol-related harm. To date, there is no high-quality experimental evidence to suggest whether reducing the strength of alcohol is effective at reducing alcohol consumption. Before implementing a randomised controlled trial (RCT), its feasibility, and the acceptability of the intervention, need to be established.

Aim

The primary aim of this research project was to establish the feasibility of a RCT to assess the effect of lager (a subtype of beer) strength on lager consumption in a single drinking occasion within licensed premises in the United Kingdom (UK). This project sought to obtain data to estimate key parameters required when designing a RCT and to provide initial insights into the acceptability of reducing the strength of alcohol as an intervention to reduce alcohol consumption.

Method

The research project incorporated three stages of study, which utilised different designs.

Study One: a single-blind taste discrimination experiment.

Study Two: a double-blind randomised controlled crossover pilot trial based within licensed premises in the UK.

Study Three: semi-structured qualitative telephone interviews.

Findings

Study One: Nineteen frequent lager drinkers aged 18 years and over completed the taste experiment. Most participants (58%) reported that, out of a small range of regular-strength lager brands, Becks® (B) tasted most similar to the reduced-strength lager Bud Light® (BL). B was therefore instated as the control product for the pilot trial, alongside the pre-determined intervention product, BL.

Study Two: Thirty-six frequent lager drinkers aged 18 years and over completed two pilot trial study sessions in one of four licensed premises. Results indicated that it is feasible to conduct a double-blind randomised controlled crossover trial to assess the effect of alcohol strength on alcohol consumption in a single drinking occasion within licensed premises in the UK. Sufficient data were obtained to estimate key parameters for a RCT.

Study Three: A subsample of seven pilot trial participants each undertook a semi-structured telephone interview. Reflexive thematic analysis identified several factors associated with the acceptability of reducing the strength of alcohol as an intervention to reduce alcohol consumption. These included the taste of the reduced-strength product, freedom of choice, perceived intervention efficacy and perceived motives of the alcohol industry.

Conclusion

Findings from this research project can be utilised to design a definitive RCT to assess the effect of alcohol strength on alcohol consumption in a single drinking occasion within licensed premises in the UK. The main limitations of this research project were that the pilot trial intervention and control products were not optimally matched, and they were not favourable to participants, and trial participants may have deviated from the study protocol as they were not officially observed. These limitations should be addressed, to the greatest extent possible, in the design stage of future studies.

Publications and Conference Presentations

Publications

Perman-Howe, P. R., Davies, E. L. and Foxcroft, D. R. (2018) 'The effect of alcohol strength on alcohol consumption: a randomised controlled cross-over pilot trial', *Pilot and Feasibility Studies,* 4(138). (Appendix B).

Conference presentations

Oral presentations

Perman-Howe, P. R. (2017) *The effect of alcohol strength on alcohol consumption: a study protocol,* Oxford Brookes University's Alcohol Mixer Symposium, 13 June, Oxford.

Perman-Howe, P. R. (2018) *The effect of alcohol strength on alcohol consumption,* Oxford Brookes University's Faculty of Health and Life Sciences Annual Research Students' Symposium, 10 January, Oxford.

Perman-Howe, P. R. (2019) *The effect of alcohol strength on alcohol consumption: findings from a randomised controlled crossover pilot trial,* European Society for Prevention Research's Annual Conference, 16-18 September, Ghent. (Prize winner).

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Poster presentations

Perman-Howe, P. R. (2017) *The effect of alcohol strength on alcohol consumption: a randomised controlled crossover pilot trial,* The Society for the Study of Addiction's Annual Conference, 8-10 November, Newcastle.

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Chapter One: An Introduction to the Research Project

1.1 Introduction

This chapter introduces alcohol harm prevention as the topic of this thesis. It provides key data on alcohol use and outlines the risks associated with excessive alcohol consumption. Drawing on dual process theories and the concept of "nudging", this chapter describes interventions that may be more or less effective at reducing alcohol consumption and its related harms. It provides a detailed description of the concept of physical environmental prevention. Key frameworks for classifying and describing interventions within physical environments are presented with illustrative examples. Finally, the rationale for undertaking research to assess the effect of alcohol strength on alcohol consumption within licensed premises is outlined.

1.2 Prevalence of alcohol use

Worldwide, in 2016, the average level of alcohol consumption was 6.4 litres of pure alcohol per person aged 15 years and older (World Health Organisation, 2018a). This is equivalent to 12.3 United Kingdom (UK) units of alcohol per week or roughly 5.4 pints (one pint is 568 millilitres (ml)) of beer at 4% alcohol by volume (ABV). The pattern of alcohol use varies between and within regions. The European region, as defined by the World Health Organisation (WHO), consistently has the highest level of alcohol consumption amongst world regions (World Health Organisation, 2018a). However, alcohol consumption within this region has decreased over recent years to a greater extent than within each other region. In 2016, consumption in the European region averaged 9.8 litres of pure alcohol per person aged 15 years and older. In the same year, alcohol consumption in the UK was higher than the regional average, at 11.4 litres of pure alcohol per person aged 15 years and older (World Health Organisation, 2018a). This equates to roughly 21.8 UK units of alcohol per week or 9.6 pints of 4% ABV beer. The WHO predicted that this figure would rise to 12.5 litres by 2025 (World Health Organisation, 2016).

In 2017, 80% of the population of England reported that they drank alcohol: 82% of men and 78% of women (Office for National Statistics, 2018a). The Health Survey for England showed that between 2011 and 2016 average weekly alcohol consumption decreased for those below 55 years of age. In 2018, the proportion of people drinking alcohol, and the average number of days per week that alcohol was consumed, were lowest among those in the 16- to 24-year-old age bracket, and increased with age (Office for National Statistics,

2019). The trend of young people consuming less alcohol appears to coincide with the increased attention and interest in temporary abstinence initiatives, and a demand for, and production of, a greater range of lower strength and non-alcoholic drinks. For example, de Visser *et al* (2017) reported a 15-fold increase in the number of people who registered to take part in the annual one-month abstinence campaign "Dry January" between 2013 and 2016. Dry January tends to attract people who are younger than the general population (de Visser, 2019). Such shifts in behaviour indicate that the younger population of the UK may be increasingly receptive to measures to reduce alcohol consumption. However, whilst weekly alcohol consumption has decreased for those below 55 years of age, it has increased for those aged 55 and over (Office for National Statistics, 2017a). Such data have led psychiatrists to suggest that older people should consume a maximum of 11 UK units of alcohol per week: three units per week less than the UK Government's recommended guidelines (Royal College of Psychiatrists, 2018). Their report states that "baby boomers" (those born in the UK between 1946 and 1964) are the age group with the highest risk of alcohol-related harm. Interestingly, the varying trends in consumption across different age groups resulted in no statistically significant change (0.8 UK units) in average weekly alcohol intake across all age groups between 2011 and 2016 (Office for National Statistics, 2017a). These data suggest that whilst there are opposing trends for younger and older alcohol consumers, at a population level alcohol consumption remains steady. It should be acknowledged, however, that household surveys, including the Opinion and Lifestyle Survey and the Health Survey for England, underestimate population-level alcohol consumption when compared with actual sales. This discrepancy was reported to equal 430 million units per week in the UK: the equivalent of one bottle of wine per adult drinker per week (Bellis *et al.*, 2009). Therefore, actual average alcohol consumption figures may be uniformly higher than reported.

Patterns of alcohol consumption in England also vary according to socio-economic status (SES). Those with the highest salaries and with a higher SES classification were more likely to have reported consuming alcohol and to have consumed alcohol on at least five days in the week prior to interview than those with lower salaries and a lower SES classification (Office for National Statistics, 2018a). However, those from the lowest SES classification who drank alcohol were likely to have consumed more units of alcohol than those from the highest SES classification on their heaviest drinking[1] occasion within the past week (Office for National Statistics, 2018a). These data signify a disparity between

[1] Within this thesis the term "drinking" refers to the consumption of alcohol.

patterns of alcohol consumption and SES. They indicate that those who have a higher SES are more likely to drink, and to drink more frequently but at moderate levels, compared to those who have a lower SES, who are less likely to drink but when they do, they are more likely to drink to excess. Such heavy episodic drinking is believed to be one factor that explains why alcohol disproportionately affects the health of those with low individual or neighbourhood SES (Jones *et al.*, 2015; Bellis *et al.,* 2016; Sadler *et al.,* 2016) This phenomenon is termed the alcohol-harm paradox. There is inconclusive evidence of the mechanisms and pathways that govern this difference in risk (Jones *et al.*, 2015). Alongside patterns of heavy episodic drinking, another factor that may explain this paradox is that deprived populations are more likely to engage in a suite of unhealthy behaviours that contribute to alcohol-related health conditions (Bellis *et al.*, 2016; Sadler *et al.*, 2016).

1.3 Prevalence of alcohol misuse

Data that are indicative of the persisting problem of alcohol consumption and its related harms in the UK show that a significant proportion of adult drinkers reported drinking at levels of increasing risk (Office for National Statistics, 2016). In 2014, 12% of all men (aged 16 years and older) and 4% of all women in the same age bracket in the UK consumed more than 14 units of alcohol in a single drinking occasion in the week prior to interview (Office for National Statistics, 2016). This exceeded the UK Chief Medical Officers recommended weekly guideline for alcohol consumption. This guideline states that people should not consume more than 14 units (140ml or 112g) of alcohol per week on a regular basis. Fourteen UK units equates to six pints of 4% ABV beer (Department of Health, 2016). Those who drink up to, and not beyond, 14 units per week are classified as being at lower risk of alcohol-related harm. As consumption increases beyond 14 units per week, the risk of alcohol-related harm increases (Table 1.1) (Public Health England, 2016).

Data revealed that of those who reported drinking alcohol in the past week in England, 26% were classified as heavy episodic, or “binge”, drinkers: the term binge can be quantified as the consumption of more than six units of alcohol within a single drinking occasion (National Health Service, 2016; Office for National Statistics, 2018a). Similarly, data were collated from 55,000 UK participants in an ongoing study, which found that of the 69% who reported drinking alcohol, 27% reported drinking at levels that are classed as high risk (Beard *et al.*, 2017). In this instance, high risk was defined as an Alcohol Use Disorders Identification Test (AUDIT) score of eight or more or an AUDIT-C (a modified

Table 1.1: The UK's unit-based classification system for alcohol use (Public Health England, 2016)

Classification	Consumption per week (UK units)
Non drinker	0
Lower risk	≤14
Increasing risk	>14 to ≤35 (women) ≤50 (men)
Higher risk	>35 (women) >50 (men)

version of AUDIT) score of five or more. It is estimated that in 2014 to 2015 there were over 595,000 people in England who were alcohol dependent and in need of specialist assessment and treatment (Pryce *et al.*, 2017). That equates to roughly 1.4% of the adult population.

1.4 Alcohol-related harm

Alcohol consumption is known to be a component causal factor for more than 200 health conditions (Rehm and Imtiaz, 2016; World Health Organisation, 2018b). It is the leading cause of premature mortality, ill health and disability amongst those aged 15 to 49 in England (Public Health England, 2016). Moreover, it is the fifth leading risk factor for ill health across all ages in England (Public Health England, 2016). Data show the average age of death for those dying from an alcohol-specific cause in England is 54.3 years, which is over 23 years younger than the average age of death from all causes (Public Health England, 2016). In 2017, there were 7,697 avoidable deaths in the UK that were directly caused by alcohol (Office for National Statistics, 2018b).

An independent expert panel of UK Government advisors claimed that there is no level of regular drinking that is completely without long-term risks to health (Department of Health, 2016). Findings from an article in the Lancet concur with this statement (Griswold *et al.*, 2018). This manuscript, published as part of the Global Burden of Disease Study, concluded that consuming any amount of alcohol increases the risk to health. Furthermore, alcohol consumption at any level has been associated with adverse brain outcomes (Topiwala *et al.*, 2017). This study additionally concluded that there is no protective effect of consuming alcohol at low levels as illustrated by the "J-shaped curve"; the J-shaped curve purports that a low level of alcohol consumption has a protective effect against ill

health above that of abstinence and heavy drinking (Public Health England, 2016). However, there is no robust evidence outlining the biological processes to explain the protective effect that is illustrated by the J-shaped curve (Public Health England, 2016). Those who advocate this model tend to focus on the effects of alcohol on cardiac disease. There is evidence to support the notion that drinking at low to moderate levels is cardio protective (Bell *et al.*, 2017). However, data modelling suggests that alcohol consumption may only be cardio protective for older women who drink at very low levels: around one UK unit (10ml or 8g of pure alcohol) per day (Holmes *et al.*, 2016). Overall, there is inconclusive evidence as to whether alcohol can be cardio protective when consumed at low levels. What is known is that the risk of alcohol-related harm increases as consumption increases beyond these low levels (Public Health England, 2016).

It is important to acknowledge that alcohol-related harm does not solely manifest in the drinker. The WHO broadly defines the harmful use of alcohol as encompassing all drinking that causes detrimental health and social consequences for the drinker, the people around the drinker and society at large (World Health Organisation, 2018b). The burden of alcohol-related harm on society is incurred through direct, indirect and intangible costs. Direct costs include costs to health and social care, policing and the criminal justice system and the welfare system. Indirect costs relate to a decrease in productivity and include absenteeism and unemployment (Bhattacharya, 2017a). Intangible costs are those which are borne by the drinker and their relatives and/or associates (Burton *et al.*, 2016). Although it is complex to accurately quantify, one of the more reliable estimates suggests that the cost of alcohol-related harm in high income countries totalled 2.5% of gross domestic product (GDP) in 2007: £47 billion for the UK in 2016 (Rehm *et al.*, 2009; Burton *et al.*, 2016). This is notably higher than the figure £21 billion, which has been regularly cited as the national cost of alcohol-related harm (House of Commons Health Committee, 2012; Bhattacharya, 2016). This figure (£21b) is often misunderstood and cited incorrectly as it fails to account for costs directly borne by the drinker, it only relates to England and Wales and it is outdated (Bhattacharya, 2016).

Although the burden of alcohol is vast, it can be considered a fundamental fabric of society. Indeed, the alcohol industry[2] supports employment and venues in which alcohol is

[2] Within this thesis the term "alcohol industry" encompasses all the individuals and companies that participate in the alcohol production and supply chain. These include: raw material suppliers such as barley and hops farmers; producers who brew, distil and bottle alcoholic products; distributors and wholesalers, who typically store and transport the products between producers and vendors; vendors, who sell alcoholic products either on the on-trade or the off-trade (defined in Footnote 3); and input suppliers and contractors

consumed offer a social environment in which relationships can be created and nurtured; social connections being a key factor in long-term positive health outcomes (International Longevity Centre UK, 2015; Bhattacharya, 2017b). Furthermore, evidence suggests that pubs in rural areas are local community hubs that have a positive impact on social engagement, volunteering and leisure activities (Cabras and Mount, 2017). Alcohol consumption is perceived to facilitate higher-quality social interaction, diminish social anxiety, and hasten social connectedness amongst younger people (Brown and Murphy, 2018; Goodman, Stiksma and Kashdan, 2018). Additionally, it is embedded in the social contexts of many older people's lives (Agahi, Dahlberg and Lennartsson, 2019). Therefore, rather than prohibiting alcohol at the population level, interventions should be developed that enable alcohol to be consumed in a manner that minimises the risk of harm.

1.5 Behaviour models and theoretical perspectives

1.5.1 The COM-B model for understanding behaviour

The COM-B model provides a framework for understanding behaviour (Michie, van Stralen and West, 2011). The model incorporates capability, opportunity and motivation as interacting components that generate behaviour that then regulates these components (Figure 1.1). Capability is defined as the individual's physical or psychological capacity to engage in the behaviour. Opportunity incorporates all the factors external to the individual that enable the behaviour. These include physical opportunities afforded by the environment, and social opportunities afforded by the cultural climate. Motivation refers to the brain processes that energise and direct behaviour. These can be reflective processes that require conscious effort or automatic processes that are habitual and/or impulsive. Apart from reflective motivation, all these factors are necessary for a behaviour to be enacted (Michie, van Stralen and West, 2011).

The COM-B model may also be used as a basis for designing behaviour change interventions. Once the behavioural target has been identified, the model can help to consider the components of the system that require change. Figure 1.2 illustrates some of the factors that enable alcohol consumption. Once these enabling factors are established,

such as those who provide farm machinery, and distillation equipment and those who are involved in marketing and lobbying (Institute of Alcohol Studies, 2018).

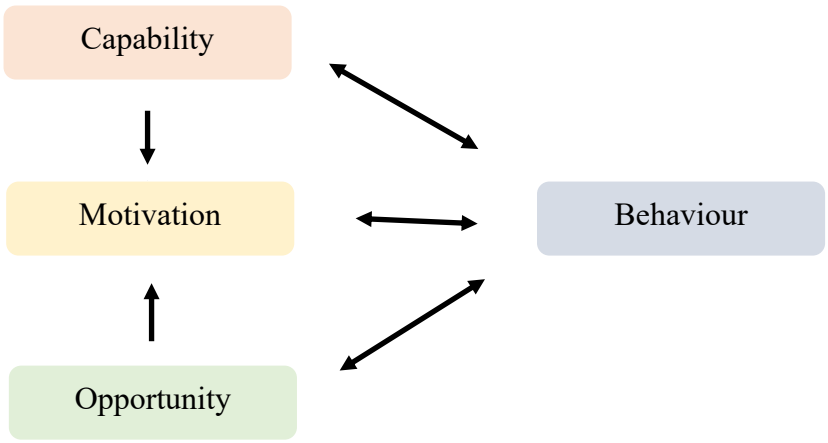


Figure 1.1: The COM-B model for understanding behaviour (Michie, van Stralen and West, 2011)

the model can help to identify the particular factor(s) that could be targeted in interventions to alter the target behaviour.

Traditionally, behaviour-change interventions that aim to reduce alcohol consumption have targeted cognitive processes that require conscious effort, rather than automatic processes (Marteau, Hollands and Fletcher, 2012). A principle focus has been on interventions which provide information about a behaviour and its consequences, leading to the formation of intentions to alter the behaviour in a health affirming direction (Hollands, Marteau and Fletcher, 2016). Such interventions have targeted entire populations, population subgroups or individuals (Foxcroft, 2014). Examples include a media campaign to correct student misperceptions of peer alcohol consumption, targeted social marketing campaigns, and brief interventions delivered to heavy drinkers who have been admitted to hospital (McQueen *et al.*, 2011; Foxcroft *et al.*, 2015; Kubacki *et al.*, 2015). Despite the implementation of a plethora of informative interventions to reduce risky alcohol consumption, alcohol behaviours have remained resistant to change. This may be because interventions that attempt to alter behaviour through providing information, with the ultimate aim of formulating more health-affirming behavioural intentions, often lack efficacy. Neal, Wood and Quinn (2006) postulate that this is due to the entrenched nature of habits, which are more powerful predictors of behaviour than attitudes and intentions. Sheeran *et al* (2005) state that when alcohol-drinking habits are entrenched, the activation of a goal related to drinking alcohol, such as socialising, can automatically evoke the habitual response to drink alcohol. It has been proposed that because behaviours are often

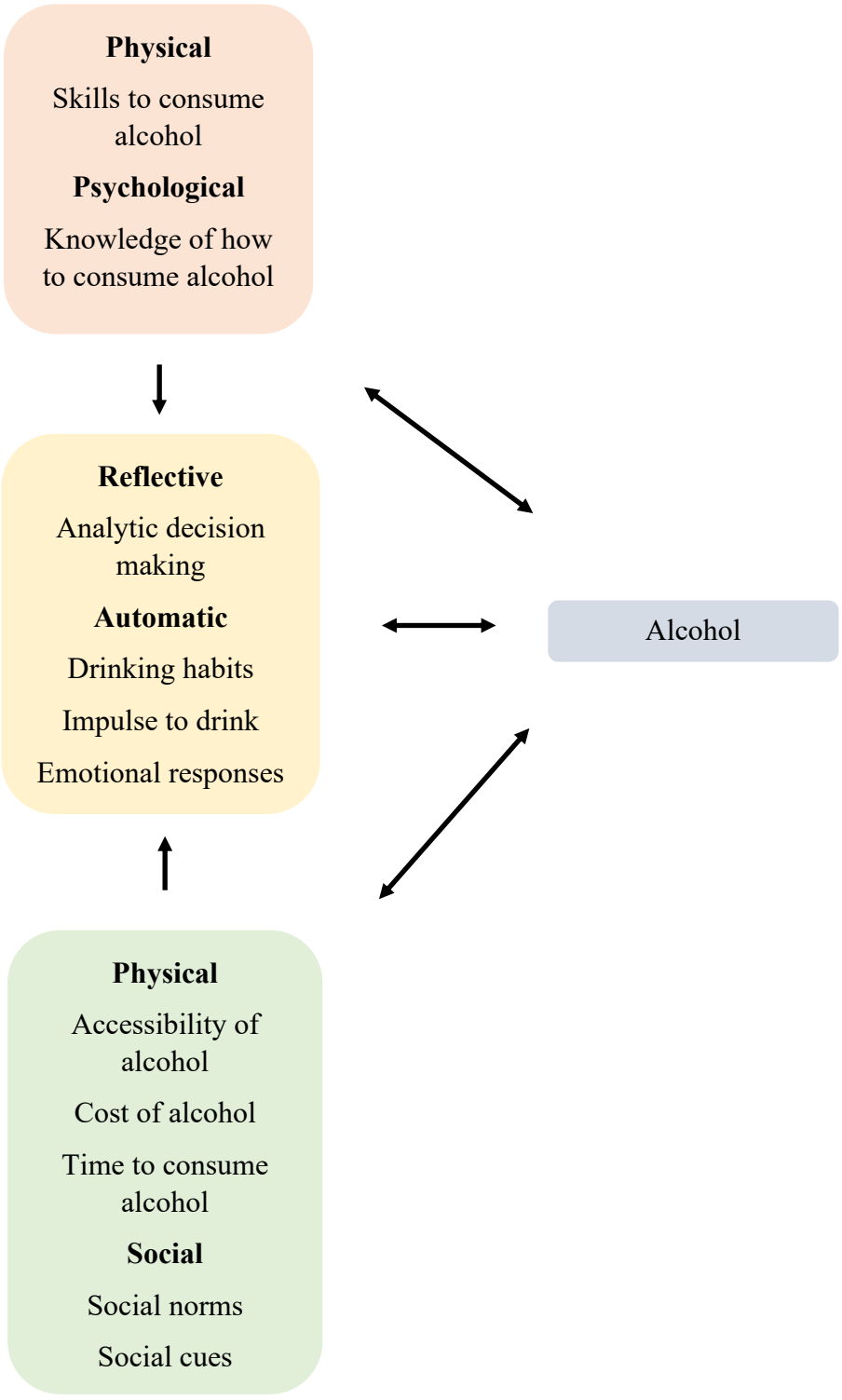


Figure 1.2: The COM-B model for understanding alcohol consumption (Michie, van Stralen and West, 2011)

automatic, based on habitual responses to environmental cues or the activation of goals, approaches to behaviour change that target non-conscious processes may prove more

effective than traditional information-based approaches that require reflection (Sheeran *et al.*, 2005; Neal, Wood and Quinn, 2006; Marteau, Hollands and Fletcher, 2012).

Before interventions that target non-conscious processes can be designed and/or implemented, there is a requirement to establish whether the target behaviour is, at least in part, non-conscious. Determining whether any given behaviour is (non-)conscious is complex (Hollands, Marteau and Fletcher, 2016). A basic classification is that non-conscious behaviour is habitual, whereas conscious behaviour is non-habitual (Lisman and Sternberg, 2013). However, there is a multitude of situations in which individuals may be aware of their habitual actions or unaware of behaviours that are not entrenched as habit. Additionally, many behaviours involve both conscious and non-conscious processes: utilising both the reflective and automatic cognitive systems (Kahneman, 2011; Hagger, 2016). An alternative has been posited: that the degree to which behaviour activated by external stimuli might be considered non-conscious is determined by the awareness of: the external stimuli, the ensuing behaviour, and the causal link between the external stimuli and the behaviour (Hollands, Marteau and Fletcher, 2016). Based on this classification, under certain circumstances alcohol consumption may be considered a non-conscious behaviour: when consumers lack awareness of the specific properties of the alcohol they are consuming (such as strength), when consumers lack awareness of the characteristics of their alcohol consumption (such as the amount they drink), and when consumers cannot link their alcohol consumption to the properties of the alcohol they are consuming (they drank X amount because the alcoholic product was X% ABV). If, as posited, alcohol consumption can, at least in part, be considered a non-conscious behaviour, then interventions that target non-conscious processes may be effective at reducing alcohol consumption.

1.5.2 Nudging

"Nudging" refers to an approach to behaviour change that targets non-conscious processes. Specifically, nudging is the term used to describe the manipulation of an aspect(s) of the environment that is intended to alter people's behaviour in a direction that is beneficial to the individual and/or society (Thaler and Sunstein, 2009). It excludes legislation, regulation and interventions that alter economic incentives (Marteau *et al.*, 2011). Nudging is embedded within libertarian paternalism: a political philosophy that upholds freedom of choice whilst legitimising the government or private sector institutions to influence people's behaviour in a way that is intended to improve their lives (Thaler and Sunstein,

2009; Marteau *et al.*, 2011). One of the key principles of libertarian paternalism is that there are instances when people's ability to judge what is in their best interests is compromised. For example, when people are under the influence of alcohol, they may lack the ability to make decisions that are truly representative of their beliefs and values: they have limited cognitive ability and reduced self-control. It is argued that in these situations judgement should be the responsibility of the government and/or private sector institutions (Thaler and Sunstein, 2009). Specifically, within these institutions the responsibility lies with a "choice architect". This is the person, or people, who manipulate the environment to evoke behaviour change. For example, an on-trade[3] licensed premises landlord/manager who places non-alcoholic drinks at eye level behind the bar to prompt people to purchase, and thereafter consume, drinks that are less detrimental to their health is a choice architect. Choice architects therefore self-consciously "nudge" people towards making favourable choices. Whilst the process of nudging by the choice architect is self-conscious, nudging tends to affect behaviour change via non-conscious mechanisms (Marteau *et al.*, 2011).

Studies have reported promising results of nudge-based interventions that aim to alter certain health-related behaviours. In 2016, Arno and Thomas noted that most of these published studies were in the nutrition field (Arno and Thomas, 2016). Literature searches conducted by the researcher in January 2020 suggested that this was still the case. These studies, which include systematic literature reviews, have demonstrated that a range of nudge-based interventions can alter food and soft drink purchasing and/or consumption (Small *et al*, 2013; Hollands *et al*, 2015; Bevet, Niles and Pope, 2018; Walmsley *et al*, 2018; Hollands *et al*, 2019; Marcano-Olivier *et al*, 2019). Whilst there is a growing body of evidence which suggests nudge-based interventions can alter behaviours pertaining to food and soft drinks, there is a paucity of evidence regarding the efficacy of nudge-based interventions that seek to alter alcohol consumption. In 2015, Hollands *et al* highlighted the absence of evidence of the effect of portion, package and tableware size on the selection and consumption of alcohol (Hollands *et al,* 2015). Since then, three studies have demonstrated that reducing the size of the glass that wine is served in, and reducing the serving size of alcohol, reduced single-occasion alcohol purchasing and/or consumption within licensed premises in the UK (Pechey *et al*, 2016; Pechey *et al*, 2017; Kersbergen *et*

[3] There are two channels by which alcohol can be legally sold or supplied within the UK market: the on-trade and the off-trade. The on-trade refers to alcohol that is sold or supplied within a licensed premises for consumption within that venue. On-trade venues include pubs, bars, nightclubs, restaurants, hotels, theatres and sporting stadia. The off-trade encompasses any alcohol that is sold or supplied for consumption away from the premises in which it is purchased or supplied. This includes the sale or supply of alcohol by supermarkets and specialist alcohol retailers (Institute of Alcohol Studies, 2018).

al, 2018). The first of these studies by Pechey *et al* (2016), which used a multiple treatment reversal design, altered the wine glass size (300ml, 370ml, 250ml) used in a bar/restaurant establishment over eight fortnightly periods whilst keeping the volume of alcohol in each glass constant. The daily volume of wine purchased was 9.4% higher when served in larger glasses (370ml) compared to standard-sized glasses (300ml). However, findings were inconclusive as to whether sales differed when wine was served in smaller glasses (250ml) compared to standard-sized glasses (300ml). This study was replicated in an additional study that was based within two different bars and used a wider range of wine glass sizes (300ml, 370ml, 510ml) (Pechey *et al*, 2017). The results demonstrated a partial replication of the first study as one bar elicited a 10.5% increase in the daily volume of wine purchased when sold in 510ml compared to 370ml glasses. However, sales were not significantly higher with 370ml versus 300ml glasses. Findings from the second bar were inconclusive. Kersbergen *et al* (2018) utilised cluster randomised experiments to assess whether reducing the standard serving size of alcoholic beverages would reduce alcohol consumption in a laboratory (Study 1) and a real-world drinking environment (Study 2). In Study 1, participants were randomly assigned to receive either standard-sized or reduced-sized (-25%) servings of alcohol during a laboratory drinking session. This resulted in a 20.7 to 22.3% reduction in alcohol consumption. In Study 2, customers at a bar were served alcohol in either standard-sized or reduced-sized (-28.6 to 33.3%) servings. This led to a 32.4 to 39.6% reduction in alcohol consumption. In 2019, Hollands *et al* highlighted the absence of evidence of the effect of accessibility and proximity on the selection and consumption of alcohol (Hollands *et al,* 2019). The authors of this review stressed the need for long-term future research to assess such nudge-based alcohol interventions within real-life settings. To date, there is still a notable gap in the literature regarding the efficacy of nudge-based interventions that aim to reduce alcohol consumption. The research project that is reported in this thesis intended to start to bridge this gap.

1.5.3 Typology of interventions in proximal physical micro-environments (TIPPME)

The typology of interventions in proximal physical micro-environments (TIPPME) is a framework for classifying and describing nudge-based interventions within micro-environments. These interventions are intended to change people's selection, purchase and consumption of food, alcohol and tobacco products (Hollands *et al.*, 2017). In this instance, proximal is defined as able to be seen, heard, smelt, touched or tasted by intervention recipients. The micro-environment is defined as a geographically distinct and relatively small place in which groups of people gather for a specific purpose (Swinburn, Egger and

Raza, 1999). Workplaces, hospitals, supermarkets and pub/bars are examples of micro-environments. These environments tend to be easy to influence. A simplified version of TIPPME depicts six different intervention types, which are aggregated into binary classifications, and three spatial foci (Hollands *et al.*, 2017). Table 1.2 provides illustrative examples of interventions that aim to alter the selection, purchase and consumption of alcohol within on-trade licensed premises. Some of these examples are evidence based, whereas, due to the paucity of evidence, others are hypothetical.

1.6 Reducing the strength of alcohol as a nudge-based intervention

Reducing the alcohol content of drinks is one nudge-based intervention, that can be implemented within the micro environment of on-trade licensed premises, which has the potential to reduce the consumption of alcohol. Reducing the alcohol content of drinks could be classified under the TIPPME intervention type "size": serving an equal volume of alcohol with a reduced alcohol content would comprise fewer units of alcohol per serving.

There are two potential mechanisms that may explain how reducing the alcohol content of drinks could reduce alcohol consumption (Rehm *et al.*, 2016). Firstly, by current drinkers replacing the alcoholic drinks they normally consume with lower-strength alternatives and without increasing the volume of alcoholic drinks consumed. For instance, replacing two pints of 5% beer with two pints of 4% beer. Secondly, by consumers replacing alcoholic with non-alcoholic alternatives some of the time thus reducing their average alcohol unit intake. The first mechanism is predicted to be the most effective in reducing alcohol consumption (Rehm *et al.*, 2016).

Prior efforts have been made by both the government and the alcohol industry to encourage the production and marketing of reduced-strength alcohol options. However, these efforts are questionable. The UK Coalition Government (2011 to 2015) made a target to reduce the number of units of alcohol available in the UK market by encouraging companies to sign up to the Public Health Responsibility Deal (PHRD) alcohol pledges. Specifically, pledge number A8 (a). Alcohol Reduction: "we will remove 1 billion units of alcohol sold annually from the market by December 2015…" (Department of Health, 2011). One point three billion units were removed from the market between 2011 and 2013 by reductions in the strength of alcohol products. This equates to the average strength of beer falling from 4.42% to 4.14% ABV (Department of Health, 2014). It is purported that this reduction was not wholly initiated by the PHRD and would have occurred regardless as signatories were

Table 1.2: Simplified version of TIPPME: illustrative example of interventions for changing the selection, purchase and consumption of alcohol within on-trade licensed premises (adapted from Hollands et al, 2017)

		Spatial focus		
Classification	**Intervention type**	*Product*	*Related objects*	*Wider environment*
Placement	*Availability*	Remove the sale of spirits with energy drink mixers	Provide more taps serving reduced-strength beers, lagers and ciders	Provide entertainment options such as pool table and board games
	Position	Place reduced-strength alcoholic options at eye level	Place a fridge with reduced-strength alcoholic options at eye level	Place reduced-strength alcoholic options at the top of a drinks list
Properties	*Functionality*	Sell beers, lager and ciders in bottles rather than from taps	Serve wine in smaller-sized glasses	Provide ample seating
	Presentation	Sell lower-strength wine with similar sensory properties to regular-strength wine	Enhance the colour of reduced-strength beer lager and cider taps	Play relaxing background music
	Size	Reduce the alcohol content of drinks	Sell beers, lagers and ciders from the tap in 2/3 of a pint measure	Provide large windows
	Information	Add nutritional information labels to bottled alcoholic products	Provide information on the ABV of beers, lagers and ciders on the front of all taps	Add nutritional information to a drinks list

already committed to such action (Knai *et al.*, 2015). Questions were raised about the validity of the interim report that stated that PHRD targets had been exceeded, due to inadequate data and analysis plans and insufficient consideration of consumer behaviour and confounding variables (Holmes, Angus and Meier, 2015). An Institute of Alcohol Studies (IAS) report concluded that the evidence on the effectiveness of the PHRD was limited and unreliable due to ambiguous goals and inadequate reporting practices (Institute of Alcohol Studies, 2015). Regardless of whether the PHRD led to a reduction in the strength of alcohol in the UK market, the average reduction of 0.28% ABV for beer is small and there is scope to further reduce the ABV of alcohol. A similar initiative was launched in 2016 by the world's largest brewer, Anheuser-Busch InBev (AB InBev). Their "Global Smart Drinking Goals" campaign claimed to seek to implement evidence-based approaches to reduce the harmful use of alcohol. Goal 3 was to "Ensure no- or lower- (≤ 3.5% ABV) alcohol beer products represent at least 20% of AB InBev's global beer volume by the end of 2025" (AB InBev, 2018). Although initially this appears promising from a public health perspective, the concern is that AB InBev will simply expand their portfolio by creating new brands of no- and lower-alcohol beer rather than reformulating their current products to contain less alcohol. Inevitably, these new brands will be heavily marketed, and research shows that marketing tactics deployed for reduced-strength wine and beer can lead to an increase in drinking occasions (Vasiljevic *et al.*, 2018). These findings suggest that consumers may compensate for drinking reduced-strength alcoholic products by drinking them more often or continue to consume regular-strength products but have additional occasions in which they drink reduced-strength products. A study from Norway that assessed whether policy control measures prompted substitution from stronger alcoholic beverages to lower-strength ones found that when availability of lower-strength drinks increased people were more likely to consume it as an addition to, rather than a replacement for, stronger alcoholic drinks (Österberg, 2012). Therefore, it is unlikely that adding new reduced-strength brands to the market will decrease average alcohol consumption and, instead, may have an opposite and detrimental effect.

There is a paucity of evidence to support government and private sector initiatives to reduce the strength of alcoholic products. The majority of studies pertaining to the strength of alcoholic drinks are laboratory-based strength discrimination studies (Milner, 1979; Cox and Klinger, 1983; Corcoran and Segrist, 1993; Standing and Blackburn, 1995; King and Heymann, 2013; Lachenmeier, Kanteres and Rehm, 2014). One study was based within a semi-naturalistic mocked-up lounge in a community centre (McLaughlin, 1988). The

majority of these studies focused on beer, mixed spirit-based drinks, or both, and a single study focused on wine (King and Heymann, 2013). All but one (Standing and Blackburn, 1995) of these studies support the hypothesis that people cannot readily distinguish between alcoholic products of different strength. This indicates that there is potential to subconsciously alter alcohol consumption by altering the alcohol content of products. Furthermore, an experiment with Canadian students found that participants could not discriminate between beers of 3.8% ABV and 5.3% ABV and, importantly, similar levels of enjoyment and perceived intoxication were reported between conditions (Segal and Stockwell, 2009). Whilst this study suggests that consumers perceive lower-strength beer as an equal to regular-strength beer in some dimensions, it has numerous limitations: it used a small sample of male students, it was based within a classroom and participants were restricted to the amount of alcohol they could consume. A more robust study that assessed the effect of the strength of beer and mixed spirit-based drinks on consumption, supports the hypothesis that reducing the strength of alcohol does not lead to an increase in the volume of alcohol consumed, therefore reducing consumption (Geller, Kalsher and Clarke, 1991). These findings contradict the titration hypothesis, which is commonly used as a counter-argument for reducing the alcohol content of drinks. This titration hypothesis states that individuals will adjust their intake of a substance to reach a desired level of intoxication (York, 1994). Although, to date, this is the only robust experimental study assessing the effect of alcohol strength on alcohol consumption within a naturalistic setting, there are still limitations in its design. Notably, the study was based within closed student fraternity parties comprising a single fraternity at one university in the United States of America (USA). This indicates that the study has weak external validity meaning the findings cannot easily be generalised to the wider population (Geller, Kalsher and Clarke, 1991).

This paucity of evidence suggests that high-quality experimental research is warranted to assess the effect of reducing the strength of alcohol on alcohol consumption within a naturalistic environment. One such naturalistic environment is on-trade licensed premises. In the UK between the years of 2004 and 2014 there was a trend towards people purchasing alcohol to drink at home. However, in more recent years on-trade licensed premises have experienced a slower downturn (Bhattacharya, 2017b). Although still witnessing a decline, in 2017 there were almost 39,000 pubs and bars in the UK (Office for National Statistics, 2017b). Beer is a more popular choice of alcoholic drink in the on-trade than wine, spirits or alcopops. In 2016, beer accounted for 54% of total on-trade alcohol

sales and 70% of all drinks sold in pubs (Oxford Economics, 2016; British Beer and Pub Association, 2017). These figures suggest that, within a declining market, beer is still an important component of the on-trade and the on-trade is still paramount to the economy of the beer industry.

1.7 Conclusion

The burden of alcohol use globally and within the UK is vast. It can have a detrimental effect on the health of the consumer, their family and associates and the wider society. Despite preventative efforts, alcohol use has proven resistant to many traditional interventions. Interventions that target non-conscious processes may be more effective at reducing the harmful use of alcohol. Interventions based within micro-environments, including on-trade licensed premises, can be influential and are usually the simplest to implement. Changing the size of a serving of alcohol, by replacing regular-strength alcoholic products with their reduced-strength counterparts, is one nudge-based intervention that could be implemented within microenvironments. One previous experimental study reported promising results: participants did not compensate for drinking reduced-strength alcohol at a fraternity party in the USA. However, to date there is no robust experimental evidence to assess the effect of alcohol strength on alcohol consumption within on-trade licensed premises in the UK. This thesis reports on a research project that was designed to take the initial steps to address this gap in the literature.

Chapter Two: The Research Question, Methodologies, Ethical Implications and Study Timeline

2.1 Introduction

This chapter states the overarching research question that is addressed in this thesis. It outlines the three stages of the research project and the methodologies utilised at each stage. The intervention is introduced, and ethical implications involved in the administration of the intervention are considered. Finally, a timeline is provided to illustrate the systematic approach that was applied to the research project.

2. 2 The research question

The overarching aim of this thesis was to establish the feasibility of a double-blind randomised controlled crossover trial to assess the effect of lager strength on lager consumption in a single drinking occasion within licensed premises in the United Kingdom (UK). The work in this thesis was conducted to answer the question:

> *Is it feasible to undertake a double-blind randomised controlled crossover trial to assess the effect of lager strength on lager consumption in a single drinking occasion within licensed premises in the UK?*

2.3 The study design

Three stages of study comprised the overall project:

1. A single-blind taste discrimination experiment.

   Aim: To establish which brand of lager to use as the control product in the pilot trial (stage two) alongside the pre-determined intervention product, Bud Light (BL) lager (see section 2.3.1 for details).

2. A double-blind randomised controlled crossover pilot trial.

   Aim: to assess the feasibility of a double-blind randomised controlled crossover trial to assess the effect of lager strength on lager consumption in a single drinking occasion within licensed premises in the UK.

3. Semi-structured qualitative telephone interviews.

Aim: to assess the acceptability of reducing the strength of alcohol as an intervention to reduce alcohol consumption.

2.3.1 The single-blind taste discrimination experiment

The primary aim of the taste discrimination experiment was to choose a lager product that was deemed similar in taste to the pre-determined intervention product, BL, to use as the control product for the pilot trial. BL was chosen as the intervention product *a priori* because it is one of few mainstream lagers sold in the UK below 3.8% ABV and it is reported to have retailed well since its UK launch in March 2017 (Robinson, 2017a). BL was the second most popular beer brand globally in terms of volume of sales in 2016, and in 2018 it was rated as the most valuable beer brand worldwide (French, 2017; Brand Finance, 2018). In the UK, BL is accessible and affordable, which made it suitable to use in the pilot trial.

Taste discrimination experiments have previously been undertaken for investigating perceived characteristics of alcoholic drinks (Schehl *et al.*, 2005; Lachenmeier, 2006). More frequently, such experiments have been used to assess the discriminability of the strength of alcoholic drinks with the focus tending to be on beer, mixed spirit-based drinks, or a combination of both (Milner, 1979; Cox and Klinger, 1983; McLaughlin, 1988; Corcoran and Segrist, 1993; Standing and Blackburn, 1995; Lachenmeier, Kanteres and Rehm, 2014). The majority of these studies were lab-based experiments and their samples mostly consisted of university students and staff (Milner, 1979; Cox and Klinger, 1983; Corcoran and Segrist, 1993; Standing and Blackburn, 1995; Lachenmeier, Kanteres and Rehm, 2014). The study by McLaughlin (1988) differed, as it was based in a semi-naturalistic environment of a mocked-up lounge within a community centre and participants were all known to the investigator or her work colleagues. In addition, the McLaughlin study provided large samples of alcohol between 125 and 175ml, whereas the majority of other studies provided much smaller samples that ranged between 20 and 60ml Milner, 1979; Cox and Klinger, 1983; McLaughlin, 1988; Corcoran and Segrist, 1993; Lachenmeier, Kanteres and Rehm, 2014). All of the studies involved either a single-blind (Milner, 1979; Cox and Kilnger, 1983; Corcoran and Segrist, 1993; Standing and Blackburn, 1995) or a double-blind (McLaughlin, 1988; Lachenmeier, Kanteres and Rehm, 2014). Additionally, the order in which the alcohol samples/drinks were provided was randomised in all of these studies.

However, there were nuances between the methods used in each study, meaning the studies were somewhat heterogenous. For example, the time that participants spent sampling the products ranged from 15 minutes to three hours (Corcoran and Segrist, 1993; McLaughlin, 1988). The exact method from any particular study was not replicated in the taste discrimination experiment. However, some of the fundamental principles were incorporated including participant blinding and randomisation.

The experiment was a single blind, meaning only the participants were unaware of the lager products they were sampling and the order in which the samples were administered (Pocock, 1983; Bowling, 2014). Participant blinding reduces the possibility of response bias: the participant having a particular (psychological) response to the conditions being administered due to their expectations (Pocock, 1983; Tilling *et al.*, 2005; Karanicolas, Farrokhyar and Bhandari, 2010). The researcher could not be blinded as they were responsible for preparing and providing the lager samples to the participants and analysing the data. This meant that researcher bias, the researcher altering their attitude and conduct towards participants and data analysis based on their knowledge of the study conditions, could not be minimised (Pocock, 1983; Tilling *et al.*, 2005; Karanicolas, Farrokhyar and Bhandari, 2010).

The order in which the samples were provided to the participants was randomised. Randomising the order that the samples were provided protected against order effects: participants' responses being influenced by the order the experimental material is provided (Pocock, 1983).

2.3.2 The double-blind randomised controlled crossover pilot trial

The primary aim of the pilot trial was to assess the feasibility of a double-blind randomised controlled crossover trial to assess the effect of lager strength on lager consumption in a single drinking occasion within licensed premises in the UK.

There is no standard definition for a pilot study or pilot trial. The National Institute for Health Research (NIHR) defines a pilot study as "…a version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure recruitment,

randomisation, treatment, and follow-up assessments all run smoothly…" (National Institute for Health Research, 2019). The NIHR states that pilot studies and feasibility studies are mutually exclusive, with a feasibility study answering the question "Can this study be done?" (National Institute for Health Research, 2019). Additionally, the NIHR regard feasibility studies as precursors to pilot studies, which, in turn, are conducted prior to a main study. In contrast, Eldridge *et al's* (2016a) conceptual framework for defining feasibility and pilot studies in preparation for a randomised controlled trial (RCT) depicts feasibility as an overarching concept, with all studies done in preparation for a main study being called feasibility studies, and pilot studies being a subset of feasibility studies (Figure 2.1). The framework illustrates three different types of feasibility studies, which can be implemented in a non-linear order: randomised pilot studies, non-randomised pilot studies and other feasibility studies. This contradicts the NIHR's definitions, which view pilot and feasibility studies as mutually exclusive and occurring in a linear order with feasibility studies occurring before pilot studies. Eldridge *et al'*s approach, however, aligns with the Medical Research Council's (MRC) guidance, which makes no distinction between pilot and feasibility studies and states that "A pilot study need not be a scale model of the planned evaluation but should examine the key uncertainties that have been identified during development." (Craig *et al.*, 2008, p. 11; Eldridge *et al.*, 2016a). Other authors have taken a similar stance that contradicts the NIHR definitions and, instead, define pilot studies and feasibility synonymously. Thabane *et al* (2010, p. 1) state "…the main goal of pilot studies is to assess feasibility so as to avoid potentially disastrous consequences of embarking on a large study…" Teare *et al* (2014) use the term pilot study to refer to the pilot work conducted to estimate key parameters for the design of the definitive trial. According to NIHR definitions, this would be regarded as a feasibility study.

The current study was defined as a randomised pilot trial in accordance with Eldridge *et al*'s conceptual framework for defining feasibility and pilot studies in preparation for a RCT (Eldridge *et al.*, 2016a). That is, the future RCT or parts of it, including the randomisation of participants, were conducted on a smaller scale to see if it could be done. For the most part, it reflected the design of a potential future RCT. In line with Teare *et al*'s definition of a pilot study, the pilot trial also provided estimates of key parameters for the design of a RCT (Teare *et al.*, 2014). It is an external pilot study: a stand-alone piece of work that has been planned and carried out independently to a main study (Lancaster,

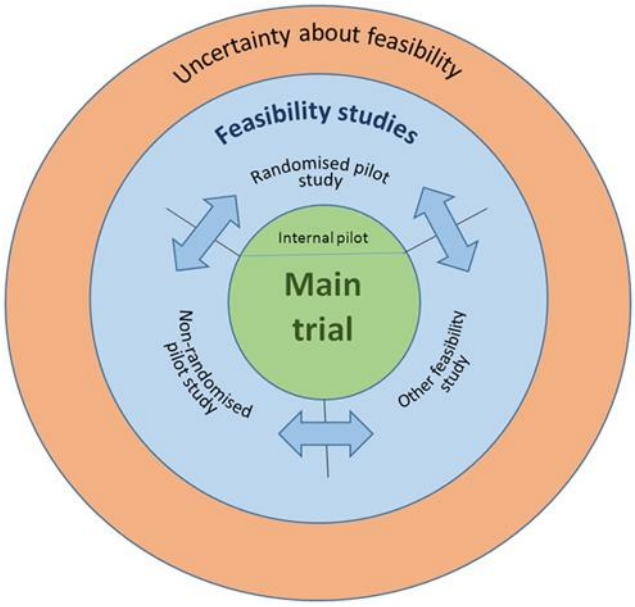


Figure 2.1: Conceptual framework for defining feasibility and pilot studies prior to RCTs (Eldridge et al (2016a). Available online at: 10.1371/journal.pone.015020)

Dodd and Williamson, 2004). However, this pilot study was planned with a future RCT in mind.

The pilot trial utilised a randomised crossover design. Senn (2002) defines a crossover trial as one in which subjects are given sequences of treatments and differences between the individual treatments are studied. Here, the term treatment is broad and does not solely refer to its medical definition: the term may encompass non-medical interventions, placebos or the status quo (normal practice) (Senn, 2002). The simplest crossover design, and the design used in this pilot trial, is the AB/BA, or two-period, design (Pocock, 1983; Sibbald and Roberts, 1998; Senn, 2002). This involves half of the participants being under one condition (condition A); followed by a period when the participants are under no condition, known as the 'wash-out' period; and then participants are under a second condition (condition B). The other half of the participants follow the same process, but they experience the conditions in the reverse order (B before A) (Sibbald and Roberts, 1998; Senn, 2002). In the pilot trial the conditions were regular-strength lager: the status quo and reduced-strength lager: the intervention. The wash out period is vital in crossover trials to ensure that the first condition does not influence the second condition: when this occurs, it is known as a carry-over effect (Senn, 2002). Instead, a participant should be returned to their natural state prior to the second condition being implemented (Senn, 2002). The wash-out period in the pilot trial was four weeks, which was ample time for the

alcohol from the previous condition to be expelled from the participants' bodies and to reduce the possibility of the participants recalling the sensory qualities of the lager administered under the first condition. The crossover design is advantageous as fewer participants are required than in parallel trials to obtain the same number of observations, fewer observations are required to gain the same precision in estimation, and between-subject variability is removed (Senn, 2002). For the pilot trial, having to recruit fewer participants was a particular advantage as time and resources were limited. There was the risk of a high level of attrition due to the four-week wash-out period. However, measures were put in place to counter this risk: participants were sent multiple reminder emails and they were offered an incentive of being entered into a prize draw to win one of two prizes of £100 if they completed the study.

Randomisation, a key feature in RCTs, is when participants are randomly assigned to either the intervention or the control conditions, or the order in which they receive the intervention, and the control (Tilling *et al.*, 2005). Randomisation performed correctly guarantees that there is no selection bias: certain participants being deliberately selected for certain conditions or to receive the conditions in a certain order (Pocock, 1983). The randomisation process additionally ensures that the intervention and the control groups do not differ systemically regarding known and unknown influencing factors (Tilling *et al.*, 2005). This allows a more accurate comparison of outcomes between the conditions (although this is less relevant in crossover trials). Due to the pilot trial's crossover design, randomisation occurred at the time level. This meant participants were randomised to the order they were administered the intervention, and the control. Randomisation at the time level eliminates the risk of a period effect: participants' health status changing over time such that it obscures the effect of the condition being administered (Pocock, 1983)

A process of stratified randomisation was utilised whereby a different randomisation sequence, albeit using the same approach, was deployed for each study venue. Pocock (1983) states that the primary aim of stratified randomisation is to protect against the treatment groups having major differences in participant characteristics. In this instance, randomisation was stratified to prevent disparities in the order the intervention and control conditions were administered based on differences related to the study venues. Within each strata a process of simple randomisation was used. This meant that each participant had an equal chance of being randomised to receive the intervention and control in the order AB or BA. Probability theory states that over time there should not be a large disparity

between the number of participants randomised to receive the intervention and the control in the order AB to those receiving it in the order BA (Pocock, 1983).

The pilot trial was designed to be a double blind. This meant that both the participants and the intervention provider were not aware of which group (the intervention or the control) the participants were allocated to in each of their study sessions (Pocock, 1983; Bowling, 2014). The researcher could not be blinded throughout the pilot trial as they designed the study and purchased and prepared the lager products for the study sessions. This may have increased the risk of assessment bias: a lack of objectivity in assessing the outcomes of a trial (Pocock, 1983). To protect against this, the outcome measures were objective and pre-specified, and the researcher aimed to be transparent in the reporting of the outcomes. This included using the Consolidated Standards of Reporting Trials (CONSORT) extension for randomised pilot and feasibility trials criteria as a framework for reporting the trial in this thesis and in any ensuing publication (Eldridge *et al*, 2016b (Appendix A); Perman-Howe, Davies and Foxcroft, 2018 (Appendix B)). To adhere to the double blind, the allocation of the order in which the conditions were administered was concealed to the researcher and the participants.

2.3.3 The semi-structured qualitative telephone interviews

The primary aim of the telephone interviews was to assess the acceptability of reducing the strength of alcohol as an intervention to reduce alcohol consumption.

The term "qualitative interview" refers to an interview that provides textually rich data, which is believed to provide a deep understanding and explanation of meaning (Kelly, 2010). Qualitative interviews are a common research method for establishing levels of intervention acceptability amongst the target audience (Ayala and Elder, 2011). Mishler (1991) described the qualitative interview as a discourse that occurs between the researcher and the participant; the participant is viewed as a collaborator in the research process and the data as a joint product of the discourse. It is through this lens that the interviews were conducted: with a perceived parity between the researcher and the participant.

Semi-structured interviews involve the researcher working from an approximate, pre-determined interview schedule with the use of prompts and probes. Such interviews enable flexibility and deviation from the interview schedule. However, they still retain a degree of standardisation above that of unstructured, or naturalistic, interviews (Kelly, 2010). Semi-

structured interviews are most suitable for exploring a well-defined area of specific interest such as discussing the acceptability of a specific behavioural change intervention (Kelly, 2010). Barriball and While (1994) claim that semi-structured interviews are superior to structured interviews when the sample is heterogenous or when responses may be ambiguous and thus require further discussion. Treece and Treece (1986) explain that central to conducting a good semi-structured interview is the ability to vary the wording but not the meaning. This approach acknowledges that not every word has the same meaning to everyone, in contrast to the principles of standardisation that underpin the structured interview. It is thus the equivalence of meaning, rather than the standardisation of words, that is fundamental to the validity and reliability of semi-structured interviews.

The semi-structured interview is commonly conducted face to face or over the telephone. Face to face interviews were originally deemed superior to telephone interviews due to the naturalistic nature of the encounter. They were believed to elicit greater rapport and thus more wholesome data (Shuy, 2003). However, evidence suggests a parity between the accuracy of data derived from each method of interview (Sturges and Hanrahan, 2004). The interview method of choice should thus be determined by individual circumstances including the safety and comfort of participants and the researcher, and available funds and resources. Telephone interviews were chosen for this study because the interview topic did not require face to face interaction, it was more financially and time efficient and it enabled the interviews to be conducted from a safe, secure and accessible location. Additionally, the participants had already interacted with the researcher face to face whilst partaking in the pilot trial, which meant that rapport was established prior to the interviews.

2.4 The participants

Due to different practices across the three stages of study, the participants, including the licensed premises participating in the pilot trial, are described separately in the subsequent chapters.

2.5 Ethical considerations and processes

There are specific ethical dimensions to consider when conducting research that involves administering alcohol to participants. As the consumption of alcohol can have adverse health consequences, the ethical principle of non-maleficence is of foremost importance. The pilot trial was designed to be a naturalistic experiment meaning it mimicked reality to

the greatest possible extent. This meant that participants' level of risk from consuming alcohol as part of the study was designed to, at worst, mimic the levels of risk participants expose themselves to whilst consuming alcohol in the absence of the study conditions. At best, it was predicted that participants would be at a lower risk whilst consuming reduced-strength alcohol (the intervention) as part of the pilot trial than they would be exposed to on a regular drinking occasion. This prediction is supported by evidence which suggests that individuals consume fewer units of alcohol when it is of reduced strength (Geller, Kalsher and Clarke, 1991). Although the study was designed to be naturalistic, one disparity between the study and real-life practice was the price of the drinks. Lengthy discussion occurred between the researcher and their supervisory team to establish a suitable price for the study-specific drinks. A balance was sought between charging enough to uphold the naturalistic element of the study and to dis-encourage abnormally excessive drinking, and not over-pricing the drinks, which could deter potential participants. The study-specific drinks were priced differently for each venue and were approximately two thirds of the price of the cheapest lager that was sold at each venue. To counter the possibility of abnormally excessive alcohol consumption due to the lower-priced drinks, a safeguard measure was put in place: participants, who had all previously stated how much alcohol they consumed on their heaviest drinking session in the past year, were assessed by the researcher when they had consumed 80% of this total during a study session. This assessment involved the researcher having a brief generic conversation with the participant to establish whether they appeared to be excessively intoxicated.

Other safeguarding measures that were implemented were: screening and preventing individuals from participating if they had a history of alcohol problems or were pregnant, the offer of a paid taxi for any participant who was over the drink-drive limit at the end of a study session and who expressed they had no safe method of returning home, and the provision of an alcohol advice leaflet to each participant when they completed their first study session (Appendix C).

Whilst safeguarding measures were implemented to prevent harm from the pilot trial, the risk was not eliminated. It was agreed with the hosting licensed premises managers that, as per the terms of their license, the license holder had the ultimate responsibility for their patrons. This meant that during study sessions the duty manager had the prerogative to intervene and/or remove participants from the venue and, therefore, from the pilot trial.

Undertaking research within licensed premises can expose researchers to risks. Measures were implemented in the pilot trial to reduce these risks: a research assistant (RA) was always in attendance at a study session, the supervisory team were aware of where and when the study sessions were taking place and staff at the study venues were aware of the researcher's role and their limitations.

Ethical approval for each stage of study was sought from Oxford Brookes University's Research Ethics Committee (UREC). Each stage of the study was fully approved by the committee: approval number 171086. Any changes to the study protocol that involved participant recruitment, methodology or data storage were sent to the UREC chairperson for approval. Copies of the letters of approval from UREC are in Appendix D.

2.6 Study timeline

Data collection for the entire project occurred between October 2017 and April 2019 (Table 2.1). The taste discrimination experiment, including recruitment, was one month in duration and occurred five months prior to the first pilot trial study session. Each of the pilot trial venues participated for a span of three months including recruitment and four data collection sessions. The interviews commenced once the first pilot trial study venue had completed four study sessions, and thereafter data collection was concurrent with that of the pilot trial. Data collection was completed in April 2019 following the final interview.

2.7 Conclusion

This chapter discussed the three different methodologies undertaken in three separate stages of study in order to answer the research questions. It highlighted some of the key features of each methodology, outlined their rationale, and explained how they were incorporated into each stage of the study. The intervention was introduced and ethical issues involving the administration of the intervention were discussed. Finally, an outline of the systematic approach to the project was provided. To align with this, the study will be systematically and transparently reported in this thesis and any ensuing publications.

Table 2.1: Timeline of the three stages of study

	Oct – Dec 2017	Jan – March 2018	April – June 2018	July – Sept 2019	Oct – Dec 2019	Jan – March 2019	April - June 2019
Taste experiment							
Pilot trial Venue 1							
Pilot trial Venue 2							
Pilot trial Venue 3							
Pilot trial Venue 4							
Interviews							

Chapter Three: The Single-Blind Taste Discrimination Experiment

3.1 Introduction

This chapter discusses the taste discrimination experiment that was undertaken in order to establish which lager brand would be the control product, alongside the pre-determined intervention product, Bud Light (BL) lager, for the pilot trial. Firstly, the chapter provides a rationale for the experiment including the choice of lager brands and the sample size. The methods section outlines how the data collection tools were developed, the process of participation, and the data analysis. The results of the experiment are reported and discussed. Finally, conclusions are made as to the suitability of the taste discrimination experiment prior to a future randomised controlled trial (RCT) and the limitations of the methodology.

3.2 Background

Prior to piloting a RCT to assess the effect of alcohol strength on alcohol consumption, the intervention and control products needed to be established. For the pilot trial, the intervention and control products were required to be a reduced-strength and a regular-strength lager brand respectively: purchased in 440 millilitre (ml) cans and resold by the pint (568ml).

The lager brands were required to be as similar as possible to each other in every aspect except for their strength, to reduce the potential for confounding. Confounding, often referred to as a "mixing of effects", occurs when a variable other than the exposure of interest influences the outcome: this can distort the true effect of the exposure on the outcome (Skelly, Dettori and Brodt, 2012). In the pilot trial, differences between the sensory aspects of the intervention and control products had the potential to be confounders. These included the temperature, carbonation, colour, smell and taste. Some of these potential confounders were controlled for in the study design. For example, all the lager cans were put in the same fridge 24-hours prior to a study session to ensure they were equally and consistently chilled. However, when choosing which lager brands to use as the intervention and control products, the taste differences between the products needed to be minimised. As taste is influenced by, or encompasses, the other sensory aspects, it was believed to be the most important sensory element to control for. Additionally, as the perception of taste can impact on peoples' food and drink choices, it was important not only to standardise the taste of the intervention and control products, but to increase their

likability (Hoffman, Cruickshanks and Davis, 2009). One way to achieve this was to undertake a taste discrimination experiment prior to the pilot trial.

The taste discrimination experiment primarily aimed to establish which, out of a range of regular-strength lagers, was deemed to taste most similar to the pre-determined intervention product, BL (3.5% alcohol by volume (ABV)). Secondly, it sought to establish the likability of the proposed intervention product, BL, and the potential control products.

The aim was to recruit 20 participants for the experiment. This was not derived statistically but it was similar to previous alcohol discrimination studies, which obtained samples of 18 and 19 (Cox and Klinger, 1983; McLaughlin, 1988). The taste discrimination experiment sought to answer the question:

Which regular-strength (4.8% ABV) lager tastes most similar to BL lager?

The outcome informed which lager brand to use as the control product, alongside BL as the intervention product, for the pilot trial.

3.3 Method

3.3.1 Study design

The study utilised a single-blind experimental design (as discussed in section 2.3.1).

3.3.2 Materials

See Appendix E for the comprehensive list of materials and equipment that were required for the taste discrimination experiment.

3.3.3 Eligibility criteria

Table 3.1 outlines the participant eligibility criteria for the taste discrimination experiment (see section 3.3.4 for details on how participants were screened against the eligibility criteria).

Table 3.1: Eligibility criteria for the taste discrimination experiment

Inclusion	**Exclusion**
18 years of age or older	Has ever sought help, or been treated, for an alcohol dependency
Regular drinker of lager (≥once in the past three months)	Has an illness or condition with which they should not be consuming alcohol
Able to attend a 30-minute study session	Is on medication with which they should not be consuming alcohol
Provides informed consent	Pregnant
	Has a BrAC >0 when they arrive for the study session

3.3.4 Data collection tools

An electronic eligibility survey (Appendix F) was devised by the researcher to gather demographic information and to ascertain who, out of those who expressed an interest, met the eligibility criteria (Table 3.1). The eligibility survey comprised two multiple choice questions to ascertain demographic information: gender and employment status; and five questions to establish eligibility: one open-ended question to ascertain age and four binary yes/no questions to ascertain whether the individual was pregnant, had a history of alcohol dependency, was a frequent lager consumer, and was able to attend the study session. The survey also incorporated an open-ended section where individuals could leave their contact details if they wanted the researcher to arrange a study session for them. The eligibility survey was designed to be easily accessible, via a link to the Qualtrics[4] page, and to be simple and fast (less than five minutes) for individuals to complete (Qualtrics, 2005). Additionally, it was designed so that the researcher could easily distinguish those who were eligible from those who were not.

To the researcher's knowledge, no research tool existed to measure the similarities and differences between lager samples in a taste experiment. Therefore, the researcher designed a questionnaire (Appendix G). The same questionnaire was repeated three times

[4] Qualtrics is a company that provides online survey software with whom Oxford Brookes University's Faculty of Health and Life Sciences holds an agreement. Further information about Qualtrics can be found at http://www.qualtrics.com/.

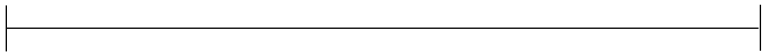
with participants, one for each set of two samples, to ensure consistency and reliability and to reduce the risk of measurement decay: any change to the measurement process over time (Bowling, 2014). The questionnaire directly measured the perceived level of similarity between the taste of the lager products being sampled (Figure 3.1). The questionnaire also measured participants' perceptions of the relative strength of each sample within each pair of samples, and their taste preferences. These questions were included to indicate the efficacy of blinding participants to the strength of the intervention and control products in the pilot trial, and to predict whether participants would "accept" the products they purchased as part of the pilot trial: thus, indicating the potential rate of attrition. As sensory perceptions are highly subjective, the questionnaire may not have elicited results that can be generalised to the wider lager-drinking population (Hoffman, Cruickshanks and Davis, 2009). This means its external validity is likely compromised. To mitigate this to the greatest extent possible, a representative sample, of a size similar to that used in previous similar studies, was sought (Cox and Klinger, 1983; McLaughlin, 1988).

3.3.5 Piloting and refining data collection tools

Ten Oxford Brookes University (OBU) PhD students were asked to pilot the eligibility survey. Feedback was received from five of the 10 PhD students plus the partner of one of the PhD students. Based on the feedback some basic amends to the wording was made.

Two unofficial pilot taste experiments were undertaken by the researcher in the home setting with three friends attending each session. These pilots tested different methods for the taste experiment and used white wine rather than lager. Initially, the researcher provided samples of four different wine products simultaneously to enable direct comparisons. However, feedback from all the participants suggested that this resulted in a sensory overload, which made it complicated to distinguish between the different tastes of the products. The researcher, together with the participants, redesigned the experiment and tested the updated version at the second unofficial pilot session. This pilot involved sampling the products in three sets of two, with the same questionnaire administered with each set of samples. A palette cleanser was provided throughout and there was a five-minute break between one set of samples being removed and the next set of samples being provided. The second pilot was well received and, based on feedback, only minor amends to the wording and format of the questionnaire was required. Following the pilot, the experiment was adapted to lager: by providing larger samples (30ml instead of 20ml) in

1. How similar or dissimilar is the taste of sample 1 to the taste of sample 2? *Put an X on the line.*



Completely dissimilar Identical

Figure 3.1: Taste experiment questionnaire Question One

recognition of the lower ABV and larger measures of lager normally purchased, and by rewording the questionnaire accordingly.

The reworded questionnaire was piloted with three OBU PhD students who all supplied feedback. Based on the feedback some basic amends to the wording was implemented

3.3.6 Participant recruitment

Three methods of recruitment were planned:

1. The researcher was to attend an Oxford Pubwatch Scheme meeting and request that pub landlords/managers advertised the study by placing flyers in their licensed premises and posting on their social media accounts.
2. An email sent by an administrator to members of the OBU Research Mailing List.
3. Flyers placed within bar and café areas at OBU's Headington Campus.

The three methods of recruitment were chosen to elicit a representative sample. However, the researcher was unable to contact the Oxford Pubwatch Scheme: no contact details were supplied on their website and the contact form that the researcher submitted did not induce a response. Therefore, participants were recruited via methods detailed in points two and three only.

Individuals who contacted the researcher with an expression of interest were sent an invitation letter (Appendix H), a participant information sheet (PIS; Appendix I) and a link to an electronic eligibility survey (Appendix F). The researcher analysed the eligibility survey responses against the inclusion/exclusion criteria (Table 3.1) and contacted those

who were eligible via email to arrange a 30-minute study session. Those who were not eligible were contacted to explain why they could not take part. Of those who completed the eligibility survey, only one individual was not eligible to take part.

3.3.7 Choosing the products for the experiment

BL was chosen as the intervention product before the taste discrimination experiment (for more information refer to section 2.3.1).

Three popular brands of lager sold in the United Kingdom (UK) were chosen as the regular-strength products for the taste discrimination experiment: Becks (B), Carlsberg Export® (CE) and Stella Artois® (SA). SA was primarily chosen as it was the top selling lager brand in the UK in 2016, and B and CE were then chosen as they are both the same strength as SA (4.8% ABV) (Robinson, 2017b; The Grocer cited in Institute of Alcohol Studies, 2018). Budweiser® was initially chosen for the taste experiment as at the time of the study's conception it was produced at 4.8% ABV. However, knowledge gained prior to the taste experiment suggested that Budweiser's producer, Anheuser-Busch InBev (AB InBev) was due to reduce the strength, and therefore the formulation, of Budweiser. This would have likely altered the taste profile of the beverage, thus invalidating the results of the taste experiment were it to be subsequently used as the control product in the pilot trial. Additionally, the reduction in strength of Budweiser from 4.8% ABV would have meant that, should it be used in the pilot trial, the anticipated effect size would differ meaning a different sample size would be required. Knowing the strength of both the intervention and control products prior to the taste experiment meant that the pilot trial effect size could be estimated and subsequently a sample size for the pilot trial could be calculated. This enabled the researcher to ascertain from the outset whether a pilot trial was feasible to undertake within the timeframe of a full-time PhD programme.

3.3.8 Preparing and concealing the randomisation sequence

A spreadsheet was devised that listed each of the 144 combinations for the potential order of sample provision (Appendix J). The director of studies (DoS) used an online randomisation tool to randomly select 20 numbers between one and 144. The DoS printed each of the 20 numbers on separate pieces of paper, which were then sealed in separate opaque envelopes.

3.3.9 The experimental process

Upon arrival for the study session, the individual was taken to a meeting room and the procedure was explained to them. The researcher took a breath alcohol concentration (BrAC) reading from the individual and if the reading was zero, they were guided through the consent process; every attendee had a BrAC of zero and consented to take part. The participant was then asked to take the next sealed envelope from the randomisation sequence pile, open it and read out the number on the piece of card inside the envelope. The participant was provided with a fresh glass of water, which they were told they could drink as required including using it as a palette cleanser.

The researcher then went to the adjacent meeting room, with the randomisation card, to prepare the samples. The number on the randomisation card was cross-referenced with the number on the randomisation sequence spreadsheet. This indicated to the researcher the order in which to present the samples to the participant (see Figure 3.2). The samples were presented in three sets of two samples, with each set containing BL and one of B, CE, or SA.

The samples were poured, one set at a time, from 440ml cans, which were stored in a fridge in the meeting room, into separate measuring vessels. A separate measuring vessel was used for each brand of lager so that the samples were not contaminated. Thirty ml of each sample was then poured into transparent plastic half pint glasses, which had been numerically labelled between one and six (Figure 3.2). Once the samples had been poured, the cans were returned to the fridge or disposed of. Fresh cans were used every half an hour to ensure the samples were adequately and consistently carbonated.

The researcher took the first set of samples to the participant with a questionnaire and instructed the participant that they had five minutes to sample and complete the questionnaire. They were instructed to consume as much or as little of the samples as required. This process was repeated twice more with a five-minute break between one set of samples being removed and the next set being presented.

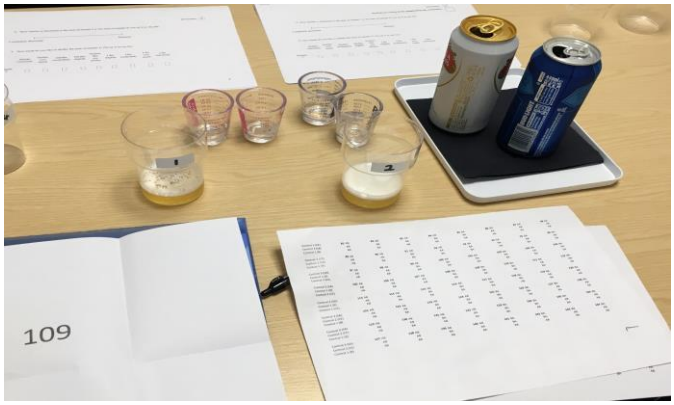


Figure 3.2: Randomisation sequence number (109), spreadsheet detailing the order to present the samples (for randomisation sequence number 109), cans of lager, measuring vessels (shot glasses) and samples number 1 and 2.

Upon completion of sampling, the researcher took another BrAC measurement from the participant and, if the reading was below or equal to the UK drink-drive limit of 35 micrograms (mcg) of alcohol per 100ml of breath, the participant was given a £10 shopping voucher and allowed to leave. Three participants had BrACs over this threshold and were asked to wait five minutes and then repeat the BrAC measurement. At the second attempt all three participants' BrAC readings were below this threshold and they were given a shopping voucher and allowed to leave the study venue.

3.3.10 Data analysis

Data were analysed using descriptive statistics.

Participants rated the similarity of the two samples within each set of three using an unanchored scale (Figure 3.1). The scale was 10cm in length and this allowed a similarity rating to be quantified. As the data for the similarity ratings were not normally distributed, the median similarity ratings were reported. From the median similarity ratings, a rank order was established as to which of B, CE and SA was deemed, by each participant, to taste most similar to BL.

Participants were asked how much they liked or disliked the taste of each of the products within each pair of samples, using a 9-point Likert scale. Data were trichotomised into the umbrella categories liked, disliked or felt neutral. The mode of the three categories was reported.

Participants were asked which sample in each pair they thought contained a higher ABV, or whether they thought the samples had the same ABV. The mode of whether participants predicted this correctly or not was reported.

The questionnaire contained one open-ended question by which participants could comment about the lager they had sampled. These data were not formally analysed but gave the researcher an indication about potential problems with the administration of the intervention and control products in the pilot trial.

3.4 Results

3.4.1 The participants

Nineteen participants (12 female: 63%) took part. The participants ranged in age from 20 to 53 with a mean age of 30.5. Nine participants stated that they worked full time, eight were students and two worked part time.

3.4.2 Outcomes

B was considered to be the product most similar to BL (Figure 3.3). Nine (47%) participants rated B as the most similar to BL, compared with seven (37%) participants who rated SA as the most similar to BL and three (16%) participants who rated CE as most similar to BL. As there was no overall majority consensus the product that was deemed the least similar to BL, (CE), was eliminated and the data were redistributed: for each of the three participants who rated CE as being the most similar to BL, the product that they rated as being the second most similar to BL was given an extra "vote". Following this redistribution 11 (58%) participants deemed B to be more similar to BL than was SA: eight (42%).

B and BL has the highest median similarity rating of 7/10 (70%), compared to SA and BL: 3.7/10 (37%) and CE and BL: 3.2/10 (32%).

An overall majority of participants liked each of the samples that they tried, compared with those who did not like the samples or felt neutral about them (Figure 3.4).

Figure 3.3: Share of responses (%) for which regular-strength lager brand was deemed most similar in taste to BL

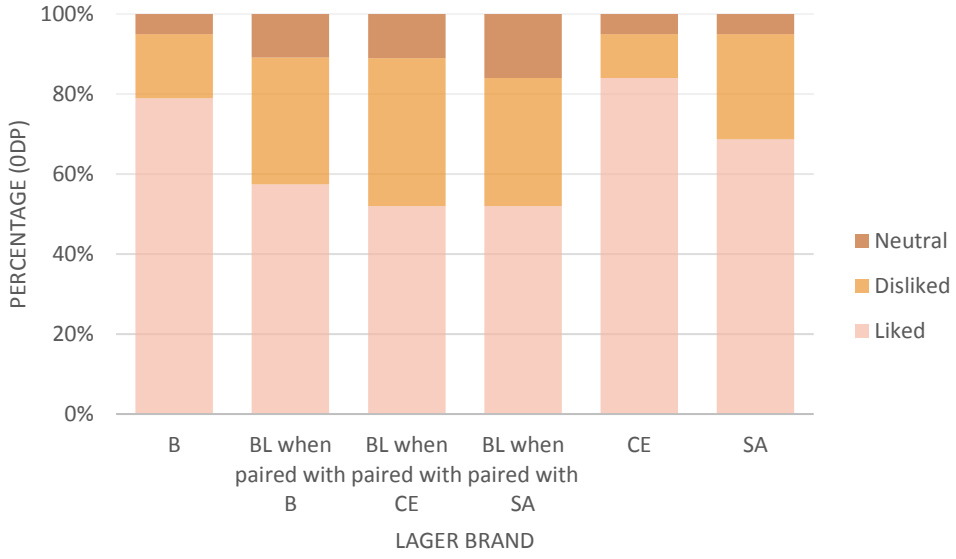


Figure 3.4: Share of responses (%) for likability of taste experiment sample products

Most participants were able to correctly identify which of the samples within each pair of samples had the higher alcohol content: 68% for B/BL, 84% for CE/BL, 68% for SA/BL.

3.5 Discussion

Based on the results of the taste experiment, B (4.8% ABV) became the control product for the pilot trial alongside BL (3.5% ABV) as the intervention product.

As outlined in the study protocol, the thresholds to be met in the taste experiment in order to classify it as successful were:

1. Participant recruitment rate should be equal to or greater than five per study session.
2. An overall majority consensus as to which regular-strength lager tastes most similar to the pre-determined reduced-strength lager, BL, is obtained within the initial taste experiment or one re-run of the taste experiment, and…
3. The mean/median similarity rating between these two products is equal to or greater than seven.

The recruitment rate for the taste experiment was 9.5 per study session. This exceeded the minimum threshold of five per study session.

An overall majority consensus as to which regular-strength lager tasted most similar to the pre-determined reduced-strength lager, BL, was not obtained with the original data. However, following lengthy discussion between the researcher and their supervisory team, it was decided not to re-run the experiment as outlined in the study protocol. This was because there lacked sufficient justification: re-running the experiment would have required additional resources, it would have been more complicated and time consuming to recruit new participants as those who initially expressed an interest had taken part in the original experiment, and additional participants may not have provided more decisive data. Regarding the latter, after consideration of the different possible scenarios that could occur in a further taste experiment, it was predicted that a similar result would likely be obtained. Therefore, a mechanism for data redistribution would have had to be built into the design of the second taste experiment. It was agreed that it made sense to apply this data redistribution to the initial experiment. Therefore, the original data were redistributed as outlined in section 3.4.2 and an overall majority was established.

The median similarity rating between the two products that were deemed to taste most alike, (B and BL) was seven. This met the minimum threshold as outlined in point three.

The study protocol also states that for a RCT to be feasible "components of the study protocol are efficient and work together or can be amended to be or do so" (Perman-Howe, Davies and Foxcroft, 2018 (Appendix B)). The screening, consent, randomisation, and data collection processes all worked efficiently and without incident. It was noted, however, that taking a BrAC reading from participants immediately after they had finished their third set of samples was futile. Not enough time had elapsed for the BrAC reading to be accurate: some participants' readings were zero, whilst others came back above the UKs drink-drive limit. In the case of the latter, within five minutes the participants were re-tested and their BrAC levels had significantly reduced to below that of the UK drink-drive limit. This indicated that the breathalyser was sensitive to residual alcohol within the mouth after consumption and thus gave a falsely high reading. If in future experiments researchers wish to take an exit BrAC reading from participants, they should wait for a minimum of five minutes from the completion of the final sample.

Figure 3.4 suggests that all the products that were sampled were likeable. However, BL was consistently rated as likable by fewer participants than the regular-strength lager products. Overall, these data indicate that the intervention and control products would be accepted, which could reduce the risk of attrition, in the pilot trial.

In the taste discrimination experiment most participants were able to identify which sample within each pair had the higher ABV. If these results were translated to the pilot trial, and participants were aware when they were drinking a reduced-strength lager, this would increase the risk of participant bias. However, in the pilot trial participants had a one month's wash-out period between study sessions, which meant they were not making direct comparisons between the intervention and control products as in the taste discrimination experiment. The lack of opportunity to directly compare the products reduced the risk of a carry-over effect, whereby participants could retain sensory knowledge of the lager product they consumed during their first study session.

The taste discrimination experiment would be suitable to run prior to a RCT to establish a control and/or intervention product. However, it should be noted that contrary to the study protocol, it may not be necessary to re-run the experiment if there is no overall majority consensus as to which regular-strength product tastes most similar to the pre-determined reduced-strength product. The taste experiment should only be re-run if the mean/median

similarity rating between these two products is less than seven. In this instance, it would be assumed that none of the regular-strength products taste similar to the reduced-strength product and therefore different regular-strength brands of lager should be sampled during a re-run. Alternatively, a different reduced-strength lager could be chosen as the pre-determined intervention product, or, ideally, a range of reduced-strength lagers could be sampled: although the latter would be more costly and time consuming.

The taste experiment could be adapted for other alcoholic products such as wine. The main consideration in this situation should be the size of the samples; wine has a higher alcohol content than lager meaning smaller sized samples should be considered. Additionally, minor amendments to the wording of the eligibility survey and the questionnaires would be required.

There are several limitations to the taste discrimination experiment, which should be addressed if the experiment is conducted again. Firstly, no formal sample size calculation was applied. Instead, the target sample size was based upon those used in previous studies (Cox and Klinger, 1983; McLaughlin, 1988). A formal sample size calculation should be applied to a future taste discrimination experiment. If the sample size is larger than 20, a wider recruitment strategy would need to be implemented. This should aim to recruit a more representative sample compared to the current study, which over-recruited students and females and under-recruited those who were older (>53 years), retired or unemployed: this being the second limitation of the current study. However, the extent to which the unrepresentative sample may have affected the data is unclear. The researcher is not aware of any studies which suggest that sensory perceptions differ between those of different ages and genders, and with different occupations and levels of drinking experience. This would suggest that whilst sensory perceptions are subjective, this does not necessarily vary based on demographics: meaning the demographic of the cohort recruited for a taste discrimination experiment is not of paramount importance. Thirdly, the ecological validity of the results obtained from the questionnaire may be compromised due to the small sample sizes (30ml) of lager provided to participants: in a real-life setting of licensed premises, individuals would usually be drinking lager in larger volumes of up to 568ml. The smaller sized samples could potentially result in altered taste perceptions from what would be experienced in “reality”. However, providing samples in quantities of up to 568ml in the taste experiment would be considered unethical and would have required further resources beyond those that were available to the researcher. In a larger-scale study

more resources should be available to increase the volume of lager in each sample. The volume could be doubled to 60ml, which would align with another taste discrimination experiment (Corcoran and Segrist, 1993). To mitigate the ethical issue of participants leaving the study venue intoxicated, they should be notified, prior to consent, that they will be asked to remain at the study venue until their BrAC is below the drink-drive limit. Lastly, the range of lager products being sampled was limited: there was only one reduced-strength lager and three regular-strength lagers, as chosen by the researcher. This was, in part, due to a lack of time and resources. Prior to a larger study, participant and patient involvement (PPI) work should be undertaken to ascertain the most popular tasting products to sample in the taste discrimination experiment. Additionally, the taste discrimination experiment should be widened to include a larger range of different strength lager products as guided by the PPI work.

3.6 Conclusion

This chapter has explained the need for pilot trial intervention and control products to be chosen scientifically and systematically. It outlined a taste discrimination experiment, which was designed and implemented by the researcher. From the data reported, the control product (B) for the pilot trial was established, alongside the pre-determined intervention product (BL). It was concluded that a similar taste discrimination experiment would be suitable prior to a larger-scale RCT if the limitations of this study were addressed first.

Chapter Four: The Double-Blind Randomised Controlled Crossover Pilot Trial

4.1 Introduction

This chapter discusses the main part of the PhD programme of study: a double-blind randomised controlled crossover pilot trial to assess the feasibility of a randomised controlled trial (RCT) to assess the effect of alcohol strength on alcohol consumption within licensed premises in the United Kingdom (UK). Firstly, the chapter provides a rationale for the pilot trial and outlines the aim and objectives. The methods section describes the participant eligibility criteria, how data collection tools were developed, strategies to aid licensed premises and participant recruitment, how the sample size was estimated, the experimental process and the methods of data analysis. The results of the trial are displayed and further discussed. Finally, four different scenarios for future studies to assess the effect of alcohol strength on alcohol consumption within licensed premises in the UK are considered.

4.2 Background

As, to the researcher's knowledge, at the time of the study's conception no trial had been conducted to assess the effect of alcohol strength on alcohol consumption within licensed premises, an initial pilot trial was necessary to obtain feasibility data. This chapter reports on the pilot trial, which was undertaken as part of the research project.

The overall aim of the study was to pilot a double-blind randomised controlled crossover trial to assess the effect of alcohol strength on alcohol consumption in a single drinking occasion within licensed premises in the UK. The pilot trial sought to answer the question:

> *Is it feasible to carry out a definitive RCT to assess the effect of alcohol strength on alcohol consumption in a single drinking occasion within licensed premises in the UK?*

The objectives were to establish whether:

- components of the study protocol were efficient and worked together or could be amended to be or do so
- a sufficient number of licenced premises could be recruited to host the study
- the participant recruitment rate per study session was sufficient
- participant retention was sufficient

- estimations of the mean, standard deviation (SD) and 95% confidence interval (CI) of the number of UK units of alcohol consumed by participants in a single drinking occasion provisionally support the hypothesis that people consume fewer units of alcohol when they consume reduced-strength alcohol
- the sample size derived from data obtained in the study was achievable for a future definitive trial.

4.3 Method

4.3.1 Study design

This study utilised a double-blind randomised controlled crossover pilot trial design (as discussed in section 2.3.2).

4.3.2 Materials

See Appendix K for the comprehensive list of materials and equipment that were required for the pilot RCT.

4.3.3 Eligibility criteria

Table 4.1 outlines the participant eligibility criteria for the pilot trial (see section 4.3.4 for details on how participants were screened against the eligibility criteria).

4.3.4 Data collection tools

An electronic eligibility survey (Appendix L) was devised by the researcher to obtain demographic data and to ascertain who, out of those who expressed an interest, met the eligibility criteria (Table 4.1) for the pilot trial. The pilot trial eligibility survey was adapted from that of the taste experiment. It contained five of the same questions: two multiple choice questions that ascertained gender and employment status, one open-ended question to ascertain age and two binary yes/no questions to ascertain whether the individual was pregnant and/or had a history of alcohol dependency. Two further questions were adapted from the taste experiment eligibility survey: participants were asked whether they frequently consumed lager within licensed premises and whether they were able to attend two study sessions. Two additional multiple-choice questions were incorporated to assess how many units of alcohol individuals drank on their heaviest drinking occasion in

Table 4.1: Eligibility criteria for the pilot trial

Inclusion	**Exclusion**
18 years of age or older	Has ever sought help, or been treated, for an alcohol dependency
Regular drinker of lager within a licensed premises (≥once in the past three months)	Has an illness or condition with which they should not be consuming alcohol
Able to attend two study sessions	Is on medication with which they should not be consuming alcohol
Provides informed consent	Pregnant
	Has a breath alcohol concentration (BrAC) >35mcg/100ml breath when they arrive for a study session

the past year and how many lager drinks individuals consumed last time they drank lager in a licensed premises. The former was included to ascertain an upper threshold for consumption allowance during each study session. The latter was used to estimate the amount of lager the researcher would need to provide for each study session. An open-ended section was included where individuals could leave their contact details if they wanted the researcher to arrange two study sessions for them. The eligibility survey was easily accessible, via a link to the Qualtrics page, and took approximately five minutes to complete (Qualtrics, 2005). The survey was designed so that the researcher could easily distinguish those who were eligible. This meant that people were promptly informed of the outcome.

BrACs were measured and recorded prior to consent and at the start and end of each participant's study sessions. The initial BrAC measurement was taken to ensure that individuals were able to provide informed consent to participate in the study: those with a BrAC over the drink-drive limit (35mcg/100ml breath) were deemed too intoxicated to consent. The measurements taken at the end of the study sessions acted as a safeguarding measure: the researcher asked participants who were over the drink-drive limit upon leaving the study venue if they had a safe way of getting home. The researcher offered to provide a taxi for those who were over the drink-drive limit and stated that they had no feasible way of getting home. It was initially proposed that the difference in the entrance and exit BrAC measurements would be calculated to corroborate data on the number of

units of alcohol each participant had consumed during a study session. However, as witnessed in the taste discrimination experiment, the exit BrAC measurements were deemed inaccurate as some participants were breathalysed shortly after consuming alcohol, which meant there was alcohol residing in their mouths. The researcher could have mitigated this issue by asking the participants to remain for approximately half an hour at the end of their study sessions. However, this was deemed impractical as some participants did not leave until the venue closed and/or wished to leave without delay.

The number of study-specific drinks each participant purchased was captured on the back of the randomisation cards; the research assistant (RA) stamped the participants' cards each time they purchased a drink. Participants were briefed that if they did not consume the entirety of a study-specific drink they should return the vessel, with the drink left in it, to the researcher. The researcher then measured the amount of alcohol remaining in the vessel: this was also reported on the back of the randomisation card.

The researcher designed a questionnaire (Appendix M) for participants to complete at the end of each of their two study sessions. Providing the same questionnaire twice for each participant ensured consistency and reliability and reduced the risk of measurement decay: any change to the measurement process over time (Bowling, 2014). The questionnaire aimed to measure participants' perceptions, preferences, and behaviours related to alcohol consumption within licensed premises. The questionnaire incorporated 13 questions. Three questions incorporated unanchored scales to ascertain the level at which participants enjoyed the study-specific lager, and their perceptions about the taste of the lager and their level of intoxication. An open-ended question asked participants what brand of lager they drink most frequently. This acted as a prompt for participants to consider this brand when answering two further questions comparing their "normal" brand of lager to the study-specific lager. A multiple-choice question, that asked which lager brand participants thought they had been drinking, was included to ascertain perceptions and awareness of the lager's strength. An open-ended question enabled further comments to be made about the lager that was consumed during the study session. Three questions were included to gain an understanding of the group effect on drinking behaviour, such as whether participants purchased alcohol in "rounds". Two questions about non-alcoholic drink consumption sought to give an indication of whether participants deviated from study-specific lager consumption between the two conditions, and, if so, the reasons for the deviation. The questionnaire did not assess whether participants deviated from the study protocol as it was

believed that participants' responses would be influenced by social desirability bias: the tendency of participants to give responses that they deem to be desirable rather than reflecting their true thoughts, feelings or actions (Grimm, 2010). Instead, the researcher and the RA observed the participants during the study sessions to ascertain, to the greatest extent possible, whether they deviated from the study protocol.

After the first four study sessions, at Venue One, it was noticed that some participants signed out of the study and then consumed other alcoholic drinks. Thereafter, the researcher recorded the sign-in and sign-out times of each participant to enable a comparison between the duration of their study sessions under the different study conditions. This indicated whether, as postulated by the researcher, participants compensated for drinking reduced-strength alcohol by reducing the duration of their study session and switching instead to non-study-specific alcohol.

The researcher maintained electronic records in Microsoft Word (Appendix N) that captured data, in the form of field notes, about any problems with the study processes. These records incorporated feedback from members of the research team, employees of participating licensed premises, and participants.

Electronic datasets were created in Microsoft Excel to monitor the frequency of:

- licensed premises that were approached by the researcher
- landlords/managers who expressed willingness to participate
- landlords/managers who signed a letter of access
- participants who consented to participate (and at each separate participating licensed premises)
- participants who consented and did not complete two study sessions
- participants who consented and dropped out during or after the intervention study session
- participants who consented and dropped out during or after the control study session.

4.3.5 Piloting and refining data collection tools

Five Oxford Brookes University (OBU) PhD students were asked to pilot the eligibility survey: feedback was received from four of the five. Based on the feedback some basic amends to the wording was implemented.

The questionnaire was piloted with five OBU PhD students, three of whom supplied feedback. Based on the feedback, changes were made to the format of the scales and to some of the wording, and one question was repositioned. The main alteration to the format of the scales standardised the direction of the anchors. Originally the researcher varied the direction of the anchors to increase the reliability of the data: it was postulated that participants would pay more attention to the questions and their responses if the scale anchors varied in direction. However, feedback suggested that this may lead to inaccurate data as potentially intoxicated participants may fail to notice that the direction of the anchors had been reversed.

4.3.6 Licensed premises recruitment

i. Target business types and geographical locations

Free houses[5] were targeted for recruitment, as, due to fewer licensing restrictions, it was supposed that they were more likely to agree to the researcher bringing alcohol onto the premises for resale. Specifically, sports club bars, and licensed premises with links to community and/or charity projects were targeted. It was predicted that the financial incentive (£500) plus the money that was taken from study-specific alcohol sales would be more valuable to such venues and, therefore, encourage them to participate in the study. Student bars were also targeted for recruitment believing that they would be more open to academic research.

Initially, licensed premises in Oxfordshire and London were sought, as they were most accessible to the researcher. However, over time the recruitment strategy expanded to include licensed premises throughout the South East of England and the Midlands.

ii. Strategies and approaches

[5] In the UK, every on-trade licensed premises is either a tied house or a free house. The terms tied house and free house refer to the extent that a licensed premises is owned or controlled by a company or brewery. A tied house is defined as "a pub that is owned by a particular beer company and only sells that company's products" (Cambridge Dictionary, 2020a). A free house is defined as "a type of bar…that is not owned and controlled by a brewery…so the range of beers and other drinks that it can sell is not limited" (Cambridge Dictionary, 2020b). These dictionary definitions do not wholly reflect the usage of these terms in contemporary society. Whilst these definitions refer solely to the "pub" or "bar", in actuality, all types of on-trade licensed premises fall into one of the two categories. Therefore, more accurate definitions would incorporate the broader term "(on-trade) licensed premises" rather than the narrower terms "pub" and "bar".

Recruiting licensed premises was an iterative process. Initially, the researcher recruited by posting on social media accounts. These posts were shared by other social media users to create a snowball effect. Five licensed premises expressed an interest and were sent further information. Of these, three agreed to host the study, but study sessions did not take part at any of the venues: two pulled out and one failed to recruit any participants. Four licensed premises expressed an interest based on word of mouth. Of these, two venues hosted study sessions. In an attempt to increase recruitment, the researcher published a blog post on the European Society for Prevention Research's (EUSPR) Young Careers Forum (Perman-Howe, 2017a). This attracted one expression of interest, whom the researcher had a meeting with, but contact was subsequently lost. At the end of May 2018, projections indicated that recruitment targets would not be met unless further licensed premises were recruited. The researcher contacted the National Union of Students' (NUS) Alcohol Impact Officer who agreed for their Commercial Development Trainer to approach student bars in the South East of England, and London. This resulted in one expression of interest, who consequently took part in the study. The researcher directly contacted four other student bars and three other bars within their local area. Of these, two agreed to host the study but study sessions only took part in one of the venues: a change of management resulted in the other venue withdrawing. The researcher also attempted to engage local communities in helping to recruit licensed premises by emailing one local newspaper and messaging local community groups over social media. The researcher requested that the newspaper send out an advert targeting local licensed premises and that the local community groups send out recruitment messages over their social media platforms. One local community group responded and, to the researcher's knowledge, they posted one message on Twitter.

4.3.7 Participating licensed premises

Four licensed premises each hosted four study sessions. Multiple sites were used in order to increase the chances of fulfilling the sample and to enhance its representativeness (Polit and Beck, 2010).

Venue One: A cricket club bar in a village in the South East of England. The venue hosted fortnightly Friday evening bar and BBQ events throughout the summer, which coincided with children's coaching. The bar was open from 18.00 until whichever occurred first between: 22.00 hours, all the patrons having left the bar, or bad weather forcing the event and bar to close early. The former was the always the case during the study sessions, which

were held during May and June. The event was weather dependent; it went ahead on each of the designated four dates for study sessions. The venue operated under a club premises certificate[6] and was, therefore, a members' bar. There was a small bar area within the clubhouse, which offered a range of alcoholic and non-alcoholic drinks, and bar snacks. The venue purchased alcohol in bulk from a warehouse, which meant they were able to re-sell it at a low price. Lager was sold in 330ml bottles or 440ml cans at £2.50 and £2 per drink respectively. Study-specific drinks were sold at £1.50 per pint in order to incentivise patrons to participate. Pints were poured from de-identified cans of lager into plastic pint vessels, akin to how the venue serves "real ale" from the barrel. The majority of patrons consumed their alcohol outside of the clubhouse in the open air, where tables and chairs were located.

The researcher and the RA were given a table to conduct the study from. Fridge space was made available for around 100 cans of lager, which meant the researcher did not have to refill the fridge during a study session. A float of £100 was provided by the venue at the beginning of each study session and the money taken from study-specific drink sales was left in the float for the bar manager to count. Two RAs attended the first study session, and then one of the two attended each of the consequent sessions.

Venue Two: A village pub in the South East of England. The venue was open seven days per week with service hours between 12.00 and 23.00. The venue provided food throughout service hours every day. Thursday evenings, between 18.00 and closing, were deemed to be the most appropriate day and time to implement the study sessions, as the landlord stated that was a popular evening for regular patrons. The study sessions were held between August and October. The venue operated under a premises license[7]. Lager was sold on "tap" in half pint and pint measures, and in 330ml bottles. The cheapest pint of lager cost £3.60. Study-specific drinks were sold at £2 per pint in order to incentivise patrons to participate. Pints were poured from de-identified cans of lager, and served in glass pint vessels to align with normal practice.

[6] In venues that operate under a club premises certificate, the sale of alcohol is the responsibility of a management committee (The Home Office, 2018). Alcohol should not be supplied, or intended to be supplied, to members on the premises otherwise than by or on behalf of the club (HM Government, 2003).

[7] Under a premises license, venues must have a designated premises supervisor (DPS) who holds a personal license. The personal license means the DPS is responsible for, and authorises, the sale and supply of alcohol within the venue (HM Government, 2003). Those who are employed in the licensed premises alongside the DPS are not required to have a personal license (The Home Office, 2018).

The researcher and the RA were given a table to conduct the study from. A fridge with a capacity of 60 cans was installed next to the table. This meant that the study-specific drinks were easily accessible to the RA, although the researcher did have to refill the fridge during study sessions. A float of £50 was provided at the beginning of each study session and the money taken from study-specific drink sales were left in the float for the landlord. One of four different RAs attended each study session.

Venue Three: A Students' Union (SU) bar in a university in the South East of England. The venue was open seven days per week during term time with normal service hours varying based on the day of the week. The venue provided different entertainment on different days of the week including a quiz on Sunday evenings between the hours of 20.00 and 23.00. This was deemed to be the most appropriate day and time to hold the study sessions as the bar manager stated that many people who partake in the quiz did so on a regular basis, therefore decreasing the risk of attrition. The study sessions were held during October and November. The venue operated under a premises license and acted as a wholesaler: they resold unused stock to local businesses. Lager was sold on "tap" in half pint and pint measures, and in 330ml bottles. The cheapest pint of lager cost £2.90. Study-specific drinks were sold at £2 per pint in order to incentivise patrons to participate. Pints were poured from de-identified cans of lager, and were served in glass pint vessels to align with normal practice.

The researcher and the RA were given a table to conduct the study from. A portable fridge was installed next to the table, with a total capacity of 20 cans. This meant that the study-specific drinks were easily accessible to the RA, although the researcher did have to refill the fridge during study sessions. A float of £50 was provided at the beginning of each study session and the money taken from study-specific drink sales was left in the float for the bar manager. One of three different RAs attended each study session.

Venue Four: A SU bar in a university in London. The venue was open between the hours of 12.00 and 00.00 Monday to Friday during term time. The venue provided different entertainment on different days of the week including a quiz and karaoke evening on Tuesdays between the hours of 20.00 and 00.00. As the study had been effective during a quiz night at Venue Three, this was deemed to be the most appropriate day and time for the study sessions. The study sessions were held in February and March. The venue operated under a premises license. Lager was sold on "tap" in half pint and pint measures, and in

330ml bottles. The cheapest pint of lager cost £3.20. Study-specific drinks were sold at £2 per pint in order to incentivise patrons to participate. Pints were poured from de-identified cans of lager, and were served in plastic pint vessels to align with normal practice.

The researcher and the RA were given a table to conduct the study from. A portable fridge, with a capacity of 50 cans, was installed next to the table. This meant that the study-specific drinks were easily accessible to the RA, and the researcher rarely had to refill the fridge during study sessions. A float of £50 was provided at the beginning of each study session and the money taken from study-specific drink sales was left in the float and handed to the bar staff to keep in the safe at the end of each study session. One RA attended all four study sessions.

4.3.8 Participant recruitment: strategies and approaches

Initially, participants were to be recruited by advertising the study within participating venues and on their social media accounts. Posters, flyers and a crib sheet of suggested social media posts were supplied by the researcher to licensed premises managers. After discussions with one participating venue's (Venue One's) manager, however, it was decided that face-to-face recruitment would be more effective. Thereafter, a new strategy was enlisted which combined posters, flyers and social media posts, and one face-to-face recruitment session per study venue.

The researcher asked the licensed premises managers to display at least two posters within the bar area of their venue, to leave flyers on the bar and/or tables for patrons to take, and to repeatedly post recruitment advertisements on their social media accounts. These advertisements all contained the same information, which guided people to contact the researcher via email or telephone for further information about the study. Based on feedback from Venue One's manager, the wording of the flyers and posters was altered to additionally specify that participants had to contact the researcher prior to the study sessions if they wished to take part. When contacted, the researcher sent those who had expressed an interest an invitation letter (Appendix O) and a participant information sheet (PIS) (Appendix Q), which both included a link to the online eligibility survey. The researcher analysed the eligibility survey and sent those who were eligible an email confirming they could take part in the study. The researcher also enquired as to which, of a range of pre-determined dates, was most suitable for them to take part.

The face-to-face recruitment sessions involved the researcher providing study information, and the opportunity for patrons to sign up for the study, from behind a table within the bar area of the venues. The researcher did not approach any patrons but engaged with those who visited the table they were manning. The researcher had supplies of PISs for people to take and paper copies of the eligibility survey for those who wished to sign up for the study. The researcher analysed the eligibility surveys immediately and those who fulfilled the eligibility criteria were asked to choose which, of a range of dates, were most suitable for their two study sessions. They were then given a letter, or later sent an email, confirming the chosen dates for their study sessions. It should be noted that during the first face-to-face recruitment session, at Venue One, most people asked, foremost, what the dates of the study sessions were. This indicated that it was an important factor in people determining whether they would/could take part. Thereafter, the invitation letter and the PIS were altered to include the dates of the study sessions at the corresponding venue: this allowed individuals more timely access to the information and, therefore, more efficient decision making.

Initially, those who said they could not attend two study sessions that were four weeks apart but could attend two study sessions with a different time period in between, were not permitted to take part: this was a common occurrence at Venue One. Thereafter, the researcher altered the protocol to allow people to take part providing they could attend any two study sessions at one venue. The researcher noted which participants had a wash-out period other than four weeks in between their study sessions to enable data comparisons.

As an incentive, each participant who completed two study sessions was entered into a prize draw to win one of two prizes of £100.

4.3.9 Sample size calculation

Conventionally, formal sample size calculations are not required for pilot trials as pilot trials are not designed to formally test a hypothesis (Leon, Davis and Kraemer, 2011; Billingham, Whitehead and Julious, 2013; Lee *et al.*, 2014). A variety of alternative conventions have been proposed to elicit an optimal target sample size for a pilot trial. These include Julious and Patterson's (2004) method of using confidence intervals for a given precision; Whitehead *et al*'s (2015) "Stepped rules of thumb" approach; and recommendations that the minimum number of participants in each trial group should be 12, 35 and 50 respectively (Julious, 2005; Sim and Lewis, 2012; Teare *et al.*, 2014). To

date, there is no standardised method for obtaining the optimal sample size for a pilot trial. The sample size that is adopted, however, should be based on a strong and clear rationale (Moore *et al.*, 2011).

Data from pilot trials are often used to inform the sample size calculation for a RCT (Thabane *et al.*, 2010). It is therefore intuitive to maximise the accuracy of these data (Craig *et al.*, 2008). Indeed, one of the key aims of a pilot trial is to estimate the direction and magnitude of an effect. However, akin to a RCT, a pilot trial with an insufficient sample size may mask the magnitude of a true effect (Altman, 1980; Leon, Davis and Kraemer, 2011). This could result in a sample size calculation for a RCT incorporating an inaccurate data parameter, which could have catastrophic effects for the trial. Furthermore, it is imperative that an unnecessarily large number of participants are not exposed to the burdens of a pilot trial (Cook *et al.*, 2018). An excessive sample size may additionally result in a failure to meet the recruitment target (Lancaster, Dodd and Williamson, 2004). Such ethical considerations should be regarded equally for pilot trials as for definitive trials. Therefore, whilst a pilot trial may not require a sample size calculation in order to enable hypothesis testing, it seems logical for a pilot trial to recruit participants in accordance with a sample size estimate in order to improve the accuracy of data and uphold good ethical practice. This notion is supported by Cocks and Torgerson (2013).

The sample size calculation for the current pilot trial was not undertaken to enable formal hypothesis testing but to provide the most accurate estimate of the effect size and variance necessary to plan a RCT. The sample size was calculated using simulated datasets as there were no data from previous studies on which to base a statistical calculation. These datasets were based on the null hypothesis that there is no significant difference between the number of alcoholic drinks individuals consume regardless of their alcohol content. This has been demonstrated in a previous study (Geller, Kalsher and Clarke, 1991).

Firstly, simulated datasets were created for 40 hypothetical patrons at each of four different hypothetical licenced premises with different demographics. These datasets were based on the average patron's characteristics: age and gender. Mean age was used to estimate the number of units that each of the 40 hypothetical patrons would consume under normal conditions, based on age-related population data for alcohol consumption (Office for National Statistics, 2016). The estimated number of units consumed under normal conditions was reduced by 27% to give the estimated number of units consumed under the

intervention condition: the difference in alcohol content between Becks (B) and Bud Light (BL) is −27%. Estimated mean and standard deviation (SD) of units consumed from B and BL were calculated; a conservative estimate for SD in the intervention arm was used: the same SD as in the control arm. Where the licenced premises' population incorporated a higher proportion of male to female consumers, this was accounted for in the calculations and the mean consumption increased accordingly. From these data, the estimated mean difference and SD of the mean difference of UK units of alcohol consumed were calculated. These data enabled Cohen's *d* (an effect size measure calculated by the mean difference divided by the pooled standard deviation) to be calculated (0.3977). In line with convention and to make the sample more achievable, the pilot trial was powered at 80% as this elicited a smaller sample size than if it were powered at 90%. The level of statistical significance was set at the 5% level to conform with convention. The SD was set at 1 as this is the default in the software package used (R Stats). Simulated data for the licenced premises with the largest SD was used to calculate the sample size using the Rstudio software 'R Stats Package' and the function power.t.test (R Core Team, 2016): this provided the most conservative calculation of sample size. The figures that were inputted into Rstudio were alpha = 0.05, beta (power) = 0.8, delta (Cohen's *d*) = 0.3977, SD = 1. The sample size for a two-sided paired *t*-test was calculated as 52. Because the study used a crossover design, this meant that each of the 52 participants would be required to participate in both arms of the trial (two study sessions). The sample size was not inflated to account for potential attrition, so participants who did not provide complete datasets from two study sessions were replaced and their data were destroyed. The sample size calculation was checked by both the researcher and the Director of Studies (DoS).

4.3.10 Preparing and concealing the randomisation sequence

The DoS compiled a randomisation sequence, which was transferred to randomisation cards using a binary colour code (pink or purple) to denote the conditions (intervention or control) that the participant would experience during their first study session. The randomisation cards were sealed in opaque envelopes. The randomisation cards were coded to correspond with a code placed on the lager cans; the lager was poured from cans, which were wrapped in duct tape to de-identify them (Figure 4.1), into pint glasses. A RA was present at each study session to act as the intervention provider. The coding system meant that the RA was unaware of the lager brand they were serving to participants.

Figure 4.1: De-identified can of study-specific lager

4.3.11 The experimental process

Individuals had been briefed as part of the sign-up process to see the researcher when they arrived at the licensed premises for their first study session. The researcher reminded each individual of what participation entailed and explained the upcoming consent process.

Individuals were asked to do a breathalyser test and if their BrAC was below the drink drive limit (35mcg/100ml breath) they were taken through the consent process. No individuals were over the drink-drive limit upon arrival for a study session. Individuals completed a consent form on carbon-copy paper and both they and the researcher kept a copy. Once the consent form had been completed individuals were officially enrolled in the study as participants.

To allocate participants to the order in which they received the intervention and control products they were asked to take the next randomisation envelope from the pile of envelopes and open it. Inside was a randomisation card, which the participant was instructed to hand to the researcher. The researcher allocated an ID number, which was then written on the card. Additionally, the researcher wrote a number on the back of the card, which was the upper threshold for the number of drinks that the RA would sell to the participant during the study session. This was determined as 80% of the number of units the participant reported drinking on their heaviest drinking session in the past year, converted into the equivalent number of study-specific drinks.

The researcher briefed participants that:

- alcohol should only be purchased from the RA during their study session, but they could purchase soft drinks from the normal bar or ask for tap water from the RA
- each time they wished to purchase a study-specific drink they needed to bring their randomisation card to the RA
- they would only be served one study-specific drink for themselves per visit to the makeshift bar but if they wished to purchase drinks for other participants, one participant could pay for multiple drinks, but the other participants would have to be present with their randomisation cards to receive their drinks; they could buy non-participants drinks from the normal bar
- if they did not wish to finish a study-specific drink they should return the vessel with the remainder of the drink in it to the researcher
- before they leave the venue, they should visit the researcher at the makeshift bar area.

Aside from the points in the briefing, participants were encouraged to act as they normally would whilst at the venue, during their study session.

Following each participant's briefing the researcher recorded the time on the study session schedule spreadsheet (this measure was put in place following the initial four study sessions at Venue One).

Each time a participant visited the makeshift bar to purchase a study-specific drink, the RA checked which coloured sticker was on their randomisation card and collected two 440ml cans of lager, displaying the corresponding coloured sticker, from the fridge. The cans of lager were completely wrapped in duct tape to blind the participant and the RA (Figure 4.1). The two cans of lager were opened and poured in a pint glass so that a full pint was served. The remainder of the lager in the cans was kept for fifteen minutes and used for another pint if one was purchased within this time period; if not the remainder of the lager was disposed of. The RA took the money from the participant and stamped the back of their randomisation card. The RA checked how many stamps the participant had on their randomisation card and compared this to the number displayed in a box on the back of the card: the upper threshold for the number of study-specific drinks the participant could purchase in a single session. When the number of stamps was one less than the number in the box on the back of the randomisation card, the RA alerted the researcher who, if the

participant returned to purchase another drink, judged whether the participant was too intoxicated to continue with their study session: no participants were removed from the study in this manner.

When participants decided to conclude their drinking session, they returned to the researcher who recorded the time and administered a questionnaire. The participant returned their randomisation card to the researcher and then completed a breathalyser. If their BrAC measurement was over the drink-drive limit (35mcg/100ml breath) then the researcher asked them whether they had a safe way of getting to a place of residence. If not, the researcher was able to provide them with a taxi: no participants required this.

The participants repeated the process, but with the alternative study-specific lager, during their second study session.

4.3.12 Data analysis

In accordance with recommendations, pilot trial data were analysed using descriptive statistics with mean and CI estimations (Lancaster, Dodd and Williamson, 2004; Lee *et al.*, 2014; Bell, Whitehead and Julious, 2018).

Field notes on the suitability of study processes (Appendix N) were not formally analysed but were used to highlight any issues and, if required thereafter, propose solutions for a future trial.

The licensed premises recruitment rate was calculated by dividing the duration of recruitment (from the first day of the recruitment campaign until the final venue signed a letter of access) by the number of licensed premises landlords/managers who signed a letter of access. Similarly, the participant recruitment rate was determined by the number of people who completed a consent form divided by the number of hosting venues divided by two: as there were two cohorts from each study venue. The percentage of participants who completed a consent form but did not complete two study sessions was calculated to give the rate of attrition, and under each study condition separately. The difference in the rate of attrition between the two study conditions was calculated by subtracting one percentage from the other.

The number of pints consumed was converted to UK units and grams of alcohol, by hand, using the formulae volume of drink(ml) x ABV of drink (%)/1000 and UK units of alcohol x8, respectively. Estimates of the mean difference, SD and 95% CI were calculated using IBM SPSS Statistics Version 25 (IBM Corp, 2017). These data were used to inform a sample size calculation for a definitive RCT, which was conducted using Rstudio software's "R Stats Package" (R Core Team, 2016). The sample size provided by Rstudio was modified to account for the rate of attrition witnessed in the pilot trial. It was then divided by the mean number of participants (who did or did not complete two study sessions) at each venue, to estimate how many venues would need to be recruited. This figure was then multiplied by the venue recruitment rate to indicate how long it would take to recruit the estimated sample for a definitive RCT.

To assess whether factors other than the strength of the lager may have influenced alcohol consumption during the pilot trial, further data analyses were undertaken. Scale data from questions one to three in the questionnaire, indicating pleasantness of taste, and perceived enjoyment and intoxication, were quantified to a number between one and 10. The time elapsed between the study session sign-in times and sign-out times were calculated to provide study session durations. Estimates of the mean difference, SD and 95% CIs for reported pleasantness of taste, perceived enjoyment and intoxication, study duration, and the number of pints consumed were calculated using IBM SPSS Statistics Version 25 (IBM Corp, 2017). Categorical data indicating how the participants rated the taste of the study-specific lagers compared to their regular brand of lager were reported as frequencies with the mode reported as the measure of central tendency.

Data on BrACs were not further analysed but were made accessible by publishing them on the Open Science Framework (OSF) website alongside the rest of the study data (Perman-Howe, 2019: https://osf.io/htx2b/).

4.4 Results

4.4.1 The participants

Thirty-six participants (32 male: 89%) completed the pilot trial (Table 4.2). The participants ranged in age from 18 to 66 with a mean age of 30.7 (±13.59). Fifteen were students (42%), 13 worked full time (36%), four were self-employed (11%), one worked

Table 4.2: Participant baseline characteristics

Mean Age (years)	30.7 (SD = 13.59), range = 18 to 66
Gender	89% M, 11% F
Employment status	42% students, 36% worked full-time, 11% self-employed, 3% worked part time, 3% retired, 3% unemployed seeking work, 3% unemployed not seeking work
Participants from each venue	28% from each of Venues One, Two and Three, 17% from Venue Four

part time (3%), one was retired (3%), one was unemployed seeking work (3%), and one was unemployed but not seeking work (3%). Ten participants came from each of Venues One, Two and Three (28% each) and six came from Venue Four (17%).

4.4.2 Outcomes

According to the study protocol a RCT would be deemed feasible if the pilot study met six criteria for success (Perman-Howe, Davies and Foxcroft, 2018 (Appendix B)). These are outlined in the following section alongside the results (data by recruitment site/gender/student vs non-student is displayed in Appendix P).

1. *Components of the study protocol were efficient and worked together or could be amended to be or do so. These include:*

- *The administration of data collection tools*

The administration of data collection tools was unremarkable except some participants found the breathalyser overly sensitive and it took them up to five minutes to provide a measurement. Additionally, some participants struggled to interpret question six on the eligibility survey: “Roughly how many drinks did you have on your heaviest drinking occasion in the last year?”. This, however, had minimal impact on the BrAC measurements, which were not subsequently analysed, and the outcome of the eligibility survey. The eligibility survey, the questionnaires, and the storage of data on the randomisation cards and the schedule spreadsheet were all suitable means of capturing data and only minor amendments are required to increase their efficiency.

- *The consent process*

The consent process was simple and efficient and was applied without incident. The process was particularly efficient once the consent forms were printed on carbon-copy paper as participants only had to complete the form once.

- *The randomisation process*

The randomisation process was efficient, although there was one sequence error whereby a participant took the second randomisation envelope from the pile rather than the next envelope. This occurred when the researcher was busy with multiple participants and the incident could have been prevented if the RA's role was expanded to increase the research team's capacity.

- *Data management processes*

Data management processes were simple to follow, and they were effective at ensuring the data were both secure but accessible to those who required it.

- *The roles and requirements of study personnel*

Three study personnel were required to enact the pilot trial: the researcher, the RA and the DoS. The researcher undertook all roles that are outlined in this chapter aside from those that the RA and DoS were required to undertake to ensure the trial was a double blind. The RA had limited responsibilities: pouring the study-specific drinks, exchanging them for a cash payment, and notifying the researcher when participants reached their consumption threshold. There was scope for the RA's role to be expanded to reduce the congestion that occurred when multiple participants signed into the study simultaneously. This would have been particularly useful during the first study session for each cohort when there was more interaction with participants as they were undertaking the consent and randomisation processes. The DoS was required to prepare the randomisation sequences and the randomisation cards and to ensure concealment. The researcher provided them with instructions, and feedback from the DoS suggested that the process was straightforward, reproducible and efficient.

2. *The licenced premise recruitment rate was a minimum of one per month for a minimum of four months or until four licenced premises were recruited.*

In total four licensed premises were recruited in an iterative process (see section 4.3.7; Figure 4.2) Venue recruitment ran for 14 months and three days between October 2017 and December 2018. The recruitment rate was one venue every 107 days: approximately one venue every three and a half months.

3. *Participant recruitment rate was a minimum of four per initial study session for each cohort.*

Sixty people completed the eligibility survey and provided contact details: 44 (73%) were completed in paper format during a recruitment or study session and 16 (27%) were completed electronically: five of the latter were completed on the researcher's laptop during a study session at Venue Four because there was a shortage of paper forms. One hundred percent of those who completed the eligibility survey were eligible and 51 (85%) booked study sessions. Forty-seven people (92% of those who booked study sessions) consented and all of these were randomised. The participant recruitment rate was 5.9 per initial study session for each cohort (Figure 4.3).

4. *The rate of attrition for the pilot trial was less than or equal to 30%, and this did not vary by more than 10% according to the arm of the trial.*

Thirty six of 47 participants completed the trial (77%). The rate of attrition was 23%. The rate of attrition varied by less than 1% according to the order in which participants were randomised to the intervention and the control conditions: 24% in the BL-B arm and 23% in the B-BL arm.

5. *Estimations of the mean and 95% CI of the number of UK units of alcohol consumed by participants in a single drinking occasion, when they consume BL and B, suggest that people consume fewer UK units of alcohol when they consume reduced-strength lager.*

There was a strong trend towards a reduction in alcohol consumption when participants consumed the reduced-strength lager (the intervention condition). The estimated mean

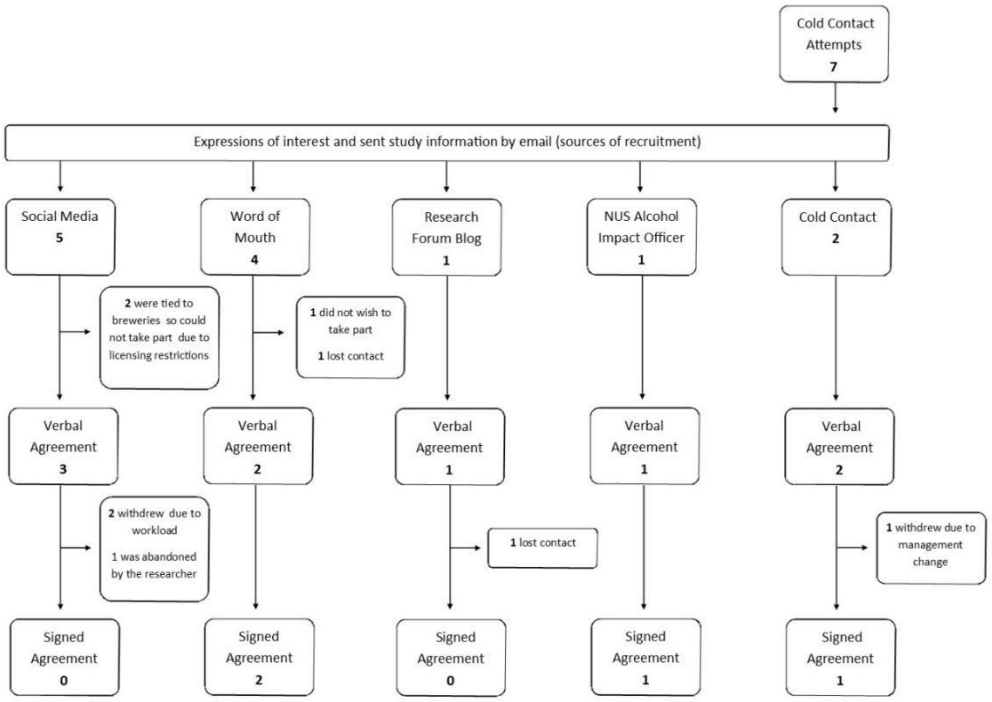


Figure 4.2 Licensed premises pathways

difference in alcohol consumed by participants when they consumed the reduced-strength lager, BL, compared to the regular-strength lager, B, was -3.76 UK units SD = 3.69 (-5.01 to -2.52) or -30.56 grams (g) SD = 29.83 (-40.65 to -20.46) (Table 4.3). Data illustrate that participants consumed 31% less alcohol when they consumed *ad libitum* a 3.5% ABV lager compared to a 4.8% ABV lager.

To assess whether the witnessed trend could be due to factors other than the strength of the lager, further analyses were undertaken. These are outlined in the following six paragraphs and displayed in Table 4.3.

Data suggest that there was no notable difference between the number of pints participants consumed between study conditions. The estimated mean difference in the number of pint consumed (BL compared to B) was -0.31 SD = 1.51 (-0.82 to 0.20).

The duration of participants' study sessions did not notably differ based on whether they were consuming BL or B: estimated mean difference in study session duration (BL compared to B) was -0:06 SD = 0:41 (-0:23 to 0:10).

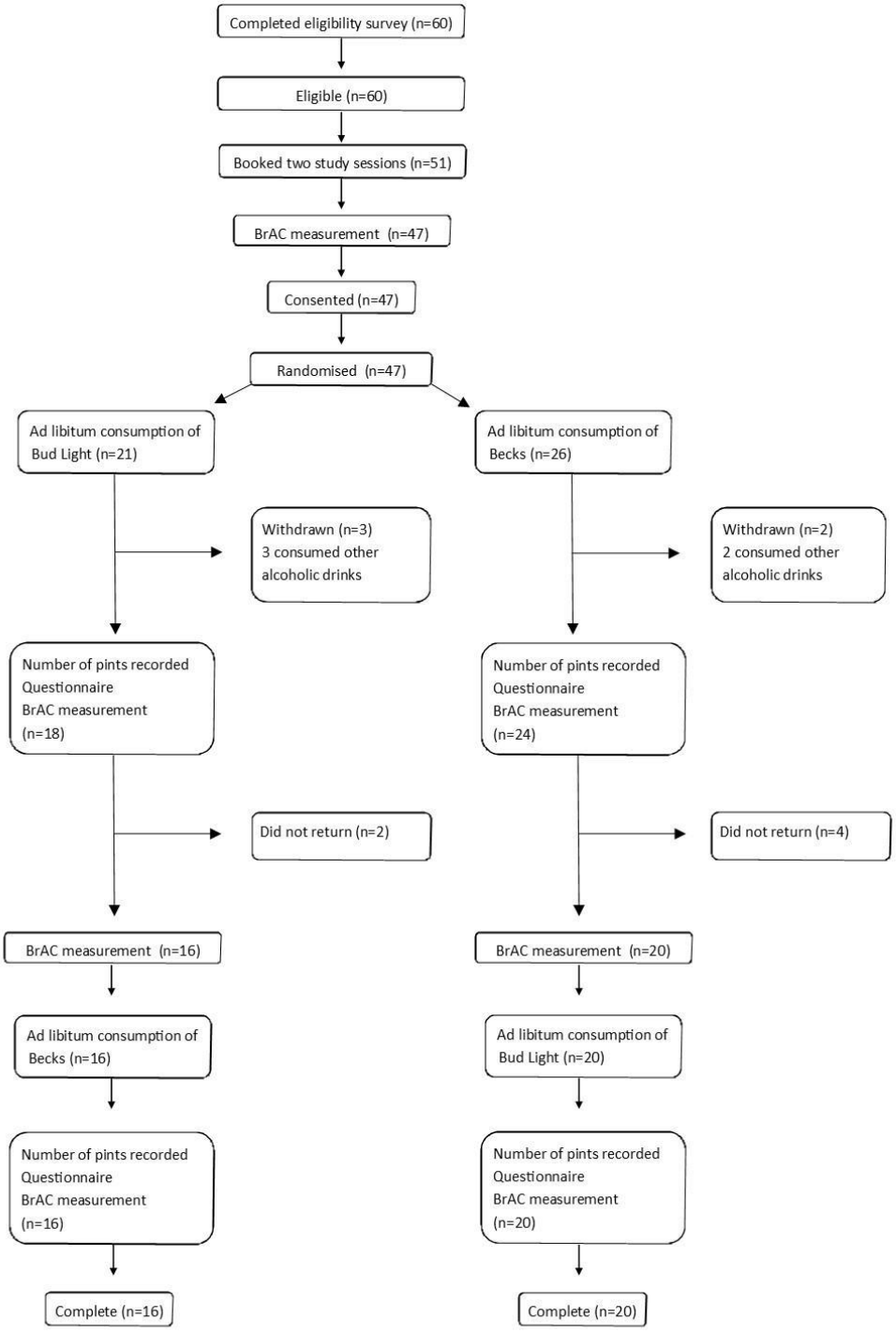


Figure 4.3: Pilot trial participant pathways

Table 4.3: Pilot trial data

	Mean (reduced-strength lager, n=36), SD, (95% CI)	**Mean (regular-strength lager, n=36), SD, (95% CI)**	**Mean difference (mean reduced-strength lager minus mean regular-strength lager), SD, (95% CI)**
Alcohol consumption (UK units)	8.28, SD = 4.17 (6.87 to 9.69)	12.04, SD = 5.33 (10.24 to 13.84)	-3.76, SD = 3.69 (-5.01 to -2.52)
Alcohol consumption (grams)	65.78, SD = 33.51 (54.44 to 77.12)	96.34, SD = 42.61 (81.92 to 110.75)	-30.56, SD = 29.83 (-40.65 to -20.46)
Pints consumed	4.14, SD = 2.09 (3.43 to 4.84)	4.45, SD = 1.96 (3.79 to 5.12)	-0.31, SD = 1.51 (-0.82 to 0.20)
Study session duration (hh:mm)	2:33, SD = 0:51 (2:12 to 2:53)	2:39, SD = 0:52 (2:18 to 3:00)	-0:06, SD = 0:41 (-0:23 to 0:10)
Pleasantness of taste	4.86, SD = 2.73 (3.94 to 5.79)	5.81, SD = 2.13 (5.09 to 6.53)	-0.95, SD = 3.43 (-2.11 to 0.21)
Enjoyment	4.79, SD = 2.79 (3.53 to 5.89)	6.23, SD = 2.21 (5.40 to 7.27)	-1.44, SD = 3.54 (-2.64 to -0.24)
Perceived intoxication	4.09, SD = 1.91 (3.44 to 4.73)	5.09, SD = 1.97 (4.42 to 5.76)	-1.00, SD = 1.79 (-1.61 to -0.40)

Data indicate that participants did not find one lager product notably more pleasant in taste than the other. The estimated mean difference of the reported pleasantness of taste (BL compared to B) on a scale of one to 10 was -0.95 SD = 3.43 (-2.11 to 0.21).

When participants compared the taste of the study-specific lager with their regular brand of lager, participants were more likely to give a negative response (much worse than my normal drink or worse than my normal drink) than a positive or neutral response for both BL (25/36) and B (15/35). The mode for BL was the response “much worse than my normal drink”, whilst the mode for B was “worse than my normal drink” (Figure 4.4).

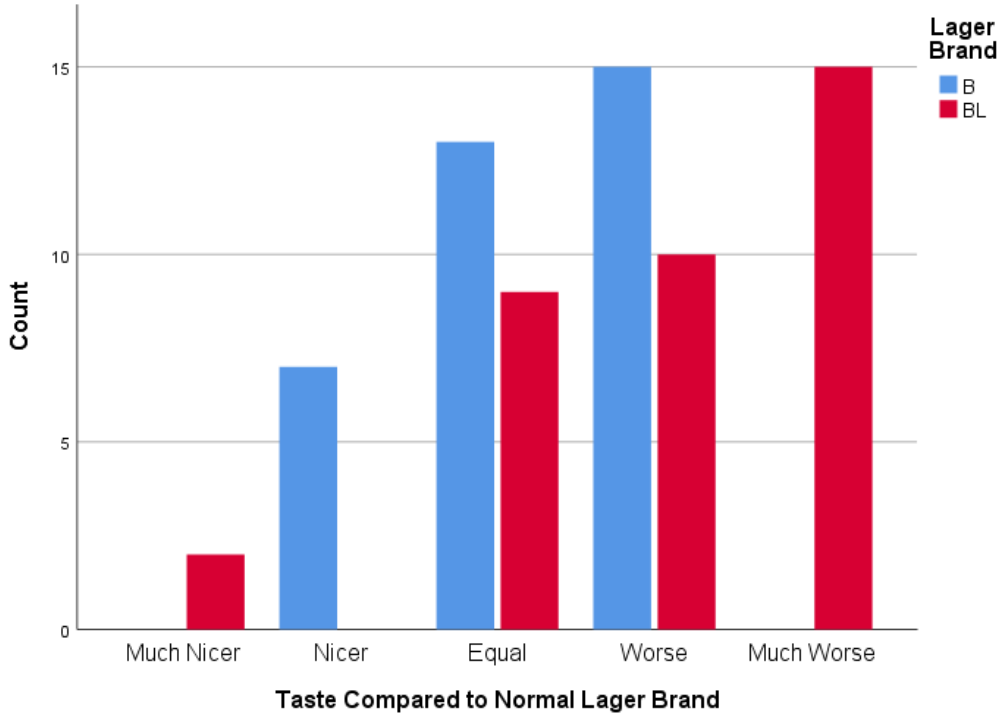


Figure 4.4: Participants' ratings for the taste of each study-specific lager compared to the lager brand they normally consume

Data illustrate that participants rated B as being notably more enjoyable than BL. The estimated mean difference of reported enjoyment (BL compared to B) on a scale of one to 10 was -1.44 SD = 3.54 (-2.64 to -0.24).

Participants perceived themselves to be notably more intoxicated at the end of the study session in which they had been consuming B compared to BL. The estimated mean difference of reported levels of intoxication (BL compared to B) on a scale of one to 10 was -1.00 SD = 1.79 (-1.61 to -0.40).

6. *The sample size is achievable to obtain within a year based on the recruitment rate of licenced premises and participants.*

The sample size calculation produced a sample size of 19. Adjusting for 23% attrition, as witnessed in the pilot trial, the sample size for a future RCT should be 23. This is based on an effect size of 0.79, statistical significance set at 95% and power set at 90%. The sample size for a future RCT (23) is notably smaller than that which was estimated for the pilot trial (52). This is because the effect size in the pilot trial was larger than anticipated.

An average of nine participants completed, and two participants did not complete, the trial at each study venue that hosted four study sessions. Therefore, it is estimated that with improved recruitment processes two venues would be required to host four study sessions each during a definitive RCT with a sample size of 23. Based on the recruitment rate of the pilot trial, two licensed premises could be recruited in approximately seven months. It is expected that both these venues would have completed their four study sessions within three months of being recruited. This means that it would take approximately 10 months to complete a RCT with 23 participants. However, this should be regarded as a worst-case scenario where venue recruitment is consecutive rather than simultaneous. If venues were to be recruited simultaneosuly, it would take significantly less time to complete a definitive RCT.

4.5 Discussion

Components of the study protocol were effective and efficient throughout the pilot trial and only a few minor amendments to study processes are recommended for a definitive RCT. Firstly, a breathalyser that is simpler to use would be more efficient as many participants took multiple attempts to get a reading. Secondly, question six on the eligibility survey could be restructured as it confused many participants who subsequently either asked for help in answering the question or answered the question incorrectly. Thirdly, the questionnaire should be restructured to: provide a box in which to record the product that the answers relate to; include more, popular, lager brands (including Fosters® and Stella Artois®) as response options to question seven; and remove questions 11 to 13. Finally, the RA's role could be expanded to include: informing participants about the study, providing them with study literature, undertaking breathalysers with the participants, and guiding participants through the consent, randomisation and questionnaire processes. These amendments would increase the efficiency of participant enrolment, sign ins and sign outs.

The licensed premises recruitment rate failed to meet the pre-determined criterion for success of a minimum of one per month for a minimum of four months. The observed recruitment rate was approximately one every three and a half months. However, this should be regarded with caution. Venues were deliberately recruited, and completed their study sessions, consecutively rather than simultaneously to enable time to rectify any issues and to ensure that the sample size was not exceeded. Pragmatically, with the use of information derived from this pilot trial to enable effective planning and simultaneous

venue recruitment, as well as sufficient resources, the recruitment rate for a definitive RCT is anticipated to be a minimum of one venue per month.

The participant recruitment rate of 5.9 per initial study session for each cohort is sufficient for a definitive RCT. Face-to-face recruitment was more fruitful than remote electronic recruitment. For a definitive RCT it would be most effective to focus on recruitment during face-to-face recruitment sessions, with support from an established figure within the venue such as the landlord/manager or the quiz master. Remote recruitment should be a secondary option. Realistically, there should be an upper limit for the number of participants taking part in each study session to ensure the study processes are manageable but thorough. It is suggested that the limit should be 10 participants per member of the research team present and able to enact all the study processes within the venue.

The rate of attrition (23%) is acceptable for a definitive RCT. The rate of attrition varied by less than 1% between study conditions. This indicates that participants did not drop out of the study because of the lager they consumed in their first study session. The rate of attrition was noticeably higher at Venue Four (a Student's Union (SU) bar (60%)) than the other three venues combined (6%). A logical explanation would be that this was due to the fluctuating nature of students' work and social demands, meaning they do not attend licensed premises consistently. Although there was complete participant retention at another SU bar, Venue Three, these venues hosted the study at different times of the year when work demands on participants may have varied. For example, participants from Venue Four may have had coursework deadlines or exams when the study sessions were implemented, whereas participants from Venue Three may not. Although every effort was taken to minimise the variability of the study sessions between (and within) venues, including seasonal changes, due to the variation in different university courses this was impossible to standardise between the two SU bars. Another explanation could be that these data occurred due to chance and the high level of attrition witnessed at Venue Four was spurious. Overall, there are not enough data to draw definitive conclusions as to why two seemingly similar venues, with a similar demographic, which both hosted study sessions during quiz nights, had varying rates of attrition. Where resources are finite for a definitive RCT, it would be intuitive to avoid recruiting SU bars or recruit them only as a last resort. This would not only reduce the risk of increased levels of attrition, but it would decrease the homogeneity, and thus increase the representativeness, of the sample.

Estimations of the mean and 95% CI suggest that people consume less alcohol when they consume *ad libitum* a 3.5% lager compared with a 4.8% lager within licensed premises. According to Lee *et al* (2014), CIs should be interpreted in relation to the minimal clinically important difference (MCID): the difference between treatment groups that is regarded as clinically meaningful. If a CI for the mean difference between conditions crosses zero and the MCID, then the results of the study could be regarded as inconclusive: either there could be no difference between conditions or there could be a difference larger than the MCID. In the pilot trial, the CI for the estimated mean difference in lager consumed did not cross zero (-5.01 to -2.52). The researcher could not ascertain a MCID pertaining to the reduction in alcohol consumption in a single drinking occasion for the general population of lager consumers. For illustrative purposes, the estimated MCID (-8.2g or -1.03 UK units) was derived from a study by Rahhali *et al* (2015) and relates to the reduction in alcohol consumption in a single drinking occasion for a population of daily, dependant, alcohol consumers. Based on these data the results appear unequivocal, which suggests that the reduction in the amount of alcohol consumed under the intervention conditions may be clinically meaningful. However, the small sample sizes that are inherent in pilot trials may make estimation uncertain if the witnessed effect size is also small (Lee *et al.*, 2014; Bell, Whitehead and Julious, 2018). It is therefore advised that a range of significance levels and corresponding CIs are used to provide preliminary evidence of efficacy (Lee *et al.*, 2014; Bell, Whitehead and Julious, 2018). Figure 4.5 shows five different CIs, the aforementioned estimated MCID, and the null value to enable an assessment of potential statistical and clinical significance. None of the CIs in Figure 4.5 cross zero or the estimated MCID indicating that the intervention may be effective regardless of the level of significance, and a definitive RCT may be warranted. However, the MCID displayed in Figure 4.5 does not specifically relate to the population of interest, and, therefore, this illustration should be regarded with caution.

An *a priori* sample size calculation may inform whether a RCT is feasible and is a fundamental aspect of a RCT proposal. The sample size calculation is often based on data obtained from a pilot trial. However, many experts warn against this approach, stating that the imprecision in data obtained from pilot trials may result in either studies being prematurely aborted or studies that or not aborted being underpowered (Kraemer *et al.*, 2006; Lee *et al.*, 2014; Bell, Whitehead and Julious, 2018). In this pilot trial, the risk of obtaining an imprecise effect size and SD was initially minimalised by creating simulated datasets from which a sample size was estimated. Although the pilot trial failed to recruit

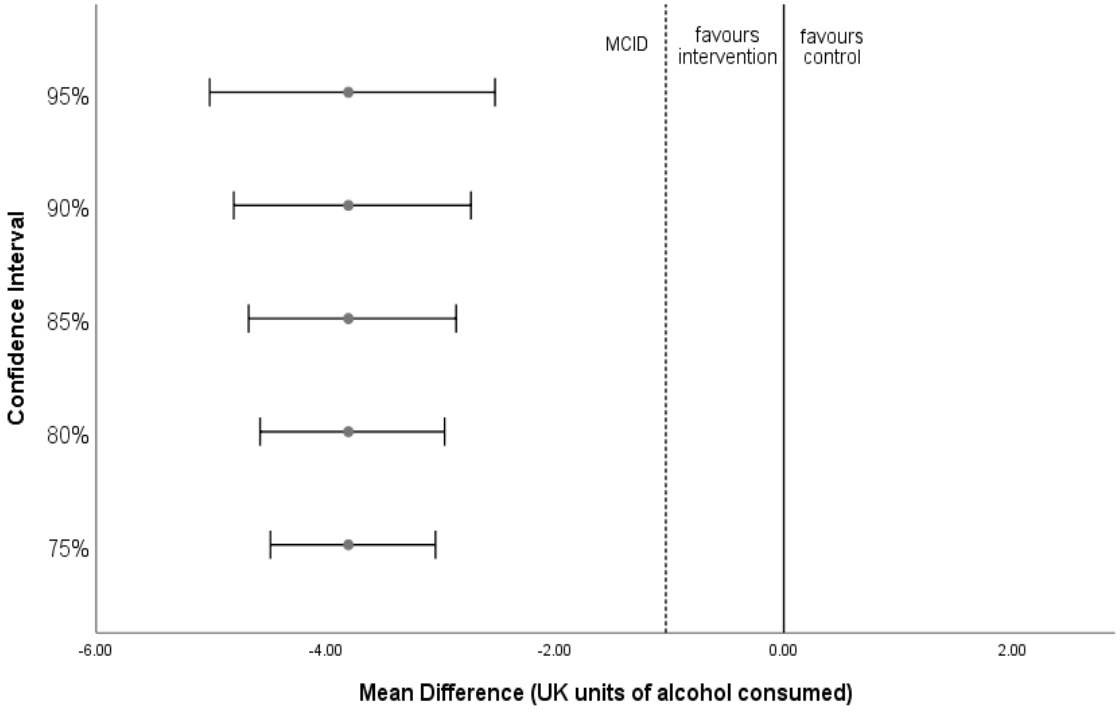


Figure 4.5: Mean difference in the number of UK units of alcohol consumed between the intervention and control conditions with CIs (based on 36 participants)

the estimated sample size, a large effect size was found. This indicates that the trial was sufficiently powered. However, the effect size should still be regarded with caution and consideration should be given to a range of possible effect sizes. Table 4.4 illustrates different sample sizes for a definitive RCT based on varying effect sizes, rates of attrition and power. The sample sizes are based on the pilot trial's effect size and effect size estimates based on the literature and the MCID provided by Rahhali *et al* (2015). In these illustrations the amount of BL consumed was inflated to reduce the effect size. This approach was taken due to the possibility that BL was under-consumed in the pilot trial: participants rated it as notably less enjoyable than B meaning its consumption may not accurately reflect participants' normal behaviour. Sample sizes are given for the observed rate of attrition (23%), >5 and <5%, the rate of attrition excluding Venue Four (6%), and for complete retention. The sample size calculated from the pilot trial data for 90% power was 23. However, sample sizes for 90% power ranged from 19 to 280. Sample sizes for 80% power ranged from 15 to 210. These wide ranges demonstrate how sample size estimates can drastically vary based on the underlying assumptions. The sample size that is implemented in a definitive RCT would therefore depend on the researcher's approach. For example, if one wanted to be cautious, and had ample resources, they could adhere to the

Table 4.4: Different sample sizes for a RCT based on different underlying assumptions

Justification	**Effect Size**	**Attrition (%)**	**Sample Size (80% Power)**	**Sample Size (90% Power)**
Pilot study data	**0.79**	0 6 18 **23** 28	15 16 18 18 19	19 20 22 **23** 24
Increase average BL consumption so that equal volume of alcohol is consumed between conditions	0.68	0 6 18 23 28	19 20 22 23 24	25 27 30 31 32
Increase average BL consumption to the MCID between conditions	0.22	0 6 18 23 28	164 174 194 202 210	219 232 258 269 280

approach outlined by Kraemer *et al* (2006) and use a sample size based on the MCID. In this thesis, the sample size (23) for a definitive RCT has been calculated based on the pilot trial data.

Further analyses were undertaken to suggest whether the large effect size that was witnessed in the pilot trial could be due to factors other than the strength of the lager. Prior to the trial it was hypothesised that there would be parity between the volume of lager consumed across study conditions. Previous research has shown that participants did not compensate for drinking reduced-strength beer by drinking a larger volume of it (Geller, Kalsher and Clarke, 1991). Data from the pilot trial support the work of Geller Kalsher and Clarke (1991), as they show no notable difference between the number of pints of lager participants consumed between study conditions. This may indicate that participants behaved habitually and consumed a personally standardised number of drinks. This aligns with research that suggests alcohol consumers have personal thresholds of what constitutes the right amount of alcohol for them to consume: assuming that people measure their

personal thresholds by the number of drinks consumed rather than the volume of alcohol consumed (Burgess, Cooke and Davies, 2019). These findings indicate that differences between the two products, other than their strength, did not influence the results. However, when considering these findings alongside data which indicate that participants rated B as being notably more enjoyable than BL, an alternative theory could be postulated: that participants did not compensate for drinking reduced-strength lager because they did not enjoy the experience of drinking it as much as they did the regular-strength lager. The term perceived enjoyment, and the participants' interpretation of the term, is complicated to define in this instance. However, it would be logical to consider that levels of perceived enjoyment may be related to levels of perceived intoxication. Data indicating that participants perceived themselves notably more intoxicated having consumed B rather than BL support this notion and could explain the difference in the perceived enjoyment ratings. However, data are too sparse to draw conclusions. Future work would be required to disentangle the term "enjoyment" or to break it down into its component parts within the questionnaire to gain a better understanding of such findings.

With myriad possible explanations for specific findings, it is important to view the totality of the data. When taking this broad perspective, most data suggest that the large effect size witnessed was due to the intervention rather than confounding factors. There was no notable difference in the duration of participants' study sessions depending on the lager they were consuming. This supports the notion that participants did not compensate for drinking reduced-strength alcohol by consuming more, or a different brand of, alcohol after their intervention study session. Additionally, participants did not find one lager product notably more pleasant in taste than the other. However, the most popular responses when participants were asked to rate BL, and B in comparison to their regular brand of lager were "much worse" or "worse", respectively. This indicates that neither drink tasted favourable to the participants, with BL being less favourable than B. This could indicate that participants would not drink reduced-strength lager outside of the study conditions. If such findings were to be repeated in future iterations of the trial, this could significantly hamper attempts to alter public health policy. Additionally, whilst participants did not report one drink as being notably more pleasant in taste than the other, they reported one product being notably more enjoyable than the other. Data on perceived enjoyment are not easy to interpret as enjoyment means different things to different people. One theory is that there was a characteristic(s) of the study-specific drinks, other than taste, which differed between products. Many of these characteristics were controlled for in the study design,

such as the temperature and the vessel in which the lager was served. The characteristics that were not standardised between the intervention and control products and which may have caused the discrepancy in the enjoyment ratings are: carbonation, colour and/or smell. Prior to a future RCT further exploratory work should be undertaken to establish an intervention and a control product that taste more favourable than BL and B and that evoke equal levels of enjoyment. Although these measures are subjective, and one cannot ensure that certain products are preferable and enjoyable to all participants, there is plenty of scope to establish two other comparable lager products which have higher average ratings than BL and B for these two variables. It is important to be aware that introducing parity between the enjoyability of the intervention and control products could result in a greater volume of the intervention product being consumed. This would, therefore, reduce the overall effect size meaning a larger sample size would be required to obtain the same level of power. However, this is something that cannot be confirmed until further data are collected.

There are four possible outcomes of a pilot study (Thabane *et al.*, 2010):

1. *Stop*: a main study is not feasible.
2. *Continue, but modify protocol*: a main study is feasible but requires modifications.
3. *Continue without modifications but monitor closely*: a main study is feasible but requires close monitoring.
4. *Continue without modifications*: a main study is feasible without modifications.

Option two most accurately describes the outcome of the pilot trial. However, the number of protocol modifications required for a definitive RCT would depend on the research team's preferences. Based on the pilot trial results there are various, plausible, scenarios for a future definitive RCT:

1. A RCT is conducted with minor protocol amendments.

The RCT would be very similar to the pilot trial but there would be minor alterations to the study processes based on data from the pilot trial. The RCT would incorporate the same study design as the pilot trial and use the same intervention and control products. The minor amendments would be those discussed within this thesis chapter (except the intervention and control products would not be changed).

2. A RCT is conducted with different intervention and control products and minor protocol amendments.

The RCT would be identical to scenario one in every aspect apart from the intervention and control products. This option would involve scoping work to establish whether different brands of beer/lager would be more favourable options for the intervention and control products. It would also involve ensuring the control and intervention products are more accurately matched in a broader range of aspects including carbonation, colour, smell and enjoyability. This scenario would require co-production between the researchers and the public to help shape and guide the research. It would therefore be more resource intensive than scenario one, but it would likely increase the validity of the findings.

3. A RCT is conducted but with alterations in the study design.

The RCT would have the same aims and objectives as scenarios one and two but a different study design, and potentially sample size, would be employed. Rather than having open study sessions whereby participants would mix with non-participants, study sessions would be closed, based within separate areas of licensed premises, and incorporate an event such as a quiz. This scenario could involve either individual randomisation or cluster randomisation: the latter having been used effectively in a study looking at the effect of serving size on alcohol consumption (Kersbergen *et al.*, 2018). Cluster randomisation would involve randomising each study session within each venue to either the intervention or control conditions in a counterbalanced order. Therefore, within any single study session all participants would be consuming the same product (either regular-strength or reduced-strength alcohol) and each participant would attend both an intervention and a control study session within the same venue (with a 4-week wash-out period in between). Although this study design would been less naturalistic than the pilot trial, it would be easier to manage larger numbers of participants simultaneously, it would minimise the possibility of protocol breaches and it would be less time consuming as study sessions could be compartmentalised.

4. A RCT is conducted in alliance with the alcohol industry.

Another consideration is the organisations and institutions that could support a definitive RCT. All the three scenarios outlined above could be conducted solely by an academic

institution(s) with no external support. An alternative option would be for an alliance between an academic institution(s) and the alcohol industry. A collaboration with a large alcohol company that owns a plethora of licensed premises could result in easy access to multiple study venues. Such a collaboration would likely make the study processes more efficient and could enable a more naturalistic study design. For instance, if the company allowed the study-specific lager to be "tapped" rather than poured from cans. However, collaborations with the alcohol industry are often criticised by public health professionals (Angus, 2018; Gilmore, Bauld and Britton, 2018; Petticrew, McKee and Marteau, 2018). Additionally, it has been argued that, in order to maintain the integrity of alcohol science research, researchers should avoid any financial ties to the alcohol industry (Stenius and Babor, 2010). This criticism stems from the belief that such collaborations threaten impartiality and are influenced by the alcohol industry's motives of profiteering and reputation rather than improving health. With a current lack of guidelines on collaborating with the alcohol industry, it is imperative that any research undertaken as an alliance is transparent. Furthermore, the alcohol industry should have no input in the scientific aspect of the research and any reporting of the study's results should be agreed upon by both parties.

4.6 Conclusion

This chapter discussed the main part of the PhD project: a double-blind randomised controlled crossover pilot trial to establish the feasibility of conducting a RCT to assess the effect of alcohol strength on alcohol consumption within licensed premises in the UK. It described how the study was designed and executed to meet the primary aim and objectives. Data were analysed and the results were presented and discussed. Finally, various scenarios for a future RCT were considered.

Chapter Five: The Semi-Structured Qualitative Telephone Interviews

5.1 Introduction

This chapter discusses the final part of the research project: semi-structured qualitative telephone interviews to explore the acceptability of reducing the strength of alcohol as an intervention to reduce alcohol consumption. The chapter introduces the study and outlines the primary aim and the research question. The methods section describes how the data collection tools were developed, how participants were recruited, the interview process, and the method of data analysis. The findings from the interviews are presented and discussed. Finally, conclusions are made in relation to the research question.

5.2 Background

Gauging the public acceptability of a behaviour change intervention is important to predict the effect of the intervention in practice and to influence policy decisions (Petrescu *et al.*, 2016). Health policies that are acceptable are more likely to have a significant and lasting impact (Cohn, 2015). As the World Health Organisation (WHO) stated, "Having a good policy is not enough: to be effective, policy requires public support" (World Health Organisation, 2009, p. 40). Although public acceptability can improve intervention adherence, the most acceptable interventions are not always the most effective (Diepeveen *et al.*, 2013; Pechey *et al.*, 2014; Somerville *et al.*, 2015; Petrescu *et al.*, 2016). Interventions that provide information are categorised as the least intrusive and are often the most acceptable but least effective (Diepeveen *et al.*, 2013). Interventions that restrict or limit choice are categorised as the most intrusive and are often the least acceptable but most effective (Diepeveen *et al.*, 2013). Nudge-based interventions fall somewhere in between: they are moderately intrusive and acceptable although more evidence of their efficacy is required (Petrescu *et al.*, 2016).

It is widely believed that highlighting the efficacy of behaviour change interventions has the potential to increase their acceptability (Pechey *et al.*, 2014; Somerville *et al.*, 2015; Petrescu *et al.*, 2016). This belief is based on two assumptions: firstly, that people base acceptability on a trade-off between gains and losses; secondly, that individuals consider the impact of interventions at the population level, which is the emphasis of most contemporary government policies (Cohn, 2015). These assumptions are challenged by a study indicating that individual levels of acceptance are not influenced by the credibility of evidence of gains and losses but by local cultural and social contexts (Cohn, 2015). Cohn (2015) also states that individuals are not oriented to consider risk, and thus the efficacy of

health interventions, at the population level. Rather, they draw on anecdotal evidence from within their local cultural and social circles. This aligns with the concept of lay epidemiology: a term coined by Davison, Smith and Frankel (1991). Lay epidemiology suggests that health risks are understood and interpreted by people based on their empirical beliefs about the nature of illness and values about health and risk (Allmark and Tod, 2006). This has been described as an "all things considered" view of what makes certain behaviours worthwhile (Allmark and Tod, 2006). It has been perceived as a concept at odds with standard epidemiology and public health messages, which are seen to dishonestly, unjustly, and sometimes disrespectfully, attempt to alter lay views (Davison, Smith and Frankel, 1991; Allmark and Tod, 2006). However, Allmark and Tod (2006) state that, in a society that places a high value on health, public health professionals are entitled to encourage reflection and change when suboptimal health behaviours are widespread. This viewpoint suggests that beliefs pertaining to the acceptability of an intervention develop in an iterative process and emerge from interaction with other people and individual reflection. The corollary is that trying to gauge public opinion from individual interviews conducted at a single point in time is limited. However, as with this study, one-off interviews are often used to gauge acceptability of an intervention (Ayala and Elder, 2011). This study was planned so that the subsample of pilot trial participants would have had time to reflect on the intervention, and discuss it with their peers, prior to being interviewed about its acceptability.

To the researcher's knowledge, at the time of the study's conception there was no existing evidence of the acceptability of reducing the strength of alcohol as an intervention to reduce alcohol consumption. The primary aim of the study was to assess the acceptability of the pilot trial intervention by interviewing a subsample of its participants. Because there is no concept of power in qualitative data analysis, a sample size could not be statistically calculated. Instead, data were planned to be collected until data saturation occurred. According to Howitt (2016), data saturation is the point at which no further ideas are being generated by the data. However, the researcher acknowledges that this term is complicated and involves a level of subjectivity. With the current study, the researcher was aware that reaching data saturation may not have been possible as the subsample was obtained from a small sampling frame (36). Therefore, to reach the saturation point, the researcher anticipated that a high proportion of the sampling frame would need to consent to take part in an interview. As certain personal characteristics may predict intervention acceptability the researcher sought to interview a diverse subsample. The aim was to recruit those who

were under represented in the pilot trial, namely women and older people. Women and older people are more likely to support restrictive alcohol measures than the rest of the study population (Diepeveen *et al.*, 2013; Pechey *et al.*, 2014). It is suggested that this is because they are less likely to regularly drink alcohol, and the level of engagement with drinking alcohol is a factor that influences the acceptability of alcohol interventions (Diepeveen *et al.*, 2013). Overall, it was anticipated that participants would be less likely to support reducing the strength of alcohol as an intervention to reduce alcohol consumption than the wider population because, as an eligibility criterion, participants were alcohol consumers.

The semi-structured interviews sought to answer the question:

> *Is reducing the strength of alcoholic beverages an acceptable intervention to reduce alcohol consumption?*

5.3 Method

5.3.1 Study design

This study utilised a qualitative design, incorporating semi-structured telephone interviews (as discussed in section 2.3.3).

5.3.2 Materials

See Appendix R for the comprehensive list of materials and equipment that were required for the interviews.

5.3.3 Eligibility criteria

Pilot trial participants who had completed two study sessions were eligible to take part in an interview provided they:

- signed and returned a consent form
- provided a contact telephone number
- agreed on a date and time to be contacted.

5.3.4 Data collection tools

A semi-structured interview schedule (Figure 5.1) was devised by the researcher. It contained 10 questions, and multiple prompts that were designed to remind the researcher what further questions to ask if the participants were not forthcoming with information. The interview schedule was constructed to follow a logical pattern of conversation, and to follow the rule of thumb to move from the general to the specific (Pope and Mays, 2006). The first question reminded participants of their alcohol consumption during the trial and asked them to offer a reflection. Questions two and three ascertained what participants thought about alcohol producers reducing the strength of their current products, and without being aware of the change. Questions four and five gauged what participants thought about their local licensed premises replacing regular-strength alcohol products with reduced-strength alternatives, and without being aware of the change. Question six asked how participants felt about the alcohol content of products being reduced if it would reduce alcohol-related harm. Questions seven and eight ascertained who participants thought was responsible for alcohol-related harm and for reducing alcohol-related harm. Question nine asked what participants would think about a policy maker who legislated that alcohol producers had to reduce the strength of their products. The final question gave participants the opportunity to add anything further. Questions were designed to appear neutral and not bias participants' responses. They were written in a style that was intended to be easy to read aloud and for participants to understand and thus respond to. The interview was devised to last for approximately 30 minutes and for a maximum of 45 minutes. This was intended to offer a balance between interviewee fatigue and depth of data.

5.3.5 Piloting and refining data collection tools

A pilot interview was undertaken with a friend of the researcher who had assisted in the pilot trial and had sampled the study-specific drinks in the home setting. Based on their feedback some minor amends to the wording of the questions were made. For example, autonomy was changed to freedom of choice. As part of the pilot process, the researcher checked that the recording equipment worked and that the audio recordings could be uploaded onto the computer system: no faults were found in this process.

1. Your results from the trial show that you drank 10 units of alcohol when you were drinking reduced strength lager, which was during your first study session, and 10.8 units of alcohol when you were drinking regular strength lager, which was during your second study session. What do you think about this?

2. What do you think about alcohol companies/breweries/producers reducing the alcohol content of their current products to try and reduce alcohol consumption?
- What do you think their motives would be?
- How effective do you think this would be?
- Explain whether it would affect which alcohol product/brand you purchase.
- How would the size of the reduction in strength make a difference to what you purchase?
- Can you talk about any instances you know of when this has happened?
- What do you think about companies bringing **new** lower strength products onto the market?

3. How would you feel about not being made aware if alcohol companies/breweries/producers products contained less alcohol than they used to?
- How do you feel this would affect your freedom of choice?

4. What do you think about your local licensed premises introducing reduced strength alcoholic drinks to replace regular strength alcoholic drinks?
- What if all of the beer were reduced in strength?
- How would the size of the reduction in strength make a difference to your views – lower threshold?
- Explain whether it would affect which licensed premises you go to.

5. How would you feel about not being made aware of this change within your local licences premises?
- How do you feel this would affect your freedom of choice?

6. How would you feel about the alcohol content of drinks being reduced if it would reduce harm caused by drinking too much alcohol?
- Why?

7. Who do you think is responsible for harm that occurs because of alcohol consumption?

8. Who do you think is responsible for reducing harm that occurs because of alcohol consumption?

9. What would you think about a policy maker who makes a law that alcohol producers have to reduce the alcohol content of their alcohol products?

10. Was there anything that I missed during the interview that you would like to add?

Figure 5.1: The semi-structured interview question schedule

After the initial three interviews the researcher added three prompts to the interview schedule to remind them to check that the audio recorder was still recording.

The interview schedule was further refined between interviews where the researcher believed questions could be reworded for clarity. For example, “If we knew that reducing the alcohol content of drinks would reduce the harm caused by drinking too much alcohol, how would you feel?” was changed to “How would you feel about the alcohol content of drinks being reduced if it would reduce harm caused by drinking too much alcohol?”

For the final two interviews two extra questions were added to the interview schedule (Figure 5.2). The two questions asked what participants remembered about the two products they consumed during their two study sessions, and how easy it was for them to compare the two products. These questions were added as a memory aid because the final two participants were recruited approximately seven months after their final study session (the other five participants were recruited within a fortnight of their final study session). Additionally, the questions enabled the researcher to determine whether the responses from the final two participants might be prone to recall bias.

5.3.6 Participant recruitment

Approximately 48-hours after the final study session at each venue, the researcher sent participants an email (Appendix S) which debriefed them about the pilot trial, provided tailored information about their lager consumption during their two study sessions and asked them if they were willing to take part in a one-off telephone interview. Participants at Venue Four were also sent a text message to prompt them to read their emails if they were interested in taking part in an interview. This prompt was included because there had been a lack of email communication from participants from this venue. Participants were instructed to read the information sheet (Appendix T) that was attached to the email and, if they wished to take part in an interview, to complete the consent form and booking form, which were also attached. The researcher sent a reminder email to participants who had not responded two weeks after the initial debrief email was sent.

1. Can you tell me what you remember about the two lager products you drank on the two separate study sessions?

2. Bearing in mind you had six weeks between your two study sessions, how easy was it for you to compare the two different products?

Figure 5.2: Additional interview questions

Once the researcher received a completed consent form and booking form from a participant, they arranged a date and time for the interview. Where possible, this aligned with the date and time that the participant had provided as their "first option". If this was not suitable, the researcher arranged the interview to align with the participants "second option", or as closest to this option as circumstances allowed. The researcher emailed the participants to confirm the date and time of their scheduled interview.

Of the nine who expressed an interest in undertaking an interview, seven completed the consent process and all of these completed an interview. The researcher lost contact with the two participants who expressed an interest but did not complete the consent process (Figure 5.3).

5.3.7 The interview process

The researcher conducted the telephone interviews from a quiet room within their home. The researcher phoned the participants on the date and at the time that had been scheduled. Prior to commencing the interview schedule, the researcher gave the participant a briefing, which incorporated an outline of the interview, a reminder of the pilot trial, a reminder of their consent and the opportunity to ask any questions. The researcher stated that the interviews would take a maximum of 45 minutes, but no interview lasted longer than 30 minutes. The interviews were audio recorded. This ensured that an exact replication of the interviews was available for analysis, thus eliminating recall error (Barriball and While, 1994). Once the interview schedule was completed, the researcher asked the participant whether they had anything to add or any questions to ask. This was to give participants the chance to express any further thoughts on the topic or the overall study.

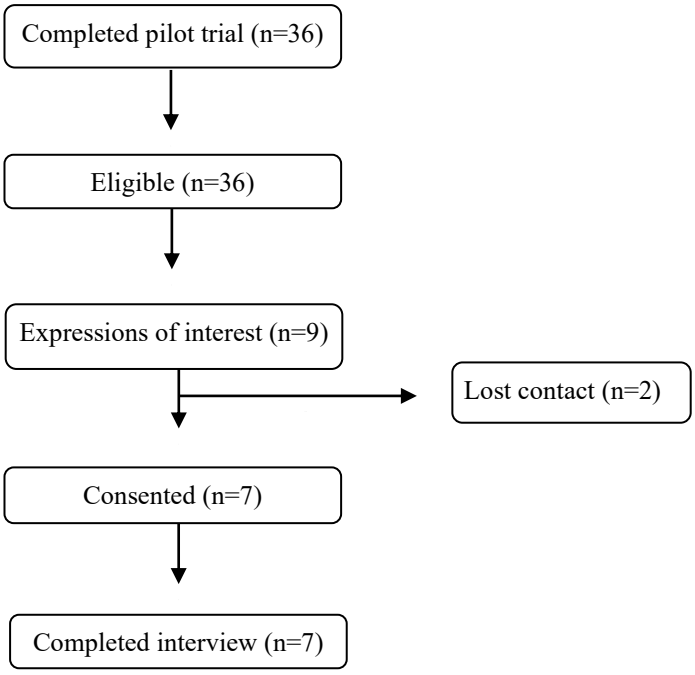


Figure 5.3: Interview participant pathways

5.3.8 Data analysis

Data were managed and analysed using thematic analysis (TA). TA is a method for identifying, analysing and reporting patterns across a dataset (Braun and Clarke, 2006). TA originated in the 1970s through the work of Gerald Horton (Joffe, 2012). Horton developed the concept of thematic analysis to go beyond the more traditional quantitative process of content analysis (CA) (Joffe, 2012; Howitt, 2016). CA relies on frequency outcomes and, as such, has been criticised for removing meaning from data (Joffe, 2012). TA was developed to provide meaningful contextual data through the identification of implicit, tacit themes and thematic structures (Merton, 1975).

Initially, TA was not recognised as a method but as a process used within different qualitative methods (Boyatzis, 1998; Ryan and Bernard, 2000; Holloway and Todres, 2003). The idea that TA should be regarded as a method in its own right was popularised by Braun and Clarke (2006). They stated that TA should be considered as a foundational method for qualitative analysis and it should be the first qualitative method that researchers learn (Braun and Clarke, 2006). Indeed, TA is accessible to novice qualitative researchers as it is relatively easy, and quick to learn and carry out (Braun and Clarke, 2014). Braun and Clarke later refined their definition of TA, calling it an umbrella term for a set of qualitative analysis approaches that aim to identify themes (Braun and Clarke, no date).

They noted that different versions of TA tend to offer theoretical flexibility but can differ in their underlying philosophy and procedures for producing themes. Thereafter, Braun and Clarke's approach to TA was renamed "reflexive TA" to differentiate it from other TA approaches (Braun and Clarke, no date).

Reflexive TA can be used to answer research questions related to people's experiences, views and perceptions (Braun and Clarke, no date). This aligns with the research question in the current study, which sought to assess participants' views and perceptions of reducing the strength of alcohol based on their experience of participating in the pilot trial. Unlike some of its counterparts, reflexive TA is not aligned with an epistemological, philosophical or theoretical approach (Braun and Clarke, 2006). This means it is a flexible method that can be used with different frameworks and to answer different types of research questions. Table 5.1 illustrates the different approaches that can be applied to reflexive TA and it highlights the most common variations in pink and blue.

The approach taken in the current study was based on a mixture of deductive and inductive enquiry. The approach was partly deductive as the research question was pre-specified rather than it "evolving" through the coding process. However, the coding and development of themes were directed by the content of the data, which aligns with an inductive approach. This mixed approach was utilised as the study was intended to answer a specific and pre-determined research question (aligning with a deductive approach) but there were no previous data on which to base codes and themes (aligning with an inductive approach). The researcher took a latent approach, which meant they looked for implicit meanings in, and provided interpretation of, the data. This approach provided a deeper understanding of the data than a semantic approach, which would focus on the explicit content of the data. The researcher viewed the interviews from a constructionist perspective, which assumes that people's engagement is socially constructed. This perspective also acknowledges that there are multiple realities and only one such reality is illustrated by the data (Braun and Clarke, 2006).

Whilst a robust TA can produce meaningful findings, there is no clear agreement about how to apply the method (Braun and Clarke, 2006; Nowell *et al.*, 2017). Braun and Clarke (2006) attempted to standardise the process by providing guidelines for TA. These guidelines were broadly followed in this study. Table 5.2 explains how the

Table 5.1: Approaches to reflexive TA (adapted from Braun and Clarke, no date)

Deductive Coding and theme development are directed by existing concepts or ideas	**Inductive** Coding and theme development are directed by the content of the data
Semantic Coding and theme development reflect the explicit content of the data	**Latent** Coding and theme development report concepts and assumptions underpinning the data
Realist/Essentialist Focuses on reporting an assumed reality evident in the data	**Constructionist** Focuses on looking at how one of multiple realities is created by the data

researcher applied these guidelines to the data. As recommended by Braun and Clarke (2006), these phases were not applied in a linear process but in a recursive process with back and forth movement between the phases.

Throughout the data analysis process the researcher was supported by one of her supervisors who is an experienced qualitative researcher. Ongoing discussions were had about coding and theme generation, and consensus was sought. This was intended to improve the reliability of the data analysis.

5.4 Results

5.4.1 The participants

Seven participants completed an interview. Four participants (three male: 75%) were from Venue One. Three participants were from Venue Two (three male: 100%). The participants ranged in age from 19 to 66 with a mean age of 39.7 (SD = 14.57). Four worked full time (57%), two were self-employed (29%), and one was retired (14%).

5.4.2 Outcomes

Analysis revealed several factors associated with the acceptability of reducing the strength

Table 5.2: Application of Braun and Clarke's (2006) six-phase guide to performing TA

Phase	Description	Application
1	Familiarising yourself with the data	Interview audio recordings were transcribed verbatim in Microsoft Word, transcripts were checked back against the original interview audio recordings and amended where necessary, transcribed data were read three times, initial ideas for coding were marked.
2	Generating initial codes	Interesting passages of data from each interview transcript were underlined and coded manually by writing notes on printed versions of the transcripts.
3	Searching for themes	Codes were transferred into a Microsoft Excel spreadsheet and these were sorted into potential themes. Similar codes had to be present in three or more transcripts to become a potential theme.
4	Reviewing themes	The entire dataset was reread, some data were removed from the analysis, some were added to the analysis, some were recoded, and additional themes were established. Coded data within each theme were reread to assess coherence.
5	Defining and naming themes	The themes were named, and these names were refined, key quotes from participants were collated, a descriptive overview of the themes was written.
6	Producing the report	The final analysis was written up within this thesis.

of alcohol as an intervention to reduce alcohol consumption. The data were sorted into six superordinate themes each with multiple subthemes (Table 5.3). The superordinate themes will be discussed systematically in the following sections with reference to the subthemes and illustrative excerpts from the interview transcripts.

Influences

The theme "influences" describes the sometimes seemingly contradictory factors that influence participants' alcohol consumption. This encompasses the subthemes habits,

Table 5.3: Themes and subthemes identified in the TA

Theme	**Subthemes**
Influences	Habits Friends Family Driving a vehicle Perceived taste of the product
Taste	As a regulator for drinking behaviour As a regulator for acceptability Taste preference related to strength Acceptable strength parameters in which taste is optimised
Choice	People should have choice People do have choice (there is a) Need for more reduced-strength beers in the UK market Wishes to be informed Does not support government mandates
Responsibility	Individual Government
Industry motives	Social responsibility Financial gain
Perceived efficacy	Effective Not effective Potentially effective over time Too unrealistic to consider

friends, family, driving a vehicle and perceived taste of the product.

When discussing their alcohol consumption, participants talked about factors that influence how much alcohol they consume within a given period. Findings were seemingly contradictory. Some participants said they follow habitual drinking patterns, referring to a "normal" number of drinks and/or brand of drink that they consume on specific days of the week and/or at certain venues. These drinking patterns appeared to be portrayed as having limited flexibility. Participant Four described how he associates going to the pub with drinking a specific and consistent amount of different types of alcohol:

> "You associate different things with, you know, different times, like for example if I was to go to the pub…I probably would have two pints and then I'd probably have a gin and tonic…" *Male, Participant Four, Venue One*

Other participants described greater external influences on their alcohol consumption and greater variability in their drinking behaviour. They reported that their alcohol consumption varies based on their physical and social environment, and the circumstances surrounding the drinking occasion. Commonly reported influences included family, friends, the taste of the alcoholic product and the requirement to drive a vehicle after having a drink. It was frequently reported that having children and/or a spouse meant participants limit their alcohol consumption. Conversely, drinking with friends in a social context was seemingly associated with an increase in alcohol consumption. Participant Three described how the amount he drinks alters depending on the amount of time spends, and pace of, drinking when socialising:

> "The amount I drink isn't necessarily related to the amount of alcohol I'm taking in, it's more about the amount of time and the pace of drinking and that sort of thing that might be happening in social occasions." *Male, Participant Three, Venue One*

One participant said that he would drink less alcohol with friends as he would drive to meet them. In this instance, driving after drinking restricts the individual's alcohol consumption. This was noted by several participants who expressed willingness to drink a limited amount of reduced-strength lager to enable them to drive. Participant One explained that he would consume one nice tasting reduced-strength lager in a single drinking occasion to stay under the drink-drive limit:

> "If there was a nice tasting…two and a half or three percent lager…I would have one and then drive to stay under the limit." *Male, Participant One, Venue One*

Taste

The theme "taste" describes how the perception of the taste of different strength alcoholic products is a seemingly crucial factor that influences the alcohol purchasing and consumption behaviours of participants. This includes the subthemes of taste as a regulator for drinking behaviour and as a regulator for acceptability, taste preference is related to strength, and acceptable strength parameters in which taste is optimised.

The perceived taste of alcoholic products appeared to be very important. Participants said that they choose and purchase alcoholic drinks based on their taste. There seemed to be a general feeling that at present there is a lack of nice tasting reduced-strength beers available in the UK. Participant Seven described how he believes the alcohol industry are not sufficiently advanced to produce a nice tasting two percent beer:

> "If the companies that make lager, or any beer for that matter, could find a way to make a beer that tastes like a beer and is a reasonably low content, you know, maybe like a two percent then I think they'd be on a winner, but the science isn't there at the moment." *Male, Participant Seven, Venue Two*

Participant Seven then explained that, consequently, he chooses to drink stronger beer. He explained that he would prefer to limit his consumption of stronger beer than consume more weaker beer because it does not taste as nice:

> "I would limit my drinking appropriately you know…I'd rather drink one pint of something nice than three pints of something horrible." *Male, Participant Seven, Venue Two*

There seemed to be an overriding belief that, currently, stronger beers are more flavoursome than reduced-strength beers. It was widely reported that participants purchase stronger beer because it tastes nicer. This is summarised by Participant Seven:

> "I would go for the higher volume of alcohol because normally it tastes better." *Male, Participant Seven, Venue Two*

On the extreme end of the spectrum, non-alcoholic beers seemed to be regarded as flavourless and were, therefore, not considered as a purchasable option. They were described as not tasting right, not tasting nice, tasting like water and tasting disgusting.

There appeared to be a positive association between perceived niceness of taste of, and willingness to consume, reduced-strength beer. This seems to indicate that reducing the strength of alcohol is more acceptable if taste is maintained or surpasses that of regular-strength beer. This sentiment was verbalised by Participant Three:

> "If the taste was maintained and the quality was maintained, and it was still interesting to drink then I don't think a reduction would impact my purchasing at all." *Male, Participant Three, Venue One*

Similarly, Participant Four concluded that he would probably continue to purchase his regular brand of lager (Peroni, 5.1%) if it was reduced in strength and the taste was not affected:

> "If they knocked two percent off the Peroni, would I still drink it? If it still tasted the same? I probably would." *Male, Participant Four, Venue One*

The 2% reduction that Participant Four specified would make Peroni 3.1%. For Participant Four this appears to be an acceptable reduction with the caveat that taste is not compromised. Similar reductions in strength, to around 3%, were reported by other participants to be acceptable (also assuming that taste is not compromised). Participant Two stated that she would not purchase a beer that was 2% but would purchase a beer that was 3% for arbitrary reasons:

> "I probably wouldn't want to buy…a beer…that was two percent alcohol. But three percent I probably would, and I don't know why that would be or where that's come from but yeah, I know there are beers out there that are two percent and I would never buy them." *Female, Participant Two, Venue One*

Participant Four provided a perspective that seems to reflect the gist of most of the narratives:

> "If they did knock a couple of percentages off…it wouldn't be the end of the world." *Male, Participant Four, Venue One*

Choice

The theme "choice" describes how participants value the concept of choice in relation to their alcohol purchasing and consumption behaviours. It includes the subthemes people should have choice, people do have choice, (there is a) need for more reduced-strength beers in the UK market, wishes to be informed, and does not support government mandates.

Although there appeared to be an overall sense that participants would consume a nice tasting reduced-strength beer, there seemed to be a strong and consistent message that people should have choice. A small number of participants stated that there are sufficient options in the market to give people a choice. A more widely reported belief appeared to

be that there is a need for more reduced-strength alcohol options in the UK. Participant Three talked at length about the long-established drinking culture around light- and mid-strength lagers in his native country, Australia. He discussed how alcohol companies in Australia provide choice compared to in the UK. This impacts on his drinking behaviour as the light- and mid-strength lagers he wishes to consume on certain occasions are not available:

> "Coming from a slightly different culture there might be a case where I'd actually be looking out for those products that don't really exist at the moment…One of the things I do note is missing from the market over here is really a selection of good light- or mid-strength lagers." *Male, Participant Three, Venue One*

Participant Five said he would like to see a 3% lager available in the UK. He believes that providing more reduced-strength options would lead to people choosing a weaker beer rather than a stronger beer:

> "I think if there was sort of a wider range of beers more people probably would go for weaker beer." *Male, Participant Five, Venue Two*

Participant Two explained how it is important for people to have the choice of a variety of different strength alcoholic products:

> "I think it's good to have that variation. I think it's good to give people the option of having a lower-alcohol drink. I wouldn't say to replace them across the board, but I think it's difficult when you go into a pub now and they're all five percent because if you wanted one that is lower you haven't got that option. I think keeping it varied, having a variety of strength, would be good because it gives people the choice." *Female, Participant Two, Venue One*

Not all participants said that they would take action if their choice was diminished. Most participants claimed that they would not stop going to a licensed premises which replaced regular-strength drinks with reduced-strength alternatives. However, several participants stated that they would stop going to a licensed premises which was selling reduced-strength drinks without notifying customers of the change. Participant Six, who is a pub landlord, explained how he would be angry if he had been consuming a reduced-strength product in a licensed premises and had not be told that the brand had been reformulated:

> "I'd probably just walk away and go somewhere else. Sorry to go back to my pub, I wouldn't do that to my customers and…I think if they hadn't told me for a few weeks I'd be fuming." *Male, Participant Six, Venue Two*

This seems to indicate that participants value their ability to make an informed choice. Participant Seven stated that he would have no problem with his local licensed premises introducing reduced-strength drinks if the change was overt:

> "No problem with it so long as they are open and honest about that's what it is." *Male, Participant Seven, Venue Two*

Participants' views on legislation to reduce the strength of alcoholic products appeared to align with their desire for choice. Such legislation seemed to be regarded as restrictive and participants felt that it would diminish their freedom of choice. One participant aligned such legislation with a totalitarian Islamic-type state. Another participant aligned such legislation with a paternalistic state like North Korea. Both participants spoke of these systems of government in a negative manner, indicating that they are against mandatory policies on alcohol strength. This sentiment seemed to be shared widely amongst participants.

Responsibility

The theme "responsibility" encompasses who participants appear to believe is responsible for alcohol-related harm and its reduction. Findings have been categorised within two subthemes: the individual, and the government.

When talking about who is responsible for alcohol-related harm and its reduction, the overwhelming belief amongst participants seemed to be that the individual consumer is responsible for their actions. This view centred on the idea that, if individuals have capacity, they are provided with plentiful information to enable them to make informed choices. Some participants spoke about this in the first person, indicating their belief that the alcohol-related information they are provided empowers them to make responsible choices. Participant Two discussed how alcohol product labelling enables her to have control over, and responsibility for, her purchasing:

> "I would still ultimately have control because I'm buying the product and it's my responsibility to find out what product I'm buying and the way they label it now I'm able to do that." *Female, Participant Two, Venue One*

In addition, a subset of participants mentioned that the government should take some responsibility for reducing alcohol-related harm. Participant Six expressed his frustration at his belief that the government should be, and are not, prioritising alcohol harm reduction:

> "The amount the country's drinking, you see it in the budget just recently they didn't really touch alcohol..." *Male, Participant Six, Venue Two*

Limited ideas were offered as to how the government could reduce alcohol-related harm. Participants mentioned legislation to reduce the strength of alcohol and reduce accessibility, minimum unit pricing (MUP), and increasing taxes. However, the latter two ideas were offered as potential solutions but also as being potentially detrimental. Participant Two discussed how MUP could increase financial insecurity amongst, and fail to treat, people with an alcohol addiction:

> "I know that in Scotland…there's a certain minimum charge per unit. But I'm not sure what I think about that because maybe people with addiction charging more, you know, we need to treat the cause of that rather than further impeding those people financially." *Female, Participant Two, Venue One*

Industry Motives

The theme "industry motives" describes the sometimes seemingly contradictory perceptions of what would motivate the alcohol industry to reformulate their current products, so they contain less alcohol. This includes the two subthemes social responsibility and financial gain.

In discussing perceived motives for the alcohol industry to reduce the alcohol content of their drinks, two contrasting ideas seemed to dominate. Firstly, that the alcohol industry is motivated by making money. In particular, participants focused on the industry reducing the strength of their products to avoid paying a higher rate of tax. Participant Six described alcohol producers as sneaky for having previously reformulated one of their products (Stella Artois) to avoid higher taxation:

> "Like that Stella Artois thing a few years ago, they dropped it to avoid a higher level of tax, which is a bit sneaky." *Male, Participant Six, Venue Two*

Participant Six continued by explaining how he would feel about having to pay the same amount of money for a reduced-strength lager even though the alcohol industry would be paying less tax on it:

> "If the price would come down as well as the percentage then I wouldn't mind as much but the price never goes down does it?" *Male, Participant Six, Venue Two*

The second motive that participants discussed for the alcohol industry reducing the content of their drinks was social responsibility. In particular, participants focused on the alcohol industry seeking to improve consumer health. In the following excerpt, Participant One pondered why the alcohol industry would reduce the strength of their products other than to improve the health of consumers:

> "I suppose health is probably the main reason…I don't really know…why they would…other than for health reasons." *Male, Participant One, Venue One*

As indicated in the above excerpt, participants seemed to view the alcohol industry from a binary perspective. It is either regarded negatively: as an industry motivated by their own financial gains, or it is regarded positively: as a socially responsible industry who are concerned about the health of their consumers. The viewpoint of participants appeared to be associated with whether they accepted reducing the strength of alcohol as an intervention to reduce alcohol consumption. Those who believe the alcohol industry are motivated by profit did not seem to find the intervention as acceptable as those who believe the alcohol industry are motivated by improving consumer health.

Perceived efficacy

The theme "perceived efficacy" describes the extent to which participants seem to perceive the efficacy of reducing the strength of alcohol as an intervention to reduce alcohol consumption. This includes the subthemes effective, not effective, potentially effective over time, and too unrealistic to consider.

When considering how effective participants thought reducing the alcohol content of drinks to reduce alcohol consumption might be, there appeared to be contradictions between and within participants' responses. There seemed to be a trend for participants to say that reducing the strength of alcohol could be effective in reducing alcohol consumption and its related harms. However, these were often stand-alone statements,

which suggests that the participants may have made such speculations to appear socially desirable to the interviewer.

Several participants gave more consideration to the matter and expressed concern that people might compensate for a reduction in the strength of beer. In the following excerpt it appears that Participant Five is reconsidering how effective a reduction in alcohol strength might be as he speaks. He concluded that reducing the strength of alcohol may increase consumption:

> "I definitely don't think it would be a bad thing but then again…would that maybe make people drink more? Just to…get drunk. It could actually increase…a person's consumption." *Male, Participant Five, Venue Two*

The main mechanisms that were mentioned were people drinking a greater volume of beer, and people replacing beer with stronger alcoholic products, namely wine and spirits. Participant Six talked about how he would switch from drinking beer to drinking spirits in a licensed premises if the beer was reduced in strength:

> "If they're going to drop the alcohol content then yeah, I'd probably go to the top shelf: move away from beer and go on to shorts or something." *Male, Participant Six, Venue Two*

Furthermore, there seemed to be a strong opinion that people will find a way to drink what they want to drink, thus rendering an intervention to reduce the strength of alcohol ineffective. Participant Seven explained how he believes that people will always find a way to get what they want. He used the analogy of cannabis and cocaine to describe how he believes that restricting people to reduced-strength alcohol will result in people purchasing stronger alcohol illegally:

> "That's why people still smoke cannabis, still take cocaine, you know, it's all illegal but it doesn't stop it happening." *Male, Participant Seven, Venue Two*

Some participants discussed how the drinking culture in the UK would have to change to enable reductions in the strength of alcohol to be effective at reducing alcohol consumption. Although it was acknowledged that it is challenging to change people's culture, there was hope that it could happen slowly. Participant Three explained how cultural change regarding alcohol strength took many decades to evolve in his native country, Australia. He believes that the same process of change can occur in the UK:

> "It didn't happen straight away, like any big changes across culture, but it's probably over ten or twenty years that that whole culture around alcohol strength and that sort of thing changed." *Male, Participant Three, Venue One*

5.5 Discussion

Findings from this study appear to demonstrate that acceptability of a behaviour change intervention is not a simple binary concept but a more complex issue where the level of acceptability relates to personal factors, and key aspects of the intervention and its enforcement.

Several factors were found to be associated with the acceptability of reducing the strength of alcohol as an intervention to reduce alcohol consumption. These were sorted into the themes: influences, taste, choice, responsibility, industry motives and perceived efficacy.

There seemed to be no apparent association between variation in drinking pattern and acceptability of replacing regular-strength alcohol with reduced-strength alcohol. Those who reported drinking a specific and consistent amount of alcohol on certain drinking occasions appear to share many views with those who reported a large variation in their alcohol consumption. The amount of alcohol these participants reported regularly consuming was also highly variable: ranging from two pints per drinking occasion to drinking enough to get "wrecked". This seems to indicate that the intervention may be similarly acceptable across a wide spectrum of lager drinkers. Witnessing consistent levels of acceptability, however, does not gauge how acceptable the intervention is: the intervention could be consistently reported as highly acceptable or consistently reported as highly unacceptable.

There appears to be an overall positive reaction to reducing the strength of alcohol as an intervention to reduce alcohol consumption. However, this is based on several caveats. Foremost is the concept of taste: reduced-strength lagers would have to taste nice for them to be a purchasable and consumable option. When participants used the phrase "taste nice" they would often talk about it in relative terms: they would like a reduced-strength lager that tastes similar to, or nicer than, a regular-strength lager. The overriding belief appeared to be that currently there are not enough nice tasting reduced-strength lagers available in the UK. Participants seemed to support the idea of new reduced-strength alcoholic

products being created but less so current products being reformulated to contain less alcohol. This is concerning from a public health perspective, as the alcohol industry market new reduced-strength products as an addition to, rather than a substitute for, regular-strength products (Vasiljevic *et al.*, 2018). The corollary is that people will purchase and consume more, rather than less, alcohol if the market is expanded to include new reduced-strength products. Participants appeared to regard the flavour of lager on a continuum with non-alcoholic lagers representing "tasteless" at one extreme and the strongest lagers with the most taste at the other extreme. Three percent ABV lagers seemed to be regarded as not being very flavoursome. However, there appeared a common thread that a nice tasting 3% ABV lager would be acceptable, purchasable and consumable. Even those who listed intoxication as one of their motives for drinking, said they would drink a nice tasting reduced-strength lager, that was around 3% ABV, in certain situations. For example, when they are driving or during long drinking sessions at sporting events. It thus appears that change needs to start with the alcohol producers; they need to create a reduced-strength lager, at around 3% ABV, which has similar sensory qualities to its regular-strength counterparts. However, as one participant suggested, it may be that alcohol producers are currently unable to create such a product and that the science around brewing would need to develop before this is feasible.

The second caveat is that reducing the strength of alcohol would only be acceptable if it did not apply to all products. Participants delivered a strong message that they want choice, and that choice involves having access to a variety of different strength alcoholic products. Participants seemed to stress the importance of having plentiful information to empower them to make informed choices. For example, labelling on alcohol packaging was noted as an enabling factor. This aligns with research which suggests that people are more likely to accept interventions that provide information compared to more intrusive interventions, even though the former are less effective (Diepeveen *et al.*, 2013). The overarching view appeared to be that the individual consumer is responsible for their own choices and, therefore, their own drinking behaviour and the harm that occurs as a result of alcohol consumption. As consumers with the capacity to make decisions, participants seemed eager to take responsibility for their actions. This appeared to have a large influence on their views of government legislation to reduce alcohol consumption and its related harms. Even though participants thought that the government should take some responsibility for reducing alcohol-related harm, they did not express support for mandatory action. This apparent advocation of minimal state intervention and maximum liberty, freedom of

choice, autonomy and individual judgment aligns with a libertarian approach (Thaler and Sunstein, 2009; Kahneman, 2011). Those with libertarian tendencies view government interventions as restrictive. The term "nanny state" was coined to describe a government that is perceived to have excessive influence over the welfare of its citizens. The term has become increasingly recognised and used in UK society as a political slur in opposition to potential, and realised, government interventions. Accusations of a nanny state are often made arbitrarily or incoherently to demonise health promotion messages (Coggon, 2018). Sections of the UK media regularly berate the nanny state when reporting on public health policies and interventions (Heffer, 2012; Drake, 2017; Welsh, 2017; Thompson, 2018). This negative framing of a nanny state is likely to have influenced the public's views on mandatory government interventions and could explain why participants appeared to strongly oppose government mandates to reduce the strength of alcoholic products (Coggon, 2018). Some participants seemed to allude to a preference for alcohol producers to voluntarily reduce the alcohol content of their products. In the past such voluntary initiatives, including the Public Health Responsibility Deal (PHRD), have proven ineffective (Institute of Alcohol Studies, 2015). If the public were aware of the relative efficacy of mandatory interventions that seek to change behaviour compared to such voluntary interventions, mandatory interventions may be more acceptable (Diepeveen *et al.*, 2013; Pechey *et al.*, 2014; Somerville *et al.*, 2015; Petrescu *et al.*, 2016). Thus, the framing of interventions in the public domain appears to be crucial in improving their acceptability.

Highlighting efficacy has been shown to increase the acceptability of behaviour change interventions (Pechey *et al.*, 2014; Somerville *et al.*, 2015; Petrescu *et al.*, 2016). In the current study participants appeared to think that reducing the strength of alcohol could be an effective intervention. However, this sentiment was generally offered as a standalone statement and participants offered no further explanation. This suggests that participants were responding to the interviewer in a way they believed would be socially desirable rather than expressing their true thoughts. Indeed, when some participants considered their response further, they seemed to query whether reducing the strength of alcohol could lead consumers to over compensate and thus inadvertently consume more alcohol. Furthermore, there appeared to be an underlying feeling that people will always find a way to get what they want. Therefore, if people are unable to legally purchase the stronger alcoholic products that they desire, the belief is that they will purchase them illegally. This viewpoint offered further support for the notion that, at best, reducing the strength of alcohol would

be ineffective at reducing alcohol consumption and its related harms; at worst, reducing the strength of alcohol could lead to people consuming more alcohol. At present there is a paucity of evidence to indicate whether reducing the strength of alcohol would be effective at reducing alcohol consumption or whether it could increase alcohol consumption. Further long-term research is required at the population level. If such research highlighted that reducing the strength of alcohol is effective at reducing alcohol consumption, disseminating this message to the public would be crucial in gaining public approval for any resulting policy (Pechey *et al.*, 2014; Somerville *et al.*, 2015; Petrescu *et al.*, 2016).

Another factor that altered the acceptability of reducing the strength of alcohol as an intervention to reduce alcohol consumption was the perceived motives of the alcohol industry. Participants who believe the alcohol industry are motivated by improving consumer health seemed to express greater willingness to accept the intervention. Participants who believe the alcohol industry are motivated by financial gain appeared to express a lack of willingness to accept the intervention. These viewpoints are relevant if alcohol producers were to voluntarily reduce the alcohol content of their products, however, they become obsolete when considering mandatory change. If change was to occur voluntarily, the alcohol industry could potentially attempt to increase the acceptability of their reduced-strength products by convincing the public that their main motive is consumer health. However, from a public health perspective, the alcohol industry is only motivated to appear socially responsible to ultimately achieve their aim of profiteering. Research has found flaws in the alcohol industry's corporate social responsibility activities. Alcohol industry messages of "responsible drinking" were found to be deliberately ambiguous to allow multiple interpretations (Maani Hessari and Petticrew, 2018). Information provided by the alcohol industry about alcohol and cancer extensively misrepresented the evidence of the alcohol-related risk of cancer (Petticrew *et al.*, 2018a). Furthermore, initiatives in which the alcohol industry worked in partnership with local governments to attempt to reduce alcohol-related harm lack evidence of efficacy despite industry claims (Petticrew *et al.*, 2018b). It is speculated that the main role of such initiatives is to limit the reputational damage of the alcohol industry rather than improve the public's health (Petticrew *et al.*, 2018b). It is unlikely that public health professionals, including the author of this thesis, would endorse any action by the alcohol industry that promotes the message that the alcohol industry are motivated by consumer health.

Although this study provided some useful initial data, there are several limitations. Most notably, the researcher was not sure whether data saturation was reached. Ideally, the sample would have been larger so that the researcher could establish whether new insights were forthcoming. This lack of clarity means that data may not accurately reflect the full range of views of those within the sampling frame. Another limitation is that interviewer bias, recall bias and social desirability bias may all have influenced the participants' responses. These biases tend to be inherent in qualitative interviews and although measures were taken to reduce the risk of bias during the interview process, this could not be fully eliminated. To further reduce, or eliminate, the risk of these biases a different method could have been used to answer the research question. For example, a self-completed questionnaire, or focus groups. However, these different methods also have limitations. Compared to qualitative telephone interviews a self-completed questionnaire would have been less flexible, it would not have provided such rich data, and it would have been prone to recall, and social desirability biases. Compared to qualitative telephone interviews focus groups would have been more expensive and time consuming to implement, they would have been more burdensome on participants, and they are especially prone to social desirability bias.

The study did meet the aim of qualitative research, to provide a contextual account, albeit with a small sample (Merton, 1975). This exploratory piece of work has thus provided some useful insights for future research. The study illustrates that it is feasible to undertake semi-structed telephone interviews with a subsample from a RCT that assesses the effect of alcohol strength on alcohol consumption. The interview process required few resources, had limited ethical implications and was concluded without incident. The researcher's approach, which sought parity between the researcher and the participants, enabled participants to express their views openly and without judgement. The researcher remained impartial throughout data collection and analysis so as not to influence the outcomes. Crucially, the researcher enlisted a member of their supervisory team to support the coding and theme generation to improve the reliability of the data. This study has the potential to be scaled up if the sample from a definitive RCT enables a greater number of participants to be recruited.

5.6 Conclusion

This chapter discussed the final part of the research project: semi-structured qualitative telephone interviews to assess the acceptability of reducing the strength of alcohol as an

intervention to reduce alcohol consumption. It described how the study was designed and executed to meet the aim and answer the research question. Data were analysed in accordance with Braun and Clarke's guidelines for thematic analysis, and the results were discussed. Finally, the strengths and limitations of the study were detailed.

Chapter Six: An Overall Discussion of the Research Project, and Conclusions

6.1 Introduction

This thesis presented a research project which sought to establish the feasibility of future work to assess the effect of alcohol strength on alcohol consumption and the acceptability of reducing the strength of alcohol as an intervention to reduce alcohol consumption. The overall project incorporated three studies, which addressed three separate research questions (RQs):

Study one: a single-blind taste discrimination experiment (see Chapter 3).

RQ: Which regular-strength lager tastes most similar to Bud Light lager?

Study two: a double-blind randomised controlled crossover pilot trial (see Chapter 4).

RQ: Is it feasible to carry out a definitive randomised controlled trial (RCT) to assess the effect of alcohol strength on alcohol consumption in a single drinking occasion within licensed premises in the United Kingdom (UK)?

Study three: semi-structured telephone interviews (see Chapter 5).

RQ: Is reducing the strength of alcoholic beverages an acceptable intervention to reduce alcohol consumption?

Studies one and two focused on collecting quantitative data, whilst study three obtained qualitative data. Data from each study were analysed separately. These studies have been reported systematically in this thesis. This concluding chapter aims to provide an overall discussion of the research project, its strengths and limitations and the implications of its findings for future work.

6.2 The single-blind taste discrimination experiment

6.2.1 Overview

The single-blind taste discrimination experiment was conducted to establish a control product to use alongside the pre-determined intervention product, Bud Light (BL) lager, in the pilot trial. BL was chosen as the intervention product *a priori* because it is one of few

mainstream lagers sold in the UK below 3.8% ABV and it is reported to have retailed well since its UK launch in March 2017 (Robinson, 2017a). Additionally, BL is accessible and affordable. The taste discrimination experiment sought to select a regular-strength lager that was perceived to taste most similar to the reduced-strength lager BL, to minimise the risk of confounding from taste differences in the pilot trial.

The taste experiment met two of the three criteria for success:

1. Participant recruitment rate was (equal to or) greater than five per study session.
3. The mean/median similarity rating between the two products deemed most alike was equal to (or greater than) seven (70%).

The second criterion for success was not met:

2. An overall majority consensus as to which regular-strength lager tasted most similar to the pre-determined reduced-strength lager, BL, was not obtained within the initial taste experiment or one re-run of the taste experiment.

After consideration by the researcher and the supervisory team, there was deemed insufficient justification to re-run the taste experiment. Instead, the data were redistributed so that an overall majority was obtained in a process akin to the alternative vote (AV) system (Johnston, 2017, as outlined in section 3.4.2). These findings demonstrated that participants perceived Becks lager (B, 4.8% ABV) to taste more like BL than Carlsberg Export (CE) or Stella Artois (SA) (both 4.8% ABV). Thus, B was instated as the control product for the pilot trial.

6.2.2 Strengths

A major strength of the taste discrimination experiment was its design. Although the researcher could not be blinded for practical reasons, the participants were blinded. This minimised the possibility of response bias (Pocock, 1983; Tilling *et al.*, 2005; Karanicolas, Farrokhyar and Bhandari, 2010). The order in which participants received the lager samples was randomised, which protected against order effects (Pocock, 1983). Additionally, the sequence allocation was concealed from the researcher, which prevented allocation bias (Pocock, 1983).

The study was designed to be efficient and require few resources. Data were collected from 19 participants within two days. Only one researcher was required to plan and conduct the

experiment and analyse the results. Whilst there were costs incorporated in purchasing the study equipment, some of the more expensive items could be reused for future iterations of the study. For example, the mini fridge. The main expenditure was the participant incentives: one £10 shopping voucher per participant. Whilst on reflection this may appear generous, it is unclear whether a lesser incentive would have negatively impacted recruitment. Therefore, it would be advisable to offer the same incentive in future iterations of the study or to explore incentives during collaborative work with the public prior to running another taste discrimination experiment.

Another strength of the taste experiment is that it could be adapted for other types of alcohol. For example, wine or real ale. This would only require minimal amendments to the protocol such as altering the volume of alcohol provided in each sample and amending the wording of the study resources and data collection tools. This flexibility means that the taste experiment would be suitable to conduct prior to controlled trials incorporating lager and/or other types of alcoholic products.

6.2.3 Limitations and future work

One of the main limitations of the study was that participants sampled a narrow variety of lagers. This meant that taste comparisons were limited: they compared three regular-strength lagers (4.8% ABV) to the pre-determined intervention product, BL (3.5% ABV), in pairs of samples. When making these comparisons, most participants correctly reported which of the two samples within each pair had the higher alcohol volume. This was contrary to findings from previous strength-discrimination studies, which found that participants could not distinguish between alcoholic products of different strengths (Milner, 1979; Cox and Klinger, 1983; McLaughlin, 1988; Corcoran and Segrist, 1993; Segal and Stockwell, 2009; King and Heymann, 2013; Lachenmeier, Kanteres and Rehm, 2014). This disparity in findings indicates that the different strength alcohol products used in the current study were more distinctive than those used in previous studies. For example, the reduced-strength lager, BL, used in the current study may have had a distinctly "watery" (weaker) taste. The corollary is that if pilot trial participants were aware of the different strengths of the intervention and control products, this could bias their behaviour and questionnaire responses due to lack of blinding. If time and resources allow, future iterations of the taste discrimination experiment should incorporate a wider selection of lagers and of different strengths. Additionally, the choice of the intervention lager should

not be pre-determined but guided by participants' responses. This would help to ensure that the intervention and control products for the pilot trial tasted more alike than BL and B.

A further limitation is that the sample of participants was not representative of the wider lager-drinking population. There was an over-recruitment of students. Those who were male, older (>53 years), retired or unemployed were under-recruited. It is probable that this occurred because one of the three proposed methods of recruitment failed. The researcher sought to attend an Oxford Pubwatch Scheme meeting and request that pub landlords/managers advertised the study to their patrons. However, when the researcher attempted to contact the Oxford Pubwatch Scheme they did not respond. This meant that participants were recruited solely from Oxford Brookes University (OBU) or through word of mouth via the University's staff and students. It is unclear as to whether including a representative sample would notably alter the data as, to the researcher's knowledge, there is no evidence to suggest that sensory perceptions differ based on demography. If a sample representative of the wider lager-drinking population had been recruited, there would still have been questions regarding the generalisability of findings. This is because sensory perceptions are highly subjective. Therefore, data from a broader sample may still not accurately reflect the spectrum and distribution of these sensory perceptions across the wider lager-drinking population. However, if sufficient resources are available, it would still seem sensible to improve the representativeness of the sample in future iterations of the taste discrimination experiment. In this instance, researchers should aim to recruit a larger sample (>19) from multiple and diverse settings.

An additional consideration is that the lager samples may have been too small (30ml) for accurate comparisons to be made. The small volume of samples also compromised the ecological validity of the study: in licensed premises consumers would normally drink lager in larger volumes of up to 568ml. The volume of the samples could be increased (to 60ml) in future iterations of the study. However, the effect of larger samples on breath alcohol concentration (BrAC) readings and, therefore, the ethical implications of the experiment, would have to be considered. For instance, participants would be expected to remain at the study venue once they have completed the taste experiment until their BrAC reading is below the drink-drive limit.

6.3 The double-blind randomised controlled crossover pilot trial

6.3.1 Overview

The pilot trial was conducted to assess the feasibility of a definitive RCT to evaluate the effect of alcohol strength on alcohol consumption in a single drinking occasion within licensed premises in the UK. The pilot trial met five of the six criteria for success (Perman-Howe, Davies and Foxcroft, 2018 (Appendix B)):

1. Components of the study protocol were efficient and worked together.
3. Participant recruitment rate was greater than four per initial study session for each cohort.
4. The rate of attrition was less than 30% and did not vary by more than 10% according to the arm of the trial.
5. Estimations of the mean and 95% CI suggest that people consume fewer UK units of alcohol when they consume reduced-strength lager.
6. The sample size required for a definitive RCT (23: allowing for attrition) is achievable to obtain within a year.

The second criterion for success was not met:

2. The licenced premise recruitment rate was less than one per month and it took over 14 months to recruit four premises.

The licensed premises recruitment rate was low because the venues were recruited, and completed their study sessions, consecutively rather than simultaneously. This was implemented to ensure that any problems with the study processes could be rectified as the trial progressed. In a definitive trial, it is recommended that venues are recruited and complete their study sessions simultaneously. It is anticipated that this would notably increase the venue recruitment rate and thus improve the efficiency of the study.

Overall, the study demonstrated that a definitive RCT to assess the effect of alcohol strength on alcohol consumption in a single drinking occasion within licensed premises in the UK is feasible. It is recommended that a definitive RCT incorporates different intervention and control products to those used in the pilot trial and that minor revisions to the protocol are made.

6.3.2 Strengths

The main strength of this study was its design: a double-blind randomised controlled crossover pilot trial. The crossover design meant that fewer participants were required compared to a trial of parallel design, fewer observations were required to gain the same precision in estimation, and between-subject variability was removed (Senn, 2002). As the study was of crossover design, participants were randomised to the order they were administered the intervention, and the control. This protected against a period effect (Pocock, 1983). The double-blinding of participants and the intervention provider (the research assistant (RA)) meant there was a reduced possibility of both response and experimenter bias (Pocock, 1983; Tilling *et al.*, 2005; Karanicolas, Farrokhyar and Bhandari, 2010). Furthermore, the allocation sequence was concealed, which eliminated allocation bias (Pocock, 1983).

Although sample size calculations are not usually conducted for pilot trials, an estimation of the sample size was calculated using simulated datasets (Leon, Davis and Kraemer, 2011; Billingham, Whitehead and Julious, 2013; Lee *et al.*, 2014). This was conducted to improve the accuracy of the data and uphold good ethical practice by not under- or over-recruiting participants (Cocks and Torgerson, 2013). Although the calculated sample size for the pilot trial was not obtained, a large effect size was still found. This suggests that the study had sufficient power. The corollary is that the data obtained from the pilot trial should enable an accurate sample size calculation for a definitive RCT.

A further strength of the pilot trial is that it was preregistered (American Economic Association (AEA) Randomised Controlled Trial (RCT) Registry: AEARCTR-0002266), it was published and updated on the Open Science Framework (OSF) and the protocol was published in a peer-reviewed open-access scientific journal (Perman-Howe, 2017b; Perman-Howe, Davies and Foxcroft, 2018 (Appendix B); Perman-Howe, 2019). This means that the study processes were transparent, as there is a dated audit trail, and replicable. This aligns with the concept of “open science”.

6.3.3 Limitations and future work

One of the limitations of the pilot trial is the uncertainty as to whether participants adhered to the study protocol and only consumed the study-specific lager and the soft drinks they reported. There is also the possibility that participants bought study-specific drinks for

non-participants as they were cheaper than the regular lager sold at each venue. Either of these situations would have resulted in inaccurate data on the amount of alcohol each participant consumed during a study session. The risk of participants deviating from the protocol could have been mitigated by placing researchers within the venues during study sessions to covertly observe participants' drinking behaviour. A similar strategy was successfully implemented in a study assessing the effect of serving size on alcohol consumption within licensed premises in the UK (Kersbergen *et al.*, 2018). In this study, six researchers posed as patrons within participating licensed premises during each study session to covertly observe participants' alcohol consumption. In the current study, the researcher and the RA did observe participants' drinking behaviour throughout the pilot trial study sessions, however, there were not enough resources to officially observe participants. This could be considered as an addition in future iterations of the trial.

Another limitation can be inferred from the questionnaire findings: the intervention and control products were inadequately matched. This aligns with data from the taste discrimination experiment, which show that most participants were consistently able to identify which of two samples of lager had the higher ABV (including the intervention and control products). If the pilot trial participants were aware that they were consuming different strength products then this may have biased their drinking behaviour and questionnaire responses due to lack of blinding. Furthermore, when participants were asked to rate BL, and B in comparison to their regular brand of lager, the most popular responses were "much worse" or "worse". This indicates that neither drink tasted favourable to the participants and BL was less favourable than B. Prior to a future trial, further exploratory work should be undertaken to establish an intervention and a control product that taste more favourable than BL and B and that evoke equal levels of enjoyment. This should include an amended version of the taste discrimination experiment that was undertaken prior to the pilot trial.

A further limitation is that the study findings do not translate to other settings. For example, pilot trial data suggest that a definitive RCT to assess the effect of alcohol strength on alcohol consumption is feasible to enact within licensed premises in the UK. However, they do not tell us the feasibility of undertaking the study within the home setting, or within licensed premises in different countries. When designing a study to assess the effect of alcohol strength on alcohol consumption in a different setting, lessons could be learnt from the findings of this pilot trial. However, it is likely that significant

amendments to the study protocol would have to be made. A study in the home setting, for example, would require different methods for: administering the study processes (such as consent and randomisation) and data collection tools; supplying, and regulating the supply of, study-specific alcohol; and monitoring and recording alcohol consumption. Therefore, such a trial would need to be piloted before it is implemented as a definitive RCT.

Based on the inconsistent rate of attrition witnessed across two Student's Union (SU) bars in the pilot trial, it would be recommended to avoid recruiting SU bars in any future trial. This would reduce the risk of having a high level of attrition. If recruitment of other licensed premises is insufficient then SU bars could be recruited, but this should only be implemented as a last resort.

Future iterations of the trial may wish to consider how to reduce the environmental impact of the study. It was brought to the researcher's attention that the empty lager cans from the study were not recyclable because they had been wrapped in duct tape. The researcher did not remove the duct tape from the empty cans and thus the cans were not recycled. This was because the process of removing the duct tape would have been too time consuming, it would need to have been conducted away from the study venue to preserve participant blinding and the researcher did not have the capacity to recycle a large quantity of cans. Ideally, there would be another simple method of concealing the lager brands from the participants and the intervention provider (the RA), which would ensure that the packaging could be recycled. If no other method is found prior to future iterations of the trial, then plentiful resources should be mobilised to ensure that the alcohol packaging is recycled efficiently and effectively. For example, working time could be dedicated to the researcher and/or the RA the day after each study session to remove the duct tape from the cans and take them to a recycling centre.

6.4 The semi-structured qualitative telephone interviews

6.4.1 Overview

Semi-structured interviews were conducted with a subsample from the pilot trial to explore the acceptability of reducing the strength of alcohol as an intervention to reduce alcohol consumption. The study found several factors associated with the acceptability of reducing the strength of alcohol as an intervention to reduce alcohol consumption. Six superordinate themes were identified:

1. Influences.
2. Taste.
3. Choice.
4. Responsibility.
5. Industry Motives.
6. Perceived Efficacy.

Each superordinate theme comprised multiple subthemes. The study provided exploratory data as a basis for future work. Findings suggested that reducing the strength of alcohol as an intervention to reduce alcohol consumption would be acceptable if: the reduced-strength products tasted similar to their regular-strength counterparts, the reduction in strength did not apply to all products, people perceived the intervention to be effective, and people perceived the alcohol industry to be motivated by consumer health rather than financial gain. Importantly, the study established that it is feasible to undertake semi-structured interviews with a subsample from a RCT that assessed the effect of alcohol strength on alcohol consumption in a single drinking occasion within licensed premises in the UK.

6.4.2 Strengths

The semi-structured telephone interviews complement the findings of the taste discrimination experiment and the pilot trial by contributing to the wider understanding of reducing the strength of alcohol as an intervention to reduce alcohol consumption. The qualitative data were derived from participants who had already taken part in the pilot trial. Therefore, their responses were guided by their experience of consuming reduced-strength lager rather than it being an abstract concept, which may have been the case if the interviews were conducted prior to the pilot trial. These data have enabled the researcher to go beyond assessing feasibility, to consider how the intervention could be embedded in policy.

Another strength of the study was it required few resources. Only two study personnel were required: the researcher, who carried out all the study processes, and one member of the researcher's supervisory team, who supported the data analysis. There were no costs associated with borrowing the electronic equipment that was needed to conduct and record the interviews. Additionally, the researcher conducted the interviews from their home, which improved the efficiency of the study.

6.4.3 Limitations and future work

The main limitation of the study was that the researcher could not confirm whether enough data had been elicited to provide meaningful conclusions. This is because there are no pragmatic guidelines that specify how to recognise when data saturation has been reached (Guest, Bunce and Johnson, 2006). There is a level of agreement on some of the principles of data saturation. Namely, that it is reached when there are no new data, and therefore no new themes or coding, and when there are enough data to replicate the study (Guest, Bunce and Johnson, 2006; O'Reilly and Parker, 2012; Walker, 2012; Howitt, 2016). However, it could be argued that there is always the potential for new data to be elicited and for new themes and coding to be developed. In addition, one can never be sure that there are enough data to replicate a study as different participants are likely to provide nuanced data. The claim that there are enough data to replicate a study can only, accurately, be made in hindsight. The sample size (seven) of the qualitative study reported in this thesis could be considered relatively small. A larger sample could result in more useful data. However, qualitative interviews can provide insightful data with a sample as small as six (Guest, Bunce and Johnson, 2006). Burmeister and Aitken (2012) state that it is the depth of data, rather than the size of the sample *per se*, that is imperative for reaching meaningful conclusions in studies that provide qualitative data. They state that larger samples do not guarantee that data saturation will be reached. Ideally, the researcher would have interviewed more participants, however, there is no certainty that a larger sample would have elicited more meaningful data.

6.5 Original contribution to knowledge

To the researcher's knowledge, this was the first research project to pilot a double-blind randomised controlled crossover trial to assess the effect of alcohol strength on alcohol consumption within licensed premises. Additionally, this is believed to be the first research project to explore the acceptability of reducing alcohol strength as an intervention to reduce alcohol consumption.

This project has provided valuable initial data that suggest future iterations of the series of three studies are warranted. Recommendations for improvements to each of the three studies have been outlined. This is intended to enable subsequent researchers to make informed evidence-based decisions about how they conduct similar research projects.

Importantly, the successful implementation of the pilot trial within on-trade licensed premises in the UK has demonstrated that positive relationships can be forged between public health researchers and some sectors of the alcohol industry. Licensed premises landlords/managers may initially be sceptical about the purpose of alcohol harm prevention research. However, positive communication can alleviate these concerns and enable solutions that are mutually beneficial to themselves and the researchers. In this instance the landlords/managers received a financial incentive and the researcher was able to collect data from within their licensed premises.

Furthermore, this research project provides assurance to other researchers in the field of alcohol harm reduction that, at least some, research ethics committees are amenable to proposals that involve participants consuming alcohol *ad libitum*. Thus, ethics committee approval should not be regarded as a barrier to conducting experimental alcohol-based research. Instead, researchers should regard the ethics committee process as one which provides pragmatic guidance on the conduct of trials involving alcohol consumption.

This project has provided several unique additions to the public health literature. Most importantly, it has laid the foundations for the first robust experimental study to assess the effect of alcohol strength on alcohol consumption in a single drinking occasion within licensed premises in the UK.

6.6 Concluding comments

The three studies that comprised this research project are all feasible to incorporate in a definitive research project. Protocol amendments would be required for the taste experiment and the trial to improve the internal and external validity of the findings. However, these could be easily achieved with enough resources. This research project has provided sufficient data to answer the three research questions that were posed at the start of this chapter:

1. *"Which regular-strength lager tastes most similar to Bud Light lager?"*

   Answer: Becks (4.8% ABV).

2. *"Is it feasible to carry out a definitive randomised controlled trial (RCT) to assess the effect of alcohol strength on alcohol consumption in a single drinking occasion within licensed premises in the UK?"*

   Answer: Yes: with different intervention and control products to those used in the pilot trial and minor amendments to the trial protocol.

3. *"Is reducing the strength of alcoholic beverages an acceptable intervention to reduce alcohol consumption?"*

   Answer: Yes, if: the reduced-strength products tasted similar to their regular-strength counterparts, the reduction in strength did not apply to all products, people perceived the intervention to be effective, people perceived the alcohol industry to be motivated by consumer health rather than financial gain.

On a personal level, this project has helped me to develop as a researcher by enabling me to lead on a project from conception to completion. I have developed new knowledge and skills and refreshed and improved on those previously established. Most importantly, completing this research project has allowed me to take the initial steps to answering a public health question that has piqued my interest for over a decade.

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Appendices

Appendix A: CONSORT checklist for reporting a pilot or feasibility trial

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Front cover, 45
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	IV-V
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	2-17, 46
	2b	Specific objectives or research questions for pilot trial	19, 46-47
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	21-25
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	50, 55
Participants	4a	Eligibility criteria for participants	48
	4b	Settings and locations where the data were collected	52-55

	4c	How participants were identified and consented	55-56
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	41, 59-61
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	61-62
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	50
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	63-70
Sample size	7a	Rationale for numbers in the pilot trial	56-58
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	58
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	24-25
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	58
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	58-59
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	25
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	61-62

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	67
	13b	For each group, losses and exclusions after randomisation, together with reasons	67
Recruitment	14a	Dates defining the periods of recruitment and follow-up	28-29
	14b	Why the pilot trial ended or was stopped	28-29
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	63
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	68
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	63-70
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	66-69
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	112-114
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	76-78, 112-114
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	70-78, 111

	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	76-78, 112-114
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	112
Protocol	24	Where the pilot trial protocol can be accessed, if available	112, Appendix B
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	iii, Appendix B
	26	Ethical approval or approval by research review committee, confirmed with reference number	28

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix B: Pilot trial protocol publication (Perman-Howe, Davies and Foxcroft, 2018)

Perman-Howe *et al. Pilot and Feasibility Studies* (2018) 4:138
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Pilot and Feasibility Studies

STUDY PROTOCOL Open Access

The effect of alcohol strength on alcohol consumption: a randomised controlled cross-over pilot trial

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Abstract

Background: Effective interventions are required to reduce alcohol consumption and its associated harms at the population level. Reducing the alcohol content of beverages has the potential to reduce alcohol consumption through non-conscious processes. Before implementing a randomised controlled trial (RCT) to assess the effect of alcohol strength on alcohol consumption, its feasibility needs to be established. This study aims to pilot a RCT and obtain data to estimate key parameters required when designing a RCT. These key parameters include the direction and size of the intervention effect, the efficacy and efficiency of the study processes and the rates of licenced premises recruitment, participant recruitment and attrition.

Methods: A double-blind randomised controlled cross-over pilot trial comparing the number of units of reduced strength lager consumed and the number of units of regular strength lager consumed in a single drinking occasion within licenced premises in the UK.
Descriptive statistics will report the efficacy and efficiency of the study processes and the rates of licenced premises recruitment, participant recruitment and attrition. Mean and 95% confidence intervals will be used to compare the consumption of alcohol and the duration of participation in study sessions, between the intervention arm and the control arm. The mean and standard deviation of UK units of alcohol consumed will be used to calculate a sample size for a definitive RCT.

Discussion: This is the first naturalistic experimental study to assess the effect of alcohol strength on alcohol consumption in a single drinking occasion within licenced premises. Results from this pilot study will establish the feasibility of, and inform key data parameters for, a larger scale study.

Trial registration: The trial is registered in the American Economic Association (AEA) Randomised Controlled Trial (RCT) Registry as of 16 June 2017. The unique identifying number is AEARCTR-0002266.

Keywords: Alcohol, Alcohol strength, Public health, Prevention, Intervention, Licenced premises, Pub, Bar, Pilot trial

Background

Excessive alcohol consumption is a causal factor for many chronic health conditions, and it increases the risk of intentional and non-intentional harm through violence and injury [1, 2]. In 2015, there were 8758 avoidable deaths in the United Kingdom (UK) that were directly caused by alcohol [3]. A study with over 55,000 UK participants found that of the 69% who reported drinking alcohol, 27% reported drinking at levels that are classed as high risk [4]. Moreover, 2.5 million people who regularly drink alcohol report exceeding weekly alcohol thresholds in a single drinking occasion [5]. The financial burden of alcohol-related harm is estimated to annually cost UK society betwen 1.3 and 2.7% gross domestic product (GDP) [6].

The most effective alcohol harm prevention interventions may be those that target non-conscious processes and that are readily scalable to the population level [7–11]. These include interventions that alter the properties or placement of external stimuli, such as the strength of alcoholic

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products [10–12]. Such interventions could be particularly beneficial within licenced premises where individuals may not have direct access to information such as the strength of alcoholic products. For example, lager "taps" often display a brand logo but do not incorporate information about the strength of the product. Labelling drinks as lower in strength has been shown to increase the amount of alcohol consumed within a laboratory setting [13]. However, we propose that when information about alcohol strength is not forthcoming, such as when lager is purchased from the "tap", most consumers will not consciously seek this information. Therefore, consumers cannot knowingly compensate for drinking lower strength alcohol. Reducing the alcohol content of popular lager products that are sold on "tap", or in other situations where information about alcohol content is not readily available, may lead to a reduction in alcohol consumption. Interventions that utilise non-conscious processes have the added benefit of potentially reducing health inequalities as their recipients are not required to be health literate and numerate or have high-functioning cognition: lack of which are more prevalent with higher levels of deprivation [9, 14].

Reducing the alcohol content of drinks, thereby reducing the number of alcohol units each drink comprises, was proposed as a means to reduce alcohol consumption by the UK Coalition Government (2010–2015) as part of the Public Health Responsibility Deal (PHRD) [15]. Between 2011 and 2013, 1.3 billion UK units of alcohol were removed from the UK market by reductions in the alcohol content of beverages. This equates to the average strength of beer falling from 4.42 to 4.14% alcohol by volume (ABV) [16]. There is scope to further reduce the ABV of alcohol in the UK market, but to date, there is insufficient evidence that reducing the alcohol content of drinks reduces the number of alcohol units consumed.

There is a paucity of studies that assess the effect of the strength of alcohol on alcohol consumption within a naturalistic setting. Most studies of alcohol strength are strength discrimination studies. The majority of these are laboratory based [17–21] and one study was based within a mocked-up lounge in a community centre [22]. All but one incorporate beer, or beer and spirits, and a single study focuses on wine [20]. These studies all support the hypothesis that people cannot readily distinguish between alcoholic products of different strength, which indicates that there is potential to subconsciously alter alcohol consumption by altering the ABV of alcoholic products. An experiment with Canadian students found that participants reported similar levels of enjoyment and perceived intoxication after consuming an equivalent volume of lower strength lager and regular strength lager [23]. However, this study has numerous limitations: it used a small sample of male students, it was based within a classroom, and participants were restricted to the amount of alcohol they could consume. A more robust study that assessed the effect of the strength of beer and mixed spirit-based drinks on consumption supports the hypothesis that reducing the alcohol content of drinks does not lead to an increase in the volume of alcohol consumed, therefore reducing consumption [24]. There were also limitations in this study's design, however, most notably that it was based within closed student fraternity parties comprising a single fraternity at one university in the United States of America (USA) [24].

High-quality research is warranted to assess the effect of alcohol strength on consumption within a naturalistic environment. Prior to a definitive randomised controlled trial (RCT), a pilot study is required to test feasibility and estimate key parameters for the RCT's design. This study aims to determine the feasibility of a RCT, which would assess whether people consume fewer units of Bud Light lager 3.5% ABV (BL) compared to Becks lager 4.8% ABV (B) in a single drinking occasion within licenced premises. The intervention product, BL, is one of few mainstream lagers sold in the UK that is below 3.8% ABV, and it is reported to have retailed well since its UK launch in March 2017 [25]. Results of a taste discrimination experiment to establish a control product for the pilot trial concluded that, out of a range of mainstream regular strength lagers, B tasted the most similar to BL (unpublished observations: Perman-Howe, Davies and Foxcroft). To reduce confounding from difference in taste, BL and B were therefore chosen as the intervention and control products for the pilot trial.

The current study is defined as a randomised pilot trial, in accordance with Eldridge et al.'s conceptual framework for defining feasibility and pilot studies in preparation for a RCT [26]. That is, the future RCT, or parts of it, including the randomisation of participants, will be conducted on a smaller scale to see if it can be done. It could also legitimately be called a randomised feasibility study, but for clarity it will not be referred to as a feasibility study [27]. Additionally, and in line with Teare et al.'s definition of a pilot study, it will provide data with which to estimate key parameters for the design of a RCT [27]. It is an external pilot study: a stand-alone piece of work that has been planned and will be carried out independently to a main study [28].

Methods/design

Aim/objectives

The overall aim of the study is to pilot a double-blind randomised controlled cross-over trial to assess the effect of alcohol strength on alcohol consumption. The feasibility objectives are to establish whether:

- Components of the study protocol are efficient and work together or can be amended to be or do so
- A sufficient number of licenced premises can be recruited to host the study
- The participant recruitment rate per study session is sufficient
- Participant retention is sufficient
- The sample size derived from data obtained in the study is achievable for a future definitive trial.

The participant-centred objective is to establish whether:

- Estimations of the mean and 95% confidence intervals of the number of UK units of alcohol consumed by participants in a single drinking occasion support the hypothesis that people consume fewer UK units of alcohol when they consume reduced strength lager.

Design

The study is a double-blind randomised controlled AB/BA cross-over pilot trial. The AB/BA cross-over design means that each participant experiences both the intervention and the control conditions, within a two-arm trial, on separate occasions and in a randomised order. There will be a four-week washout period between each participant´s study sessions, which is deemed adequate for participants to have desensitised to the sensory aspects of the alcohol they consumed in their first study session. There is no risk of carryover effects from the alcohol consumed during participants' first study session, as alcohol is expelled from the body at the rate of approximately one unit per hour. There is a possibility of period effects as the characteristics of the participants may alter between their two study sessions: this will be tested for using a t test between the sequences AB and BA.

Setting

The pilot trial will be based within on-trade licenced premises in the South East of England, and London, UK. For more information, refer to the "Recruitment of licenced premises" section.

Participants

Fifty-two adults who regularly consume lager within licenced premises will be recruited for the pilot trial. See Table 1 for the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).

Participants must meet all of the inclusion criteria and not meet any of the exclusion criteria (Table 2).

Figure 1 illustrates the participants' pathways through the pilot trial.

Interventions

Intervention product

The intervention product is Bud Light lager 3.5% ABV. It will be poured from 440-ml cans into a pint glass so that a full pint (568 ml) is served. Participants may consume the intervention product ad libitum during their study sessions.

Table 1 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) figure

Time point	Study period							
	Enrolment	Allocation	Post-allocation					Close-out
	≥ 24 h before study session 1	When participant arrives for study session 1	Study session 1	End of study session 1	When participant arrives for study session 2: 4 weeks after study session 1	Study session 2	End of study session 2	Approx 48 h after the final study session at the venue
Enrolment								
Eligibility screen	X							
Consent		X						
Allocation		X						
Interventions								
Bud Light			X			O		
Becks			O			X		
Assessments								
BrAC reading		X		X	X		X	
Time recorded		X		X	X		X	
UK units of alcohol consumed counted				X			X	
Questionnaire				X			X	
Debrief email/letter								X

Table 2 Inclusion/exclusion criteria

Inclusion	Exclusion
≥ 18 years old	Has ever sought help, or been treated, for an alcohol dependency
Regular drinker of lager within a licenced premises (≥ once in the past three months)	Has an illness or condition with which they should not be consuming alcohol
Able to attend two study sessions	Is on medication with which they should not be consuming alcohol
Provides informed consent	Pregnant
	Has a BAC > 35 μg/100 ml breath when they arrive for a study session

Control product

The control product is Becks lager 4.8% ABV. It will be poured from 440-ml cans into a pint glass so that a full pint (568 ml) is served. Participants may consume the control product ad libitum during their study sessions.

Provision of intervention/control products

Before a study session, the principal investigator (PI: PPH) will estimate the number of study-specific drinks that will be required during the forthcoming session and the corresponding number of 440-ml cans of BL and B will be completely de-identified with duct tape.

The intervention and control products will be chilled in a fridge 24 h before a study session.

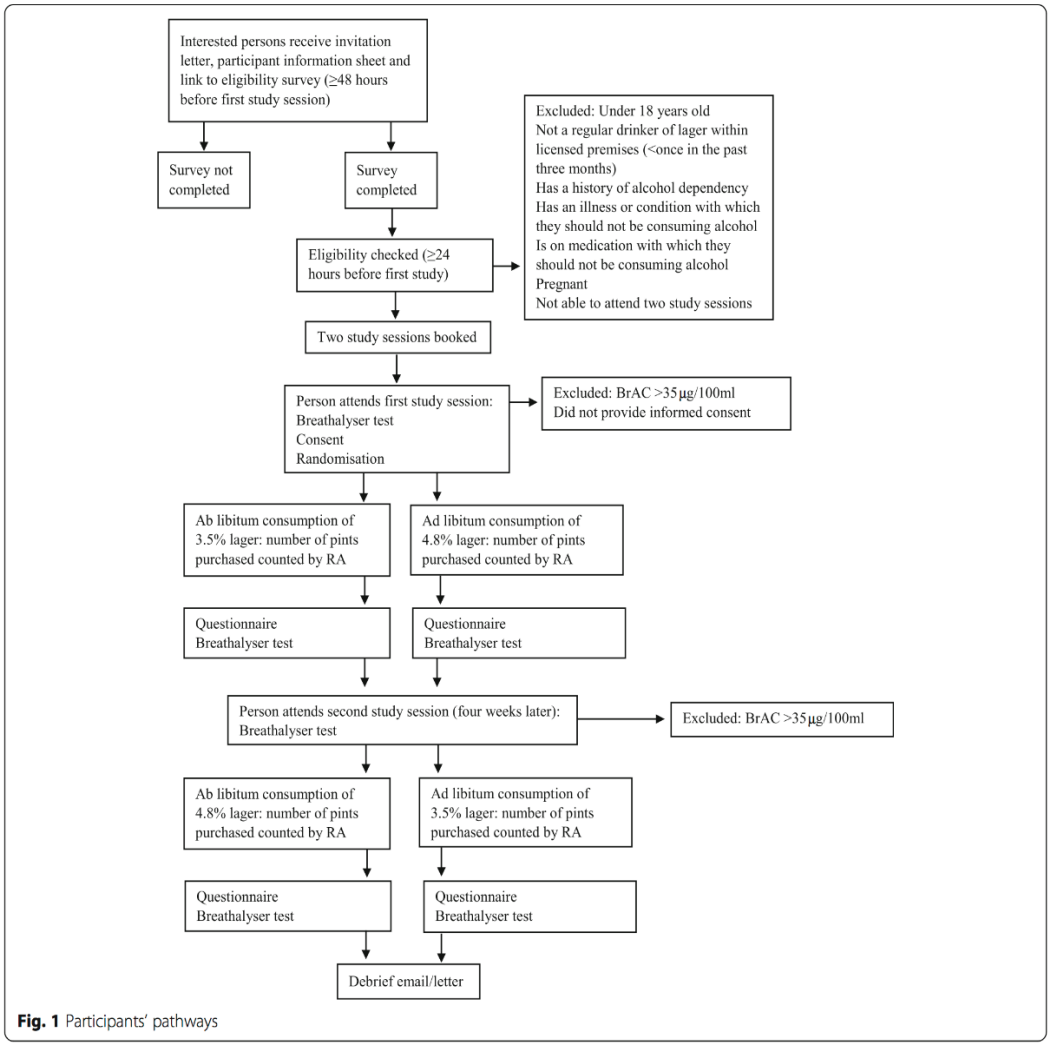

Fig. 1 Participants' pathways

Participants will pay for study-specific drinks and drink them ad libitum during a study session. The price of the drinks will be specific to each venue and reflect a small reduction (approximately 33%) in the normal price for similar products at each venue: as participants will not be able to choose their brand of lager and will not know what brand they are purchasing.

When a participant wishes to purchase a study-specific drink, they will go to a makeshift bar area that the research assistant (RA: JW) will be manning. The RA will exchange the participant's money for BL or B and stamp their randomisation card: a coloured square on the randomisation card will refer to a coloured sticker on the lager cans to notify the RA which cans to serve.

The drinks will be poured from 440-ml lager cans into pint glasses so that a full pint is served: each pint will therefore contain more than one can of lager. The RA will be responsible for disposing of the empty cans and giving the used glasses to the bar person (BP) to put into the glass washer. The RA should not have to restock the designated fridge space as the PI will ensure that the fridge space is large enough to accommodate plentiful alcohol for each study session: based on an estimation of each participant drinking four pints.

Participants will be briefed that they may purchase soft drinks from the normal bar area or be given free tap water by the RA, but the only alcoholic drinks they should purchase during a study session are the study-specific lagers.

Discontinuing or modifying intervention/control products

The intervention and control products will not be replaced or modified during the pilot trial.

Outcome measures

The primary outcome is the feasibility of a RCT. A RCT would be deemed feasible if it adheres to the following points:

1. Components of the study protocol are efficient and work together or can be amended to be or do so. These include:
   - The administration of data collection tools
   - The consent process
   - The randomisation process
   - Data management processes
   - The roles and requirements of study personnel
2. The licenced premise recruitment rate is a minimum of one per month for a minimum of 4 months or until four licenced premises have been recruited.
3. Participant recruitment rate is a minimum of four per study session.
4. The rate of attrition for the pilot trial is less than or equal to 30%, and this does not vary by more than 10% according to the arm of the trial.
5. The sample size is achievable to obtain within a year based on the recruitment rate of licenced premises and participants.

In addition, one participant-centred outcome will be assessed:

1. Whether estimations of the mean and 95% confidence intervals of the number of UK units of alcohol consumed by participants in a single drinking occasion, when they consume BL and B, suggest that people consume fewer UK units of alcohol when they consume reduced strength lager.

Sample size

As there are no data from previous studies on which to base a statistical calculation, and there is no consensus in the literature about the required sample size for pilot trials, the sample size has been calculated using preliminary datasets. These preliminary datasets are based on the hypothesis that there is no significant difference between the number of alcoholic drinks individuals consume, regardless of their ABV, which has been shown in a previous study [24].

Firstly, preliminary datasets were created for 40 patrons at each of four different licenced premises with different demographics, based on their average patron's characteristics, i.e. age and gender. The mean patrons' age was calculated from each licenced premises' preliminary dataset. Mean age was used to estimate the number of units that each of the 40 hypothetical patrons would consume under normal conditions, based on age-related population data for alcohol consumption [29]. The estimated number of units consumed under normal conditions was reduced by 27% to give the estimated number of units consumed under the intervention: the difference in ABV between BL and B is − 27%. Estimated mean units and SD for units consumed from BL and B were calculated; a conservative estimate for SD in the intervention arm was used: the same SD as in the control arm. Where the licenced premises' population incorporated a higher proportion of male to female consumers, this was accounted for in the calculations and the mean consumption increased accordingly. From these data, the estimated mean difference and SD of the mean difference of UK units of alcohol consumed were calculated. These data enabled delta to be calculated, 0.3977.

Preliminary data for the licenced premises with the largest SD was used to calculate the sample size using the Rstudio software 'R Stats Package' and the function power.t.test [30]: this provided the most conservative calculation of sample size. The figures that were inputted

into Rstudio were alpha = 0.05, beta (power) = 0.8, delta = 0.3977, SD = 1. The sample size for a two-sided paired *t* test was calculated as 52: 52 participants participating in two trial arms. As this does not account for attrition, participants who drop out of the pilot trial will be replaced.

Trial withdrawal

Participants who wish to withdraw from the study will be directed to contact the PI via email or telephone or express this to the PI verbally during a study session.

Participants who are seen by the PI, the RA or the BP to be obviously and persistently breaching the protocol will be withdrawn from the study. These breaches include consuming any alcohol other than the study-specific lager which they have purchased, supplying non-participants with study-specific drinks, and disposing of any study-specific lager without declaring it.

Definition of end of study

The study will officially end when the final participant has been sent a debrief email/letter. If the pilot trial is deemed to be eliciting too many adverse events, then the University Research Ethics Committee (UREC) Chairperson may terminate it early.

Recruitment

Recruitment of licenced premises

All licenced premises are eligible to participate regardless of whether they function under a premises licence or a club premises certificate.

A minimum of one and maximum of six licenced premises will be recruited via posts on Facebook and Twitter; blogs on scientific forums; local newspaper, magazine and radio advertisements; PI's presentations at local Pubwatch meetings; targeted emails to licenced premises managers; and word of mouth. Recruitment will work on a first come, first served basis.

Managers of licenced premises that contact the PI with an expression of interest will be sent further details of the study by email or post. If they wish to proceed thereafter, then a meeting will be arranged between the premises manager and the PI. If the PI regards the venue as suitable to host the study, and the premises manager wishes to proceed, both parties will agree on the dates and times for a minimum of four study sessions. During study sessions, the licenced premises will still be open to the public. The licenced premises manager will sign a letter of agreement for research access.

Recruitment of participants

Fifty-two participants will be recruited through posts on the licenced premises social media accounts and through placing flyers and posters within the premises.

The recruitment advertisements will ask people who are interested to contact the PI via email or telephone. Once a potential participant has contacted the PI, they will be sent an invitation to participate in the study, a participant information sheet (PIS) and a link to an online eligibility survey. By default, these documents will be sent electronically. The documents will be sent through the post upon request with a stamped addressed envelope.

Recruitment will commence two months before the initial study session at each participating licenced premises.

Recruitment will continue until the sample size ($n = 52$) has been reached.

Recruitment will be monitored by the PI. The PI will stop recruiting at a participating licenced premises if either:

- The manager of the licenced premises expresses they do not wish for any more study sessions to take place (after the agreed four sessions)
- The licenced premises is failing to yield participants at an adequate rate: less than four per study session
- It is no longer feasible for the licenced premises to host the study

The PI may recruit from multiple participating licenced premises at any one time, and this will be at their discretion.

Screening

Potential participants will be screened to assess their eligibility by completing an electronic survey using Qualtrics software. The survey will be sent through the post with a stamped addressed envelope upon request.

The PI will analyse the survey responses and contact those who are eligible to arrange two study sessions. Study sessions will be a month apart, on the same day of the week and at the same start time.

Those who do not fulfil the eligibility criteria will be sent an email or letter to thank them for expressing an interest in the study and explaining the reason why they are not eligible.

Consent procedure

When potential participants leave their contact details at the end of the electronic screening survey, they consent to their contact details being made available to the research team and for them to be contacted in relation to the study at any given time.

Individuals will take a breathalyser test when they arrive for their first study session and those whose breath alcohol concentration (BrAC) is equal to or below the UK's drink-drive limit, of ≤ 35 μg/100 ml breath, will be

asked to complete a consent form. If the individual's BrAC exceeds this level, they will be told they cannot take part in the study during the current session as they may be too intoxicated to give informed consent.

Potential participants will be given the time they require to read the consent form (or have it read to them by the PI), ask any questions and complete the form. They will have received the PIS at least 48 h before their study session, so their consent will be regarded as fully informed.

Allocation

Sequence generation

Participants will be randomly assigned to the order that they receive BL and B, using the AB/BA format, therefore counterbalancing conditions. A separate computer-generated randomisation sequence will be produced for each study venue using Randomization.com software [31].

Concealment

The first "treatment" label (pink or purple) designated to each subject in the randomisation sequence will be translated as a discrete, coloured label on a randomisation card that will be concealed in a sealed and numbered opaque envelope. The sealed envelopes will be placed in a pile, which will be overturned and placed within a box once all envelopes are present so that the sequence is in ascending numerical order.

Implementation

The chief investigator (CI: DF) will generate the allocation sequence and conceal the allocation. The PI will enrol participants and assign them to the interventions by asking them to take the next numbered envelope from the sequence and opening it.

Blinding

The participants and the RA will be blinded to the intervention and control products and the order in which they are assigned. Due to limited study personnel, the PI cannot be blinded.

Randomisation cards will display a colour-coded label, and the participants and the RA will be unaware of the colour-coding system. Coloured labels will be placed on the de-identified lager cans that will correspond to the coloured labels on the randomisation cards. The RA will ask the participants to show their randomisation card when they purchase a study-specific drink, and the colour of the label on the card will inform the RA which drink to serve.

Emergency un-blinding

In exceptional circumstances, whereby the participant's welfare would be compromised without the disclosure of the alcohol product that they have consumed, the participant and any other relevant persons will be un-blinded to the intervention and/or control. Participants who are un-blinded will be removed from the study. The PI will report all disclosures to the CI.

Data collection methods

Baseline measures

Participants' BrACs will be measured at the start of each of their study sessions with an Alcosense Pro Fuel Cell Digital Breathalyser, using a one-way valve mouthpiece. The breathalyser is accurate to − 0.00‰ BrAC, + 0.1‰ BrAC, and will be calibrated annually by Alcosense [32].

Data collection methods

The PI will maintain up-to-date records that cover point 1 in the "Outcome measures" section. Feedback from members of the research team, participating licenced premises and participants will be obtained and recorded throughout the study.

Electronic datasets will be created in Excel to monitor:

- Licenced premises that are approached by the PI
- Landlords/managers who express willingness to participate
- Landlords/managers who sign a letter of access
- Participants who consent to participate (and at each separate participating licenced premises)
- Participants who consent and do not complete two study sessions
- Participants who consent and drop out during or after the intervention study session
- Participants who consent and drop out during or after the control study session

To track the number of study-specific drinks served, the RA will stamp the participant's randomisation card each time they are supplied with a fresh drink. The randomisation card will be handed to the PI at the end of each study session.

Participants will be briefed that if they do not consume the entirety of a study-specific drink they should return their drinking vessel to the RA. The RA will alert the PI who will measure the amount of alcohol that has been left in the vessel. The PI will quantify, in UK units, the amount of alcohol that each participant has left throughout each study session and deduct this from the number of UK units of alcohol served to each participant, which will be calculated by the PI. The number of UK units of alcohol will be converted to, and additionally displayed as, grams of alcohol for an international audience.

The PI will also record the times at which each participant commences and concludes each of their study sessions. This will enable a comparison between the duration

of participants' study sessions under each of the study conditions, which will indicate whether participants may be concluding their study sessions and then consuming non-study drinks.

Collecting data from deviant participants

Participants who are seen by the PI, the RA or the BP to be obviously and persistently breaching the protocol will be removed from the study, and their data will not be utilised. Similarly, if a participant wishes to discontinue in the pilot trial during a study session, no further data will be collected.

Data analysis

The efficacy and efficiency of the study processes and the rates of licenced premises recruitment, participant recruitment and attrition will be analysed and reported using descriptive statistics.

Mean value and 95% confidence intervals will be used to compare the number of UK units of alcohol consumed and the mean duration of participation in study sessions, between the intervention arm and the control arm.

The mean and SD of the number of UK units of alcohol consumed will be used to calculate a sample size for future, larger scale studies. The components of the sample size calculation will be delta (mean difference/SD of mean difference) = derived from a calculation of the data, alpha (sig.level) = 0.05, beta (power) = 0.8.

A *t* test, between the sequences AB and BA, will be undertaken to test for a period effect.

Monitoring

Safety/harms

There is no reason to believe that this study will lead to an excessive number of adverse events. Although participants will be consuming alcohol, they will be briefed to consume alcohol in their normal manner and processes have been put in place to safeguard against study-related harms. Any adverse events that are reported to the PI will be logged using an adverse event form and reported to the CI and the UREC Chairperson. It will be the UREC Chairperson's decision whether to terminate the study should the number of adverse events reach a level beyond which would be deemed unacceptable.

Participant confidentiality and access to data

Data will be de-identified, using a numerical code, where this is feasible. The final anonymised trial dataset will be made publically available in a repository as detailed in the "Data handling, record keeping and retention" section. In accordance with OBU's Research Data Management Policy, participants will remain anonymous in the thesis and any publication(s) that result(s) from the study [33].

Participants' information will be used for research purposes only and will only be accessed by the PI, the CI and the co-investigator (Co-I: ED).

Data handling, record keeping and retention

Relevant information from electronic correspondence with participants will be encrypted and saved in password-protected folders on an Oxford Brookes University (OBU) computer's hard drive and deleted from the email account. All hard correspondence will be stored in a locked filing cabinet within a lockable room at OBU.

All hard data collected at the study sites will be securely transferred to locked filing cabinets within a lockable room at OBU at the first available opportunity following each study session. Prior to this, it will be stored in locked cabinet drawers at the PI's residence. Identifiable and non-identifiable information will be transferred and stored separately.

Qualtrics [34] will host the eligibility surveys, with whom OBU's Faculty of Health and Life Sciences hold an agreement. Identifiable data from the eligibility surveys will be stored in encrypted and password-protected Excel spreadsheets on an OBU computer's hard drive.

If a participant withdraws from the study, then all of their information will be destroyed.

Datasets will be kept in accordance with the General Data Protection Regulation (GDPR) [35] and OBU's Research Data Management Policy [33]. The latter states that study data will be offered and assessed for deposit and retention in a University repository, such as the Research Archive and Digital Asset Repository (RADAR). Data on RADAR will be kept for a minimum of 10 years.

Data monitoring and auditing

Progress with data collection will be discussed by the PI, the CI and the Co-I who will meet on a fortnightly basis.

OBU has procedures in place to audit students' conduct during, and output from, their research. This audit process will accommodate the current study, which is part of a PhD programme.

Financing and insurance

Licenced premises incentives

Each licenced premises that hosts a minimum of four study sessions will be given £500 via an invoice and bank transfer. The licenced premises will also retain all of the participants' payments for study-specific drinks.

Participant incentives

Every participant who completes the trial will be automatically entered into a free prize draw to win one of two prizes of £100, delivered via bank transfer. Participants

can opt out of entry into the free prize draw by checking a box on the consent form.

Legal liability/insurance

OBU has liability insurance for this research project.

Discussion

The aim of this pilot trial is to assess the feasibility of a RCT to assess the effect of alcohol strength on alcohol consumption in a single drinking occasion within licenced premises; to our knowledge, no trials to date have investigated this. If the pilot trial is successful, a larger scale RCT could be undertaken, which would test an intervention that has the potential to improve public health by reducing alcohol consumption.

The pilot trial is of a cross-over design, which has the advantages of eliminating between participant variation, and being more economic due to a smaller sample. Whilst there is no risk of a carryover effect, the main disadvantage of using a cross-over design in this study is the potential for a period effect. This will be tested for during data analysis and, if present, subsequently reported.

Whilst one of the main advantages of this study is its naturalistic design, due to the complexity of undertaking research within licenced premises, some compromises have been necessary. For example, ideally the intervention and control lagers would be supplied from "tapped" barrels to align with how the majority of lager is sold to customers within licenced premises. As this is not feasible for a small-scale study, lager will be supplied from duct-taped cans. Although this reduces the face validity of the study, other measures have been put in place to improve the study's face validity. For instance, lager will not be sold by the can but poured from multiple cans into a pint glass so that a full pint is served.

There are some associated challenges that may be encountered during the pilot trial. These include recruiting licenced premises, retention of participants across two study sessions and participant adherence to the study protocol. Processes that have been put in place to minimise these challenges are discussed below.

Recruiting licenced premises

A number of licenced premises managers who have been given details of the pilot trial have expressed that their business is tied to a brewery, meaning they are not at liberty to sell any products on the premises that are not provided by the brewery. If a licenced premises is tied to a brewery, then it would be the responsibility of the licenced premises manager to gain permission from the brewery to host the study: to date, no manager has been willing to do this. Therefore, recruitment has focused on "free houses", which are licenced premises that may obtain stock from any supplier. In particular, free houses that have links to members of the research team, that are involved in local community or charitable projects, or that function as bars within sports clubs have proven particularly fruitful. Such licenced premises are more likely to be incentivised by the financial gain: £500 plus money from the sales of study-specific drinks.

Retention of participants

The two study sessions that participants are required to attend will be one month apart to control for confounding from day of the month, particularly around payday. To reduce the chance of attrition, participants will be sent reminder emails or letters one week and 24 h before their second study session.

An additional concern is that participants may not like the study-specific drink they have purchased and will withdraw from the pilot trial during a study session. To incentivise participants to remain in the pilot trial, and continue to purchase study-specific drinks only, these drinks will cost approximately one third less than the cheapest lager sold within the venue. An additional incentive of entry into a prize draw to win one of two prizes of £100 has been included to reduce attrition.

Participant adherence to the study protocol

As participants will be free to mix with other participants and non-participants during their study sessions, there is concern that they can easily obtain and consume drinks other than that which they have been assigned to. Encouraging groups of friends to participate in the study together may reduce the risk of contamination, as everyone within the group will be bound by the same rules and restricted to study-specific drinks. Recruitment advertisements will therefore reflect this strategy. Additionally, participants will be reminded that if they do not adhere to the protocol they will be withdrawn from the study and lose the opportunity to win £100.

As this is a pilot trial, suitable changes will be implemented if any unforeseen problems occur. These will be discussed when assessing the feasibility of a definitive RCT.

Abbreviations

ABV: Alcohol by volume; B: Becks lager; BL: Bud Light lager; BP: Bar person(s); BrAC: Breath alcohol concentration; CI: Chief investigator; Co-I: Co-investigator; GDP: Gross Domestic Product; GDPR: General Data Protection Regulation; OBU: Oxford Brookes University; PHRD: Public Health Responsibility Deal; PI: Principal investigator; PIS: Participant information sheet; RA: Research assistant; RADAR: Research Archive and Digital Asset Repository; RCT: Randomised controlled trial; SD: Standard deviation; UK: United Kingdom; UREC: University Research Ethics Committee

Funding

The pilot trial is part of a PhD programme at OBU. The PhD programme is being funded by an OBU Nigel Groome Studentship award.
The study equipment, participant incentives, licenced premises incentives and field work expenses are being funded by a grant from OBU.

Availability of data and materials
The study documents and datasets generated and/or analysed during the current study will be available in the Open Science Framework repository: https://osf.io/htx2b/. Additionally, study data will be offered and assessed for deposit and retention in OBU's Research Archive and Digital Asset Repository (RADAR).
Study results will be submitted to scientific journals for publication and disseminated as presentations at scientific conferences.

Authors' contributions
PPH conceived of the study, is implementing the study and collecting and analysing the data. DF and ED contributed to the development of the study and are supervising the study and its write up. PPH, DF and ED contributed to the refinement of the study protocol. All authors read and approved the final manuscript.

Ethics approval and consent to participate
The study has been approved by the Oxford Brookes University Research Ethics Committee (UREC), assignment number 171086. The study is being conducted in accordance with the Declaration of Helsinki [36].
Informed consent to participate will be obtained from all participants.
Any modifications to the study protocol that may impact on the conduct of the study or participant safety will be formally amended and agreed upon by the UREC prior to implementation. Any modifications to the study protocol will be communicated to all relevant parties.

Consent for publication
Consent to publish will be obtained from all study participants.

Competing interests
The authors declare that they have no competing interests.

Publisher's Note

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Alcohol Information Leaflet

Appendix C: Alcohol information leaflet

It is advisable not to drink:

- when operating a vehicle or machinery
- when pregnant or considering pregnancy
- if a contraindicated medical condition is present
- if you have taken certain medications such as sedatives, analgesics, and selected antihypertensives

The Government recommends that:

- people **do not drink more than 14 units of alcohol per week on a regular basis**
- if you regularly drink 14 units of alcohol per week, it is **best to spread your drinking over three or more days**
- it is good to **have several alcohol-free days** per week

One unit of alcohol is equal to:

- 250ml of 4% beer, cider or alcopops
- 76ml of 13% wine
- 25ml of 40% spirits

Alcohol Information Leaflet

If you feel worried about your own or someone else's drinking, you can approach your doctor or contact an organisation that can help with alcohol-related issues.

The telephone numbers and website addresses of a number of organisations that can help are listed below:

Addaction
Telephone: 020 7251 5860 / www.addaction.org.uk

Alcoholics Anonymous
Telephone: 0800 9177 650 / www.alcoholics-anonymous.org.uk

Frank
Telephone: 0300 123 6600 / www.talktofrank.com

If you would like more information about the Government recommended guidelines for alcohol consumption, you can visit: www.drinkaware.co.uk

Date: 24/01/17 Version 1

Appendix D: Letters of ethics committee approval

Professor David Foxcroft
Director of Studies
Department of Psychology, Social Work and Public Health
Faculty of Health and Life Sciences
Oxford Brookes University
Marston Road Site

23 February 2017

Dear Professor Foxcroft

UREC Registration No: 171086
Differences in the consumption of alcohol of regular strength and reduced strength within licensed
premises

Thank you for submitting the application to the University Research Ethics Committee on behalf of your research student Parvati Perman-Howe. The Committee reviewed the application at its meeting on 16 February 2017 and have agreed approval subject to meeting the following conditions:

1. Owing to the complexity of the use of a public licensed premise, the committee suggest that the use of the proposed cricket club would be a more suitable and manageable environment and that this setting should be the preferred option.

2. Please provide detailed clarification on the type of breathalyser to be used in this study and how it will be calibrated for accuracy.

3. The participant information sheet should contain a clear description of both the inclusion and exclusion criteria, possibly as a table for both parts of the study.

4. The wording on any inclusion /exclusion criteria should be changed from ‘subjective determination by researcher’ to ‘as determined by x breathalyser’.

5. Please confirm whether any legal liability has been checked with the university’s legal department by the supervisory team.

6. Lone researcher safety protocols should be adhered to, especially leaving any premise late at night after conducting part 2 of the study.

7. The wording on the recruitment posters, whilst engaging, is not suitable for a doctoral study involving alcohol consumption and this needs reconsideration.

8. Please provide a justification for the inclusion of a question regarding ethnicity on the eligibility survey.

9. The practical aspects of reimbursing taxi fares after the event and upon producing receipts requires
reconsideration. For example, a participant might not have the money available on the night to pay for a taxi home.

10. The participant information sheet should include the phrase ’any unprocessed data will be removed from the study’ in relation to withdrawing from the study. Further to this clause 5 on the consent form is incorrect and must be amended to state ‘any unprocessed data will be removed from the study’.

Could you please confirm in writing to both the UREC administrator (louise.wood@brookes.ac.uk) and myself, within the next three weeks, that you will meet these conditions? Please use the attached template to explain how the conditions have been met along with copies of any revised documentation. When this has been received and agreed, I will send another letter indicating full approval.

Yours sincerely

Dr Sarah Quinton
Chair of the University Research Ethics Committee

cc Parvati Perman-Howe, Research Student
Hazel Abbott, Research Ethics Officer
Jill Organ, Research Degrees Team
Louise Wood, UREC Administrator

OXFORD BROOKES UNIVERSITY

Professor David Foxcroft
Director of Studies
Department of Psychology, Social Work and Public Health
Faculty of Health and Life Sciences
Oxford Brookes University
Marston Road Site

24 March 2017

Dear Professor Foxcroft

UREC Registration No: 171086
Differences in the consumption of alcohol of regular strength and reduced strength within licensed
premises

Thank you for the emails of 20 and 23 March 2017 outlining the response to the points raised in my previous letter about the PhD study of your research student Parvati Perman-Howe and attaching the revised documents. I am pleased to inform you that, on this basis, I have given Chair's Approval for the study to begin.

The UREC approval period for this study is two years from the date of this letter, so 24 March 2019. If you need the approval to be extended please do contact me nearer the time of expiry.

Should the recruitment, methodology or data storage change from your original plans, or should any study participants experience adverse physical, psychological, social, legal or economic effects from the research, please inform me with full details as soon as possible.

Yours sincerely

Dr Sarah Quinton
Chair of the University Research Ethics Committee

cc Parvati Perman-Howe, Research Student
Hazel Abbott, Research Ethics Officer
Jill Organ, Research Degrees Team
Louise Wood, UREC Administrator

INVESTORS IN PEOPLE | Gold

Parvati Perman-Howe
PhD student
Department of Psychology, Social Work and Public Health
Faculty of Health and Life Sciences
Oxford Brookes University
Marston Road Site
19 May 2017
Dear Parvati

UREC Registration No: 171086
Differences in the consumption of alcohol of regular strength and reduced strength within licensed
premises

Thank you for your email of 18 May 2017 requesting an amendment to the original study approved by UREC on 24 March 2017.

I confirm that you wish to undertake approximately 20 qualitative semi-structured in-depth telephone interviews with participants who were involved in parts one and two of your study.

You have provided updated documentation including an information sheet and details of the questions to be asked. On this basis I give Chair's approval for this change. The UREC approval remains the same as the original study, so until 24 March 2019.

Should the recruitment, methodology or data storage change from your original plans, or should any study participants experience adverse physical, psychological, social, legal or economic effects from the research, please inform me with full details as soon as possible.
I wish you continued success with your research.
Yours sincerely

Dr Sarah Quinton
Chair of the University Research Ethics Committee

cc David Foxcroft, Director of Studies
Hazel Abbott, Research Ethics Officer
Jill Organ, Research Degrees Team
Louise Wood, UREC Administrator

Parvati Perman-Howe
PhD student
Department of Psychology, Health and Professional Development
Faculty of Health and Life Sciences
Oxford Brookes University
Marston Road Site
27 September 2017
Dear Parvati

UREC Registration No: 171086
Differences in the consumption of alcohol of regular strength and reduced strength within licensed
premises

Thank you for your email of 18 September 2017 requesting minor amendments to the original study approved by UREC on 24 March 2017.

I confirm that you wish to recruit participants via the SU website and their social media channels and have slightly altered the study protocol to remove the reduced strength wine as an intervention and will now only be using reduced strength lager.

You have provided updated documentation and clarified that the SU have given permission for you to recruit via them. On this basis I give Chair's approval for these changes. The UREC approval remains the same as the original study, so until 24 March 2019.

Should the recruitment, methodology or data storage change from your original plans, or should any study participants experience adverse physical, psychological, social, legal or economic effects from the research, please inform me with full details as soon as possible.
I wish you continued success with your research.
Yours sincerely

Dr Sarah Quinton
Chair of the University Research Ethics Committee

cc David Foxcroft, Director of Studies
Kellie Tune, Research Ethics Officer
Jill Organ, Research Degrees Team
Louise Wood, UREC Administrator

Parvati Perman-Howe
PhD student
Department of Psychology, Health and Professional Development
Faculty of Health and Life Sciences
Oxford Brookes University
Marston Road Site
15 May 2018
Dear Parvati

UREC Registration No: 171086
Differences in the consumption of alcohol of regular strength and reduced strength within licensed
premises

Thank you for your emails of 26 April 2018 and 9 May 2018 requesting a further amendment to the original study approved by UREC on 24 March 2017.

To help in the recruitment to the study you would like to go into licensed premises in person. You have been given permission from the licensed premises to recruit in this way and you have confirmed that you will be seated behind a table with study resources available rather than approaching people directly.

Please ensure your personal safety is considered for each of the premises; it is important that someone knows your location at all times.

On this basis I give Chair's approval for this addition. The UREC approval remains the same as the original study, so until 24 March 2019.

Should the recruitment, methodology or data storage change from your original plans, or should any study participants experience adverse physical, psychological, social, legal or economic effects from the research, please inform me with full details as soon as possible.
I wish you continued success with your research.
Yours sincerely

Dr Sarah Quinton
Chair of the University Research Ethics Committee

cc David Foxcroft, Director of Studies
Kellie Tune, Research Ethics Officer
Jill Organ, Research Degrees Team
Louise Wood, UREC Administrator

Appendix E: Taste discrimination experiment materials and equipment

Taste experiment materials

Item	Quantity
Combination number spreadsheet	1
Consent form	25
Participant briefing outline	1
Participant information sheet	3 (spares)
Questionnaire part one	25
Questionnaire part two	25
Questionnaire part three	25
Randomisation cards/envelopes	25
Shopping voucher	20 x £10
Study session schedule	1 (per study session)

Taste experiment equipment

Item	Manufacturer/supplier	Quantity
Adhesive labels (blank)	Generic	200
Bottled water (2 litres)	Sainsbury's	4
Breathalyser: pro fuel cell digital	Alcosense	2
Breathalyser tubes	Alcosense	50
Fridge (45 litres)	Russel Hobbs	1
Lager (440ml cans): Becks Bud Light Carlsberg Stella Artois	Sainsbury's	16 of each
Measuring vessels	Sainsbury's	4
Reusable plastic cups (285ml)	Amazon	100

Appendix F: Taste discrimination experiment eligibility survey

Welcome to the survey!

You are being asked to take part in this survey to see if the study 'The effect of alcohol strength on alcohol consumption' is right for you. You can refer to the information sheet that you have been given for more information about the study.

By taking part in this survey you automatically give consent for the information you provide to be used for research purposes only, in the study 'The effect of alcohol strength on alcohol consumption'. The information you provide will be kept confidential.

This survey will take around five minutes to complete.

If you are suitable to take part in the study the researcher, Parvati Perman-Howe, will contact you to arrange a suitable time for your study session.

1. What is your age? ☐

2. What is your gender?
   Female/Male/Non-binary/Other/Rather not say

3. What is your current employment status? *Give your main employment status if more than one applies.*
   Full-time employed
   Part-time employed
   Self employed
   Unemployed – seeking work
   Unemployed – not seeking work but able to work
   Unemployed – unable to work for health reasons
   Looking after the family home
   Retired
   Student
   Other (please specify)

4. Is there any possibility that you are pregnant?
   Yes/No

5. Have you ever sought or received help or treatment for alcohol dependency?
   Yes/No

6. Do you drink lager at least once per month?
   Yes/No

7. Are you able to attend a 30-minute study visit to Oxford Brookes University, Headington Hill Campus?
   Yes/No

If you are eligible for the study the Researcher, Parvati Perman-Howe, will contact you to arrange a suitable time for you to take part. If you are not eligible for the study Parvati will

contact you to let you know and then your contact details will be destroyed. By giving your contact details you consent to being contacted for research purposes related to this study. Please leave your details below.
Name (to be known by):
Telephone number:
Email address:
Address (if you would prefer to be contacted by post rather than email):

You have now completed the survey.

Thank you very much for your time.

Appendix G: Taste discrimination experiment questionnaire (sample set one)

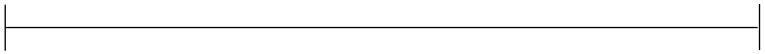
ID Number: ☐

Breathalyser reading: ☐

The information you provide in this questionnaire will be kept confidential. It will be used in the study 'The effect of alcohol strength on alcohol consumption'.

Please read the questions thoroughly before answering. A new set of questions will be brought to you with each new set of alcohol samples.

2. How similar or dissimilar is the taste of sample 1 to the taste of sample 2? *Put an X on the line.*



Completely dissimilar Identical

3. How much do you like or dislike the taste of sample 1? *Put an X in one box.*

	Dislike extremely	Dislike very much	Dislike moderately	Dislike slightly	Neither like nor dislike	Like slightly	Like moderately	Like very much	Like extremely
Sample 1	☐	☐	☐	☐	☐	☐	☐	☐	☐

4. How much do you like or dislike the taste of sample 2? *Put an X in one box.*

	Dislike extremely	Dislike very much	Dislike moderately	Dislike slightly	Neither like nor dislike	Like slightly	Like moderately	Like very much	Like extremely
Sample 2	☐	☐	☐	☐	☐	☐	☐	☐	☐

5. Which sample do you think is stronger (has the highest alcohol content)? *Put an X in one box.*

Sample 1	
Sample 2	
They are both the same strength	

6. Any other comments about sample 1 and sample 2.

Appendix H: Taste discrimination experiment invitation letter/email

OXFORD BROOKES UNIVERSITY

Dear *****,

My name is Parvati and I am a PhD student at Oxford Brookes University.

I am emailing/writing to you to you as you have expressed an interest in taking part in a study about alcohol and I would like to give you some more information about the study.

Please read the information leaflet that is attached to this email/contained in the envelope with this letter, which contains more detailed information about the study.

There is no obligation to take part. If you do wish to take part, please access the link below that will take you to an online screening survey/complete and return the screening survey in the stamped addressed envelope provided. If your answers to the survey show that you are suitable to take part in the study then I will contact you to arrange a suitable date and time for your study session.

Link: https://brookeshls.co1.qualtrics.com/jfe/form/SV_eh3zWMP4tXVbnFP

Thank you for reading this email/letter and the information leaflet.

Yours sincerely,

Miss Parvati Perman-Howe (Student)
Professor David Foxcroft (Student's Supervisor)

Appendix I: Taste discrimination experiment participant information sheet

Department of Midwifery, Community and Public Health

Faculty of Health and Life Sciences

Researcher: Parvati Perman-Howe, PhD Student
(Email: 16016348@brookes.ac.uk)

Supervisor: Professor David Foxcroft
(Email: david.foxcroft@brookes.ac.uk)

'The effect of alcohol strength on alcohol consumption'

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully.

What is the purpose of the study?

Little is known about people's drinking behaviour when they consume different strength alcohol products. To be able to test this fairly, lower strength alcohol products must taste the same as regular strength alcohol products. The aim of this study is to find out which regular strength lager has the closest taste to a lower strength lager.

The study is a single blind experiment. This means that participants will not know the brands of the lager they are consuming.

The study is a pilot study, which means there may be a similar larger study in the future, but you would not be taking part in this. The study is part of a PhD project, which is three years in length. This experiment will run for about one month. You would only be required to attend for one 30-minute slot.

Why have I been invited to participate?

You have been invited to take part in the study as you are over 18 years of age and you are a regular consumer of lager. We will not let you take part if you have a dependence on alcohol, if you are on any medication which may react badly to alcohol, if you have any illness or condition which may react badly to alcohol, or if you are pregnant. We will also not let you take part if you arrive at the study venue under the influence of alcohol.

We will be asking 20 people in total to take part in the study.

Do I have to take part?

It is up to you to decide whether or not to take part in the study. If you decide to take part you would be given this information sheet to keep and be asked to complete an eligibility survey and consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

If you are a student, your choice to either take part or not take part in the study would have no impact on your marks, assessments or future studies.

What will happen to me if I take part?

If you decide to take part in the study you would be asked to visit Oxford Brookes University for one 30-minute time slot. You would be asked to sample lager. You would sample two different lager products at a time and this will happen three times. You would answer a set of questions about the different lager products.

You should not have consumed any alcohol before coming for your study session. You would be strongly advised not to drive to or from the study venue.

The risks of taking part should be no more than the normal risks of consuming a small amount of alcohol (a maximum of 180ml of lager), including risks of being under the influence of alcohol.

What are the possible benefits of taking part?

There are no direct benefits for you in taking part, but you would be reimbursed with a £10 voucher. The study is of benefit to the researcher who will use the data to decide which regular strength lager to use in the second part of their PhD project.

Will what I say in this study be kept confidential?

All the information that is collected as part of the study will be kept as strictly confidential and used for research purposes only. Only the researcher and their supervisor would have access to the information provided by you.

Electronic information will be stored securely on a password protected computer. Information on paper will be stored within a secure locked cabinet at Oxford Brookes University in accordance with the Oxford Brookes University policy on data storage.

Any information that could be used to identify you, such as your name and email address, would be stored separately from the data we collect from you during the study. Once this information has been used for research purposes it would be coded so that no-one can access it.

If you withdraw from the study any unprocessed data would be removed from the study.

If a publication emerges from the research, the researcher and their supervisor will follow the University Guidelines.

Data generated by the study will be retained in accordance with the University's Policy on Academic Integrity. It will be kept securely in electronic or paper form for a period of ten years after the completion of the research project.

What should I do if I want to take part?

If you want to take part in the study please access this link https://brookeshls.co1.qualtrics.com/jfe/form/SV_eh3zWMP4tXVbnFP to the online screening survey or email 16016348@brookes.ac.uk to request a paper copy. If you are eligible to take part in the study the researcher will contact you to confirm details for your study session.

What will happen to the results of the research study?

The results of the research will be used in the researcher's PhD thesis. They may be published in a peer-reviewed scientific journal. If you would like a copy of the results of the study email 16016348@brookes.ac.uk before September 2019.

Who is organising and funding the research?

The researcher is conducting the research as a student at Oxford Brookes University, in the Department of Midwifery, Community and Public Health, in the Faculty of Health and Life Sciences. The research is being funded by Oxford Brookes University.

Who has reviewed the study?

The research has been approved by the University Research Ethics Committee, Oxford Brookes University.

For further information, or to withdraw from the study, contact the Researcher, Parvati Perman-Howe:
Email: 16016348@brookes.ac.uk
Tel: 07724111095

If you have any concerns about the way in which the study has been conducted, contact the chair of the university research ethics committee on ethics@brookes.ac.uk.

Thank you for taking time to read this information sheet.

If at any time during the study you feel worried about your own or someone else's drinking, you can approach your doctor or contact an organisation that can help with alcohol-related issues.

The telephone numbers and website addresses of a number of organisations that can help are listed below:

Addaction
Telephone: 020 7251 5860 / www.addaction.org.uk

Alcoholics Anonymous
Telephone: 0800 9177 650 / www.alcoholics-anonymous.org.uk

Frank
Telephone: 0300 123 6600 / www.talktofrank.com

For the purposes of carrying out this survey, the University uses the survey tools provided by Qualtrics with whom the University's Faculty of Health and Life Sciences holds an agreement. There is always a certain element of risk of data loss when data is collected and processed in an internet environment. This risk cannot be eliminated entirely and participants consenting to take part in the screening survey need to be aware of this risk. However, personal data will be minimised to the extent possible for the survey and the University believes that Qualtrics offers sufficient guarantees to keep the data secure while it is being processed. These security obligations are set out in the agreement between Qualtrics and the University.

Further information about Qualtrics can be found on the following web site: http://qualtrics.com/

Date: 18/09/2017

Version 2

Appendix J: Taste discrimination experiment randomisation sequence spreadsheet

A = BL / B = control															
Control 1 (B)	**1**	AB	**2**	AB	**3**	AB	**4**	AB	**5**	BA	**6**	BA	**7**	BA	**8**	BA
Control 2 (CE)		AB		AB		BA		BA		BA		BA		AB		AB
Control 3 (SA)		AB		BA		AB		BA		BA		AB		BA		AB
Control 1 (B)	**9**	AB	**10**	AB	**11**	AB	**12**	AB	**13**	BA	**14**	BA	**15**	BA	**16**	BA
Control 2 (CE)		AB		AB		BA		BA		BA		BA		AB		AB
Control 3 (SA)		AB		BA		AB		BA		BA		AB		BA		AB
Control 1 (B)	**17**	AB	**18**	AB	**19**	AB	**20**	AB	**21**	BA	**22**	BA	**23**	BA	**24**	BA
Control 2 (CE)		AB		AB		BA		BA		BA		BA		AB		AB
Control 3 (SA)		AB		BA		AB		BA		BA		AB		BA		AB
Control 1 (B)	**25**	AB	**26**	AB	**27**	AB	**28**	AB	**29**	BA	**30**	BA	**31**	BA	**32**	BA
Control 3 (SA)		AB		AB		BA		BA		BA		BA		AB		AB
Control 2 (CE)		AB		BA		AB		BA		BA		AB		BA		AB
Control 1 (B)	**33**	AB	**34**	AB	**35**	AB	**36**	AB	**37**	BA	**38**	BA	**39**	BA	**40**	BA

Control 3 (SA)		AB		AB		BA		BA		BA		BA		AB		AB
Control 2 (CE)		AB		BA		AB		BA		BA		AB		BA		AB
Control 1 (B)	**41**	AB	**42**	AB	**43**	AB	**44**	AB	**45**	BA	**46**	BA	**47**	BA	**48**	BA
Control 3 (SA)		AB		AB		BA		BA		BA		BA		AB		AB
Control 2 (CE)		AB		BA		AB		BA		BA		AB		BA		AB
Control 2 (CE)	**49**	AB	**50**	AB	**51**	AB	**52**	AB	**53**	BA	**54**	BA	**55**	BA	**56**	BA
Control 1 (B)		AB		AB		BA		BA		BA		BA		AB		AB
Control 3 (SA)		AB		BA		AB		BA		BA		AB		BA		AB
Control 2 (CE)	**57**	AB	**58**	AB	**59**	AB	**60**	AB	**61**	BA	**62**	BA	**63**	BA	**64**	BA
Control 1 (B)		AB		AB		BA		BA		BA		BA		AB		AB
Control 3 (SA)		AB		BA		AB		BA		BA		AB		BA		AB
Control 2 (CE)	**65**	AB	**66**	AB	**67**	AB	**68**	AB	**69**	BA	**70**	BA	**71**	BA	**72**	BA
Control 1 (B)		AB		AB		BA		BA		BA		BA		AB		AB
Control 3 (SA)		AB		BA		AB		BA		BA		AB		BA		AB
Control 2 (CE)	**73**	AB	**74**	AB	**75**	AB	**76**	AB	**77**	BA	**78**	BA	**79**	BA	**80**	BA
Control 3 (SA)		AB		AB		BA		BA		BA		BA		AB		AB

Control 1 (B)		AB		BA		AB		BA		BA		AB		BA		AB
Control 2 (CE)	**81**	AB	**82**	AB	**83**	AB	**84**	AB	**85**	BA	**86**	BA	**87**	BA	**88**	BA
Control 3 (SA)		AB		AB		BA		BA		BA		BA		AB		AB
Control 1 (B)		AB		BA		AB		BA		BA		AB		BA		AB
Control 2 (CE)	**89**	AB	**90**	AB	**91**	AB	**92**	AB	**93**	BA	**94**	BA	**95**	BA	**96**	BA
Control 3 (SA)		AB		AB		BA		BA		BA		BA		AB		AB
Control 1 (B)		AB		BA		AB		BA		BA		AB		BA		AB
Control 3 (SA)	**97**	AB	**98**	AB	**99**	AB	**100**	AB	**101**	BA	**102**	BA	**103**	BA	**104**	BA
Control 1 (B)		AB		AB		BA		BA		BA		BA		AB		AB
Control 2 (CE)		AB		BA		AB		BA		BA		AB		BA		AB
Control 3 (SA)	**105**	AB	**106**	AB	**107**	AB	**108**	AB	**109**	BA	**110**	BA	**111**	BA	**112**	BA
Control 1 (B)		AB		AB		BA		BA		BA		BA		AB		AB
Control 2 (CE)		AB		BA		AB		BA		BA		AB		BA		AB
Control 3 (SA)	**113**	AB	**114**	AB	**115**	AB	**116**	AB	**117**	BA	**118**	BA	**119**	BA	**120**	BA
Control 1 (B)		AB		AB		BA		BA		BA		BA		AB		AB
Control 2 (CE)		AB		BA		AB		BA		BA		AB		BA		AB

Control 3 (SA)	**121**	AB	**122**	AB	**123**	AB	**124**	AB	**125**	BA	**126**	BA	**127**	BA	**128**	BA
Control 2 (CE)		AB		AB		BA		BA		BA		BA		AB		AB
Control 1 (B)		AB		BA		AB		BA		BA		AB		BA		AB
Control 3 (SA)	**129**	AB	**130**	AB	**131**	AB	**132**	AB	**133**	BA	**134**	BA	**135**	BA	**136**	BA
Control 2 (CE)		AB		AB		BA		BA		BA		BA		AB		AB
Control 1 (B)		AB		BA		AB		BA		BA		AB		BA		AB
Control 3 (SA)	**137**	AB	**138**	AB	**139**	AB	**140**	AB	**141**	BA	**142**	BA	**143**	BA	**144**	BA
Control 2 (CE)		AB		AB		BA		BA		BA		BA		AB		AB
Control 1 (B)		AB		BA		AB		BA		BA		AB		BA		AB

Appendix K: Pilot trial materials and equipment

Pilot trial recruitment session materials

Item	Quantity (available per recruitment session)
Eligibility survey	25
Participant information sheet	25

Pilot trial recruitment session equipment

Item	Manufacturer/supplier	Quantity (available per recruitment session)
Pens	Generic	5
Files	Generic	2

Pilot trial materials

Item	Quantity (available per study session)
Alcohol advice leaflet	12
Consent form	12
Eligibility survey	10
Participant information sheet	10
Questionnaire	12
Randomisation sequence envelopes	1 set per venue
Randomisation cards (for 2nd sessions)	As required
Study session schedule	1

Pilot trial equipment

Item	Manufacturer/supplier	Quantity (available per study session)
Cash float	Borrowed from the venue	Minimum of £30 float
Bin bag	Generic	1 large
Breathalyser: pro fuel cell digital	Alcosense	2
Breathalyser tubes	Alcosense	20
Files	Generic	3
Fridge	Borrowed from the venue	1
Lager (440ml duct-taped cans): Becks Bud Light	Sainsbury's	Estimated based on eligibility survey responses
Pens	Generic	5
Pint glasses (non-branded)	Borrowed from the venue	As required

Appendix L: Pilot trial eligibility survey

You are being asked to take part in this survey to see if the study 'The effect of alcohol strength on alcohol consumption' is right for you. You can refer to the information sheet that you have been given for more information about the study.

By taking part in this survey you automatically give consent for the information you provide to be used for research purposes only, in the study ‘The effect of alcohol strength on alcohol consumption’. The information you provide will be kept confidential.

This survey will take around five minutes to complete.

If you are suitable to take part in the study the researcher, Parvati Perman-Howe, will contact you to arrange suitable times for your two study sessions.

1. What is your age? ☐

2. What is your gender? *Circle one response.*
   Female/Male/Non-binary/Other/Rather not say

3. What is your current employment status? *Give your main employment status if more than one applies.*

Full-time employed	
Part-time employed	
Self employed	
Looking after the family home	
Unemployed: seeking work	
Unemployed: not seeking work but able to work	
Unemployed: not able to work for health reasons	
Retired	
Student	
Other	

4. Is there any possibility that you are pregnant?
   Yes/No

5. Have you ever sought or received help or treatment for alcohol dependency?
   Yes/No

6. Roughly how many drinks did you have on your heaviest drinking occasion in the last year? *Put a number in all of the boxes that apply to you or an 'X' in the final box.*

Pint of beer, lager or cider	
Half pint of beer, lager or cider	
Regular (330ml) bottle of beer, lager or cider	
Large (500ml) bottle of beer, lager or cider	
Regular (440ml) can of beer, lager or cider	
Small (125ml) glass of wine, champagne or prosecco	
Medium (175ml) glass of wine, champagne or prosecco	
Large (250ml) glass of wine, champagne or prosecco	
Bottle (750ml) of wine, champagne or prosecco	
Single (25ml) measure of spirits	
Double (50ml) measure of spirits	
Regular (330ml) bottle of alcopops	
Other (please state type/brand, strength and amount)	
I have not drank in the last year	

7. Have you drank lager within a licensed premises (pub, bar or club) at least once in the past three months?
   Yes/No

8. Last time you drank **lager** in a licensed premises (pub, bar or club) how many drinks of **lager** did you have? *Put a number in all of the boxes that apply to you or an 'X' in the final box.*

Pint of lager	
Half pint of lager	
Schooner of lager (2/3 of a pint)	
Small bottle or can (330ml) of lager	
Other (please state size of drink and number of these drinks consumed)	
I have never drank lager in a licensed premises	

9. Are you able to attend two study visits (which will be arranged with the researcher) to the licensed premises (pub, bar or club) where you saw this study advertised?
   Yes/No

If you are eligible for the study the Researcher, Parvati Perman-Howe, will contact you to arrange two suitable times for you to take part. If you are not eligible for the study Parvati will contact you to let you know and then your contact details will be destroyed. By giving

your contact details you consent to being contacted for research purposes related to this study. Please leave your details so that she can contact you.

Name (to be known by):

Telephone number:

Email address:

Address (if you would prefer to be contacted by post rather than email):

You have now completed the survey.

Thank you very much for your time.

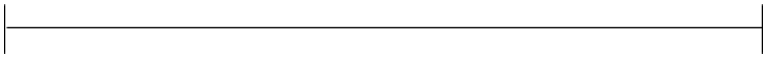
Appendix M: Pilot trial questionnaire

ID Number:

The information you provide in this questionnaire will be kept confidential. It will be used in the study 'The effect of alcohol strength on alcohol consumption'.

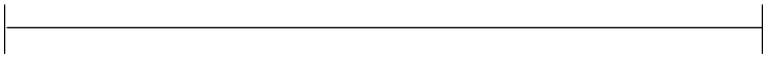
Please read through the whole questionnaire and answer questions **1 to 13**.

1. How enjoyable did you find the drink? *Put an X on the line.*



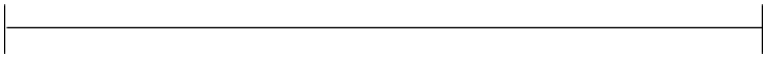
Not at all enjoyable — Highly enjoyable

2. How did the drink taste? *Put an X on the line.*



Extremely unpleasant — Extremely pleasant

3. How do you feel now? *Put an X on the line.*



Completely sober — Completely intoxicated

4. Which brand of lager do you drink most frequently?

5. How did the drink taste compared to the brand of lager you drink most frequently? *Put an X in one box.*

Much nicer than my normal drink	
Nicer than my normal drink	
Equally as nice as my normal drink	
Worse than my normal drink	
Much worse than my normal drink	
I have no opinion on its taste	
Other (please specify below)	

6. Would you consider switching from the brand of lager you drink most frequently to this one if the price was the same? *Put an X in one box.*

Yes	
No	
Maybe	

7. Thinking about the lager you have just consumed, what brand would you say you were drinking? *Put an X in one box.*

Amstel 4.1%	
Becks 4.8%	
Becks Vier 4%	
Budweiser 4.5%	
Bud Light 3.5%	
Carlsberg 3.8%	
Carlsberg Export 4.8%	
Heineken 5%	
San Miguel 5%	
San Miguel Gluten Free 5.4%	
Skol Lager 2.8%	
Other – please specify below:	

8. Do you have any other comments about the lager you have just consumed?

9. How many soft drinks did you drink whilst you were in the licensed premises today?

10. **If you consumed soft drinks whilst you were in the licensed premise today**: What is the main reason that you consumed soft drinks?

11. How many **other adults** were in your drinking group whilst you were in the licensed premises today?

12. Did you buy a round for your drinking group whilst you were in the licensed premises today? *Put an X in one box.*

Yes	
No	
I bought drinks for some people in the group but not for all of them	

13. Would you normally buy a round for your drinking group whilst you are in a licensed premises? *Put an X in one box.*

Yes	
No	
Sometimes	
I would buy drinks for some people in the group but not for all of them	

Thank you for participating in the study and for completing this questionnaire.

Appendix N: Summary of field notes

Blue = Comment
Green = Thought
Orange = Observation

Patrons (Venue One and Two): Would like to participate in a wine-based experiment. *This may be a popular option for future alcohol-strength-based studies.*

The participant information sheet (PIS) should include the study session dates.

The weather could influence drinking behaviour. *May wish to consider keeping a weather diary.*

Participants were checking out of the study and then consuming other types of alcohol. For example, real ale or red wine. *Could ask participants (via email) how much alcohol they consumed after their study sessions but over the same evening (similar to MF et al @ Liverpool's study protocol).*

Participant (Venue One): Concern over the environmental impact of the pilot trial as cans could not be recycled because they were wrapped in duct tape. *May wish to consider alternative methods of blinding or put aside time to remove the duct tape from the cans so that they can be recycled.*

Overheard participants (Venue One) discussing which was the nicer of the two study-specific lagers. *The intervention and control products need to be better matched. Labelling the cans and randomisation cards with a small coloured label (purple or pink) made it too obvious that there were only two lagers being supplied. May wish to consider using a more complex labelling system that incorporates three labels on each of the cans and randomisation cards, one of which is purple or pink and the other coloured labels are used as a decoy.*

RA (JW): BL is creating more wastage than B as it is frothier. *Should consider whether to increase BL supplies for study sessions.*

Participant (Venue One): BL is too fizzy: prefers B.

Wife of participant (Venue One): All (husband's name's) friends who were drinking the purple drink (B) were hungover the next day. *Participants are aware that there are two study-specific lagers, which are colour coded purple and pink. This needs to be less overt in future iterations of the trial.*

Could the variation in background music affect people's drinking behaviour within a licensed premises? *Research suggests so. However, the evidence is of poor quality.*

Breathalyser manual states it should not be used within 90 minutes of consuming alcohol: this makes it useless for trial purposes. *As BrACs are not an outcome measure, future iterations of the study would only need to measure them at the start of each participant's study session. The readings taken at the end of the study sessions will be inaccurate if the same model of breathalyser is used.*

Two venues supplied spare fridges, which were not plugged in prior to the study session. Therefore, the beer was not optimally and consistently chilled between study venues. *For future iterations of the study, the researcher should specify to the landlord/venue manager that the fridge needs to be plugged in 24-hours prior to a study session.*

Participants at Venue Four were unreliable. A large number signed up for the trial but failed to confirm and attend the study sessions. This could be because the study sessions were held during quiz and karaoke nights where the culture appeared to be one of intoxication. People who expressed an interest in the trial when intoxicated were unreliable. *Future iterations of the trial should consider avoiding SU bars and/or licensed premises that are raucous.*

Having a DJ/quizmaster promote the study to patrons during study sessions helped to recruit more participants.

Appendix O: Pilot trial invitation letter/email

OXFORD BROOKES UNIVERSITY

Dear *****

My name is Parvati and I am a PhD student at Oxford Brookes University.

I am emailing/writing to you as you have expressed an interest in taking part in a study about alcohol and I would like to give you some more information about the study.

Please read the information leaflet that is attached to this email/contained in the envelope with this letter, which contains more detailed information about the study.

There is no obligation to take part. If you do wish to take part, please access the link below that will take you to an online screening survey/complete and return the screening survey in the stamped addressed envelope provided. If your answers to the survey show that you may take part in the study, then I will contact you to arrange suitable dates and times for your study sessions.

Link: https://brookeshls.co1.qualtrics.com/jfe/form/SV_e5R3myRupvzFzwh

Thank you for reading this email/letter and the information leaflet.

Yours sincerely,

Miss Parvati Perman-Howe (Student)
Professor David Foxcroft (Student's Supervisor)

Appendix P: Pilot trial data by recruitment site/gender/student vs non-student

	Mean (reduced-strength lager)	Mean (regular-strength lager)	Mean difference (mean reduced-strength lager minus mean regular-strength lager)
Alcohol consumption (UK units)			
Overall (n=36)	8.28 (SD = 4.17)	12.04 (SD = 5.33)	-3.76 (SD = 3.69)
Venue One (n=10)	8.20 (SD = 3.58)	12.51 (SD = 5.26)	-4.31 (SD = 3.52)
Venue Two (n=10)	11.60 (SD = 4.30)	14.89 (SD = 5.64)	-3.29 (SD = 2.60)
Venue Three (n=10)	6.80 (SD = 3.01)	11.90 (SD = 3.69)	-5.10 (SD = 4.31)
Venue Four (n=6)	5.33 (SD = 1.43)	6.75 (SD = 1.67)	-1.42 (SD = 4.01)
Female (n=4)	5.50 (SD = 1.91)	7.43 (SD = 1.35)	-1.93 (SD = 1.67)
Male (n=32)	8.63 (SD = 4.26)	12.62 (SD = 5.36)	-3.99 (SD = 3.82)
Student (n=15)	6.80 (SD = 3.53)	10.45 (SD = 4.58)	-3.65 (SD = 4.60)
Non-student (n=21)	9.33 (SD = 4.35)	13.18 (SD = 5.63)	-3.84 (SD = 3.00)
Alcohol consumption (grams)			
Overall (n=36)	65.78 (SD = 33.51)	96.34 (SD = 42.61)	-30.56 (SD = 29.83)
Venue One (n=10)	65.60 (SD = 28.67)	100.08 (SD = 42.04)	-34.48 (SD = 28.20)
Venue Two (n=10)	92.80 (SD = 34.40)	119.14 (SD = 45.16)	-26.34 (SD = 20.82)
Venue Three (n=10)	52.80 (SD = 23.91)	95.20 (SD = 29.48)	-42.39 (SD = 34.96)
Venue Four (n=6)	42.67 (SD = 28.02)	54.00 (SD = 32.76)	-11.33 (SD = 32.07)
Female (n=4)	44.00 (SD = 15.32)	59.40 (SD = 10.80)	-15.40 (SD = 13.36)
Male (n=32)	68.50 (SD = 34.30)	100.95 (SD = 42.91)	-32.45 (SD = 30.89)
Student (n=15)	53.33 (SD = 28.15)	83.62 (SD = 36.59)	-30.29 (SD = 37.48)
Non-student (n=21)	74.67 (SD = 34.81)	105.42 (SD = 45.69)	-30.75 (SD = 23.96)
Pints consumed			
Overall (n=36)	4.14 (SD = 2.09)	4.45 (SD = 1.96)	-0.31 (SD = 1.51)
Venue One (n=10)	4.10 (SD = 1.79)	4.63 (SD = 1.94)	-0.53 (SD = 1.34)
Venue Two (n=10)	5.80 (SD = 2.15)	5.50 (SD = 2.07)	0.30 (SD = 0.95)
Venue Three (n=10)	3.4 (SD = 1.51)	4.4 (SD = 1.35)	-1.00 (SD = 1.83)
Venue Four (n=6)	2.67 (SD = 1.75)	2.50 (SD = 1.52)	0.17 (SD = 1.72)
Female (n=4)	2.75 (SD = 0.96)	2.75 (SD = 0.50)	0.00 (SD = 0.82)
Male (n=32)	4.31 (SD = 2.13)	4.67 (SD = 1.97)	-0.35 (SD = 1.58)
Student (n=15)	3.40 (SD = 1.76)	3.87 (SD = 1.68)	-0.47 (SD = 1.92)
Non-student (n=21)	4.67 (SD = 2.18)	4.87 (SD = 2.07)	-0.20 (SD = 1.17)
Study session duration (hh:mm)			
Overall (n=36)	2:33 (SD = 0:51)	2:39 (SD = 0:52)	-0:06 (SD = 0:41)
Venue One (n=10)	N/A	N/A	N/A

Venue Two (n=10)	3:07 (SD = 1:05)	3:01 (SD = 1:14)	0:06 (SD = 0:43)
Venue Three (n=10)	2:10 (SD = 0:16)	2:27 (SD = 0:09)	-0:17 (SD = 0:17)
Venue Four (n=6)	2:13 (SD = 0:34)	2:24 (SD = 0:44)	-0:10 (SD = 1:04)
Female (n=2)	2:02 (SD = 0:10)	2:37 (SD = 0:03)	-0:35 (SD = 0:07)
Male (n=24)	2:35 (SD = 0:52)	2:40 (SD = 0:54)	-0:04 (SD = 0:42)
Student (n=15)	2:15 (SD = 0:27)	2:26 (SD = 0.27)	-0:11 (SD = 0:45)
Non-student (n=11)	2:57 (SD = 1:06)	2:57 (SD = 1:11)	0:00 (SD = 0:37)
Pleasantness of taste			
Overall (n=36)	4.86 (SD = 2.73)	5.81 (SD = 2.13)	-0.95 (SD = 3.43)
Venue One (n=10)	4.97 (SD = 2.41)	5.38 (SD = 2.00)	-0.41 (SD = 3.36)
Venue Two (n=10)	4.17 (SD = 2.32)	4.86 (SD = 2.63)	-0.69 (SD = 3.32)
Venue Three (n=10)	5.1 (SD = 3.48)	6.73 (SD = 1.74)	-1.63 (SD = 4.19)
Venue Four (n=6)	5.43 (SD = 3.00)	6.57 (SD = 1.56)	-1.13 (SD = 2.97)
Female (n=4)	4.50 (SD = 2.30)	7.40 (SD = 1.07)	-2.90 (SD = 3.03)
Male (n=32)	4.91 (SD = 2.81)	5.61 (SD = 2.16)	-0.70 (SD = 3.44)
Student (n=15)	4.91 (SD = 3.33)	6.49 (SD = 1.76)	-1.57 (SD = 3.60)
Non-student (n=21)	4.82 (SD = 2.30)	5.32 (SD = 2.28)	-0.50 (SD = 3.32)
Enjoyment			
Overall (n=36)	4.79 (SD = 2.79)	6.23 (SD = 2.21)	-1.44 (SD = 3.54)
Venue One (n=10)	5.00 (SD = 2.58)	5.96 (SD = 1.98)	-0.97 (SD = 3.21)
Venue Two (n=10)	4.40 (SD = 2.66)	5.18 (SD = 2.78)	-0.78 (SD = 3.53)
Venue Three (n=10)	5.03 (SD = 3.53)	6.86 (SD = 2.03)	-1.83 (SD = 4.69)
Venue Four (n=6)	4.70 (SD = 2.65)	7.38 (SD = 1.07)	-2.68 (SD = 1.97)
Female (n=4)	5.50 (SD = 3.01)	7.05 (SD = 1.25)	-1.55 (SD = 3.89)
Male (n=32)	4.70 (SD = 2.80)	6.13 (SD = 2.30)	-1.43 (SD = 3.57)
Student (n=15)	4.80 (SD = 3.22)	6.73 (SD = 2.03)	-1.93 (SD = 3.90)
Non-student (n=21)	4.78 (SD = 2.53)	5.87 (SD = 2.32)	-1.09 (SD = 3.32)
Perceived intoxication			
Overall (n=36)	4.09 (SD = 1.91)	5.09 (SD = 1.97)	-1.00 (SD = 1.79)
Venue One (n=10)	4.90 (SD = 1.83)	6.00 (SD = 1.17)	-1.10 (SD = 1.70)
Venue Two (n=10)	4.03 (SD = 1.56)	4.39 (SD = 2.01)	-0.36 (SD = 1.36)
Venue Three (n=10)	3.35 (SD = 1.72)	5.02 (SD = 1.77)	-1.67 (SD = 1.74)
Venue Four (n=6)	4.05 (SD = 2.70)	4.85 (SD = 3.02)	-0.80 (SD = 2.61)
Female (n=4)	4.38 (SD = 0.89)	5.65 (SD = 2.05)	-1.28 (SD = 2.43)
Male (n=32)	4.05 (SD = 2.00)	5.02 (SD = 1.98)	-0.97 (SD = 1.75)
Student (n=15)	3.85 (SD = 2.16)	4.93 (SD = 2.26)	-1.08 (SD = 2.16)
Non-student (n=21)	4.25 (SD = 1.74)	5.20 (SD = 1.79)	-0.95 (SD = 1.53)

Appendix Q: Pilot trial participant information sheet

Department of Midwifery, Community and Public Health

Faculty of Health and Life Sciences

Researcher: Parvati Perman-Howe, PhD Student
(Email: 16016348@brookes.ac.uk)

Supervisor: Professor David Foxcroft
(Email: david.foxcroft@brookes.ac.uk)

'The effect of alcohol strength on alcohol consumption'

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully.

What is the purpose of the study?

Little is known about people's drinking behaviour when they consume different strength alcohol products. The aim of this study is to find out whether people's drinking behaviour changes when they drink different strength lager products within licensed premises.

The study is a randomised controlled trial using a cross-over design. This means that each participant will consume different strength lager products on two separate occasions. The order in which they consume the products will be randomly allocated.

The study is a pilot study, which means there may be a similar larger study in the future, but you would not be taking part in this. The study is part of a PhD project, which is three years in length. The actual experiment will run for about six months. You would only be required to attend the licensed premises where the study is taking place twice.

Why have I been invited to participate?

You have been chosen to take part in the study because you are over 18 years of age, you drink lager and you are a customer at one of the licensed venues which are taking part in the study. We will not let you take part if you have a dependence on alcohol, if you are on any medication which may react badly to alcohol, if you have any illness or condition which may react badly to alcohol, or if you are

pregnant. We will also not let you take part if you arrive at the study venue under the influence of alcohol.

We will be asking 52 people in total to take part in the study.

Do I have to take part?

It is up to you to decide whether or not to take part in the study. If you do decide to take part you would be given this information sheet to keep and be asked to complete an eligibility survey and a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

If you are a student, your choice to either take part or not take part in the study would have no impact on your marks, assessments or future studies.

What will happen to me if I take part?

If you decide to take part in the study you would be asked to visit the licensed premises where you saw this study advertised on two occasions: the researcher would contact you to arrange this. You would be asked to behave as you normally would whilst in the licensed premises and you can stay for as long as you normally would.

You would be required to consume lager whilst at the licensed premises but you would not get to choose the brand of lager, and you would not be told which brand of lager, you are consuming. You would be asked to consume your drinks as you normally would in the licensed premises including paying for the drinks (£2 per pint), but you would only be able to purchase lager in pints. You would be required to undertake a breathalyser test at the beginning and end of your visit to the licensed premises and you would be asked some questions before you leave. You would be automatically entered into a free prize draw with 51 other participants to win one of two prizes of £100.

You should not have consumed any alcohol before coming for your study sessions. You would be strongly advised not to drive to or from the licensed premises on either study session.

The risks of taking part should be no more than the normal risks of visiting the licensed premises, including risks of being under the influence of alcohol.

What are the possible benefits of taking part?

There are no direct benefits for you in taking part, but you would be automatically entered into a free prize draw with 51 other participants to win one of two prizes of £100. The study will improve understanding of whether the strength of alcohol alters consumption. The study is of benefit to the researcher who will use the data in their PhD project.

Will what I say in this study be kept confidential?

All the information that is collected as part of the study will be kept as strictly confidential and used for research purposes only. Only the researcher and their supervisors will have access to the information provided by you.

Electronic information will be stored securely on a password protected computer. Information on paper will be transported from the licensed premises to Oxford Brookes University in a locked box and it will be stored within a secure locked cabinet at Oxford Brookes University in accordance with the Oxford Brookes University policy on data storage.

Any information that could be used to identify you, such as your name and email address, would be stored separately from the data we collect from you during the study. Once this information has been used for research purposes it would be coded so it will no longer be accessible.

If you withdraw from the study any unprocessed data would be removed from the study.

If a publication emerges from the research, the researcher and their supervisor will follow the University Guidelines.

Data generated by the study will be retained in accordance with the University's Policy on Academic Integrity. It will be kept securely in electronic or paper form for a period of ten years after the completion of the research project.

What should I do if I want to take part?

If you want to take part in the study please access this link https://brookeshls.co1.qualtrics.com/jfe/form/SV_e5R3myRupvzFzwh to the online screening survey or email 16016348@brookes.ac.uk or phone 07724 111095 to request a paper copy. If you are eligible to take part in the study the researcher will contact you to arrange your two study sessions at the licensed premises.

What will happen to the results of the research study?

The results of the research will be used in the researcher's PhD thesis. They may be published in a peer-reviewed scientific journal. If you would like a copy of the results of the study email 16016348@brookes.ac.uk or phone 07724 111095 before September 2019.

Who is organising and funding the research?

The researcher is conducting the research as a student at Oxford Brookes University, in the Department of Midwifery, Community and Public Health, in the Faculty of Health and Life Sciences. The research is being funded by Oxford Brookes University.

Who has reviewed the study?

The research has been approved by the University Research Ethics Committee, Oxford Brookes University.

For further information, or to withdraw from the study, contact the Researcher, Parvati Perman-Howe:
Email: 16016348@brookes.ac.uk

Tel: 07724 111095

If you have any concerns about the way in which the study has been conducted, contact the chair of the university research ethics committee on ethics@brookes.ac.uk.

Thank you for taking time to read this information sheet.

If at any time during the study you feel worried about your own or someone else's drinking, you can approach your doctor or contact an organisation that can help with alcohol-related issues.

The telephone numbers and website addresses of a number of organisations that can help are listed below:

Addaction
Telephone: 020 7251 5860 / www.addaction.org.uk

Alcoholics Anonymous
Telephone: 0800 9177 650 / www.alcoholics-anonymous.org.uk

Frank
Telephone: 0300 123 6600 / www.talktofrank.com

For the purposes of carrying out this survey, the University uses the survey tools provided by Qualtrics with whom the University's Faculty of Health and Life Sciences holds an agreement. There is always a certain element of risk of data loss when data is collected and processed in an internet environment. This risk cannot be eliminated entirely and participants consenting to take part in the screening survey need to be aware of this risk. However, personal data will be minimised to the extent possible for the survey and the University believes that Qualtrics offers sufficient guarantees to keep the data secure while it is being processed. These security obligations are set out in the agreement between Qualtrics and the University.

Further information about Qualtrics can be found on the following web site: http://qualtrics.com/

Date: 18/09/17 Version 2

Appendix R: Interview materials and equipment

Interview materials

Item	Quantity
Booking sheet	1 per participant
Interview schedule	1

Interview equipment

Item	Manufacturer/supplier	Quantity
Connecting leads	Generic	2
Headset	Sony	1
Telephone	BT Converse	1
Recording device	Sony	1

Appendix S: Pilot trial debrief letter/email

OXFORD BROOKES UNIVERSITY

Dear *****,

Thank you for taking part in the study 'The effect of alcohol strength on alcohol consumption'.

The study was looking at how much alcohol people consumed when they were given regular strength alcohol, and lower strength alcohol.

On your first study session you drank ** pints of **** (*.*% ABV). On your second study session you drank ** pints of **** (*.*% ABV).

The results of the study are still being analysed but if you would like to see the results when they are published then please email the researcher, Parvati Perman-Howe, to request this: contact details can be found on the information leaflet.

We are also recruiting for an extra part of the study. We would like people who took part in the first part of the study to take part in a one-off telephone interview. If you are interested in taking part, please read the information leaflet that is attached to this email, which contains more detailed information about the interview.

There is no obligation to take part and if you do not wish to take part you will still be entered into the prize draw to win £100. If you do wish to take part, please complete and return the consent form and the booking form that are attached to this email. The researcher, Parvati Perman-Howe, will contact you on the scheduled date and time for your interview.

Thank you for reading this email and thank you once again for your participation in the study.

Yours sincerely,

Miss Parvati Perman-Howe (Student)

Professor David Foxcroft (Student's Supervisor)

Appendix T: Interview participant information sheet

Department of Midwifery, Community and Public Health

Faculty of Health and Life Sciences

Researcher: Parvati Perman-Howe, PhD Student (Email: 16016348@brookes.ac.uk)

Supervisor: Professor David Foxcroft (Email: david.foxcroft@brookes.ac.uk)

'The effect of alcohol strength on alcohol consumption'

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully.

What is the purpose of the study?

The aim of this study is to find out whether reducing the strength of alcohol is an acceptable way to reduce alcohol consumption.

The study involves qualitative semi-structured telephone interviews. This means that you would be asked a set of questions and you would be able to give detailed answers to these questions.

The study is a pilot study, which means there may be a similar larger study in the future, but you would not be taking part in this. The study is part of a PhD project, which is three years in length. You would only be required to complete a telephone interview once.

Why have I been invited to participate?

You have been invited to take part in the study because you have taken part in the previous trial and it would be interesting to know what you thought about it.

We will be asking up to 15 people in total to take part in the interviews.

Do I have to take part?

It is up to you to decide whether or not to take part in the study. If you do decide to take part you would be given this information sheet to keep and be asked to complete a consent form and a booking form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

If you are a student, your choice to either take part or not take part in the study would have no impact on your marks, assessments or future studies.

What will happen to me if I take part?

If you decide to take part in the study you would be contacted by telephone by the researcher on the date and time scheduled for your interview. You would be asked a set of questions and you would be able to give detailed answers. The interview would last a maximum of 45 minutes.

There are no obvious risks in taking part in the study.

What are the possible benefits of taking part?

There are no direct benefits for you in taking part. The study will improve understanding of whether reducing the strength of alcohol is an acceptable way of lowering consumption. The study is of benefit to the researcher who will use the data in their PhD project.

Will what I say in this study be kept confidential?

All the information that is collected as part of the study will be kept as strictly confidential and used for research purposes only.

Audio recordings of the interviews will be used to electronically transcribe the interviews and then they will be deleted. Electronic information will be stored securely on a password protected computer.

No one apart from the researcher would know what you have said in the interview and you would not be identified in the transcripts. The researcher would not discuss the content of the interview with anyone in a way that would identify you.

As the researcher is only speaking to a small number of people in total for this part of the study, then you need to be aware that you or someone who knows you might recognise something you say when the study is written up. However, in any written work using quotes from the interview, every effort will be made to ensure that individuals are not likely to be identified by their comments.

If you withdraw from the study any unprocessed data would be removed from the study.

Data generated by the study will be retained in accordance with the University's Policy on Academic Integrity. It will be kept securely in electronic or paper form for a period of ten years after the completion of the research project.

What should I do if I want to take part?

If you want to take part in the study please complete the consent form and the booking form that are attached/enclosed and return these to the researcher.

What will happen to the results of the research study?

The results of the research will be used in the researcher's PhD thesis. They may be published in a peer-reviewed scientific journal. If you would like a copy of the results of the study email 16016348@brookes.ac.uk before September 2019.

Who is organising and funding the research?

The researcher is conducting the research as a student at Oxford Brookes University, in the Department of Midwifery, Community and Public Health, in the Faculty of Health and Life Sciences. The research is being funded by Oxford Brookes University.

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For further information, or to withdraw from the study, contact the Researcher, Parvati Perman-Howe:
Email: 16016348@brookes.ac.uk
Tel: 07724111095

If you have any concerns about the way in which the study has been conducted, contact the chair of the university research ethics committee on ethics@brookes.ac.uk.

Thank you for taking time to read this information sheet.

If at any time during the study you feel worried about your own or someone else's drinking, you can approach your doctor or contact an organisation that can help with alcohol-related issues.

The telephone numbers and website addresses of a number of organisations that can help are listed below:

Addaction

Telepone: 020 7251 5860 / www.addaction.org.uk

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