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Preoperative behavioural intervention to reduce drinking before elective orthopaedic surgery: the PRE-OP BIRDS feasibility RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Abstract

Preoperative behavioural intervention to reduce drinking before elective orthopaedic surgery: the PRE-OP BIRDS feasibility RCT

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Background: Heavy alcohol consumption is associated with an increased risk of postoperative complications and extended hospital stay. Alcohol consumption therefore represents a modifiable risk factor for surgical outcomes. Brief behavioural interventions have been shown to be effective in reducing alcohol consumption among increased risk and risky drinkers in other health-care settings and may offer a method of addressing preoperative alcohol consumption.

Objectives: To investigate the feasibility of introducing a screening process to assess adult preoperative drinking levels and to deliver a brief behavioural intervention adapted for the target population group. To conduct a two-arm (brief behavioural intervention plus standard preoperative care vs. standard preoperative care alone), multicentre, pilot randomised controlled trial to assess the feasibility of proceeding to a definitive trial. To conduct focus groups and a national web-based survey to establish current treatment as usual for alcohol screening and intervention in preoperative assessment.

Design: A single-centre, qualitative, feasibility study was followed by a multicentre, two-arm (brief behavioural intervention vs. treatment as usual), individually randomised controlled pilot trial with an embedded qualitative process evaluation. Focus groups and a quantitative survey were employed to characterise treatment as usual in preoperative assessment.

Setting: The feasibility study took place at a secondary care hospital in the north-east of England. The pilot trial was conducted at three large secondary care centres in the north-east of England.

Participants: Nine health-care professionals and 15 patients (mean age 70.5 years, 86.7% male) participated in the feasibility study. Eleven health-care professionals and 68 patients (mean age 66.2 years, 80.9% male) participated in the pilot randomised trial. An additional 19 health-care professionals were

recruited to one of three focus groups, while 62 completed an electronic survey to characterise treatment as usual.

Interventions: The brief behavioural intervention comprised two sessions. The first session, delivered face to face in the preoperative assessment clinic, involved 5 minutes of structured brief advice followed by 15–20 minutes of behaviour change counselling, including goal-setting, problem-solving and identifying sources of social support. The second session, an optional booster, took place approximately 1 week before surgery and offered the opportunity to assess progress and boost self-efficacy.

Main outcome measures: Feasibility was assessed using rates of eligibility, recruitment and retention. The progression criteria for a definitive trial were recruitment of $\geq 40\%$ of eligible patients and retention of $\geq 70\%$ at 6-month follow-up. Acceptability was assessed using themes identified in qualitative data.

Results: The initial recruitment of eligible patients was low but improved with the optimisation of recruitment processes. The recruitment of eligible participants to the pilot trial (34%) fell short of the progression criteria but was mitigated by very high retention (96%) at the 6-month follow-up. Multimethod analyses identified the methods as acceptable to the patients and professionals involved and offers recommendations of ways to further improve recruitment.

Conclusions: The evidence supports the feasibility of a definitive trial to assess the effectiveness of brief behavioural intervention in reducing preoperative alcohol consumption and for secondary outcomes of surgical complications if recommendations for further improvements are adopted.

Trial registration: Current Controlled Trials ISRCTN36257982.

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Contents

List of tables	xiii
List of figures	xv
List of boxes	xvii
Glossary	xix
List of abbreviations	xxi
Plain English summary	xxiii
Scientific summary	xxv
Chapter 1 Introduction	1
Structure of this report	1
Background	1
Orthopaedic surgery and postoperative complications	2
The role of the preoperative assessment clinic	3
Alcohol consumption	3
Alcohol consumption and postoperative complications	3
Preoperative alcohol screening	4
Preoperative alcohol cessation interventions	5
Brief alcohol interventions	6
Behavioural interventions in the preoperative period	7
Feasibility and acceptability of preoperative screening and alcohol intervention	9
Outcomes of interest for trials of preoperative alcohol interventions	10
Characterising treatment as usual in preoperative assessment	10
Conclusions	10
Aim and rationale	11
<i>Summary of rationale</i>	11
<i>Aim</i>	11
<i>Patient, public and professional involvement</i>	12
Chapter 2 Defining the intervention and comparator	13
Introduction	13
Aims	13
Optimisation of screening and behavioural intervention process	13
<i>Screening tool selection</i>	13
<i>Optimisation of the intervention tools</i>	14
<i>Description of intervention delivery</i>	15
<i>Training development</i>	15
Characterising treatment as usual	21
<i>Methods</i>	21
<i>Results</i>	23
<i>Appointment details</i>	32
<i>Conclusions</i>	36

Chapter 3 Feasibility study	37
Background	37
Aims	37
Methods	37
<i>Design</i>	37
<i>Setting</i>	37
<i>Outcome measures</i>	37
<i>Procedure</i>	37
<i>Protocol amendments during the study</i>	41
Results	42
<i>Sample</i>	42
<i>Analysis</i>	43
<i>Patient screening and recruitment</i>	44
<i>Patient alcohol consumption</i>	45
<i>Intervention delivery</i>	45
<i>Qualitative results</i>	46
<i>Discussion</i>	58
<i>Conclusions</i>	59
<i>Changes made prior to pilot randomised controlled trial</i>	59
Chapter 4 Pilot randomised controlled trial	61
Introduction	61
Aims	61
<i>Primary objective</i>	61
<i>Secondary objectives</i>	61
Methods	61
<i>Design</i>	61
<i>Setting and subject population</i>	61
<i>Sample size</i>	61
<i>Progression criteria</i>	62
<i>Procedure</i>	62
<i>Data collection</i>	63
<i>Results</i>	67
Alcohol health communication	84
<i>Talking to older patients</i>	86
Gender differences	88
<i>Health-care professional interview results</i>	88
Coherence	89
<i>Differentiation and individual specification</i>	89
<i>Communal specification</i>	89
<i>Internalisation</i>	90
Cognitive participation	90
<i>Initiation</i>	90
<i>Enrolment</i>	91
<i>Legitimation</i>	91
<i>Activation</i>	92
Collective action	92
<i>Interactional workability</i>	92
<i>Skill set workability</i>	93
<i>Contextual integration</i>	93
Reflexive monitoring	94
<i>Systematisation</i>	94
<i>Communal appraisal</i>	94

<i>Individual appraisal</i>	94
<i>Reconfiguration</i>	95
<i>Conclusions</i>	95
Chapter 5 Discussion	97
Screening and recruitment	98
Intervention compliance and fidelity of delivery	99
Follow-up and retention	100
Surgical care pathway variation	101
Implementation of trial processes	101
Chapter 6 Conclusions and recommendations	103
Conclusions	103
Recommendations	103
Acknowledgements	105
References	107
Appendix 1 Behaviour change techniques present in intervention materials	117
Appendix 2 Capability, Opportunity and Motivation to perform a particular Behaviour questionnaire	119
Appendix 3 Capability, Opportunity and Motivation to perform a particular Behaviour questionnaire responses	123
Appendix 4 Affordability, Practicability, Effectiveness, Acceptability, Safety and Equity questionnaire	125
Appendix 5 Training feedback form	127
Appendix 6 Focus group participant information sheet	129
Appendix 7 Focus group consent form	131
Appendix 8 Focus group discussion guide	133
Appendix 9 Treatment-as-usual survey	135
Appendix 10 Feasibility study health-care professional interview participant information sheet	147
Appendix 11 Feasibility study health-care professional interview topic guide	149
Appendix 12 Feasibility study patient interview information sheet	153
Appendix 13 Feasibility study patient interview discussion guide	157
Appendix 14 Pilot randomized controlled trial patient participant information sheet	161
Appendix 15 Pilot randomised controlled trial patient participant interview topic guides	169

List of tables

TABLE 1 Intervention Template for Intervention Description and Replication (TIDieR) summary	16
TABLE 2 Barriers identified and addressed post feasibility study	19
TABLE 3 Pilot RCT intervention details	20
TABLE 4 Focus group participants	23
TABLE 5 Survey respondent details	32
TABLE 6 Availability of alcohol screening, information and referral	33
TABLE 7 Alcohol screening, intervention and referral details	33
TABLE 8 Identification of patients to receive information or referral	35
TABLE 9 Feasibility study schedule of enrolment, interventions and assessments	40
TABLE 10 Feasibility study patient participant baseline characteristics	43
TABLE 11 Feasibility study patient participant health behaviour at consent	43
TABLE 12 Recruitment rates before and after amendments to the feasibility study	45
TABLE 13 Pilot RCT schedule of events	65
TABLE 14 Pilot RCT patient recruitment and randomisation by arm	65
TABLE 15 Reasons that participants did not meet eligibility criteria	68
TABLE 16 Reasons eligible participants declined to participate in the trial	69
TABLE 17 Comparisons of screening and recruitment rates for feasibility and pilot studies	69
TABLE 18 Demographic characteristics at baseline by trial arm	70
TABLE 19 Participant health at baseline by trial arm	70
TABLE 20 Distribution of time interval between baseline and surgery	71
TABLE 21 Rates of completion for outcome measures at baseline and follow-up visits by trial arm	72
TABLE 22 The AUDIT scores by arm and study visit	74
TABLE 23 The EQ-5D visual analogue scale scores by trial arm and study visit	75

TABLE 24 The WOMAC scores by trial arm and study visit	75
TABLE 25 Postoperative complication rates and length of stay by trial arm	76
TABLE 26 Total number of patients needed in definitive trial when outcome is % AUDIT score of ≥ 8 at 6 months	77
TABLE 27 Participant characteristics (of those who attended the interview) at baseline by arm	78
TABLE 28 Summary of findings and implications	97
TABLE 29 Behaviour change techniques present in BA and BI tools	117
TABLE 30 Behaviour change techniques present in patient information leaflet	117
TABLE 31 The COM-B questionnaire responses from HCPs	123

List of figures

FIGURE 1 Feasibility study process	39
FIGURE 2 Feasibility study Consolidated Standards of Reporting Trials (CONSORT) flow diagram	44
FIGURE 3 Recruitment graph for feasibility study	45
FIGURE 4 Pilot RCT process	64
FIGURE 5 Pilot RCT CONSORT flow diagram	67
FIGURE 6 Pilot RCT recruitment graph	68
FIGURE 7 Number of weeks between baseline and surgery	72

List of boxes

BOX 1 Goals set (verbatim)	20
BOX 2 Core constructs of NPT	50

Glossary

Abstainer A person who does not drink alcohol.

Abstinence Never consuming alcohol.

Alcohol Ethanol (ethyl alcohol) the psychoactive ingredient of alcoholic drinks.

Alcohol dependence A cluster of behavioural, cognitive and physiological factors including craving alcohol, tolerance, continuing to drink despite experiencing the harmful consequences and prioritising alcohol consumption over other activities and obligations.

Alcohol misuse A term used to capture both alcohol dependence and higher-risk ('harmful') drinking.

Alcohol use disorder(s) A range of alcohol-related mental health problems including alcohol dependence, higher-risk drinking (previously harmful drinking) and increased risk drinking (previously hazardous drinking) recognised in the international disease classification systems [*International Statistical Classification of Diseases and Related Health Problems*, Tenth Revision (ICD-10), and *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition (DSM-IV)].

Alcohol Use Disorders Identification Test A validated alcohol screening tool to assess the presence of increased risk and higher-risk alcohol consumption and to identify possible instances of alcohol dependence requiring further assessment.

Alcohol Use Disorders Identification Test Consumption A validated alcohol screening tool consisting of the three consumption-focused questions (the first three questions) of the Alcohol Use Disorders Identification Test.

Alcohol withdrawal Physical symptoms resulting from a reduction in the amount of alcohol consumed or the complete cessation of alcohol consumption.

Alcoholic drink A beverage containing ethanol.

Binge drinking Single-occasion high-volume alcohol consumption, specifically the consumption of six or more units of alcohol on one occasion.

Blood alcohol concentration The concentration of alcohol in the blood.

CAGE questionnaire A four-question validated screening tool used to identify the presence of possible alcohol dependence.

Dependence See *Alcohol dependence*.

Feasibility study A research study used to assess the practicality of planned methods.

Harmful drinking Previously used to describe a pattern of alcohol consumption resulting in mental or physical harm. Now termed 'higher-risk' drinking.

Hazardous drinking Previously used to describe a pattern of alcohol consumption that increases an individual's risk of experiencing harm. Now termed 'increased risk' drinking.

Lower-risk drinking guidelines Guidelines set by the UK Government detailing amounts of alcohol and patterns of alcohol consumption that can be consumed without a serious impact on health.

Pilot randomised controlled trial A small-scale randomised controlled trial employed to determine the feasibility of a full trial and to inform the design of such a trial.

Preoperative assessment An assessment focused on identifying factors and comorbidities that may present a risk of complications during anaesthesia, during surgery or in the postoperative period.

Preoperative assessment clinic A hospital clinic dedicated to conducting assessments of patients prior to surgery.

Randomised controlled trial A trial in which individuals are randomly allocated to two or more groups, one of which (the control) is 'treatment as usual' or no treatment.

Randomised trial A trial in which individuals are randomly allocated to two or more groups.

Risky drinking Drinking alcohol in a way that increases the person's chance of experiencing physical, mental or social harm, specifically drinking in excess of the lower-risk drinking guidelines. In this report, the term it is used to capture both 'increased risk' and 'higher-risk' (formerly harmful and hazardous) drinking but not alcohol dependence.

Standard drink A measurement of alcoholic drinks. In the UK, one standard drink contains 8 g or 10 ml of ethanol and is equivalent to 1 unit.

Unit A standardised measurement of alcoholic drinks. One unit contains 8 g or 10 ml of ethanol.

List of abbreviations

AUDIT	Alcohol Use Disorders Identification Test	GP	general practitioner
AUDIT-C	Alcohol Use Disorders Identification Test Consumption	HCA	health-care assistant
BA	brief advice	HCP	health-care professional
BBI	brief behavioural intervention	LFT	liver function test
BCT	behaviour change technique	MAST	Michigan Alcoholism Screening Test
BI	brief intervention	NPT	normalisation process theory
BMI	body mass index	PA	preoperative assessment
COM-B	Capability, Opportunity and Motivation to perform a particular Behaviour	PAC	preoperative assessment clinic
CONSORT	Consolidated Standards of Reporting Trials	POMS	Post Operative Morbidity Survey
CQUIN	Commissioning for Quality and Innovation	RCT	randomised controlled trial
EQ-5D	EuroQol-5 Dimensions	SD	standard deviation
		TAU	treatment as usual
		TSC	Trial Steering Committee
		WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index

Plain English summary

Most patients undergoing knee and hip replacements are over 65 years old. Older patients have an increased risk of complications following surgery.

Heavy alcohol consumption in the weeks before surgery increases the risk of complications after surgery, which can extend recovery times. Advice that helps patients reduce their alcohol consumption before surgery may have benefits for recovery.

The PRE-OP BIRDS study had two parts: a feasibility study followed by a pilot randomised controlled trial with focus groups and an electronic survey used to characterise usual care in the preoperative assessment clinic.

The feasibility study took place at one hospital. It aimed to develop materials that help health-care professionals provide brief advice to patients on how to reduce alcohol consumption before surgery. This brief advice was delivered to eligible patients and the acceptability to staff and patients was assessed in interviews.

The pilot trial took place in three hospitals. Patients who agreed to take part were placed, by equal chance, into either a group that received usual care or a group that received usual care plus brief advice about reducing alcohol use. The aim was to count how many people agreed to take part and how many also agreed to complete a follow-up 6 months later. Interviews were carried out with patients and staff to explore their views on the intervention and the trial as a whole.

All of this information was collected to help decide if a future larger trial was possible. This work found that the tools used were acceptable to both patients and staff. Although the number of people who agreed to take part was smaller than hoped, almost all of those who took part also completed the 6-month follow-up. Therefore, a future larger trial was found to be possible, but some changes could be made to encourage more people to take part.

Scientific summary

Background

Increased preoperative alcohol consumption is associated with an increased risk of postoperative complications and extended length of hospital stay following surgery. Many of the physiological effects of alcohol consumption can be reduced or reversed within 2–7 weeks. As such, reducing alcohol consumption before surgery represents a modifiable target to improve postoperative outcomes. Previous evidence has identified a benefit of pharmacological interventions for alcohol cessation for dependent drinkers. However, aiming these interventions specifically at patients with preoperative alcohol dependency would have limited effect on outcomes, given that these patients represent only a small proportion of those at risk because of alcohol consumption.

By contrast, brief behavioural interventions have shown effectiveness in reducing alcohol consumption in the larger population of 'increased risk' and 'risky drinkers' in other health-care settings. These interventions may offer one method of addressing alcohol intake reduction in a significantly higher proportion of surgical patients, than concentrating on the alcohol dependent group, thereby increasing the possible impact on associated postoperative complications.

Our study aimed to investigate the feasibility and acceptability of a brief behavioural intervention to reduce alcohol consumption before surgery in patients being listed for elective orthopaedic surgery.

Objectives

The primary objectives of the project were to:

1. investigate the feasibility of introducing a screening process to assess adult preoperative drinking levels and to deliver a brief behavioural intervention adapted for the target population group
2. conduct a two-arm (brief behavioural intervention plus standard preoperative care vs. standard preoperative care alone) multicentre, pilot randomised controlled trial to test processes that would be used in a definitive trial and, hence, assess the feasibility of proceeding to a definitive trial
3. conduct focus groups and a national web-based survey to establish current treatment as usual regarding alcohol screening and intervention in preoperative assessment.

Each aspect of the project (feasibility, pilot randomised controlled trial, characterising treatment as usual) had its own specific secondary objectives.

Methods

This was a non-randomised feasibility study conducted at a single secondary care hospital site followed by a three-centre pilot randomised controlled trial.

The feasibility study commenced with a group training session that enabled health-care professionals employed in the preoperative assessment clinic to conduct screening and intervention. Following this, potential participants were approached in a surgical outpatient clinic and asked to complete the Alcohol Use Disorders Identification Test Consumption screening tool. Patients who screened eligible (Alcohol Use Disorders Identification Test Consumption score of ≥ 5 and drinking six or more standard drinks on a single occasion at least weekly) were provided with a verbal introduction to the study; those who expressed interest were provided with a copy of the

patient information sheet and completed the expression of interest form giving their permission to be contacted further about the study. Research staff contacted patients by telephone or e-mail to confirm ongoing interest in the study and arrange intervention delivery. On the day of the preoperative assessment, patients were met by a member of the research team and completed the consent process before completing the full Alcohol Use Disorders Identification Test questionnaire. Those who scored ≥ 8 , indicating that they were drinking at risky levels, received the brief behavioural intervention.

In the pilot randomised controlled trial, group training sessions covering the delivery of preoperative alcohol screening and brief intervention were provided to health-care professionals employed in the preoperative assessment clinic. Patients were initially approached either in a surgical outpatient clinic or by post and then by telephone and asked to complete Alcohol Use Disorders Identification Test Consumption screening. Patients who were screened as eligible (Alcohol Use Disorders Identification Test Consumption score of ≥ 5) were provided with a verbal introduction to the study. Those who expressed interest were given or sent a copy of the patient information sheet. Ongoing expression of interest was gauged after a minimum of 24 hours. Consent, randomisation, baseline assessment and, where appropriate, intervention were conducted in the preoperative assessment clinic. Patients were followed up at 1 week pre surgery (intervention group only), 1–3 days pre surgery, 3–5 days post surgery, 6 weeks post surgery and 6 months post intervention.

Patient and health-care professional participants had the option of participating in qualitative interviews about their experience of taking part in the trial.

In both the feasibility study and the pilot randomised controlled trial, intervention sessions were audio-recorded (when patients provided consent for this) and an assessment of the fidelity of delivery was carried out. Fidelity assessments employed a predefined standardised checklist of 18 behaviour change techniques.

Treatment as usual was characterised through focus groups ($n = 3$ groups) with health-care professionals involved in the surgical care pathway at the three sites included in the pilot randomised controlled trial ($n = 19$ participants) and a quantitative online survey of health-care professionals employed in preoperative assessment centres across the country.

Results

The initial recruitment of eligible patients to the feasibility study was low but improved with amendments to optimise the screening and recruitment process. Fifteen patients and nine health-care professionals consented to participate in the feasibility study, with 13 patients and three health-care professionals going on to participate in qualitative interviews about their experience of being involved in the study. Interviews identified the optimised screening and intervention processes as broadly acceptable. However, patient participants rejected any categorisation of themselves as 'risky drinkers' and showed poor understanding of the term 'standard drink'. Interviews with health-care professionals also identified some barriers to intervention delivery, including not having adequate time available and the need for regular delivery of interventions in order to gain experience and familiarity with the process.

Recruitment to the pilot randomised controlled trial was 85% of target, with 34% of eligible patients recruited to the trial. The most frequent reason patients were found ineligible was negative Alcohol Use Disorders Identification Test Consumption screen. The most frequent reasons eligible patients declined participation were lack of interest and not having enough time.

Retention at 6 months post consent was very high (96% at 6-month follow-up) and was complemented by small numbers of missing data on the proposed primary outcome measure (Alcohol Use Disorders Identification Test).

Compliance with randomisation was high, with 32 of the 33 patient participants allocated to the intervention arm receiving the intervention. Fidelity of delivery improved between the feasibility study (40%) and the pilot trial (65.9%). The delivery of behaviour change techniques aimed at increasing motivation to change was more consistent than the delivery of volitionally focused ones.

The results of the survey and focus groups show that treatment as usual relating to alcohol screening, availability of advice and availability of referral varies between individuals and sites, with few employing validated screening tools.

Conclusions

Preoperative alcohol screening using the Alcohol Use Disorders Identification Test Consumption and full Alcohol Use Disorders Identification Test is acceptable to patients and health-care professionals. Similarly, delivering a brief behavioural intervention in the preoperative assessment clinic is possible, and the intervention methods adopted were acceptable to patients and health-care professionals. The evidence supports the feasibility of a definitive trial to assess the effectiveness of these methods in bringing about reductions in preoperative alcohol consumption and secondary outcomes of surgical complications.

Trial registration

This trial is registered as ISRCTN36257982.

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Chapter 1 Introduction

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Structure of this report

This report documents a feasibility study and pilot randomised controlled trial (RCT) of brief behavioural interventions (BBIs) to reduce alcohol consumption before elective orthopaedic surgery.

Chapter 1 describes the context of the issue, considering postoperative complications and the role of the preoperative assessment clinic (PAC) in identifying and addressing surgical risk in the context of reducing postoperative complications. This is followed by a review of the literature regarding brief interventions (BIs) and alcohol-focused interventions in the perioperative period.

Chapter 2 details the development of the intervention, the intervention training package and research conducted to characterise the comparator condition of 'treatment as usual' (TAU).

Chapter 3 presents the methods and results from the feasibility study, including qualitative interviews with health-care professionals (HCPs) and patient participants.

Chapter 4 describes the methods and results of the pilot RCT, including rates of recruitment and retention of patient participants, rates of completion of outcome measures and qualitative work exploring the acceptability of processes to both patient and HCP participants.

The key findings of the project are summarised and discussed in *Chapter 5*, with conclusions and recommendations for future research presented in *Chapter 6*.

Background

Perioperative morbidity and mortality after elective surgery is an important public health issue.² Although surgical mortality is reducing worldwide,^{3,4} even at the lowest mortality rate estimation of 1.1%, the volume of surgery being performed means that approximately 85,000 patients per year will not survive to 30 days following surgery. By contrast, postoperative morbidity or ill health is more common than mortality and remains at a relatively consistent level across sites and over time.³ This clinical paradox has led to the accepted concept of 'failure to rescue', whereby the failure to identify and treat complications at an early stage following surgery leads to early mortality.^{3,5}

Although overall mortality rates remain important in a global sense,² there has been a shift of focus to the reduction of morbidity after both high- and low-risk surgeries.⁵ Postoperative complications have profound implications in terms of both patient well-being⁴ and utilisation of health-care resource increasing the costs of surgery two- to threefold.^{2,6,7}

The spectrum of alcohol use from abstinence to dependence is broad and can be subdivided in a number of ways. The research and clinical literature has, and still does, employ a variety of terms, often interchangeably, to describe different patterns of drinking. Many of these terms are included in the *Glossary*. Terms of specific interest to this work are described here. In the UK, 'lower-risk' drinking is considered to be the consumption of ≤ 14 units of alcohol per week (1 unit is 8 g of alcohol), with additional guidelines specifying that drinks should be spread evenly over ≥ 3 days and that 'binge drinking' (i.e. the consumption of ≥ 6 units on a single occasion) should be avoided. Any drinking above this level can be considered to increase the risk of experiencing alcohol-related harm. The term 'increased risk' drinking has replaced the term 'hazardous drinking' and is used to describe patterns of alcohol consumption that exceed the lower-risk drinking guidelines and are associated with an increased risk of experiencing harm as a result of alcohol consumption, although actual harm may not yet have occurred. Regular consumption in the range of 15–35 units per week for women and 15–50 units per week for men would usually fall into this category.⁸ Higher-risk drinking, previously 'harmful drinking', is a pattern of alcohol consumption that results in harm to physical or mental health, with regular consumption in excess of 35 units per week for women and of 50 units per week for men.⁸

A number of screening tools have been developed to identify different patterns of alcohol use. One of the most frequently employed in health-care settings is the Alcohol Use Disorders Identification Test (AUDIT).^{9,10} The AUDIT, originally developed by the World Health Organization⁹ and validated for use in medical settings,¹¹ is a 10-item questionnaire that assesses alcohol consumption alongside social and health consequences of drinking behaviour and indications of possible alcohol dependence.¹² Scores range from 0 to 40 and a cut-off point of ≥ 8 has been found to have a sensitivity of 92% and a specificity of 94% for detecting increased risk or higher-risk drinking.⁹

Following the development of the AUDIT, a number of shorter variants have been developed. The Alcohol Use Disorders Identification Test Consumption (AUDIT-C) measure, which comprises the first three items of the AUDIT that focus on assessing frequency and volume of consumption as well as the frequency of high intensity or binge drinking,¹³ has been shown to have a similar level of accuracy,¹⁴ including validity and reliability, as the full AUDIT.^{13,15} With a cut-off point of 5, this measure has been found to have a sensitivity of 74% and a specificity of 83% for detecting increased risk drinking.¹⁶

Orthopaedic surgery and postoperative complications

Among the elective orthopaedic surgical population, average rates of mortality (0.2–0.6%)^{17–19} and morbidity (4–6%)^{17,20–22} are relatively low when compared with those for other surgical populations such as cardiac or abdominal surgery. However, orthopaedic surgery is a high-volume elective specialty,²³ meaning that even low rates of mortality and morbidity can have a significant population impact. In 2017, over 100,000 primary knee replacements and 90,000 total hip replacements were performed in England and Wales.²⁴ The most common complications include systemic infections and cardiovascular events (e.g. pulmonary embolism), deep-vein thrombosis, wound infections, wound dehiscence, perioperative fracture and nerve injury.^{17,22} In general non-cardiac surgery, any complication is associated with an average 101% increase in hospital costs.²⁵ In orthopaedic surgery specifically, surgical site infections are associated with, approximately, a 61% increase in costs.²⁶

In addition, many elective orthopaedic procedures are performed in an older population. Advancing age predisposes patients to an increased risk of acquired, multiple comorbidities, which in turn confer an increased risk of post-surgical complications. As life expectancy continues to increase, more orthopaedic procedures will be performed in older people, leading to an increase in overall surgical morbidity.^{17,22,27}

Any perioperative intervention that aims to reduce known preoperative risk factors that predispose patients to postoperative complications will be important in improving future postoperative outcomes.

The role of the preoperative assessment clinic

Preoperative assessment clinics aim to assess patients' suitability for elective surgery early in the surgical pathway through the detection, optimisation and modification of coexisting conditions. Indirectly, these clinics have been shown to reduce surgical cancellations and improve day-of-surgery arrival rates.²⁸ Importantly, they also provide an early opportunity to identify and address modifiable risk factors associated with postoperative complications, an approach often referred to as 'prehabilitation'. This approach has included interventions to improve nutritional status, correct diet-induced iron deficiency anaemia,²⁹ promote smoking cessation,³⁰ reduce anxiety,^{31,32} provide patients with information regarding the perioperative pathway^{33,34} and increase physical activity. Regarding the last, the promotion of structured exercise regimes has been shown to improve aerobic fitness^{35,36} and enhance functional capacity both pre- and postoperatively in total knee arthroplasty patients³⁷ and decrease length of stay in hospital for adult surgical patients across a range of specialties.³⁸

Preoperative alcohol intake also represents an important target for modifiable risk factor reduction. Subsequent sections of this chapter present existing literature concerning the association of alcohol consumption and postoperative outcomes, the identification and management of alcohol consumption in the PAC and interventions that have been found to be effective in other clinical settings.

Alcohol consumption

Alcohol is a component cause of > 200 health conditions³⁹ and has a range of negative social consequences, including familial and relationship problems,⁴⁰ involvement in crime,^{41,42} loss of productivity and unemployment.^{43,44} Alcohol consumption is a leading cause of ill health globally, accounting for an estimated 4.2% of the global burden, of disease and injury.⁴⁵ In addition, alcohol-related harm represents a large economic burden, with the combined cost of alcohol-related health harms, crime, antisocial behaviour and loss of productivity in England estimated at £21B in 2012.⁴⁶ Both volume of consumption and drinking pattern are important predictors of alcohol-related health harms.⁴⁵

With a dose–response relationship between alcohol consumption and many forms of harm, those who consume the most alcohol, including those who are alcohol dependent, undoubtedly experience the highest levels of alcohol-related harm at the individual level. However, because a far greater number of individuals drink at increased risk and higher-risk levels, it is these drinking patterns that account for the largest proportion of population-level alcohol-related harm.⁴⁷ Therefore, it is this group, who drink in excess of the lower-risk guidelines but are not alcohol dependent, who are a primary target of interventions seeking to minimise alcohol-related harm,⁴⁸ a phenomenon known as the prevention paradox.

Alcohol consumption and postoperative complications

The physiological effects of alcohol (e.g. liver damage, risk of accidental injury) may directly result in a need for surgery, or may indirectly increase surgical risk. Of specific concern are systems that are inhibited by both alcohol consumption and surgery. These include the haemostatic, immune, cardiac and endocrine systems.⁴⁹ The same mechanisms by which moderate alcohol consumption can protect against the formation of blood clots⁵⁰ also place those with increased levels of alcohol consumption at increased risk of prolonged bleeding during and after surgical procedures.⁵¹ Reduced immune system function as a result of alcohol consumption is further inhibited by surgery⁵² and leaves the patient susceptible to both surgical site and systemic infections; subclinical cardiac insufficiency and arrhythmias⁵³ present increased risks of cardiac complications and an altered endocrine stress response^{49,51} may also increase the risk of complications.

With this myriad of physiological effects of alcohol, it is not surprising that studies have identified associations between alcohol intake and perioperative complication rates across a wide range of surgical procedures (e.g. cardiac, orthopaedic and gastric). The complications most frequently associated with alcohol use are infection, sepsis, bleeding, cardiac events and deep-vein thrombosis.^{51,54,55}

Within this literature, a number of studies have focused on those consuming ≥ 60 g of alcohol per day and those identified as having alcohol use disorders (AUDs) or alcohol dependence.^{52,56} In 1999, a review⁵¹ identified a two- to threefold increase in postoperative morbidity among individuals consuming > 60 g of alcohol per day for a minimum period of 'several months'. However, the risk of increased postoperative complication rates may not be limited to those identified as 'alcohol misusers' or those with alcohol use disorder. Comparison of postoperative complication rates with scores on validated alcohol screening tools has demonstrated that the incidence of complications increases with increased screening scores among all adult drinkers. Bradley *et al.*⁵⁷ identified that patients with an AUDIT-C score of ≥ 5 (score range 0–12) were at increased risk of postoperative complications. Complication rates increased from 5.6% for those scoring 0–4 on AUDIT-C to 14% for those scoring 11–12 on the screening tool.

In 2013, a review conducted by Eliassen *et al.*⁵⁸ assessed the association between preoperative alcohol consumption and postoperative complications across a wider population of drinkers than were included in the review by Tønnesen and Kehlet.⁵¹ They found that alcohol consumption (of 24 g per day for women and 36 g per day for men) was associated with increased rates of postoperative complications, including a 23% increased risk of wound complications, an 80% increased risk of pulmonary complications, a 24% increased risk of prolonged hospital stay and a 29% increased risk of intensive care admission. Furthermore, high, but not low to moderate (< 24 g per day for women and < 36 g per day for men), alcohol consumption was associated with increased mortality. Two similar reviews by Wåhlin and Tønnesen⁵⁹ and Shabanzadeh and Sørensen⁶⁰ in 2014 and 2015, respectively, concluded that the consumption of two or more standard drinks per day is enough to increase the rate of postoperative complications.

This pattern of dose-dependent association of alcohol intake with postoperative complications is also reported in orthopaedic surgical populations. Among patients undergoing total hip or knee arthroplasty, those with high levels of alcohol use showed significantly higher incidences of complications (12 out of 15 assessed),⁶¹ with an overall complication rate of 33.5% among alcohol misusers compared with 22.6% in their non-alcohol-misusing counterparts. This population was also found to have significantly longer stays in hospital.⁶¹ Another study⁶² reported a 29% increase in the number of complications for every additional point on the AUDIT screening tool in patients undergoing total joint arthroplasty. This is also supported by the results of a registry-based study that considered patients who reported abstinence, low to moderate or high alcohol consumption and found a similar dose-dependent association with rates of mortality and morbidity.⁶³

With a strong evidence base for an association between increased alcohol consumption and increased rates of postoperative complications, it is reasonable to suggest that interventions that reduce or cease alcohol consumption in the preoperative period may result in fewer complications and better postoperative outcomes. Existing literature suggests that many of the physiological effects of increased alcohol consumption thought to explain the increased risk of postoperative complications may be improved or entirely reversed within a relatively short period of alcohol cessation (between 2 weeks and 3 months depending on the specific effect considered).^{51,64,65} The effects of reduction rather than cessation of alcohol consumption are less clear.

Achieving such improvements requires two key things: first, clinicians must be able to effectively identify patients at increased risk of perioperative complications as a result of alcohol consumption and, second, they must be able to provide an acceptable and effective intervention to bring about timely changes in alcohol consumption behaviour.

Preoperative alcohol screening

Although the assessment of alcohol consumption is part of standard care in preoperative assessment (PA), the use of validated screening tools is not widespread. Until recently, the more formal validated screening tools developed to assess of alcohol consumption (e.g. AUDIT, AUDIT-C), had not been employed in the preoperative setting.

Concerning the detection of alcoholism in the preoperative period, Martin *et al.*⁶⁶ found that routine practice identified only 16% of alcohol-dependent patients at the first visit, although this increased to 34% if the patient was seen three or more times in the preoperative period. When a screening questionnaire was used, the rates of detection on first visit were much higher (64%).

Because alcohol-dependent patients are at highest risk of intra- and postoperative complications and are at risk of the life-threatening complication of experiencing alcohol withdrawal syndrome, it is critical that they be identified and effectively managed in the preoperative period. However, they represent only a small proportion of those who may be at increased risk as a result of alcohol consumption. Kip *et al.*⁶⁷ considered a wider range of AUDs and compared detection rates from screening with computerised AUDIT questionnaire with those from anaesthesiologist assessment. The findings support those of Martin *et al.*,⁶⁶ with only 17.4% of patients who were found to be AUDIT positive (score of ≥ 8) also detected by anaesthesiologists. In addition, although anaesthesiologists were reliably able to detect patients who showed signs of dependence (25.2%), the patients with harmful (20%) or hazardous (17.2%) drinking were not detected. Furthermore, subgroup analysis found that anaesthesiologists were significantly less likely to identify AUDs in women and those aged < 50 years.⁶⁷

Among both elective and emergency orthopaedic surgical patients in Australia, 34% were identified as having hazardous drinking behaviour using the AUDIT questionnaire but only 38% of these patients reported a history of problematic alcohol consumption,⁶⁸ indicating that a majority of those drinking at hazardous levels may be unaware that their drinking could represent a risk to their health.

In combination, these findings demonstrate that utilisation of validated screening tools in the preoperative period is likely to increase detection rates of AUDs across the spectrum.

Alcohol screening using validated screening tools has been shown to have good patient acceptance in both preoperative and wider health-care settings.^{57,62,68–70} Indeed, the need to improve detection rates for increased risk alcohol consumption (and smoking behaviour) in hospitals has been recognised in the UK, where the Commissioning for Quality and Innovation (CQUIN) has identified these health behaviours as a priority.

The CQUIN framework aims to improve care by providing financial incentives to health-care providers in the UK who demonstrate delivery of quality and innovation in prespecified areas. The 2017–19 CQUIN targets include a goal to support people to change their behaviour in order to reduce the risk to their health from alcohol and tobacco use through identification, advice and referral to specialist services for inpatients in all acute trusts.⁷¹ Regarding alcohol consumption, the CQUIN promotes screening with the AUDIT-C questionnaire followed by delivery of brief advice (BA) to those identified as increased risk or higher-risk drinkers and the referral of those identified as alcohol dependent. Although PA is an outpatient appointment, patients are subsequently admitted as inpatients for the surgical procedure. Thus, the PA provides an important opportunity for the CQUIN screening, intervention and referral package to be implemented earlier in the surgical pathway.

Preoperative alcohol cessation interventions

A small number of studies have considered interventions concerned with bringing about preoperative alcohol cessation among heavy drinkers with a minimum level alcohol consumption equivalent to between 4.5 and 7.5 units per day (36–60 g of alcohol) or 31.5 and 52.5 units per week (252–420 g of alcohol). The results of three RCTs (one published,⁶⁴ two unpublished^{72,73}) that targeted alcohol cessation in the preoperative period have been included in the most recent update of the Cochrane review concerning preoperative alcohol cessation interventions.⁷⁴ All three trials employed intensive interventions, including the provision of disulfiram (Antabuse® Pliva, East Hanover, NJ, USA), and aimed to achieve between 1 and 3 months of alcohol abstinence prior to surgery. Two trials also offered chlordiazepoxide hydrochloride for

the treatment of withdrawal symptoms and provided motivational counselling each week, with staff available for telephone contact if required.^{72,73} All three trials identified significantly higher rates of abstinence in the intervention groups than in the control. An associated finding of lower rates of postoperative complications following intervention was not statistically significant. However, when pooled data were analysed,⁷⁴ there was a significant reduction in complication rates associated with reduced alcohol consumption immediately following completion of the intervention.

It is important to consider that all three of these trials were conducted in Denmark and results cannot be assumed to be generalisable to the UK setting. These trials are all concerned with individuals drinking at more than double the current UK lower-risk drinking guidelines, levels that suggest possible dependence, and thus require the provision of specialist support including pharmacotherapy. However, such intensive interventions are unlikely to be acceptable to, or appropriate for, patients drinking at increased risk levels (> 14 units per week). Because this group also confer additional risk as a result of their alcohol consumption, present for surgery in much greater numbers and are unlikely to recognise the risks associated with their own drinking behaviour, it is necessary to consider alternative, more appropriate interventions. BIs in the form of structured advice or behaviour change counselling, have been shown to be effective in bringing about reductions in alcohol consumption in other health-care settings, including primary and emergency care,^{75–77} and represent a potential alternative that could be employed in the PAC at relatively low cost and with minimal burden to the patient.

Brief alcohol interventions

The terms ‘brief intervention’, ‘brief behavioural intervention’ and ‘brief advice’ are often used interchangeably in the literature to describe short sessions of advice and/or behaviour change counselling that are usually delivered by a care provider. Such methods have frequently been used to address increased and higher-risk drinking behaviours. BIs usually last between 5 and 30 minutes with key intervention content including feedback on alcohol consumption often with comparison to social norms; identification of the drinker as the only one who can change their behaviour; identification of the potential harms of drinking behaviour and the potential benefits of reducing alcohol intake; advice about how to reduce alcohol consumption; and goal-setting or the development of a plan to reduce drinking. In addition to this content, the interventionist or care provider adopts a non-judgemental, empathic approach with roots in motivational enhancement therapy, which seeks to increase motivation to change and enhance self-efficacy. These core components and the associated therapeutic approach are summarised by the FRAMES (Feedback, Responsibility, Advice, Menu, Empathy, Self-efficacy) acronym.⁷⁸

Although research trials often identify decreases in alcohol consumption in both intervention and control groups (e.g. Fleming *et al.*⁷⁹ and Lock *et al.*⁸⁰), systematic reviews and meta-analyses have consistently identified positive effects of providing BI over and above changes in comparator groups.^{81–83} This approach has been most frequently studied in primary care settings, where the focus is on reducing alcohol consumption in the longer term.^{75,84,85} In these settings, BIs have been shown to result in an average reduction of between 20 g⁷⁵ and 38 g⁸² of alcohol per week (2.5–5 units) compared with control groups at 6–12 months post intervention.

However, the implementation of BIs into standard practice has been limited,⁸⁶ with a number of studies documenting barriers to implementation, including lack of resources, training and support.⁸⁷

There is now a small, but growing, body of evidence considering the use of BIs for alcohol consumption in other settings including general hospital wards^{76,88} and outpatient clinics.⁸⁹ A recent review and meta-analysis of interventions delivered to general hospital inpatients identified a significant benefit of BIs over control conditions in terms of reduction in alcohol consumption at 6 (–70 g per week) and 9 months (–183 g per week) post intervention as well as a reduction in mortality rates at 6-month (relative risk 0.42) and 1-year (relative risk 0.60) follow-up.⁷⁶ Meanwhile, it has been shown that screening and BI in

outpatient clinics can reach a large number of patients⁹⁰ and can result in significant reductions in alcohol consumption and in the percentage of hazardous drinkers (intervention, reduction from 60% to 27%; control, reduction from 54% to 51%).⁸⁹

With the implementation of BIs in primary care being limited, it is important to establish when and where such interventions can best be implemented in standard care. Previous research shows that patients are more accepting of health behaviour advice when it is delivered in an appropriate setting or linked to the presenting health condition.^{91,92} In some settings, such as emergency care, some level of alcohol-related harm may already be present (e.g. alcohol-related injuries). On the other hand, the PAC offers an opportunity to introduce the idea of health behaviour and behaviour change before many will have incurred any significant harm but when there is a positive, salient and temporally proximal focus (i.e. elective surgery). In other words, it offers a 'teachable moment'. The benefit of BIs targeting shorter-term changes in alcohol consumption (e.g. preoperative alcohol reduction or cessation) has not been widely studied and thus it is unclear what magnitude of effect is likely in such contexts. However, broader intervention studies predominantly show a higher level of behaviour change post intervention and at early follow-up (e.g. ≤ 3 months) than at longer-term follow-up (e.g. 12 months).⁹³

Further to this, the PAC patient population is both large and diverse, with most patients who receive elective surgeries being referred for at least some level of assessment. As such, the PAC offers an opportunity to screen and intervene with a large number of patients across a wide age range, many of whom may not frequently present to primary or emergency care.

If brief alcohol interventions are to be implemented in PACs, it is likely that they will be delivered by nurses rather than anaesthetists because the clinics tend to be nurse led. Although there is some evidence to suggest that physician-delivered interventions may be better received by patients,⁹¹ others have reported that nursing staff may be best placed to deliver interventions⁹² and that patients view interventions delivered by nursing staff as equivalent to those delivered by general practitioners (GPs).⁹⁴

Behavioural interventions in the preoperative period

To date, four trials have considered the effectiveness of behavioural interventions (including both brief and more extended interventions) targeting alcohol reduction or cessation in the preoperative period. The majority have included alcohol interventions as part of a multimodal intervention package targeting multiple health behaviours, which precludes firm decisions on the effectiveness of isolated intervention components for individual behaviours. The only trial to assess an alcohol intervention alone was reported by Shourie *et al.*⁹⁵ This trial commenced as a randomised trial but difficulty in recruiting patients at least 7 days before surgery led to the adoption of a non-randomised method whereby those with ≥ 7 days to surgery received the intervention and those with < 7 days to surgery were allocated to the control condition. The intervention employed was a revised version⁹⁶ of the manualised BI from the 'Drink-less' campaign,⁹⁷ which aimed to facilitate preoperative alcohol cessation. No significant intervention effect on alcohol consumption was demonstrated. This finding was attributed the intervention being delivered too close to surgery, thereby allowing too little time for either behaviour or physiological change. Three further trials used behavioural interventions targeting preoperative alcohol consumption as part of multimodal intervention packages. McHugh *et al.*⁹⁸ conducted a RCT with patients awaiting coronary artery bypass surgery. Patients allocated to the intervention group had their physical and mental health needs assessed and were provided with a tailored intervention package delivered in monthly health education sessions. Interventions targeted smoking, alcohol use, physical activity, diet, hypertension and hypercholesterolemia as indicated by screening and patients' readiness to change. In addition to providing advice and information, the interventionists used a 'pros and cons' approach to behaviour change, goal-setting and progress monitoring. Patients in the intervention group showed greater rates of smoking cessation, physical activity and weight loss than the control group and greater improvements in blood pressure. Alcohol consumption outcome data were not published in this original study report but were included in a subsequent review,⁹⁹ which

identified a significant group \times time interaction whereby the intervention group decreased their weekly alcohol consumption by 1.2 standard drinks per week between baseline and follow-up, whereas the control group showed an average increase of 1.3 drinks per week over the same period. With an average of > 8 months from trial entry to surgery date, patients had adequate time to implement behaviour change and observe positive health outcomes. However, the maintenance of change over an extended period, alongside the targeting of multiple health behaviours, presents its own difficulties.

Kummel *et al.*¹⁰⁰ conducted a RCT to assess the effects of guidance and counselling delivered in individual and group sessions on health behaviours in older (> 65 years) coronary artery bypass patients. Patients received one group session in the preoperative period and four sessions postoperatively. Sessions included health counselling, guidance and adjustment education, including information on risk factors for coronary heart disease, peer support and goal-setting. The primary focus of this intervention package was outcomes in the postoperative period rather than preoperative changes in health behaviour. The intervention was found to reduce alcohol consumption relative to baseline at 3-month follow-up, whereas the control group showed greater alcohol consumption at 6- and 12-month follow-up than at baseline.

The third trial¹⁰¹ assessing the effectiveness of a multimodal intervention package used a quasi-experimental design with patients referred for fast-track hip and knee arthroplasty. Patients were recruited over 4 months, with those undergoing surgery in the first 2 months of 2007 allocated to the control group and those receiving surgery in the next 2 months of the same year allocated to the intervention. The intervention involved completion of a preoperative risk-screening questionnaire, followed by a motivational conversation addressing identified risks with interventions for nutritional risk, physical activity, health, medication and alcohol use and/or smoking. Interventions for smoking and alcohol consumption involved the provision of information and identification of the potential benefits of stopping or abstaining in the preoperative period. Information leaflets about the identified risks were also provided. Findings showed a reduced number of 'unplanned' surgical pathways (including complications, readmission and mortality in the postoperative period) among intervention patients compared with controls. However, it is notable that only 4 of the 78 participants in the intervention condition were identified 'at risk' in terms of drinking more than the recommendations from the Danish National Board for Health (i.e. 21 units per week for men, 14 units per week for women).¹⁰¹ As a result, it is not possible to conclude what, if any, benefits were gained from identifying and intervening to address risky drinking in this population.

A further trial considered preoperative alcohol consumption as part of a multimodal 'prehabilitation' package and planned to provide interventions for risky drinking but did not identify any patients drinking at risky levels.¹⁰²

The four studies assessing behavioural interventions for alcohol consumption in the preoperative period have been drawn together in a narrative review conducted by Fernandez *et al.*⁹⁹ This review identified some positive findings, with two of the trials identifying significant reductions in alcohol consumption and one identifying a significant reduction in postoperative complications. However, it also highlighted a number of methodological weaknesses of the current evidence and made multiple recommendations for future research. They pointed to difficulties in recruitment across the trials. Specifically, the studies by Shourie *et al.*,⁹⁵ McHugh *et al.*⁹⁸ and Kummel *et al.*¹⁰⁰ took between 15 months and 3.5 years to recruit 117–136 participants. These issues were further exacerbated by the fact that rates of risky drinking in participants recruited to multimodal trials were low. For example, Hansen *et al.*¹⁰¹ identified just 4 out of 78 intervention participants as drinking above recommended guidelines and Kummel *et al.*¹⁰⁰ identified 12 out of 49 intervention patients and 21 out of 68 control patients as using alcohol at least once per week at baseline. This is in contrast to alcohol screening data, which identify 8–43% of surgical patients as screening positive for alcohol misuse,^{57,62–103} and rates increase to as high as 82% when considering surgeries for conditions strongly associated with alcohol use (e.g. head and neck tumour surgeries).¹⁰³ This suggests a number of possibilities: alcohol consumption levels may be much lower in certain surgical populations, those drinking at risky levels may be less likely to participate in intervention trials or alcohol consumption may be under-reported by trial participants. Fernandez *et al.*⁹⁹ recommend adopting clear, precise definitions of risky drinking and using unbiased screening to detect those drinking at risky levels.

Further recommendations resulting from this review⁹⁹ include assessing change in alcohol use preoperatively as well as postoperatively to allow the assessment of preoperative change on postoperative outcomes; a focus on the needs of older adults because the average age of trial participants is < 50 years; using empirically supported interventions and improving the reporting of both intervention content and fidelity of delivery; delivering interventions early enough in the preoperative care pathway to allow adequate time for behaviour change and subsequent pathophysiological improvement; and careful consideration of the sample size required to ensure adequately powered evaluations.

Feasibility and acceptability of preoperative screening and alcohol intervention

There has been limited work exploring the acceptability of screening and BI methods to patients and HCPs in the context of perioperative care. Acceptability has tended to be judged on rates of uptake of screening and interventions.^{57,62,68} Considering the difficulties experienced in recruiting patients to trials of preoperative alcohol interventions in previous studies, qualitative methods may provide important insight.

To the authors' knowledge, only two studies have used qualitative methods to provide more detailed findings regarding the acceptability of perioperative alcohol intervention methods. Pedersen *et al.*¹⁰⁴ carried out qualitative interviews to assess patients' views of the intervention materials and methods used in their trial of postoperative alcohol interventions following surgery for ankle fractures. Findings show that patients held positive views about the intervention in relation to surgery and the proposed materials. Approximately half of the patients interviewed reported that they were open to changing their drinking behaviour. The validity of these findings is restricted by the sampling technique. Specifically, patients interviewed did not receive the intervention as part of the trial but were presented with the intervention materials and asked to provide their views. Lauridsen *et al.*¹⁰⁵ interviewed 11 participants from the ongoing 'STOP-OP' trial of alcohol and smoking cessation interventions delivered to patients awaiting radical cystectomy. Of those interviewed, three had received an alcohol intervention alone and two had received both the smoking and the alcohol interventions. The authors reported that the interventions were well received and that patients perceived it to be a part of their treatment package rather than something separate or distinct. A number of facilitators of effective intervention were identified, including having intervention sessions scheduled alongside other appointments or delivered over the telephone, and the empathic approach of interventionists. Facilitators of alcohol and smoking cessation were also identified; these included aspects of undergoing surgery (e.g. hospital stay, nausea) that removed either the desire or the opportunity to smoke/drink, as well as a feeling of obligation to do what they could for their own health or to please family or HCPs who were 'invested' in the outcome of their surgery.

Despite the limited research in perioperative care, trials of BI for alcohol reduction and cessation in other contexts have assessed the acceptability of methods that may inform work in PA. Qualitative studies in other health-care settings support the findings of Pedersen *et al.*¹⁰⁴ and Lauridsen *et al.*,¹⁰⁵ with patients and staff expressing generally positive attitudes towards alcohol screening and intervention (HCPs^{106,107} and patients^{108,109}). However, they have also identified a number of barriers to alcohol screening and intervention in health-care settings. These barriers include logistical issues, having the necessary alcohol knowledge and having the required training and skills.^{106,110}

In combination, findings from these qualitative works suggest that alcohol screening and intervention is likely to be acceptable to patients, and that surgery may increase the salience of health behaviour change and facilitate change in the short term. However, there is a need for further exploration, and overcoming or addressing logistical barriers will be important to ensure effective implementation.

Outcomes of interest for trials of preoperative alcohol interventions

With previous research having identified that alcohol consumption in the preoperative period is associated with increased risk of postoperative complications, interventions leading to alcohol reduction or cessation in the preoperative period may reduce postoperative complications and improve outcomes. Therefore, the effectiveness of a preoperative alcohol intervention would be judged initially in terms of changes in alcohol consumption behaviour and, later, by any resultant reduction in complications or improvements in outcomes. A trial of a preoperative alcohol intervention should therefore include measures of alcohol consumption, complications and condition-specific as well as general health outcomes.

As detailed in *Background*, the AUDIT-C and full AUDIT tools are frequently used to screen for different patterns of drinking and to assess changes in drinking behaviour.

Regarding postoperative complications, two measures are frequently used in health-care settings: the Post Operative Morbidity Survey (POMS),¹¹¹ which collects data on minor complications related to postoperative pathways, and the Clavien–Dindo tool,¹¹² which classifies the presence of more significant postoperative complications.

Specific to the disease process requiring orthopaedic surgical intervention is the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC),¹¹³ which aims to evaluate the functional ability of patients with knee and hip osteoarthritis and includes items related to pain, stiffness and physical functioning of the affected joints. In addition, broader patient-reported health outcomes may be of interest. These are frequently assessed with quality-of-life¹¹⁴ questionnaires, such as the EuroQol-5 Dimensions (EQ-5D).^{114,115}

Characterising treatment as usual in preoperative assessment

In a setting where alcohol consumption is routinely assessed as part of TAU, it is important to clearly document the characteristics of TAU to allow accurate comparisons between that and any intervention delivered, and to ascertain whether or not the proposed intervention is in fact sufficiently different from TAU. A national survey¹¹⁶ of consultant anaesthetists involved in perioperative care found that the majority of PACs involve some form of alcohol screening, with almost half having alcohol intervention services available. However, the survey provided little detail of screening approach, or of the form and content of any interventions available. Although anaesthetists play a key role in leading PA units, the majority of PAs are conducted by nurses, who are therefore likely to be better placed to provide insight into the delivery of alcohol screening and intervention in PA.

Conclusions

Preoperative alcohol consumption is firmly associated with postoperative complications and poorer surgical outcomes and represents a modifiable risk factor suitable to be addressed using an appropriate presurgical intervention. Evidence exists to support the effectiveness of intensive interventions, combining pharmacological and behavioural aspects, in bringing about abstinence in heavy and dependent drinkers and leading to reduced rates of postoperative complications.^{64,72–74} However, these methods are unlikely to be either appropriate or acceptable for the majority of increased risk drinkers, who represent a greater proportion of the surgical patient population. Although there is evidence for the effectiveness of BIs in other settings (e.g. primary care, emergency care), less is known about the use of such methods in the preoperative period. Studies employing preoperative behavioural interventions have been confounded by several methodological issues, including:

- the use of multimodal interventions targeting a number of health behaviours^{98,100,101}
- poor reporting of the uptake, content and delivery^{98,100,101} of interventions
- small numbers of risky drinkers in the overall trial population¹⁰¹
- delivery of interventions close to the date of surgery, allowing little time for behaviour change⁹⁵
- the use of non-randomised study designs.⁹⁵

Given these limitations, drawing firm conclusions about the effectiveness of any intervention to reduce or cease alcohol consumption in the perioperative period is difficult, and further high-quality RCTs are required. In addition, with a number of the studies conducted to date having also identified issues with recruitment and having limited data regarding the acceptability of preoperative alcohol screening and intervention, it is important to explore the acceptability of proposed screening, recruitment and intervention methods with participants in order to optimise both research and intervention methods before seeking to assess effectiveness.

Aim and rationale

Summary of rationale

Brief behavioural interventions are effective in reducing alcohol consumption among increasing risk and risky drinkers and have been demonstrated to be acceptable to patients and HCPs in several clinical settings.

Upcoming major surgery provides an opportunity to deliver a BBI for reducing preoperative alcohol consumption. Reducing risky drinking preoperatively may have immediate benefits on short-term clinical outcomes after surgery. Sustained reductions in alcohol consumption are likely to support longer-term recovery, as alcohol has immunosuppressant effects. Furthermore, any such sustained changes would also decrease alcohol-related risk to future well-being in a predominantly older, orthopaedic population.

Aim

The overall aim of the project was to establish if a definitive trial of a BBI to reduce drinking prior to elective orthopaedic surgery is feasible.

Three overarching objectives reflected three sections of work, each of which had its own secondary objectives:

1. Characterise the intervention and comparator (TAU) conditions.
 - Train HCPs to deliver structured screening and BBI to eligible patients in the PA setting.
 - Assess fidelity of delivery of the BBI.
 - Characterise TAU in the PAC for elective orthopaedic surgery at the three pilot RCT sites using focus groups.
 - Characterise TAU for elective orthopaedic surgery at PACs nationally using a quantitative electronic survey.
2. Assess the feasibility and acceptability of consent, screening, intervention and outcome assessment procedures.
 - Optimise the screening and behavioural intervention process in a way that nurses and patients find acceptable.
3. Estimate rates of eligibility, recruitment and retention in a pilot RCT.
 - Assess completion rates for all data collection tools, including measures of alcohol consumption, quality of life and joint functionality.
 - Establish response variability of proposed outcome measures for a definitive trial, which will include drinking status and quality of life.
 - Estimate rates of secondary outcomes and perioperative complication rates, including bleeding and infections.
 - Explore the acceptability of intervention and research methods with HCPs and patients through qualitative interviews.

Patient, public and professional involvement

There was patient, public and professional involvement at all stages of the study from inception to completion.

Prior to commencement of the study, formative work conducted at the primary site provided initial estimates of screening uptake and eligibility based on an AUDIT score of ≥ 8 .

Prior to commencing the feasibility study, all patient materials were reviewed by members of a local patient and public involvement group, Voice North: (www.ncl.ac.uk/ageing/partners/internal_ageing/voice/; accessed 4 February 2019). Comments were used to inform amendments to the materials before they were submitted for relevant approvals.

Three members of this group expressed an interest in being involved in the Trial Steering Committee (TSC) and attended meetings during the research programme. When these members were unable to attend meetings they were sent a copy of the meeting minutes and asked to provide comments. Further to this, a member of the research team (EL) met with lay members to discuss proposed changes between the feasibility study and the pilot RCT phase to ensure that these were considered acceptable.

During the feasibility study, anecdotal feedback from researchers and HCPs involved in the screening and recruitment of patient participants was collected. With initial rates of recruitment being lower than anticipated, this information was used to inform the amendments made to the feasibility study processes. The proposed changes were then discussed with the lay members of the TSC before being submitted for approval.

Prior to commencing the feasibility study, researchers engaged with HCPs employed in PA to inform the design of the training session. The HCPs completed questionnaires identifying their training needs and the acceptability of the proposed training methods. HCPs were also asked to complete feedback questionnaires after the group training session was delivered.

Prior to commencing the pilot RCT, HCPs involved in pre-assessment at each of the three trial sites were invited to a launch meeting, where they had the opportunity to discuss the pilot RCT and consider how the research processes would be implemented at each site. Members of the research team also met with pre-assessment leads from each site. These meetings led to the decision to allow either face-to-face screening or postal invitations followed by telephone screening to minimise the impact of extended waiting times between listing for surgery and attendance at the PAC on recruitment times. With HCPs also explaining that some patients would attend satellite hospitals for follow-up appointments, the option to conduct follow-up visits over the telephone was also included in the pilot RCT.

Chapter 2 Defining the intervention and comparator

Introduction

When considering behavioural interventions to target alcohol consumption in the preoperative setting, a key limitation of the literature is the lack of information on intervention content.⁹⁹ This prevents intervention replication¹¹⁷ and further exploration of what makes an intervention effective. Furthermore, fidelity of intervention delivery has not been assessed in the trials reporting on behavioural interventions in the preoperative period.⁹⁹ This makes it difficult to determine whether or not the intervention was delivered as planned and, therefore, has implications for the assessment and interpretation of intervention effectiveness. Recent reviews of alcohol interventions further highlight the importance of clear reporting of intervention content.^{75,118}

The field of behavioural science offers a precise and systematic approach to reporting on the content of behavioural interventions. Specifically, the Behaviour Change Technique (BCT) Taxonomy v1¹¹⁹ provides standardised definitions of BCTs to make reporting more consistent across disciplines, allowing comparisons of interventions to be made. Accordingly, in the current study, the behavioural intervention delivered was described in terms of behavioural components (i.e. BCTs) and fidelity of delivery was assessed in terms of whether or not specific BCTs were delivered.

Although existing screening and intervention training packages are available, these are not specific to the PA setting. For this reason, adaptations were made to an existing package to provide HCPs with the knowledge and skills they required to deliver the screening and intervention during routine clinics.

This chapter provides an overview of the development of the intervention that was then delivered during the feasibility study and pilot RCT.

Aims

- Train HCPs to deliver structured screening and BBI to eligible patients in the PA setting.
- Assess fidelity of delivery of the BBI.
- Characterise TAU in the PAC for elective orthopaedic surgery at the three pilot RCT sites using focus groups.
- Characterise TAU for elective orthopaedic surgery at PACs nationally using a quantitative electronic survey.

Optimisation of screening and behavioural intervention process

Screening tool selection

Both the AUDIT⁶⁷ and the AUDIT-C⁶² have been used in studies in PA to report on the association of alcohol consumption with postoperative complication rates, and they have shown good patient acceptability.^{57,62,68} Therefore, either or both of these tools were considered appropriate for the current study.

Qualitative evidence⁹² has identified time and burden of new processes as key barriers to the implementation of alcohol screening and BI, and findings from alcohol screening studies conducted in PA have reported that the majority of patients drink at 'safe' or 'sensible' drinking levels.^{62,103} Therefore, it is appropriate to use a short initial screen (AUDIT-C) to identify potentially eligible patients, with the longer full AUDIT being used to inform intervention delivery and, potentially, the tailoring of intervention content.

Optimisation of the intervention tools

It is appropriate to adopt and adapt an intervention package that has demonstrated effectiveness in other health-care settings.⁷⁵ The 'How much is too much? Simple Structured Advice' and the 'How much is too much? Extended Brief Intervention' tools, originally developed by the World Health Organization for use in a collaborative study on alcohol screening and BI,¹²⁰ later revised for use in the UK as part of the Drink-Less Brief Intervention programme¹²¹ and subsequently updated and utilised in the Screening and Intervention Programme for Sensible Drinking (SIPS),⁸⁴ were adopted to guide the BBI. In addition, the Department of Health and Social Care's 'How much is too much?' booklet¹²² was used as a leaflet for patients to motivate and facilitate behaviour change after the session.

The most recent iteration of these intervention materials was reviewed by three members of the project team (EL, LA and CH) and revised in accordance with developments in alcohol intervention research and to maximise integration and acceptance among the orthopaedic surgical population and in the preoperative setting. The following amendments were made:

- The term 'unit' was replaced with 'standard drink' (standard drink = 1 unit = 8 g of pure alcohol) in accordance with current research and international agreement.
- Additional drink icons were included to indicate the alcohol content of standard drinks.
- The terms sensible, hazardous and harmful drinking were replaced with low, increased and high risk, respectively, to reflect the updated Department of Health and Social Care terminology.
- The graphic displaying normative drinking data was amended to show risk categories in place of alcohol disorders.
- Information relating to the common effects of alcohol use and the benefits of 'cutting down' was tailored to fit the pre-surgical population by including additional information about the relationship between alcohol use and immune function, recovery time and postoperative complications.
- The category of 'sensible drinking' was amended to include one single recommendation for both male and female drinkers, in line with updated guidelines.
- Information on avoiding alcohol when pregnant was removed as patients who were pregnant would not undergo this type of elective surgical procedure.
- Information about risks relating to alcohol consumption and the potential benefits of reducing drinking was reordered so that the items most relevant to surgery appeared first (e.g. risk of complications, potential for weight loss), followed by those most relevant to older patient populations.

The revised intervention materials were then circulated to members of the patient and public involvement group Voice North for their consideration and feedback. Comments on the patient booklet were reviewed, summarised and responded to. Changes made were as follows:

- Addition of 'when you get bad news' to the list of examples of difficult times.
- Replacement of the previous logo with a project-specific logo.
- Specification that goal-setting and behavioural monitoring would work only if individuals were honest about their consumption.
- Clarification that the amount of alcohol in a drink depends on the size and strength of the drink.
- Rewording of the definition of a small glass of wine from '8–10% alcohol by volume in a 125 ml glass' to 'a 125 ml glass of wine (8–10% alcohol by volume)'.

No comments on the simple structured advice or extended BI tools were received, so no further amendments were made to these. For the purposes of this study, and to avoid confusion with previous iterations, the tools were renamed as follows:

- BA tool – formerly the 'How much is too much? Simple Structured Advice' tool
- BI tool – formerly the 'How much is too much? Extended Brief Intervention' tool
- patient leaflet – formerly the Department of Health and Social Care's 'How much is too much?' booklet.

Once changes had been made in response to comments, the content of the intervention tools was coded in terms of BCTs (see *Appendix 1*).

Description of intervention delivery

The AUDIT-C, with a cut-off point of 5, was employed as an initial screen to identify potentially eligible patients. After patients provided informed consent to participate, the full AUDIT, with a cut-off point of 8, was used to assess baseline alcohol use and identify those eligible to receive the intervention. The intervention was designed to be delivered in up to two sessions, the first to be delivered face to face in the PAC. The second, an optional booster, could be delivered either over the telephone or face to face in the PAC (as per patient preference) approximately 1 week before surgery. The screening and intervention tools were used to guide the content of the sessions, and HCPs were also trained in the use of brief motivational techniques to enhance motivation to change, which helped guide the style of delivery.

The first session lasted up to 30 minutes and was delivered following completion of the full AUDIT questionnaire. The outcome of AUDIT was used to provide patients with their screening score and feedback in relation to this (i.e. whether this related to low- or high-risk drinking behaviour). This was followed by 5 minutes of structured BA using the BA tool. The BA delivered was designed to be tailored to individual patients. As such, patients were asked about existing knowledge of alcohol consumption and its effects to avoid the delivery of information that might not be relevant or appropriate. BA could include information about the lower-risk drinking guidelines, explanation of the term 'standard drink', normative comparison of drinking behaviour, feedback on risk including risk of postoperative complication, the potential benefits of reducing alcohol consumption and strategies that could be used to reduce drinking (e.g. goal-setting). This component of the intervention targeted motivation by providing information to increase intention to make behavioural changes. The remainder of the intervention session (15–20 minutes) involved the delivery of a behaviour change intervention that aimed to target volition (i.e. enactment of behaviour change). This component of the intervention could cover assessment of motivation and confidence to change drinking behaviour; identification of the pros and cons of changing drinking behaviour; goal-setting, problem-solving and action planning; and identification of sources of social support. Patient participants were given copies of the BA and BI tools, as well as a copy of the patient leaflet.

As a follow-up to the intervention described above, patients were offered an optional booster session. Patient participants either consented or declined to be contacted about the booster session during initial informed consent. Those who consented were contacted approximately 1 week before surgery, when their interest in the booster session was confirmed and a suitable date and time to receive the booster session was arranged. The session could be delivered over the telephone or face to face in the PAC as per patient preference. The booster session commenced with patients completing the full AUDIT questionnaire to facilitate a review of their progress since delivery of the initial intervention. For patients who had previously set goals, these could be reviewed and revised if necessary. For those who had not yet set goals or made action plans, this session provided an opportunity to do so. The session aimed to prompt behaviour change maintenance for those who had made changes and increase self-efficacy with a view to making changes for those who had not.

The finalised BBI is summarised in *Table 1*.

Training development

The HCPs employed in PA at the primary site were involved in the development of the training to make sure it met their needs. The training was developed in accordance with the Behaviour Change Wheel¹²³ and the various components were selected based on a needs assessment using the Capability, Opportunity and Motivation to perform a particular Behaviour (COM-B)¹²⁴ and Theoretical Domains Framework.¹²⁵ The BCT Taxonomy version 1¹¹⁹ was then used to help select BCTs to help operationalise the theory within the training.

TABLE 1 Intervention Template for Intervention Description and Replication (TIDieR) summary

Item	Details
Name	Preoperative Behavioural Intervention to Reduce Drinking before elective orthopaedic Surgery (Preop BIRDS)
Why?	Preoperative alcohol consumption is related to increased risk of postoperative complications. The aim of the intervention is to support patients to reduce or cease alcohol consumption prior to elective orthopaedic surgery
What?	Materials: HCPs are trained to screen for increased risk alcohol consumption and to deliver the following behavioural intervention materials – BA tool, BI tool, patient leaflet Training also covers use of brief motivational techniques to increase motivation for change. Training of HCPs is supported by a training manual Procedures: the intervention is delivered over two sessions (the second is optional). The first session involves provision of 5 minutes of structured advice that aims to increase motivation via use of a 'BA sheet'. This is followed by delivery of a behaviour change intervention lasting 15–25 minutes using the BI sheet. This intervention targets volitional aspects of behaviour change. The aim of the second optional booster session is to review and/or revise behavioural goals, provide feedback on performance and discuss self-monitoring to increase self-efficacy. This session is also designed to allow those individuals who have shown an initial intention to make changes, but who have not formally set behavioural goal(s) and made plans, to do so if desired
Who provided?	HCPs employed in the PACs who received training in the delivery of screening and BBI
How?	The initial intervention session is delivered face to face during routine clinics. The second session, an optional booster, is delivered either face to face in clinic or over the telephone, depending on patient preference. All intervention sessions are delivered one to one
Where?	Intervention sessions are delivered during routine PACs. Where the patient opts to receive a booster session over the telephone, the HCP delivering the session calls from the PAC
When and how much?	The first session involving delivery of BA and BBI lasts approximately 30 minutes and is delivered during routine PACs once all clinical procedures have been completed. The second optional 'booster' session lasts approximately 20 minutes and is delivered around 1 week before surgery
Tailoring	Intervention materials incorporate specific BCTs that target intention formation and enactment of behaviour change (e.g. information on health consequences, social support, goal-setting behaviour, problem-solving, restructuring the physical environment). HCPs are trained to use these techniques to tailor the intervention to the needs and preferences of individual patients, for example providing information relevant to and requested by the patient and supporting them to set meaningful and realistic goals that fit in with their own specific circumstances. Brief motivational techniques are used by HCPs allow them to determine level of motivation to change and tailor the intervention to target motivation or volition at the appropriate times
How well?	Consultations with participating patients are audio-recorded to allow an assessment of skill acquisition and fidelity of delivery of the intervention post training. The aim is to improve fidelity of delivery by providing feedback to HCPs including aspects of intervention delivery that went well and where they could improve. A member of the research team provided feedback to each HCP following delivery of intervention sessions 2 and 4

The HCPs were asked to complete an adapted version of the COM–B self-evaluation questionnaire (see *Appendix 2*) containing 19 items designed to assess existing levels of COM–B, in this case to deliver alcohol screening and behavioural intervention to patients. They were asked to assess what they felt needed to change for that behaviour to occur. Tick boxes were provided for each question, with free-text boxes to collect additional information and context. Twelve HCPs completed and returned questionnaires (see *Appendix 3* for a summary of responses). Assessment of questionnaire responses identified that HCPs required support to increase all three domains (capability, opportunity, motivation). Having an understanding of why alcohol reduction or cessation was important in the preoperative period was seen as key to enhancing HCPs' motivation to deliver a screening and behavioural intervention, while also providing them with the capability to motivate patients to change their behaviour.

To enhance capability, HCPs reported that they needed training in the BBI and that this should include a clear plan of how to deliver it. In addition, HCPs requested supporting materials to facilitate intervention delivery that would include visual aids to help communicate information. The need for adequate 'protected' time in their appointment schedule to facilitate delivery was emphasised, as was knowing that all colleagues would work together to facilitate delivery of the intervention.

The TDF¹²⁵ was used to identify potential candidate techniques to address HCPs' training needs. The provision of education, training and modelling, along with the use of persuasion, incentivisation, and enablement, was identified as a potential component of the training package. To determine the acceptability of these methods to HCPs, the lead nurse from the primary site completed an amended version of the APEASE questionnaire (see *Appendix 4*), which assessed the anticipated affordability, practicability, effectiveness, acceptability, safety and equity of these techniques. All suggested techniques were found to be acceptable.

These techniques were subsequently used to guide the selection of training content in terms of BCTs.¹¹⁹ A draft training strategy describing how these BCTs would be delivered was developed and then expanded into a 2-hour face-to-face group training session with a supporting manual.

Training content

The group training sessions included the following components: education about alcohol consumption (i.e. recommended limits and accepted terms and definitions) and surgical outcomes; the potential benefits of delivering a BI for alcohol reduction/cessation during PAs (BCT – education about health consequences, information about social and environmental consequences, credible source); instructions on how to perform alcohol screening and intervention with demonstration videos (BCT – instructions on how to perform the behaviour, demonstration of behaviour); role-play activities to practice intervention delivery (BCT – behavioural practice/rehearsal, feedback on behaviour); brainstorming of potential barriers to delivery and formation of plans to address these (BCT – problem-solving); and a quiz and prize to test nurses' knowledge (BCT – material incentives). To allow tailoring of the intervention to the needs and preferences of individual patients, HCPs were trained to identify and use the BCTs embedded in the intervention tools, for example providing information relevant to and requested by the patient and supporting them to set meaningful and realistic goals. In addition, the training covered the use of brief motivational techniques to allow HCPs to determine the level of motivation to change and tailor the intervention to target motivation or volition at the appropriate times.

Training delivery

During the feasibility study, the training was delivered as a group session led by three psychologists (EL, LA and Sebastian Potthoff), each of whom covered different aspects of the training based on their own areas of expertise and experience. Microsoft PowerPoint® (Microsoft Corporation, Redmond, WA, USA) slides and video recordings of intervention delivery were used as visual aids during the training sessions. A training manual was also given to each staff member who attended the session alongside a copy of the screening and behavioural intervention tools.

When new staff members joined the study, additional training sessions were delivered by one of the psychologists (EL).

Evaluation of the training

The HCPs were asked to complete an evaluation form (see *Appendix 5*) on completion of the training. This asked them to indicate how strongly they agreed or disagreed with 15 statements relating to the delivery and content of the training as well as knowledge and skills gained. Responses were on a scale from 1 (strongly agree) to 5 (strongly disagree). Five of the 10 HCPs who attended completed the evaluation form. Feedback indicated that the training was enjoyable and well structured and that the content was appropriate, with adequate time allocated for questions and discussion. Although the training was considered beneficial for the delivery of screening and behavioural intervention during the study, it was not rated as beneficial for clinical practice more generally.

Fidelity of delivery: feasibility study

Fidelity of delivery was assessed during the feasibility study; the findings were used to document whether or not interventions were being delivered as intended and to inform further refinement of the intervention and training package. To facilitate skill acquisition and support effective delivery of interventions by HCPs, written feedback was provided on the initial intervention sessions delivered by each HCP. During the feasibility study, feedback was provided on sessions 1 and 4. However, following feedback from HCPs, this was amended to sessions 2 and 4 for the pilot RCT.

All intervention sessions were audio-recorded when the patient had provided consent for this. Recordings were transcribed verbatim and anonymised. Transcripts were read and independently coded by two members of the research team (EL and LA). Where applicable, feedback on skill acquisition and fidelity of delivery was constructed by the same two researchers (EL and LA). When fidelity of delivery was > 80%, written feedback was provided to the HCP. When fidelity of delivery was < 80%, the research associate (EL) contacted the HCP to arrange an additional, one-to-one, face-to-face feedback and training session, lasting up to 1 hour, to focus on components of the intervention that had been omitted when it might have been appropriate to deliver them.

When patient participants in sessions 1 and/or 4 did not consent to audio-recording, fidelity of delivery assessments were conducted and feedback was provided for the next recorded session.

Fidelity of delivery was assessed using a standardised checklist of 18 BCTs (those present in the intervention materials; see *Appendix 1*). As interventions were designed to be tailored, coders first rated which BCTs and counselling techniques were delivered before assessing whether or not they had been delivered appropriately (i.e. were BCTs delivered that best met the needs of the patient). This was to determine whether or not any BCTs had been delivered simply because they formed part of the intervention.

Of the 10 HCPs who consented to take part in the study, four went on to deliver intervention sessions. Staff allocation to each intervention varied based on shift patterns and availability. A total of nine initial intervention sessions were delivered during the study, with seven of these audio-recorded and assessed for fidelity of delivery.

All intervention sessions included delivery of BA, BI and the patient leaflet. Delivery of 9 of the 18 possible BCTs was coded as occurring. Specific content varied between sessions indicating tailoring of interventions. The most consistently delivered BCTs were information about health consequences (5.1), goal-setting behaviour (1.1), social support (unspecified) (3.1) and pros and cons (9.2).

Fidelity of delivery was low, with 20–50% (mean = 40%) of BCTs considered to be appropriate being successfully delivered. However, there were clear indications of attempts to deliver additional BCTs but, as delivery did not fully meet the definitions in the BCT Taxonomy v1, these were not coded.

Optimisation of the training package

Intervention and interview transcripts generated during the feasibility study were reviewed by three members of the project team in (EL, LA and CH) to identify barriers to effective intervention delivery and to inform revision of the training, screening and intervention package ahead of delivery during the pilot RCT. Barriers identified and addressed are detailed in *Table 2*.

Pilot randomised controlled trial training delivery

During the pilot RCT, training was delivered as group sessions led by two or three psychologists (EL, LA, and Sebastian Potthoff) (depending on availability). Training was delivered in two formats. Staff at the primary centre who had already been involved in the feasibility study received a shorter refresher version, covering aspects of the training that had been revised after the feasibility study and including revised project aims and objectives. The staff who had not participated in the feasibility trial (predominantly those from the two additional centres) received a longer training session that provided a more comprehensive

TABLE 2 Barriers identified and addressed post feasibility study

Barrier	Explanation	Addressed
Time lag between training and intervention	A substantial period of time elapsed between training and commencement of intervention delivery	Training in the pilot RCT phase to be delivered as close as possible to the commencement of screening and recruitment without risking delays to the project
Infrequent intervention delivery	With only a small number of patient participants recruited in the feasibility trial and consent rates fluctuating, intervention delivery occurred infrequently over a fairly extended period	The pilot RCT to include a greater number of patients and resolution of issues with recruitment during feasibility trial, which should lead to more consistent recruitment rates in the pilot RCT
Adequate time to deliver intervention	HCPs felt that they sometimes had to 'make time' to deliver the intervention and could be pressured if the clinic was not running to time or if other patients arrived either late or early for their appointments	Extended appointments to be arranged for research participants, with the participant attending ahead of their PA appointment to complete consent and randomisation processes and additional time for intervention delivery allocated. Each site in the pilot RCT to have a HCA available to aid facilitation of the intervention sessions
Identifying level of motivation	HCPs were not always able to identify how motivated patients were to change	Instruction on how to use the questions exploring motivation to change and confidence in changing behaviour, which appear in the BI tool, to identify how motivated patients are to change their behaviour. During training, explicitly identify skills HCPs already use that will help them to identify level of motivation, specifically 'listen, ask, think'
Tailoring intervention content to level of motivation	HCPs were aware that they should tailor the interventions but intervention transcripts showed they were not always successful in tailoring content to level of motivation	Additional educational aspect in the training to explain intervention aspects relevant to motivating patients or targeting volition. Addressed in expanded 'action-planning' section of the training
Tailoring screening and interventions to address screening reactivity	HCPs were not clear about how to tailor intervention sessions or how best to complete AUDIT questionnaires when patient participants had changed their drinking between initial screening and intervention delivery	Be explicit in training that initial AUDIT is concerned with drinking over the past 6 months. Include time scale for each AUDIT questionnaire on the questionnaire. Address this in the training session along with tailoring of the intervention to level of motivation
Delivery of BCTs attempted but not successful	BCTs 'social support', 'goal-setting' and 'problem-solving' were frequently attempted but not successfully delivered during interventions	Additional instruction provided on delivery of these BCTs. These examples were targeted in expanded coping planning section of the training

HCA, health-care assistant.

introduction to the project and information about the use of the screening and intervention package before covering areas that had not translated well from training to delivery at the primary centre in the feasibility study. As with the feasibility study, additional training sessions were arranged and delivered by Ellen Lynch if required.

Pilot randomised controlled trial intervention fidelity of delivery

Of the 11 HCPs who consented to participate in the pilot RCT, nine went on to deliver at least one intervention session. One HCP conducted screening only.

During the pilot RCT, HCPs delivering the intervention sessions were asked to record whether or not the patient attended the intervention session, which aspects of the intervention were delivered and whether or not the patient set any behavioural goals. These details are provided in *Table 3* and *Box 1*.

TABLE 3 Pilot RCT intervention details

Intervention aspect	Site						Total	
	1		2		3			
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Attended intervention	8	100	16	94.1	8	100	32	97.0
Consented to audio-recording	19	100	28	82.4	11	73.3	58	85.3
BA delivered	8	100	16	100	8	100	32	100
BI delivered	8	100	16	100	8	100	32	100
Patient leaflet given	8	100	17	100	8	100	33	100
Goals set	4	66.7	15	88.4	8	100	27	87.1

BOX 1 Goals set (verbatim)

Motivational goals

Health, does not want to gain weight as won't be as active, better recovery time and save money.

Weight, save money, feel better in the morning.

Healthy weight and for surgery.

Weight management and healthy lifestyle.

More money better outcome to reduce the risk of any complications in surgery and to reduce recovery time.

Volitional goals

Swap non-alcoholic drinks for usual drinks and leave environment for drinking (match day/pool nights).

Reduce drinking, at home and to start from today.

Reduce drinking from now and to try and stop drinking altogether.

Stop drinking for 2 days a week and to reduce intake by a third.

To reduce from seven pints per day to four by the surgery day.

To reduce intake to 10 units 1 week for surgery.

Try and reduce alcohol intake.

Reduce alcohol intake.

Reduce number of units of alcohol.

To still have a reduced intake of alcohol.

Other

Patient will see how it goes after intervention session.

Of the 33 patient participants allocated to the intervention arm, 32 attended the initial session and received BA, BBI and the patient leaflet. The remaining patient participant received the patient leaflet only. Twenty-seven of these participants also set goals, details of which were recorded for 16 patient participants and are provided in *Box 1*. The level of detail included in the goals varied. Goals can be broadly divided into two categories: motivationally focused goals, concerning the possible benefits of reduced alcohol consumption; and volitionally focused goals, which centred on methods of reducing alcohol consumption.

Patient participants were also asked to consent to their intervention session being audio-recorded to allow a fidelity of delivery assessment to be made. More than half of participants who consented to take part in the trial also consented to audio-recording of the session, and 17 of the intervention sessions delivered were audio-recorded (as patients consented to audio-recording before randomisation, the number consenting to recording exceeds the number allocated to receive the intervention).

As with the feasibility study, all audio-recorded sessions were transcribed verbatim and transcripts were assessed for fidelity of delivery. Written feedback was provided to HCPs based on early sessions (2 and 4) to facilitate skill acquisition and support effective intervention delivery. When patient participants in sessions 2 and/or 4 did not consent to audio-recording, feedback was provided for the next recorded session. The same standardised checklist developed during the feasibility study was used to code intervention content, and all transcripts were coded independently by two researchers (EL and LA).

Fidelity of delivery improved from the feasibility study to the pilot RCT (from 40% to 65.9%), with evidence of delivery of 13 out of 18 possible BCTs identified in coding and an average of 65.9% of BCTs considered to have been appropriately delivered. Specific content varied between sessions, indicating tailoring of interventions, but fidelity of delivery also varied among staff members, suggesting different levels of skill acquisition from training.

The BCTs that targeted motivation were most frequently coded as both appropriate and delivered. Specifically, those involving informing participants about the health, social and emotional consequences of alcohol consumption (5.1, 5.3, 5.6) were coded most frequently. Feedback on behaviour (2.2) in the form of an alcohol screening score was successfully delivered in the majority of sessions; however, feedback on the outcomes of behaviour (2.7), which would have been appropriate in all sessions, was never successfully delivered.

Delivery of BCTs that targeted volition (i.e. enactment of behaviour change) generated a less consistent picture: goal-setting (1.1) and social support unspecified (3.1) were frequently utilised/delivered, whereas pros and cons (9.2) and problem-solving (1.2) were frequently attempted but less often delivered successfully. Some volitionally focused BCTs were also those most frequently rated as not appropriate [restructuring the social environment (12.2), reducing exposure to cues for behaviour (12.3), behaviour substitution (8.2)], although motivationally focused social comparison (6.2) also fell into this grouping.

Characterising treatment as usual

This chapter concludes by reporting on a series of focus groups ($n = 3$ groups) and an electronic survey that were utilised to characterise 'TAU' in respect of screening and intervention for alcohol consumption in the context of PA for hip and knee arthroplasty.

Methods

A mixed-methods approach was adopted:

- During the feasibility study, focus groups were used to provide in-depth descriptions of PA for hip and knee arthroplasty in the three centres included in the pilot RCT.
- During the pilot RCT, a quantitative survey was used to gather data relating to alcohol screening and intervention in PACs across the UK.

Focus group methods

The HCPs were eligible to participate in focus group sessions if they were currently involved in the orthopaedic patient pathway in one of the three centres identified to take part in the pilot RCT. It should be noted that focus groups were held during the feasibility study recruitment period. As such, some HCPs from the primary site were already familiar with the project and a smaller number had been involved in screening and intervention delivery.

Potential participants were sent an e-mail inviting them to participate in one of the focus groups (one was held at each of the three sites). The HCPs who replied to indicate their intention to attend the sessions were sent an electronic version of the focus group information sheet (see *Appendix 6*) at least 24 hours in advance of the session.

Focus groups were conducted by the research associate (EL), who greeted each participant on arrival and provided hard copies of the information sheet for further consideration. Before the focus group discussion commenced she introduced herself to the group, providing a description of her research background and qualifications before giving a verbal introduction to the project and her role. As a result of her role in the feasibility study, the associate was already known to some HCPs from the primary site where she had been involved in training delivery and intervention feedback.

This personal introduction was followed by an explanation of the purpose of the focus group session (to establish TAU), ethics considerations and ground rules for the discussion. Participants then had the opportunity to ask any questions and to suggest any of their own ground rules for the session. Once all questions had been answered, participants completed informed consent forms (see *Appendix 7*), which included consent for the session to be audio-recorded.

Discussion commenced by asking the HCPs to introduce themselves and state their job role. The research associate then used a semistructured topic guide (see *Appendix 8*) to guide discussion to cover the preoperative care pathway, alcohol screening, alcohol intervention and referral, perceptions of the current approach to alcohol screening, previous experience of intervention delivery and acceptability of preoperative alcohol interventions.

Two hours were allocated per focus group, with the discussion itself lasting between 50 minutes and 1.5 hours.

All focus group recordings were transcribed verbatim and subject to framework analysis,¹²⁶ with a deductive approach adopted to focus on the characteristics of the 'TAU' condition. All transcripts were dual coded, with codes discussed and agreed periodically.

Survey methods

An electronic web-based survey was used to gather data from PA staff nationally regarding TAU, with a specific focus on alcohol screening and intervention in PA.

The electronic survey included 20 questions (see *Appendix 9*) that collected demographic details (age and gender) brief information about job role and experience (current job role, time employed in current role, total time employed in PA) and basic information about preoperative appointment length before proceeding to explore the current approach to alcohol screening and intervention, with fixed-response questions asking participants to indicate if alcohol screening, intervention and referral were conducted as part of PA, what form these took and how patients were identified for information provision or referral. Finally, participants were asked to indicate any previous or current involvement in intervention delivery for a number of health behaviours (alcohol, smoking, physical activity, diet or nutrition). Free-text response boxes were provided for participants to provide additional detail if they chose.

The link to the electronic survey was circulated to informal groups of PA HCPs, predominantly nurses and health-care assistants (HCAs), via an e-mail mailing list ($n = 22$ recipients) and a social media group ($n = 98$ members). On following the survey link, potential participants were presented with an electronic version of the survey information sheet. The next screen presented an electronic 'tick box' consent form, which asked participants to indicate their agreement to each point on the consent form. Participants had to agree to each statement before being able to proceed with the survey. The subsequent screens presented the survey questions, with branching logic applied to ensure that subquestions (e.g. detail of alcohol interventions) were displayed only if applicable. At the end of the survey, participants had the option to either submit or discard their responses. Finally, an electronic thank-you and debrief screen was presented. The survey took an average of 6 minutes to complete.

Data were subject to descriptive analysis only with frequency of each response category reported.

Results

Focus group results

A total of 19 HCPs, ranging from band 5 nurse to consultant anaesthetist, took part in the focus groups; all were female (*Table 4*).

Framework analysis of focus group transcripts revealed five key themes relating to TAU in PA for hip and knee arthroplasty.

TABLE 4 Focus group participants

Group	Participant	Job role	Site
1	1	PA nurse band 6	1
	2	PA nurse band 6	1
	3	Student nurse	1
	4	PA nurse band 6	3
	5	PA lead nurse	3
	6	Substance use lead	1
	7	PA nurse band 5	1
2	8	PA lead nurse	2
	9	PA sister	2
	10	PA sister	2
	11	PA sister	2
	12	PA sister	2
3	13	Consultant anaesthetist	3
	14	PA lead	3
	15	PA nurse band 6	3
	16	PA team leader	3
	17	PA nurse band 5	3
	18	PA nurse band 6	3
	19	PA nurse band 5	3

It's a big and busy appointment

The PA appointment for hip and knee arthroplasty was described as lasting 45 minutes at one site and 1 hour at the other two sites. However, staff identified that this could vary if patients were seen as 'walk rounds' immediately following listing for surgery where appointment length was seen to be dictated by 'supply and demand'. The HCPs identified a variety of tasks, tests and assessments that needed to be completed as part of PA for primary hip and knee arthroplasty. This included gathering information about health and social history as well as assessing a variety of physiological systems and considering medication management:

... you start off doing it's like a 'major form' that we use for pre-assessment of orthopaedics if it's a hip or a knee erm so you start off like with height, weight and obs and you do bloods and you do breathing tests and you do an ECG [electrocardiogram] and you do a full medical questionnaire, look at their drugs erm and ask them all sorts of questions ...

ID 1, PA nurse band 6, site 1

The HCPs expanded on this to explain that although the PA appointment was a demanding one for them, the burden on the patient was higher still, with a number of additional forms and assessments. Further to this, patients also have to see a number of HCPs, including occupational and physiotherapists, as well as the PA nurse:

They go for the ECG [electrocardiography] that's usually the last thing we do, get them to go for ECG when we're finished, give them the paperwork, they take that with them so they're busy looking at the paperwork and it's quite an in-depth questionnaire, tick-box questionnaire erm and then when they've done that, when they come back then the OT [occupational therapist] wants to see them, she takes them somewhere else, brings them back. So it's quite a, it seems like quite a long drawn-out assessment by that time they've had enough.

ID 1, PA nurse band 6, site 1

These numerous assessments and appointments were also seen to result in a large amount of information being provided to patients, both during the appointment and for them to read and consider in their own time. The HCPs expressed some concerns that this could be too much for patients and that elderly patients especially may not be able to process all of this information:

... you're giving them a lot of information, you're giving them an anaesthetic leaflet and a meds [medications] leaflet, they've got to sign two forms, you're giving them a leaflet to say why you're taking blood for transfusion and sometimes these elderly people maybe can't see what the hell you're talking about sometimes by the time you go away they've got bags of paperwork and they don't even know what they're doing with it ...

ID 1, PA nurse band 6, site 1

Despite concerns about the burden placed on patients, HCPs explained that the duration and intensity of the assessment process was necessary because of the complexity of the planned surgery as well as the nature of the orthopaedic patient population, who were considered to be older and more likely to have comorbid conditions:

... the majority still are elderly patients who have the nature of the beast is they've got other medical conditions going on anyway and they've got a drugs list like a roll of whatever, yeah so and that's a big thing as well we've got like a medication list that we instruct 'em about what drugs they can and can't take so those kind of things take quite a while [Interviewer: Yep] just for the type of patients they are ...

ID 1, PA nurse band 6, site 1

... it is a big PAC [pre-assessment], it is a major surgery and it needs to have the time and that credence to do it properly or else you're just skating around corners ...

ID 1, PA nurse band 6, site 1

In line with the purpose of PACs, the assessments conducted could be seen as focusing, first, on the identification of risk and, second, on the mitigation of these risks and the optimisation of the patient ahead of surgery. Factors identified included both known conditions and previously unidentified risks, with the identification of cardiac conditions being discussed by HCPs from all three sites:

... we may pick up on newly diagnosed heart problems and erm things so they may have to be referred to a cardiologist ...

ID 14, PA lead, site 3

... umm and as you said sometimes we see a lot of new atrial fibrillations, we see abnormal heart rhythms or they've got poor lung function or they're diabetic on insulin ...

ID 1, PA nurse band 6, site 1

Procedures to mitigate risks and optimise patients ahead of surgery addressed a number of factors; these included medication management, diabetes control and correction of anaemia:

... so the patients that are low in iron we transfuse them preoperatively with iron err so it optimises their post-op care ...

ID 5, PA lead nurse, site 3

... prior to surgery we do some medication management as well because we might have to stop certain drugs, may have to give them some erm injections prior to surgery to help thin the blood because we've stopped them having a particular drug ...

ID 14, PA lead, site 3

The only optimisation process identified that directly related to health behaviour was smoking cessation but one HCP identified that they expected to undertake further optimisation processes in the future:

... I know there's obviously plans afoot, you know pre-assessment's going to change and there's going to be more optimisation of patients ...

ID 1, PA nurse band 6, site 1

Having the time to identify and manage these different factors was seen to be the predominant reason for conducting PA well in advance of the date of surgery and this was explained to be important for avoiding cancellations:

The reason why we see them from same day in our same-day clinic is because it gives them weeks and weeks and weeks because in our patients we find that we've had a lot of brand new heart problems that weren't there before so it saves postponing the patients as well so we get all that sorted first, optimise the patient as much as possible before we give them a date for surgery.

ID 14, PA lead, site 3

The vast majority of the PA was described as being undertaken by members of the nursing team, who clearly identified themselves as responsible for requesting information and tests, interpreting the results and identifying how to proceed:

... that's really the nurse who is doing it what she does about it, whether she sees it as a red flag or not ...

ID 1, PA nurse band 6, site 1

However, staff from all three sites discussed the fact that anaesthetists were available to offer additional support for complex patients or to conduct further assessments when required:

Also we do have a, a consultant anaesthetist or an anaesthetist allocated every single day. [Interviewer: Yep] In case there's a patients who needs to see an anaesthetist so there's somebody available to see that patient 'cause others got concerns with their GAs [general anaesthetic] previous GA problems and things like that so we get them seen before they go home. And also he takes patient with complex is history via our anaesthetist to have a look and decide what to do . . .

ID 7, PA nurse band 5, site 1

Alcohol is asked about but not 'screened for'

Health-care professionals from all three sites explained that alcohol was 'always' asked about as part of the PA and that 'as long as you ask the question it needs to be answered'. However, none of the HCPs referred to this as 'screening' and none currently used validated alcohol screening tools. Instead, the PA form included a box to indicate how many units the patient consumed per week:

There isn't any screening but we are mindful of their intake. We always ask that.

ID 9, PA sister, site 2

. . . we do ask them how many units they will drink in an average week . . .

ID 16, PA team leader, site 3

Alcohol consumption did not appear to be a focus of PA, and HCPs described it as 'just another question'. There was some indication that HCPs felt that they could be doing more to assess and address alcohol consumption but that they were restricted by the amount of time available and the small amount of space on the PA form:

. . . really the space is just how many units a week it doesn't really give you that much scope. I mean you could go on if they say yeah I drink every night and whatever but it doesn't give you a lot of scope . . .

ID 1, PA nurse band 6, site 1

. . . you know really you could spend so long doing so much and making these things so much better but as it is, the way it is at the moment you just don't have the time or the resource to do it but I think you're just skipping over it . . .

ID 1, PA nurse band 6, site 1

The reliance on self-reports of alcohol consumption was seen as a potential issue. The HCPs discussed difficulties in gaining honest and accurate information from patients. They were of the opinion that some patients would be honest about their alcohol consumption whereas others would under-report or 'lie' about how much they drank. Reasons for under-reporting included being 'ashamed' and providing socially desirable responses, with some patients having a tendency to 'tell you what you want to hear':

But it's only what people say how many units you know you're just going by what they say [Interviewer: Mmm] some people will give you the minimum or just they'll tell you what you want to hear . . .

ID 1, PA nurse band 6, site 1

You have to rely on the honesty of the patient and sometimes if you are a heavy drinker you don't want to acknowledge it like others do. They are quite happy to tell you their units.

ID 9, PA sister, site 2

Some HCPs felt that older patients were more likely to be honest about their drinking and were often comfortable with the amount that they drank and did not see it as 'problematic' regardless of whether or not this was in excess of the recommended drinking guidelines. Reasons given for this included the fact

that drinking was part of their routine, that it was part of their social lives, that they had been drinking in a particular way for a long time and that significant others, including previous generations, had shown similar drinking patterns:

I think a lot of the older people that we get through and we ask they're like not proud of it but very confident they're like I go out three times a week and I have three pints every time they don't see that as a problem because it's what they've always done for years, that's what their dads done it's a social event for them they don't see that that's excessive because it's only three pints and it's only three times a week . . .

ID 2, PA nurse band 6, site 1

In some cases it was explained that patients' responses may be inaccurate not because they wanted to mislead the HCP but because they did not realise how much alcohol they were consuming until they were asked to report it day by day:

. . . then you've gotta say right so how many do you drink on a weekend when you add it up it's like two bottles of wine well that's 18 units, that's above and they go 'oh is it' . . .

ID 4, PA nurse band 6, site 3

Descriptions of frequency of drinking by patients were also often inconsistent with HCPs interpretations with perceptions of what constituted 'regular' drinking being particularly problematic:

They are totally oblivious, they're not bothered. I've had quite a few say oh I drink occasionally and you go well when would that be? 'On a Friday and Saturday.' Well that's not occasionally that's regular . . .

ID 16, PA team leader, site 3

In combination, these issues point to the need for HCPs to probe patients about alcohol consumption rather than simply ask how many units they drink per week if they are to gain accurate information. Despite identifying possible issues with self-reports of alcohol consumption, HCPs identified that patients were the only ones who would actually know how much alcohol they consumed and thus asking them was the best way to gain the required information:

. . . because nobody knows more than them if they are drinking more than they should be nobody knows more than them . . .

ID 6, substance use lead, site 1

Objective assessments of alcohol-related harm were available at all three sites in the form of liver function tests (LFTs) and HCPs from all three sites also talked about conducting LFTs as part of PA. However, this was not done for every patient but rather was an optional test that could be conducted for patients considered to have a high alcohol intake to provide a more detailed assessment of surgical risk:

We ask about their intake, how many units a week [Interviewer: Yeah, yeah] and if it was a massive amount, we would probably check their liver function.

ID 8, PA lead nurse, site 2

It's not what you ask, it's how you ask

The majority of HCPs were comfortable asking patients about alcohol consumption but explained that patient responses to questions about alcohol consumption varied with some being very comfortable and others being more reluctant or defensive:

ID 1: . . . it's all, its variable isn't it?

ID 7: . . . it's different . . .

ID 3: . . . you get some that are really defensive when you ask . . .

ID 1, ID 7, ID 3, site 1

I think our patient population here, err they're very down to earth, they're very laid back. Yeah I think it's quite easy to ask them questions like that.

ID 13, consultant anaesthetist, site 3

Some HCPs explained that patients would laugh or offer joke responses, which they appeared to interpret as an indication of patients being comfortable with the questions but could also be considered a defensive response:

ID 8: *They usually laugh.*

ID 12: *Yes.*

ID 11: *I was gonna say laugh . . .*

ID 9: *Or they say, 'Do you want the truth?'*

ID 8, ID 12, ID 11, ID 9, site 2

However, HCPs explained that alcohol could be a sensitive subject for some patients and that how the questions were asked was important. Asking questions about alcohol use in among a large number of other questions and once a rapport had been established were seen as ways to reduce the possibility of adverse responses. HCPs also talked about different methods of 'selling' the questions to patients with techniques such as explaining that the questions were routine and pointing out the relevance of the questions to their health or the planned surgery being discussed:

I know it can be a bit of embarrassment but don't worry we ask everybody it' it's just that's how I sell it as . . .

ID 6, substance use lead, site 1

. . . it's really important we know how much alcohol you have because that really can affect your general anaesthetic we need to know whether to bring you in a day early do we need to you know we need to look after you, we need to make sure that you're fine you know we don't want anything going wrong while you're here.

ID 6, substance use lead, site 1

The fact that alcohol consumption was routinely asked about was not only a way of assuaging patients' anxiety about the questions but also meant that HCPs became experienced in asking about alcohol consumption, which was seen to be beneficial:

I've done this a long time so it's kind of you know it's not too difficult a conversation for me to have because I'm used to broaching it . . .

ID 6, substance use lead, site 1

This experience meant that HCPs had been able to develop the skills necessary to broach the subject of alcohol consumption effectively. Skills described as important included adopting a non-judgemental approach and knowing when to 'take a step back':

I think if people felt you were challenging them and didn't like it I think we would always, sort of, be aware of when to draw back a bit because if they don't want you to know and they don't want to tell you, you feel like you are invading their privacy . . .

ID 9, PA sister, site 2

... it's about as well I think saying to people this is not about judging you ...

ID 6, substance use lead, site 1

In addition to the experience and skills of the HCPs, patients' acceptance of questions about alcohol use was considered to relate to the reason that they were attending the PA. The orthopaedic population were seen to have a strong desire to have their surgery and HCPs explained that many patients were in pain and would have waited a long time for surgery. This was seen to make them more compliant:

ID 6: Yeah, yeah] you know they're a [Interviewer: Ah hu] they are willing and they're sitting there listening to you ...

ID 2: ... they want their operation ...

ID 1: ... they'll do anything to get it ...

ID 6, ID 2 and ID 1, site 1

Managing preoperative alcohol consumption

The HCPs talked about a number of different strategies that were available for the management of alcohol consumption in the preoperative period. How alcohol consumption was managed appeared to be dependent on the amount of alcohol being consumed. Patients who were drinking more than the drinking guidelines were often advised simply that it would be beneficial to reduce their alcohol consumption:

I just say someone who drinks like 30-odd units a week I just say something like 'that's above the national guidelines have you thought about cutting down?' ...

ID 5, PA lead nurse, site 3

All three sites also had alcohol specialist or alcohol liaison nurses to whom they could refer patients who required additional support to reduce their drinking. However, not all of the PA staff were aware of this service, perhaps because outpatient clinics were not focus points for identifying increased risk or dependent drinkers. Further to this, many of those who were aware reported that their patients consistently declined any offer of support from this service:

... we ask them if they would like any further information, you know once we've pointed out that that is over the national guideline limit and erm they all say no ...

ID 14, PA lead, site 3

The HCPs reported that those patients who were viewed to be drinking to excess or those identified through LFTs would be referred on regardless of their preference. In some cases, patients would be referred to an anaesthetist who would either review the patient's notes or see the patient in person to further assess their surgical risk and decide how to manage them:

... if that flags up through the like bloods or whatever you've taken [Interviewer: Yeah, yeah] and then alcohol erm anaesthetic review ...

ID 2, PA nurse band 6, site 1

Alternatively, patients could be referred to the alcohol specialist nurses to help them prepare for surgery rather than to support them in reducing their drinking. Such management often involved a more in-depth assessment of alcohol consumption and then preparations to bring the patient into hospital a day before their surgery date so that withdrawal could be managed and surgery could proceed as planned:

... how are they when they've not been drinking [Interviewer: Mmhmm] because that's gonna guide you when they're gonna be nil by mouth and whether you're gonna have to get some meds [medications] prescribed or whether you need to be advising this chap will need to come in early or

we need to be prepared or do they need to have a conversation or do they need to come back to have a full intervention . . .

ID 6, substance use lead, site 1

This option was considered to be only for the 'big drinkers' who were thought to be unlikely or unable to change, indicating possible alcohol dependence:

We do have somebody but that tends to be for if they're you know drinking loads [Interviewer: Yeah] like need detox or something. Not for your erm not for the vast majority of patients . . .

ID 1, PA nurse band 6, site 1

The option to refer patients back to their GP was also discussed by some HCPs, albeit less frequently than other options. The description of patients being 'referred back' to the GP suggested that surgery would be postponed until the GP had seen and reassessed the patient:

It would be referral onto the anaesthetist for him and then he would make a decision as to whether they needed referring on or back to the GP for further advice.

ID 8, PA lead nurse, site 2

It was clear from the descriptions offered by HCPs that, although measures were in place to ensure the safety of patients who showed signs of alcohol dependence, little provision was made for those drinking at 'risky' or 'increased risk' levels:

The ones I've referred are the ones who would be having a bottle of vodka every night, not the ones who would be having, sharing a bottle of wine with their husband every night, that just is gets ignored really. Not ignored but you would still do certain blood tests but it it's the big drinkers like hundreds of units that get referred . . .

ID 18, PA nurse band 6, site 3

. . . there's nothing really in place for this group of patients as it stands at the moment because they're not so high risk that you're concerned about their perioperative period you, you know you accept it that I think there's such a big proportion of people that fall into this category that it becomes normal erm I think if you can say to patients we're trying to do this because we're worried it's going to take your wound longer to heal or you're more at risk of getting an infection afterwards then to be able to say something like that you know 15-minute chat and if you reduce for 6 weeks it might improve your outcome that's very different . . .

ID 13, consultant anaesthetist, site 3

Could be more, could be better

The descriptions of alcohol screening and management in PA showed variation in practice both between and within the three sites. Although some assessment of alcohol consumption was part of formal PA at each of the three sites, there did not appear to be any clear or consistent guidelines as to what to do in response to this questioning. Individual HCPs tended to talk about 'big drinkers', 'excessive drinkers' and those consuming 'a massive amount' as being referred for review or identified as requiring LFTs. Otherwise, in the absence of specific guidelines and procedures, the HCPs drew on their own training and experience to make decisions about how to manage alcohol consumption in the preoperative period:

. . . it is very much what the nurse does herself but you know we are all obviously trained enough to know that someone who drank god knows how many units you would do something about it.

ID 1, PA nurse band 6, site 1

The HCPs explained that asking questions about alcohol consumption often felt purposeless as the vast majority of patients received no feedback, intervention or further testing even though their alcohol consumption exceeded the drinking guidelines. In the absence of any method of addressing risky and increasing risk drinking, HCPs described simply moving on to the next question in their list:

... well you work it out 'well that's 70-odd a week' right have you got any allergies? you think what do you ask that for because you're just sweeping over it ...

ID 1, PA nurse band 6, site 1

Although all three of the sites had alcohol specialist nurses available to whom patients from any part of the hospital could be referred, the awareness of these services varied between individual HCPs and across sites, indicating that further communication and clarification of services available was required:

ID 6: ... if someone asked you that would you know who to refer them to would you know what the referral process is in [site 1]?

ID 2: No.

ID 6: OK so you need to know that.

ID 2: Because I've never done that so I do think we do need a structure like that in PAC.

ID 2, ID 6, site 1

Further to this, even when staff were aware of the processes for making referrals to alcohol specialist services, they felt that they had no method of following up on this or ensuring that the patient was actually seen. Beyond this, there was some concern that referrals may not actually lead to any further treatment or support, and staff did not always agree that the guidelines were appropriate for the effective delivery of alcohol-related care:

... we ask the question, refer them on but nobody there follows them up and makes sure that they come or go and see [alcohol specialist nurse] ...

ID 14, PA lead, site 3

What I've got concerns with is I don't think five should be a referral to us because five is six units once a month ...

ID 6, substance use lead, site 1

In addition to the variations between and within sites in current practice, it was clear that practice changed over time. National incentivised programmes had influenced practice at two sites. Site 3 had previously employed the Michigan Alcoholism Screening Test (MAST)¹²⁷ with BA and referral available, and site 1 was in the process of implementing alcohol screening for all inpatients; both of these were part of the CQUIN initiative:

ID 14: It used to be a CQUIN target so we've got the questions on the pro forma like how many do you drink a week and then we've got like ...

ID 16: ... the MAST score ...

ID 14: ... the MAST score yeah nought to one and then two to four we have to fill that out and then you've got erm brief intervention given ...

ID 14, ID 16, site 3

However, negative personal experiences with these processes could lead to failure to adopt or maintain them, with staff from site 3 identifying that they stopped using the full screening, intervention and referral process when patients showed little interest in the additional information and support available to them:

... we did used to have some written information booklets that mapped it out ...

... no one none of the patients wanted to take it on [Interviewer: Yep] and have this further information provided so [Interviewer: OK] sort of fizzled out ...

ID 18, PA nurse band 6, site 3

Survey results

Survey participation Sixty-two participants (51.7% response rate) completed the survey. The majority of respondents were female (90.3%) but covered a diverse age range, the full spectrum of nursing job roles (from HCA to matron) and included those new to PA (< 1 year) as well as those with over a decade working in PACs. Demographics of the sample are summarised in *Table 5*. All were familiar with PA for hip and knee arthroplasty.

Appointment details

The typical length of PA appointments for hip and knee arthroplasty ranged between 30 minutes and 1 hour, with the majority of respondents (knee, 61.3%; hip, 59.7%) reporting appointments lasting 45 minutes. All respondents indicated that patients were asked about alcohol consumption as part of PA, although two stated that this was not part of the formal procedure. However, the type of questions used to assess alcohol

TABLE 5 Survey respondent details

Variable	Category	Respondents, n (%)
Gender	Female	56 (90.3)
	Male	6 (9.7)
Age	21–30	10 (16.1)
	31–40	30 (48.3)
	41–50	13 (21.0)
	51–60	9 (14.6)
Job role	HCA/senior HCA	7 (11.3)
	Band 4	2 (3.2)
	Band 5	33 (53.2)
	Band 6	12 (19.4)
	Band 7	1 (1.6)
	Team leader	4 (6.5)
	Sister/senior sister	1 (1.6)
	Matron	2 (3.2)
Time working in PA	< 1 year	4 (6.5)
	1–5 years	35 (56.5)
	6–9 years	11 (17.8)
	≥ 10 years	12 (19.4)

consumption varied, with only 29% using a formal screening tool or questionnaire (Table 6). Similarly, although > 50% reported that patients were given information about alcohol consumption in PA (14.5% indicated that this was part of the formal PA procedure) and 80.6% indicated that they could refer patients for additional advice or support related to alcohol consumption, what information patients received and to whom they could be referred varied (Table 7).

TABLE 6 Availability of alcohol screening, information and referral

Response option	Yes, standard practice/formal procedure, n (%)	Yes, but not standard practice/formal procedure, n (%)	No, n (%)	Don't know, n (%)	Missing, n (%)
Patients asked about alcohol use	59 (95.2)	2 (3.2)	– (–)	1 (1.6)	– (–)
Patients given information about alcohol use	9 (14.5)	23 (37.1)	26 (41.9)	3 (4.8)	1 (1.6)
Referral for additional advice or support available	34 (54.8)	16 (25.8)	7 (11.3)	1 (1.6)	4 (6.5)

TABLE 7 Alcohol screening, intervention and referral details

Category	Response option	Yes, n (%)	No, n (%)	Don't know, n (%)	Missing, n (%)
Alcohol screening (N = 62)	Yes/no indication of alcohol consumption	34 (54.8)	26 (41.9)	1 (1.6)	1 (1.6)
	'How much do you drink?'	19 (30.6)	42 (67.7)	–	1 (1.6)
	'How often do you drink?'	25 (40.3)	35 (56.5)	1 (1.6)	1 (1.6)
	How many units/standard drinks per week?	27 (43.5)	34 (54.8)	–	1 (1.6)
	How many units/standard drinks per day?	18 (29.0)	40 (64.5)	1 (1.6)	1 (1.6)
	Screening tool or questionnaire	18 (29.0)	40 (64.5)	3 (4.8)	1 (1.6)
Alcohol information (N = 32)	Information leaflet about alcohol in general	11 (34.4)	17 (53.1)	4 (12.5)	–
	Information leaflet about alcohol and surgery	10 (31.3)	17 (53.1)	5 (15.6)	–
	Face-to-face information about alcohol in general	7 (21.9)	22 (68.8)	3 (9.4)	–
	Face-to-face information about alcohol and surgery	21 (65.6)	7 (21.9)	4 (12.5)	–
	Websites to access in their own time	2 (6.3)	24 (75.0)	6 (18.8)	–
	Contact numbers for telephone information/support	3 (9.4)	24 (75.0)	5 (15.6)	–
Referrals for additional information or support (N = 50)	Patient is told to contact their GP surgery	1 (3.1)	26 (81.3)	5 (15.6)	–
	Referral to consultant anaesthetist	37 (74.0)	9 (18.0)	4 (8.0)	–
	Referral to GP	5 (10.0)	41 (82.0)	4 (8.0)	–
	Referral to alcohol liaison or nurse specialist	28 (56.0)	20 (40.0)	2 (4.0)	–
	Referral to in-hospital addiction psychiatrist	1 (2.0)	42 (84.0)	7 (14.0)	–
	Referral to Alcoholics Anonymous	2 (4.1)	43 (87.8)	4 (8.2)	–
Referral to other external organisation	3 (6.0)	42 (84.0)	5 (10.0)	–	

The form of alcohol screening varied; patients were most frequently asked if they drank alcohol and to provide details of how many units they drank, or how often and how much they drank, so that HCPs could calculate the number of units consumed:

We have to record units per week so I ask if they drink, when they drink and what they have . . .

ID S4

One respondent provided a possible explanation about why patients are not always directly asked to report their consumption in units:

Patients don't always know units so I ask what they drink and calculate . . .

ID S7

A number of respondents also used the text boxes to explain that they had previously used less structured questioning about alcohol consumption but had recently replaced this with the AUDIT-C questionnaire as part of the CQUIN initiative:

We have always asked patients if they drink and how much they drink but we recently started using the AUDIT-C questionnaire as part of the CQUIN . . .

ID S31

A number of sites appeared to provide minimal information or simple advice to cut down or avoid alcohol before surgery:

Patients told to avoid alcohol before surgery . . .

ID S2

In some cases information was provided only to those considered to be 'heavy' drinkers:

I generally suggest that heavy drinkers cut down before surgery and we have some booklets about alcohol that we can give them . . .

ID S11

This information was not always delivered by PA staff:

Physios [physiotherapists] provide this info . . .

ID S27

Regarding referral, respondents most frequently indicated that they could refer patients to consultant anaesthetists and alcohol liaison or alcohol nurse specialists.

As can be seen in *Table 8*, there was a similar level of variation in how patients were identified to receive information and to be referred for additional information and support. Responses recorded in the free-text boxes provide some further insight into this. The specialist or service to which patients were referred was often related to how they had been identified. Specifically, those identified through LFTs would be referred for consideration by an anaesthetist, whereas those identified by screening tools would be referred to alcohol liaison or nurse specialists:

If a patient asked for help I'd give them a leaflet and tell them to get in touch with their GP or arrange alcohol liaison but this has never happened. I usually give patients who score five or more on AUDIT a bit of advice and/or leaflet. Liver function tests flag and the patients notes go to anaesthetist . . .

ID S11

TABLE 8 Identification of patients to receive information or referral

Response option		Yes, n (%)	No, n (%)	Don't know, n (%)	Prefer not to say, n (%)
Information provided to (N = 32)	All patients	11 (34.4)	18 (56.3)	2 (6.3)	1 (3.1)
	All patients who report drinking	3 (9.4)	26 (81.3)	2 (6.3)	1 (1.6)
	All patients who request information	12 (37.5)	17 (53.1)	3 (9.4)	–
	Patients who consume over a specified number of units	16 (50.0)	12 (37.5)	4 (12.5)	–
	Patients who state, when asked, that they would like to reduce their alcohol consumption	5 (15.6)	23 (71.9)	4 (12.5)	–
	Patients identified through LFTs	9 (28.1)	17 (53.1)	6 (18.8)	–
	Patients identified through other blood tests	–	26 (81.3)	6 (18.8)	–
Other	4 (12.5)	23 (71.9)	5 (15.6)	–	
Patients receive referral (N = 50)	All patients	–	48 (96.0)	2 (4.0)	–
	All patients who report drinking alcohol	–	49 (98.0)	1 (2.0)	–
	Patients who consume over a specified number of units	30 (60.0)	18 (36.0)	2 (4.0)	–
	Patients who state, when asked, that they would like to cut down their alcohol consumption	10 (20.0)	37 (74.0)	3 (6.0)	–
	Patients identified through LFTs	39 (78.0)	8 (16.0)	3 (6.0)	–
	Patients identified through other blood tests	–	45 (90.0)	5 (10.0)	–
	Patients who ask to be referred	9 (18.0)	37 (74.0)	4 (8.0)	–
	Patients who show signs of alcohol dependence	25 (50.0)	21 (42.0)	4 (8.0)	–
	Patients who are already identified as alcohol dependent	31 (62.0)	14 (28.0)	5 (10.0)	–

Some respondents from sites participating in the implementation of the initial CQUIN initiative explained that this also included the provision of information and, for screen-positive patients, the option to refer to alcohol specialists:

CQUIN has referral to alcohol liaison. We can refer to [anaesthetist] . . .

ID S26

Finally, a number of staff indicated that, although patients did not routinely ask for information about alcohol, this information would be provided if it was requested:

If patients asked I'd give them information but they don't . . .

ID S6

Methods of identification showed considerable variation, suggesting that there are not clear policies outlining which patients should receive a referral. Further to this, some respondents indicated that referrals for additional support would be made only if patients wanted to be referred, whereas referral for review by an anaesthetist would be made either way:

Patients only referred to alcohol nurse if they want to be. Notes seen by anaesthetist either way . . .

ID S1

Conclusions

The focus group and survey results both indicated that asking patients about alcohol consumption and recording their responses was a formal part of PA at almost all sites. Focus group discussions built on this, with HCPs explaining that they were experienced in asking about alcohol consumption and had the necessary skills to broach this subject with patients. As a result they were likely to be well placed to provide additional guidance on alcohol use and surgical risk. The majority of HCPs also stated that they could refer 'heavy' drinkers for review by an anaesthetist prior to surgery, with LFTs and units of alcohol consumed being used to assess whether a patient or their notes should be reviewed by an anaesthetist. However, few specific details were provided on how LFTs were interpreted and what, if any, cut-off points were used to decide if such a referral was appropriate.

This suggests that there are few formal guidelines regarding how to identify alcohol consumption that potentially represents a risk for surgery and when and how to address alcohol consumption as a 'risky' behaviour. Just over 50% of survey respondents indicated that they provided patients with some form of information related to alcohol consumption but < 15% stated that this was part of formal PA; the form of information varied from a simple leaflet about alcohol consumption to face-to-face information about alcohol consumption and surgery. Free-text responses indicated that when face-to-face information was provided, this was predominantly in the form of a brief recommendation to avoid alcohol consumption before surgery, with little or no explanation of why or guidance on how long alcohol intake should be altered.

At the point of conducting the focus groups (October–December 2016), none of the three sites used a validated alcohol screening questionnaire. This is in line with the previous survey of medical perioperative assessment leads.¹¹⁶ At the time of the PRE-OP BIRDS survey (2018), 29% of respondents indicated that they used a validated screening tool. Many of these utilised the free-text response boxes to indicate that this was a recent change as a result of the CQUIN initiative, which came into effect in the period between the focus groups being completed and the survey commencing. With previous research⁶⁷ demonstrating that using screening tools improves the detection of both alcohol dependence and increased risk drinking, the deployment of a validated tool may lead to a reduction in alcohol-related complications.

Awareness of in-hospital alcohol specialist services was low among PAC staff at two of the three sites included in the focus groups, with the third site requiring patients to agree to a referral to alcohol specialist nurses, something that they indicated was widely refused. Awareness appeared to be higher among survey respondents, with 45% indicating that they could refer patients to alcohol liaison or alcohol specialist nurses. However, the methods for identifying patients to receive information or referral also varied, with biological tests (LFTs), self-reported alcohol consumption, indications of alcohol dependence and previous alcohol history all being used.

Chapter 3 Feasibility study

Background

Feasibility studies offer the opportunity to work with patients and HCPs from the proposed target populations to gain insight and to explore the appropriate optimisation and acceptability of interventions, outcome measures and research processes. Pilot trials may then be performed to provide an accurate estimation of rates of eligibility, recruitment and retention to inform a decision about the feasibility of proceeding to a definitive trial.

Aims

The study aims were to:

- assess the feasibility and acceptability of consent, screening, intervention and outcome assessment procedures.
- optimise the screening and behavioural intervention process in a way that nurses and patients find acceptable.

Methods

Design

A mixed-methods design was used, including qualitative interviews combined with assessment of screening and recruitment rates.

During the feasibility study, focus groups ($n = 3$ groups) to characterise TAU and assessments of fidelity of delivery of intervention sessions were also conducted. These are reported in *Chapter 2*.

Setting

Patient participants were recruited from a single site, a large secondary care teaching hospital in an urban location in the north-east of England. The site has an orthopaedic preoperative surgical care pathway of 6–10 weeks from PA to surgery. Patient screening took place in a surgical outpatient clinic with the BBI delivered in the PAC, and an optional booster session was delivered either over the telephone or face to face at the PAC.

Outcome measures

Acceptability and feasibility were assessed using a combination of quantitative (eligibility, screening, recruitment and retention rates) and qualitative (themes identified in analysis of staff and patient interview transcripts) data.

Procedure

Health-care professional recruitment, training and interviews

Screening and intervention were conducted by HCPs employed in the PAC. As such, it was necessary first to recruit and train HCPs to deliver the screening and intervention processes.

Health-care professionals were eligible if they were currently employed in the PA unit and were both willing and able to attend study-specific training. HCPs were excluded if they were unwilling to consent to audio-recording of intervention sessions, which was required in order to conduct assessments of fidelity of delivery (described in *Chapter 2*), or if they were unwilling or unable to attend the required training. A group training session (described in detail in *Chapter 2*) was delivered to HCPs on 15 April 2016 and a further session was held on 1 September 2016 to train a newly appointed HCA dedicated to the role of conducting initial eligibility screening with patients.

Health-care professional interviews

All HCPs involved in screening or screening and intervention delivery were eligible to participate in a qualitative interview about their experience of being involved in the research. The research associate (EL) sent all HCPs involved in the delivery of screening and/or interventions an e-mail inviting them to take part in an interview. E-mail invitations included the HCP interview-specific information sheet (see *Appendix 10*) as an attachment. Interviews were arranged at a time and place that suited the HCP participant; all three were conducted in a private room at the hospital immediately following a shift in the PAC. Interviews were conducted by the research associate, who gave a verbal introduction to the interview process before completing the informed consent form with the HCP participant. A topic guide (see *Appendix 11*) was used to structure the interview, which included questions about participants' experience of being involved in the study, the acceptability of the study processes, barriers and difficulties encountered during alcohol screening and/or intervention delivery and recommendations for improvements. Interviews lasted between 20 minutes and 1 hour; all were audio-recorded and transcribed verbatim.

Patient screening and recruitment

From the patient perspective, the feasibility study was based around four key points of contact or 'visits'. This study process is summarised in *Figure 1*. The activities completed at each visit are displayed in *Table 9* and all processes are described in detail here.

Inclusion and exclusion criteria

Patients were eligible for the study if they:

- were aged ≥ 18 years and listed for elective primary hip or knee arthroplasty
- had capacity to provide informed consent
- were able to write and converse in English (i.e. able to understand English sufficiently to complete the study questionnaires without the need for an interpreter)
- had screened positive for increased risk drinking (AUDIT-C score of ≥ 5 and reported consuming ≥ 6 units in one session at least weekly).

Patients were excluded from the study if they:

- scored < 5 on the AUDIT-C screen or did not report consuming of 6 units on a single occasion at least weekly
- were likely to undergo sequential (on different dates) joint replacements (for bilateral disease) within the scope of the proposal (because of reduced availability for follow-up)
- displayed current (active) withdrawal from alcohol
- had a severe psychiatric disorder requiring medical therapy, or severe cognitive impairment or dementia, affecting their ability to interact with the intervention and increasing the likelihood of postoperative delirium.

Patient participants were eligible to receive the intervention if they reported a score of ≥ 8 and consumption of ≥ 6 units in one session at least weekly on the full AUDIT questionnaire. Patient participants were excluded from the intervention if they scored < 8 on the full AUDIT or reported consuming ≥ 6 units on a single occasion monthly or less frequently.

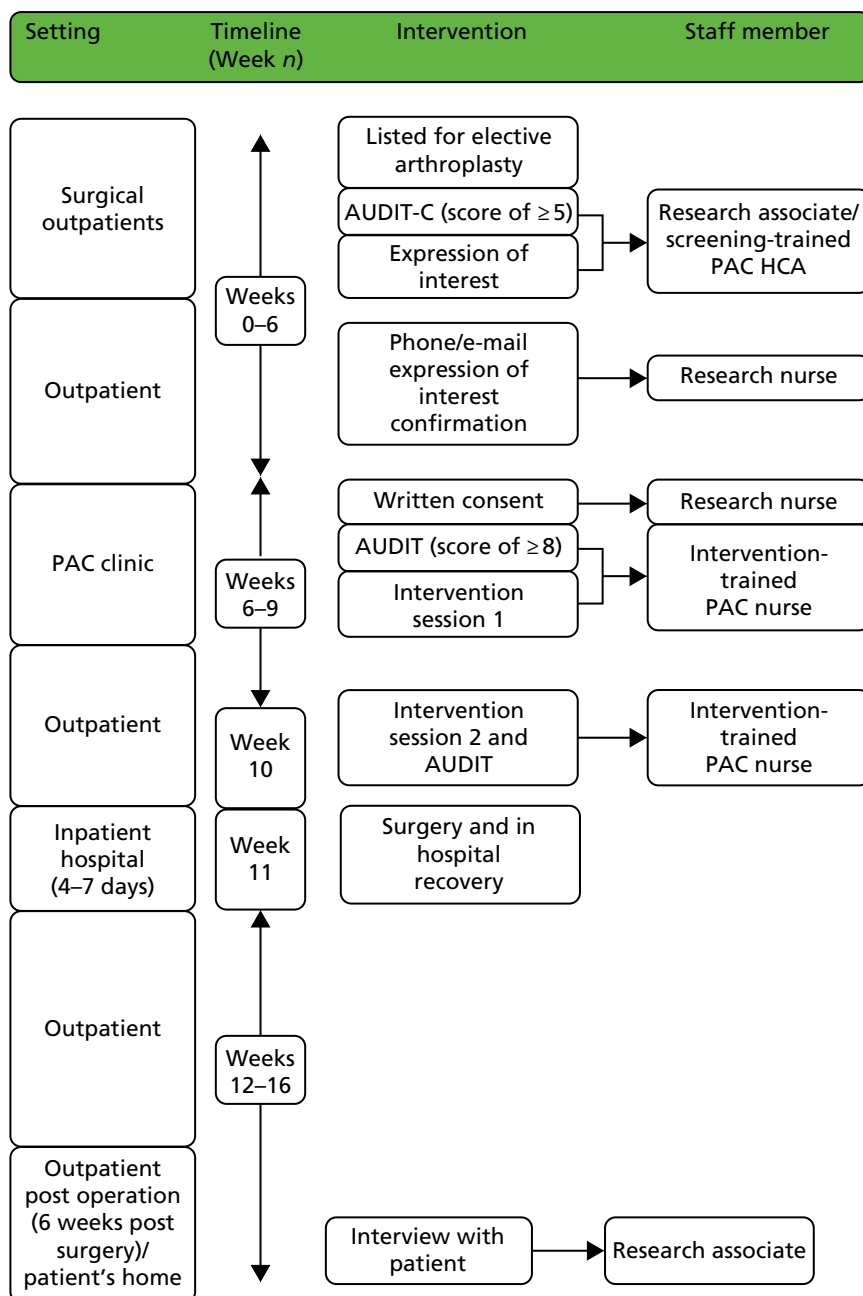


FIGURE 1 Feasibility study process.

Visit 1: screening

Initial screening for alcohol consumption using the AUDIT-C was conducted in a surgical outpatient clinic following listing for surgery. Patients were approached by a HCP trained in delivery and scoring of the AUDIT-C tool. The HCP completed the AUDIT-C with all willing patients and immediately assessed the responses for study eligibility. Eligibility was confirmed if the patient scored ≥ 5 on the AUDIT-C and reported consuming six or more standard drinks in one session at least weekly. Eligible patients were given a verbal explanation of the study and asked if they were interested in taking part. Those who expressed an interest were provided with a copy of the participant information sheet to take away with them and were asked for permission for follow-up contact to discuss the study further. Expressions of interest, contact information and preferred method of contact were recorded in writing by the HCP on the expression of interest form. Patients were then given 1 week to consider taking part in the study. After this time, the HCP contacted them by telephone or e-mail (depending on patient preference) to establish ongoing interest in participation and to arrange intervention delivery for those patients who confirmed ongoing interest.

TABLE 9 Feasibility study schedule of enrolment, interventions and assessments

Time point	Study period			
	Visit 1: screening	Visit 2: consent and intervention	Visit 3: booster session	Visit 4: qualitative interview
Enrolment				
AUDIT-C	x			
Expression of interest	x			
Consent		x		
Intervention				
AUDIT		x		
Intervention		x		
Booster			x	
Follow-up				
Interview				x

Visit 2: consent and intervention

Consent, completion of the full AUDIT questionnaire and intervention delivery (when patients were eligible) took place in the PAC. On arrival at the PAC, patients were met by a research nurse, who checked that the patient was still committed to taking part and, if so, confirmed their eligibility, including establishing their capacity to consent, before completing the informed consent discussion and asking patients to complete and sign the informed consent form; this included an indication of whether or not they were willing to have their intervention session audio-recorded and if they were willing to be contacted about participating in a qualitative interview at 6 weeks post surgery. The participant was given a copy of the completed consent form. After consenting to the study, patients completed the full AUDIT questionnaire with an appropriately trained HCP prior to intervention delivery. Patients who scored ≥ 8 on the full AUDIT or reported consuming six or more standard drinks on a single occasion at least weekly were eligible for intervention delivery. Patients who scored < 8 on the full AUDIT and reported drinking six or more standard drinks on a single occasion less than weekly were thanked for agreeing to take part, received positive feedback and were informed that the more in-depth measure indicated that their drinking fell within the lower-risk category and that nothing further was required of them in the preoperative period. As these patients were able to provide information about the acceptability of preoperative alcohol screening and study consent procedures, all those who provided consent to be contacted about a qualitative interview were contacted 6 weeks post surgery to gauge their interest in interview participation.

There was no upper limit of alcohol consumption or screening score that would lead to exclusion from the study. However, patients displaying current (active) withdrawal from alcohol were excluded from the study and assessed by the principal investigator to consider if a referral to an addiction psychiatrist for additional support was appropriate.

Intervention

The intervention and its development are described in detail in *Chapter 2* and their content, defined in terms of BCTs, is presented in *Appendix 1*. The intervention tools and processes are summarised here.

The BBI was structured around three tools utilised as follows:

- The BA tool acted as a visual aid for communicating information and provided HCPs with prompts to structure and deliver this advice to participating patients.

- The BI tool provided prompts to guide discussion of behaviour change with participating patients. This discussion could include motivation to change, pros and cons of change, goal-setting and problem-solving. This tool also provided space to record aspects of the intervention (e.g. goals and plans) to prompt behaviour outside the clinical setting.
- The patient leaflet¹⁰⁶ was introduced in the intervention sessions and given to patients at the end of the intervention session along with copies of the BA and BI.

Following completion of the full AUDIT, eligible patients received the BBI. The first session was delivered face to face in the PAC by an appropriately trained HCP. The session lasted 20–30 minutes, beginning with 5 minutes of BA delivered using the BA tool as a visual aid and prompt. The remainder of the session involved providing of the behaviour change intervention, targeting motivation and volition to target alcohol reduction or cessation in the preoperative period and using the BI tool to guide the discussion. At the end of the session, participants were provided with copies of the intervention materials to take away with them, as well as a copy of the patient leaflet.

Visit 3: booster session

Patients who indicated at the time of consent that they were willing to be contacted about participating in the optional booster intervention session were contacted by their preferred method (telephone or e-mail) approximately 2 weeks prior to surgery to gauge their continued interest in the booster session. For those who agreed to participate in the booster session, arrangements were made for the session to be delivered either face to face in the PAC or over the telephone approximately 1 week before surgery. The booster session, delivered by the same HCP who delivered the initial intervention session, lasted between 10 and 20 minutes and began with completion of the full AUDIT tool. The aim of this session was to revisit any goals and plans made during the first session, to provide feedback on performance and to boost self-efficacy, supporting behaviour change maintenance. For patients who indicated a desire to change but who did not set goals and plans during the first session, this booster provided an opportunity for them to do so. For those who had set goals and plans, it served as an opportunity to make any revisions and to receive feedback to target behaviour change maintenance.

Visit 4: post-intervention interview

All patient participants who consented to take part in the feasibility study indicated on the consent form that they were willing to be contacted about participating in a qualitative interview. These interviews aimed to explore the acceptability of screening, intervention and research processes to patient participants. The research associate (EL) contacted participants by telephone approximately 5 weeks post surgery with a view to arranging interviews to take place at, or around, the 6-week post-surgical outpatient appointment. Interviews took place in a private room at the hospital site, either immediately before or immediately after their outpatient appointment ($n = 10$) or in their own home on a day when they were not attending the hospital ($n = 3$). Those wanting to take part were provided with an interview-specific patient information sheet (see *Appendix 12*) using their preferred method (e-mail or post) prior to the interview. On the day of the interview, the research associate gave a verbal explanation of the interview process and a brief overview of her research background. Participants then completed the interview-specific informed consent form. All interviews were conducted using a topic guide (see *Appendix 13*) including questions about alcohol consumption, the acceptability and feasibility of alcohol screening and BI in the preoperative setting, their views of the intervention, their experience of being involved in the study, their opinions of the study tools and the acceptability of planned methods for a subsequent RCT. Of the 15 participants in the feasibility study, 13 took part in an interview (one could not be contacted and one failed to attend interview). All interviews were audio-recorded and transcribed verbatim.

Protocol amendments during the study

Recruitment to the study was initially lower than anticipated. Assessment of initial screening and recruitment rates identified that considerable numbers of patients were being screened as potentially eligible, with many expressing interest in the study and taking away a copy of the patient information sheet. However, on further contact (when possible) the majority did not express ongoing interest in the

study and only a small minority went on to take part in the study. A number of factors were identified as contributing to this issue and three amendments were made to address this:

- A number of patients demonstrated adverse attitudes to the term 'risky drinking', which appeared in the initial study title and study documentation (Preoperative Behavioural Intervention for Risky Drinkers before elective orthopaedic Surgery).
 - Amendment: the wording of the study title was amended to focus on the benefits of reducing alcohol consumption rather than identification of patients as 'risky drinkers'. The new title adopted was 'Preoperative behavioural intervention to reduce drinking before elective orthopaedic surgery'.
- Allowing 1 week for consideration of the study before the research team made contact with patients who had expressed interest in the study meant that many had lost interest. This gap also presented issues in terms of arranging consent and intervention around the PAC appointment, as many appointments had already been scheduled.
 - Amendment: to facilitate the arrangement of research procedures and intervention delivery, the time allowed for consideration of study participation was reduced from 1 week to 24 hours before the research team attempted to make contact to gauge ongoing interest.
- The inclusion criteria required patients to score ≥ 5 on the AUDIT-C *and* to report consuming ≥ 6 units in a single session at least weekly. This significantly reduced the number of patients who were eligible for the study and meant that many frequent heavy drinkers who could potentially benefit from the intervention were being excluded from the study because they either did not report high intensity drinking (consumption of six or more standard drinks in a single session) or reported doing so less frequently than weekly.
 - Amendment: to capture both regular heavy drinkers and high intensity drinkers, the inclusion criteria were amended to an 'and/or' criterion rather than an 'and' criterion alone.

The amendments were approved by the funder, the Research Ethics Committee and the Health Research Authority in November 2016 and were implemented at the recruiting site shortly thereafter.

Results

Sample

Health-care professional participants

A total of nine HCPs consented to take part in the feasibility study and received the study training; four (44%) were involved in screening and intervention delivery during the study period and three went on to take part in qualitative interviews.

Patient participants

Patient screening commenced on 3 May 2016 and the first patient was recruited on 24 May 2016. The study closed to recruitment on 2 March 2017; over the 10-month screening and recruitment period, a total of 15 patients consented to and participated in the feasibility study (two were recruited in the first 5 months and, 13 were recruited in the subsequent 5 months). Patient participants were predominantly male (87%) and had an average age of 70.5 years. Details of the sample are shown in *Table 10* and participant health behaviour data are displayed in *Table 11*.

TABLE 10 Feasibility study patient participant baseline characteristics

Characteristic	n (%)
Gender	
Male	13 (86.7)
Female	2 (13.3)
Ethnicity	
White British	5 (33.3)
Missing	10 (66.6)
Operation	
Hip	3 (20)
Knee	12 (80)
AUDIT score	
≥ 8	9 (60)
< 8	6 (40)

TABLE 11 Feasibility study patient participant health behaviour at consent

Variable	Mean	Standard deviation
Alcohol units per week (<i>n</i> = 7, missing = 8)	19	8.9
BMI (kg/m ²) (<i>n</i> = 6, missing = 9)	31.3	8.1
Number of days active per week (<i>n</i> = 6, missing = 9)	3.2	3.1
Physical activity (<i>n</i> , %)		
Yes	6	40.0
No	1	6.6
Missing	8	53.3
Smoking (<i>n</i> , %)		
Current smoker	0	0.0
Ex-smoker	1	6.6
Never smoked	6	40.0
Missing	8	53.3

BMI, body mass index.

Analysis

Quantitative data were subject to descriptive analysis only. Screening and recruitment rates are detailed along with mean scores on the AUDIT questionnaires completed at baseline and the booster session (when applicable).

Qualitative data from patient and HCP interviews were analysed thematically. Framework analysis was used to analyse the interview transcripts.³¹ For patient participant interview data, two experienced qualitative researchers (EL and CH) repeatedly read and coded a subset of transcripts independently. Initial codes were discussed and a framework of themes and subthemes for the analyses was produced. All transcripts were

then coded by EL and CH within this framework with additional emergent themes and subthemes added to the framework. Codes were discussed on an ongoing basis to inform the analysis and resolve any disagreement about the interpretation of the data. Analysis was discussed with the full research team to identify areas for closer consideration (including negative case analysis) and to enhance the credibility of the thematic framework and interpretation.³² Finally, themes relevant to the aim of assessing the acceptability and feasibility of the study and intervention methods were selected and are discussed here.

For HCP interviews, initial descriptive codes were generated from the transcripts and these codes were then grouped into a framework that used the components and constructs of normalisation process theory (NPT)¹²⁸ as themes and subthemes but was left open enough to allow the emergence of additional themes relating to the acceptability of the study research, screening and intervention methods. NPT is an implementation theory that can help us understand how research, screening and intervention processes translate into real-world practice. This translation is often key to the acceptability of processes to HCPs. It provides a theoretical framework to guide the exploration of how processes are implemented (operationalisation and organisation), embedded (routinised in day-to-day practice) and integrated (sustained). NPT proposes that it is the work of people individually and collectively to implement practices that lead to these becoming embedded in practice. The theory has four key constructs (coherence, cognitive participation, collective action and reflexive monitoring), each of which has four components.

Patient screening and recruitment

The flow of participants through the study is displayed in *Figure 2*. A total of 620 patients were screened, of whom 105 (17%) were potentially eligible (based on AUDIT-C score). Fifteen of these (14%) were recruited and nine of those recruited (60%) received interventions. Of the 15 patients recruited, 13 (87%) participated in qualitative interviews about their experience.

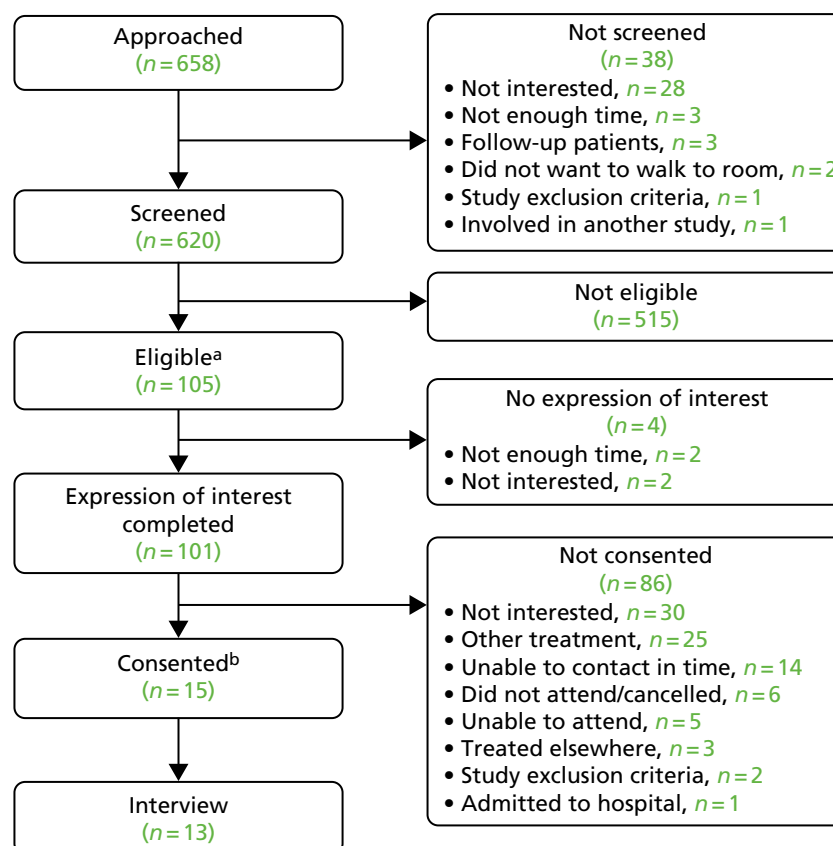


FIGURE 2 Feasibility study Consolidated Standards of Reporting Trials (CONSORT) flow diagram. a, 75 out of 470 screened eligible based on original inclusion criteria and 30 out of 150 screened eligible based on amended inclusion criteria; b, nine received the intervention, four of whom also received the booster session.

Figure 3 shows that, across the study as a whole, approximately 29% of patients screened scored ≥ 5 on the AUDIT-C, with almost 16% reporting consuming six or more standard drinks on a single occasion at least weekly and 14% of eligible patients consenting to participate in the study.

Screening and recruitment rates both before and after amendments were made to the study procedure are detailed in Table 12. These figures demonstrate that the recruitment rate improved from 9.33% of eligible patients to 26.67% following implementation of the amendments. Recruitment rates are displayed in Figure 3 and show the influence of the amendments as well as the benefit of a HCA joining the PAC team in October 2016, who, after completing the study-specific training, took ownership of the study at their site.

Patient alcohol consumption

All patients completed the full AUDIT questionnaire to assess eligibility to receive the intervention and the four participants who received a booster session also completed the full AUDIT questionnaire at this time. The mean AUDIT score at consent was 8.3 [standard deviation (SD) 3.0, $n = 15$] and at visit 3 (booster session) was 6 (SD 1.4, $n = 4$). Among AUDIT-positive patients only (≥ 8) the mean score was 10.4 (SD 1.6, $n = 9$) at consent.

Intervention delivery

As part of data collection, HCPs who delivered intervention sessions were asked to record whether or not patients received each of the three key intervention aspects (BA, BI and patient information leaflet) and,

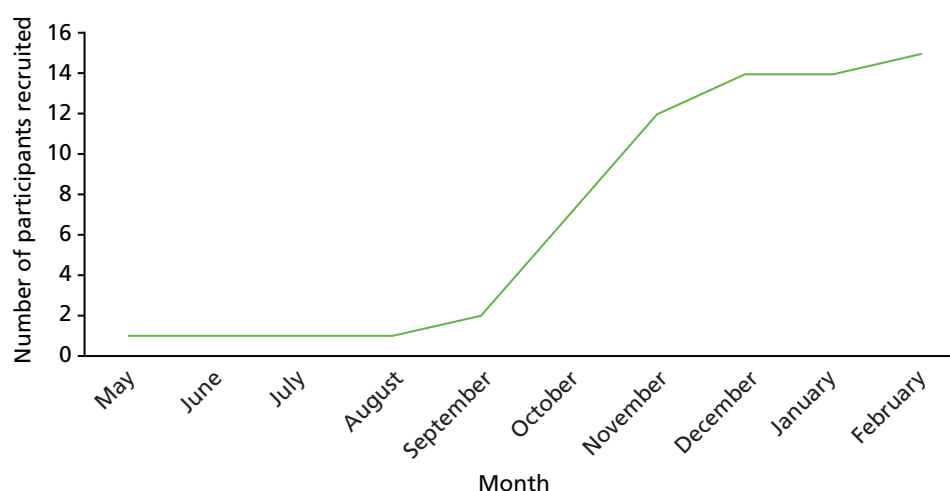


FIGURE 3 Recruitment graph for feasibility study.

TABLE 12 Recruitment rates before and after amendments to the feasibility study

Variable	Original criteria			Post-amendment criteria			Total		
	<i>n</i>	%	% of eligible	<i>n</i>	%	% of eligible	<i>n</i>	%	% of eligible
Screened	470	100.0		150	100.0		620	100	
AUDIT-C score of ≥ 5	148	31.5		30	20		178	28.7	
AUDIT-C question 3 score of ≥ 3	75	16.0		22	14.7		97	15.7	
Eligible	75	15.0	100.0	30	20	100.0	105	16.3	100
Consented	7 ^a	1.5	9.3	8	5.3	26.7	15	2.4	14.3

^a Two patients were recruited under original criteria; five patients were screened under original criteria but consented in October following the amendments.

whether or not goals were set during the initial intervention session. Of the nine patients who screened as eligible to receive the intervention, all received BA, BI and the patient information leaflet, and 56% ($n = 5$) set goals.

Qualitative results

Interviews (HCPs, $n = 3$; patients, $n = 13$) found that proposed screening and intervention techniques (i.e. behaviour change and brief motivational techniques) were acceptable both to patients and to HCPs delivering the intervention. It was also found that screening and intervention could be conducted without having a negative impact on patient care.

Patient interviews

Initial framework analysis of patient interview data identified eight themes, seven of which were considered to relate to the aim of assessing the feasibility and acceptability of the research, screening and intervention processes. Themes concerned patient perceptions of their drinking behaviour (*Defensive othering*); the acceptability of screening [*Alcohol screening is expected in the NHS but not specifically preoperative assessment; Alcohol screening (using AUDIT) is acceptable*]; the acceptability and effectiveness of intervention methods (*Preoperative assessment is a window of opportunity for screening and brief behavioural intervention, Brief behavioural intervention targeting alcohol consumption is acceptable although with mixed effects, Screening alone may lead to alcohol reduction*) and terminology used in screening and intervention (*It's pints not units, but units rather than standard drinks*). These themes, supported by quotations from the interview transcripts, are discussed below.

Defensive othering

In line with findings early in the feasibility study, which showed that patients responded adversely to the use of terminology around 'risky drinking' in the study materials, all participants interviewed resisted the narrative of being a 'risky' or 'problem' drinker. Instead they drew on the strategy of 'defensive othering', whereby they made comparisons with others who drink more or more frequently than them in order to normalise their own drinking and distance themselves from those perceived as 'problem drinkers'. In this way participants were able to admit that they drank and that they may have drunk in excess of the drinking guidelines but also to portray their drinking behaviour as acceptable. Reasons used by participants to explain why their drinking behaviour was not a concern included that it was within the old recommended limits, it was not excessive or dependent or alcoholic or alcohol abuse or binge, they were not a spirit drinker, they did not drink in the house, they drank only with meals, they drank only socially, they did not drink as much as their peers, young people or health professionals and they did not get drunk, have hangovers or drink and drive:

Well it didn't really, it didn't, the drinking, it didn't apply at all really. It's, as I say, it's I mean that's all I have, it's nothing compared with some of them I've seen, some of them and they've way more than me I have me pints that's it no more than that . . . Oh I drink a lot less than other men.

ID 120, male, 87 years

I know that I should cut down. But I also like it. I don't have a problem in as much as I'm dependent on it. I think maybe a little bit dependent but I do like it. I don't think about it all the time.

ID 14, female, 62 years

Alcohol screening is expected in the NHS but not specifically at preoperative assessment

Alcohol screening was generally viewed as a 'normal' part of health-care appointments in the NHS as a whole. As a result, just over half of participants expected to be asked about their alcohol consumption during PA:

As I say, for years I've had it [alcohol screening] from the NHS through the doctor's surgery, all my life, even the chemists ask now.

ID 108, male, 77 years

However, the majority of participants did not associate alcohol use with surgery or consider that it would be relevant to the perioperative period. As such, many did not expect to be asked about their drinking behaviour at PA:

No, I didn't think it [alcohol] had any bearing on a hip replacement basically.

ID 70, male, 68 years

However, two of the 13 participants interviewed were able to identify 'risks with the anaesthetic and drinking' and 'if you cut down beforehand and afterwards your recovery should be much better'. Despite the clearly limited patient knowledge of the associations between alcohol and surgical outcomes, a couple of participants reported that they would not consume alcohol before surgery:

When I went in for surgery I wouldn't drink any alcohol anyway really.

ID 120, male, 87 years

Alcohol screening (using AUDIT) is acceptable

Regardless of whether or not alcohol screening was expected or thought to be relevant to surgery in general and to orthopaedic surgery more specifically, it was widely considered to be acceptable. At least some of this acceptability seemed to derive from the perceived normality of alcohol screening in health-care settings, with patients explaining 'they always ask about how much alcohol you drink' and 'it's always asked in hospital'. The approach adopted by screening staff also appeared to be important in ensuring acceptability, with participants describing the process as 'non-judgemental', 'not intimidating' and 'comfortable':

I felt fine, because she asked it in such a non-judgemental way she didn't put it over to me that she was criticising or judging or anything.

ID 14, female, 62 years

The AUDIT, used for screening in this study, was found to be acceptable to patients, who described it as easy to complete and understand:

Well, I think it covers every aspect, and it gives you plenty of choices. Yes, I think it's a very good laid out questionnaire.

ID 103, male, 67 years

Although there was no indication that alcohol screening was unacceptable to even the heaviest drinkers in our sample, some participants explained that alcohol use could be a 'sensitive subject' for some people, with the amount of alcohol consumed being related to the acceptability of screening:

... people who are drinking perhaps erm to a level that is not healthy that would be a little bit uncomfortable and then you've got the people who would be in the excess area who probably would refuse to take part ...

ID 126, male, 65 years

Brief behavioural intervention targeting alcohol consumption is acceptable albeit with mixed effects

All the participants who had received the BBI reported that it was acceptable. Participants explained that they were 'comfortable with it' and 'happy to get the advice' and that the intervention gave them 'insight':

It did focus my mind more as well because I know that I have been at risk or I am at risk but it did focus my mind on do I really want that one? No well let's stop there ...

ID 14, female, 62 years

However, the acceptability of the intervention did not necessarily mean that it would lead to behaviour change. Some participants explained that although they were happy to receive the information they would 'take no notice of that', or that it 'didn't change us one bit', and some linked their lack of intent to change with their age, stating 'I'm too old to change now'.

Despite this, over half of the participants who received the intervention reported that it had led to a reduction in their alcohol consumption. However, the magnitude of the change and the period of time during which the change was maintained varied:

I knocked a pint off each session . . . and now that I'm on the mend I still probably knocked a pint off.
ID 104, male, 70 years

From the week before I had surgery I didn't have any drink for 6 weeks. Completely 6 weeks, possibly 7 . . . that I didn't have any alcohol at all.
ID 108, male, 77 years

These changes in drinking behaviour were reported by some to be a result of having the consequences of alcohol consumption on surgery explained:

. . . it was explained that it was, it would help us in healing . . . and there was less chance of catching any bugs or anything.
ID 108, male, 77 years

Screening alone may lead to alcohol reduction

Although information received in the intervention was linked to behaviour change, some participants reported that it was the AUDIT screening tool that had led them to change their drinking behaviour. These participants explained that it 'focused' or 'concentrated' the mind and 'crystallised how often I drink':

. . . answering them and going through them and I thought 'mmm that might be a little bit too much' or 'mmm I'm OK with that' so I think the information was clear and it, it did focus my mind down on things.
ID 14, female, 62 years

The issue of honesty in self-report measures of alcohol consumption also arose here. Although one participant reported that other patients may conceal the truth when asked about their alcohol consumption in a health-care setting, another identified that the time between completing the screening and attending the intervention session allowed for reflection on the reasons for screening and led to more honest responses when completing the baseline measures (i.e. the full AUDIT):

It might be in the back of your mind that you know you're going in for surgery, and that they might get a bit wobbly with you. Really I don't, but it's the syndrome where you don't tell medical people.
ID 76, male, 64 years

. . . when they've had chance to think and reflect they might think that honesty is the best policy.
ID 108, male, 77 years

Preoperative assessment as a window of opportunity for screening and brief behavioural intervention

The preoperative period and the PAC were seen as an acceptable time and place for the delivery of alcohol screening and intervention. However, it was generally seen as important that screening and intervention were conducted around existing appointments, with some participants explaining that it was a case of catching them at the 'right place, right time' and others explicitly identifying the benefit of not having to

'make a special trip'. One patient also explained that the time and setting would be beneficial to both the patient and the NHS:

Yes, it was probably good timing, with coming in, you know, to going to be coming in for an operation.

ID 103, male, 67 years

However, some patients indicated that the orthopaedic patient population may not be the ideal target for alcohol screening and intervention specifically because they tend to undergo surgery later in life than those attending PA for other conditions. When asked about screening and intervening with people of a similar age, participant responses varied. Some indicated that interventions may be less relevant as their alcohol consumption was already lower than it had been in their younger years:

I think there must be 60, 70 per cent of people who 10, 20 years ago were big drinkers. I'm not saying it's like that now [Interviewer: Mmm] but most of them have come to common sense and they don't drink as much [Interviewer: Yep] but years ago when you were younger I think most people drank far too much . . .

ID 117, male, 67 years

Others explained that older people may be less motivated to change:

I think you are wasting your time really . . . I shouldn't say that like but ah well I don't think at my age, I don't think I would take a lot of notice to be honest . . . a lot of young ones would but the older ones wouldn't I don't think oh at my age I wouldn't they are set in their ways.

ID 120, male, 87 years

On the other hand, some participants felt that screening and intervention with older people would be more effective, with one explaining that older people were likely to be more honest, and another that they were likely to listen more than younger people. One participant also explained that respect and a non-judgemental approach were particularly important if interventions were to be acceptable to older people.

It's pints not units, but units rather than standard drinks

To accurately document alcohol consumption and to understand the sensible drinking guidelines, patients and HCPs must understand the amount of alcohol in different beverages and servings. The screening and intervention tools in this study used the term 'standard drink' to describe a drink or serving containing 8 g of alcohol. From interview transcripts, it was clear that participants had little to no understanding of this term prior to participation in the study; however, they stated that they were able to understand the term when it was explained:

I've not heard it before . . . my interpretation of standard drink is how many units you should have. You hear it all the time on the television, you hear it on advertising, you hear it on all sorts of things but it, until I was actually taking part in the study it didn't really mean a lot to me.

ID 14, female, 62 years

Participants described being more familiar with the term 'unit', although it was clear that the understanding of what a unit comprised was limited. Some participants suggesting that further health promotion and communication relating to this terminology would be beneficial:

I think they advertise 3 units for a pint. So, if you go in a pub for a drink, or if you buy a can, do you have a standard drink, or do you have 3 units? Or is there only 2 units in it?

ID 103, male, 67 years

Overall, the consensus was that patients were most comfortable talking about the quantity of alcohol consumed in terms of pints or glasses:

No, well I, I only know, like, 'a pint' or 'a pint and a half', you know what I mean?

ID 109, male, 66 years

Health-care professional interview results

Five overarching themes were identified, four relating to components of NPT (defined in *Box 2*), which provide insight into the work of HCPs to implement the screening, intervention and research processes in the context of PA. Although these four themes show that interview transcripts revealed evidence of all four of the key constructs of NPT, there was no evidence that all four components were present within each construct, although findings may have emerged in these areas had the topic guide included probes for each specific construct. The final theme (*Perception of patient responses*) emerged from the data but did not directly fit within the NPT framework and relates to the various patient responses to screening and intervention processes.

Owing to the small pool of potential interviewees and the visibility of their involvement in the trial to others (e.g. colleagues in PA, research team members), quotations are labelled using ID numbers only.

Coherence

During interviews, HCPs did not directly differentiate their roles in day-to-day clinical practice from their roles in the feasibility study (differentiation). However, they did consider how the study activities fitted in with usual care and how screening and BBI may best be implemented into PA (communal specification),

BOX 2 Core constructs of NPT

Coherence

The 'sense-making' work that people do individually and collectively when an intervention is delivered (e.g. How is the intervention understood by patients? Do they share a view of its purpose, understand how it will affect them personally, and grasp its potential benefits?).

Cognitive participation

The 'relational' work involved in engaging and legitimising an intervention and associated practice (e.g. How do patients participate in an intervention? What keeps them motivated to continue taking part?).

Collective action

The 'operational' work performed by individuals to organise and enact a new practice (e.g. How do patients make the changes work? What strategies do they employ to organise and structure their lives to accommodate the new practice?).

Reflexive monitoring

The 'appraisal' work that people do to understand and evaluate the impact of a new practice (e.g. how it affects them and the people around them, and how patients come to decide whether or not the intervention is worthwhile over time).

as well as providing clear descriptions of their own roles and tasks in the study (individual specification). They also discussed the benefits of being involved in the study as well as benefits of screening and BBI (internalisation).

Communal specification

Communal specification involves individuals working together to understand the aims and objectives of a new practice. In the case of this feasibility study, much of this understanding can be seen to relate to how screening and intervention processes can be embedded in PA. HCPs considered how the screening and intervention process fitted with existing preoperative processes from both their own perspective and that of patients. The HCPs explained that, for both them and patients, discussion about alcohol use and specifically the impact of alcohol use on surgery fitted well with the existing PA because alcohol use was already asked about. Further to this, staff felt that conducting the TAU PA with the patient before going into the intervention allowed them to develop a rapport with the patient and to anticipate how the patient was likely to react to different questions. The HCPs perceived this as facilitating effective intervention delivery:

... when we are doing it as part of the PAC, I did a couple that way and that actually flows quite well. Because again, you've got that, sort of, you know, rapport going already with them and you just, kind of, you mention the alcohol thing at the start of the pre-assessment. You go, 'You're part of the study but we'll come back to that at the end,' so actually it, kind of, filters in quite nicely that way and it did work a lot better that way ...

HCP 4

However, owing to staff availability and involvement in the study, it was not always possible for the same HCP who conducted the TAU pre-assessment to deliver the intervention, which meant that these benefits could not be gained:

I think a few people I did the intervention with, I'd never met them before, I didn't have the notes, it was quite difficult to go in and go, 'All right, OK, so you've triggered you drink X amount of units,' and I think sometimes that can be a little bit hostile for people coming into that.

HCP 5

The HCPs also considered the potential burden on patient participants. Arranging screening and intervention around existing appointments so that the patient did not need to travel to the hospital specifically for the study was seen as important. Making the most of time usually spent waiting for appointments by using that time to conduct screening was also beneficial:

... they're already here in the hospital erm and if they are waiting for their appointment it passes a bit of time for them and they don't mind it if they come in early and things like that.

HCP 9

Following up on initial expressions of interest in a timely manner was also seen to be beneficial both for patients and for study staff as it meant that the study information was still fresh in patients' minds and that they were more likely to have maintained an interest in taking part:

... waiting a week for to do the 'phone call, that was a bit, because by the time they'd gone home, if they've read it or if they didn't read it they'd forgot about it and they just didn't want to know but now that that's been fixed it's just to a day thing's will go, go better ...

HCP 9

Individual specification

Individual specification relates to how individuals develop an understanding of their specific tasks and responsibilities. HCPs identified that the study training had provided them with an idea of what tasks they personally would have to complete as part of the study. However, having the opportunity to practise the screening and intervention and to develop real-world experience of delivery was more important in terms of learning how to complete these tasks:

Well, again, it comes with experience, it's good to have that initial training so you know what you're asking, you know what you're roughly wanting to get from it and then you just find your own way of asking the questions. I think yes, again, practice.

HCP 5

All three of the HCPs interviewed also demonstrated a clear understanding of their own role and responsibilities, including the specific activities that they needed to complete. There was also an indication that they had an understanding of how their role fitted with the roles of others in the project:

I have been interviewing people after they have already seen [HCA] and been identified so they have agreed to participate in it. We have spoken about strategies they might want to use or have thought of to try and, not abstain from drink, but to try to reduce the amount they drink prior to anaesthetics.

HCP 4

Internalisation

Internalisation is concerned with understanding the value and benefit of the processes being implemented. The HCPs demonstrated knowledge of the benefits both from involvement in the study and from the delivery of screening and intervention. The HCPs identified benefits for themselves as individuals as well as benefits for the patients involved. For HCPs, being involved in the study was viewed as 'interesting' and 'enjoyable'. Similarly, being involved in new care practices was seen as beneficial:

I think just being involved in something that's quite new and upcoming and will play a very big part in pre-assessment in the future, I think this is obviously just the benchmark for it now, so I think it's quite good to be involved in something like that.

HCP 5

The knowledge gained from the training, which was then communicated to patients in the intervention sessions, was also seen as worthwhile and a key driver of ensuring that patients engaged with the intervention:

... because a lot of the patients want the surgery, so if you can say to them, 'You know that it's proven that it can improve your post-operative recovery,' a lot of them are quite keen to do it. I know it was identified in a lot of our training, people hadn't realised that alcohol can be a contributing factor to blood pressure or another issue that they're dealing with, weight loss and that type of thing, so when you've actually sat and gone through stuff like that, people had responded really well to it.

HCP 5

Cognitive participation

Cognitive participation is the work individuals do to develop practice around new processes and then to sustain these. There was no specific evidence in the interviews of managers or team leaders working to drive the implementation of screening and intervention (initiation). However, there was clear evidence that the HCA responsible for screening also acted to co-ordinate the project activities, increase engagement and facilitate the roles of other staff members (enrolment). In contrast to the clear consideration that had been given to how best to implement screening and intervention in to the PA setting, there was no evidence to suggest that HCPs had considered whether or not they were the right people to be involved in delivering screening and intervention (legitimation), although the feedback provided on intervention delivery was used

by one staff member as a method of ensuring that they were fulfilling their role within the study. The HCPs did discuss difficulties in maintaining engagement with the study and the limited profile of the study within the PAC (activation).

Enrolment

The HCA responsible for conducting the initial screening of patients identified that she was involved in co-ordinating other HCPs involved in the study and facilitating their delivery of intervention sessions, as well as connecting with other HCPs in the clinic to help promote screening:

I just speak to the nurse and say 'oh I'm down here if they want to talk about some research that's going on erm bob them down' . . .

HCP 9

This work was also identified by one of the other HCPs, who explained that the HCA was the person to go to with questions about the study:

We've got [HCA] which is great, she's doing a fantastic job and anyone just goes to her now which is great to have . . .

HCP 4

Activation

The HCPs identified time lags, both between the initial training and recruitment of the first patient and between each recruited patient, as limiting implementation of the study into PA. With practice and experience of delivering screening and intervention being identified as key to effective delivery of the study activities, such delays were likely to have an impact not only on the implementation of the study but also on the quality of intervention delivery:

There are huge gaps between doing it and then, I mean, it seemed like a massive gap between our first training and then doing it because I thought it had been such a long time. Then big gaps between times when you have seen patients and then you are all ready to see them and they just don't turn up . . .

HCP 4

The HCPs explained that they thought that 'there would be more going on' as part of the study. The small number of participants recruited over a relatively extended period restricted the visibility of the study in the PAC and led to both reduced confidence and reduced capability in delivering the interventions:

I think I would just feel more comfortable and more proficient if we did it more often and if it was more visible . . . Just make it more of an established thing.

HCP 4

Collective action

Collective action is the work that people do to enact a set of new practices. Interviews included descriptions of how the HCPs and patients interacted with the screening and intervention tools (interactional workability), as well as the skills they had that enabled their delivery of the screening and intervention (skill set workability); however, there was no discussion of HCPs' trust in the intervention or in each other's ability to deliver the required tasks (relational integration). As with cognitive participation, where there was no evidence of higher-level management involvement in the implementation of the study, there was no discussion of support for the study from management, but there was some discussion of how staff time was allocated to the study activities (see *Contextual integration*).

Interactional workability

The screening and intervention processes were based around the full AUDIT and AUDIT-C screening questionnaires, the BA tool and the BBI tool. In interviews, HCPs discussed how they interacted with these

tools and how patients responded to them. The screening questionnaire was described as easy to use, with the inclusion of an infographic explaining standard drinks being particularly beneficial:

It's, it was easy, it's easy for them to understand and me as well. Erm and with it having the little table on the top of what a, a standard drink is I can [Interviewer: Yeah] show them that and they can understand it as well as me . . .

HCP 9

Similarly, the BA and BI tools were described as 'good', 'not difficult' to use, containing all the required information and acting as effective prompts to guide intervention delivery:

The intervention is really in detail, it is all there. There is loads of information and it points you to exactly where you need to be so it is good.

HCP 4

However, having time to become familiar with the intervention materials was considered to be important in improving interaction with them, which was, in turn, important in maintaining a professional demeanour during intervention delivery:

. . . once you've done it a couple of times and you, kind of, get familiar with the paperwork, with the questions, with the intended outcomes, I think it becomes a lot easier to do it and a lot more fluid . . .

HCP 5

. . . you don't want them to think you don't know what you're doing or looking through endless bits of paper. I don't feel comfortable doing that.

HCP 4

The tools were also seen to aid interaction between the HCPs and patients during intervention delivery. The tools supported the communication of information, reinforced the intervention session by offering space to record key aspects of the discussion and enhanced engagement:

. . . definitely showing them something because then they lean in and they'll start reading off the page.

HCP 5

Skill set workability

The HCPs discussed a number of skills that enabled them to deliver the screening and intervention effectively. They explained that they were experienced in and comfortable with discussing alcohol with patients and were able to do so in a non-judgemental manner:

I don't talk to people in a judging way. I feel quite comfortable and confident to talk about that kind of thing. I don't think I have to shy away from stuff . . .

HCP 4

Further to this, HCPs explained that they had existing skills in recognising and managing different patient responses, which was important in tailoring questioning and interventions to maintain a positive interaction with patient participants:

. . . the response of the patients if they were like a bit abrupt and you know about it then I would feel a little bit oh I'm I'm putting on to this patient a bit too much so I kinda back off a little bit and let them talk about it . . .

HCP 9

Contextual integration

Regarding contextual integration, HCPs discussed the allocation of staff time to deliver screening and intervention. There was a clear focus on wanting to 'do things properly', which was considered to require dedicated time:

Have you got valid time where you don't feel like you're going to be rushed? Because if you do feel rushed then I know I have to skim through it and I'm not going to do it the way I should do . . .

HCP 4

Effective co-ordination and organisation of the study sessions was necessary with pre-planning to ensure that staff were available and appointments were arranged to give them the additional time needed to deliver the intervention:

. . . it's fitting everything in it's trying to fit things in and moving other appointments around to fit the intervention in as well but if it's planned in advance it works out good . . .

HCP 9

However, in some circumstances, for example when patients arrived late, these factors were outside HCPs' control. This was particularly relevant for screening, which was usually conducted while patients were waiting for an appointment:

. . . if they turn up late it's it's hard for me to get them, they don't always want to stay and talk or they're too busy with something . . .

HCP 9

Similarly, if a HCP allocated time to deliver an intervention or indeed to deliver a number of interventions on one day but patients failed to attend the sessions, this was problematic:

I had a morning set aside, there were two or three people booked for the intervention . . . so when I was set aside the morning, I think only one or two people came for it . . .

HCP 5

Reflexive monitoring

Reflexive monitoring focuses on the work that individuals do to appraise new processes. The HCPs did not specifically discuss the collection of evidence to gauge the effectiveness of the intervention or the implementation of screening and intervention into the PA (systematisation). However, there was evidence that the individuals involved had drawn on both anecdotal evidence from their own experiences and the feedback provided by the research team (individual appraisal) to determine whether or not screening and intervention was effective. Two of the interviewees pointed to collaborative assessments of how effectively screening and intervention could be implemented in PA (communal appraisal). Finally, participants discussed formal modifications (made to the study procedures through the submission of an amendment) and informal modifications made to tailor delivery of the intervention (reconfiguration).

Individual appraisal

The HCPs appraised their involvement in the study and described it as enjoyable and interesting. Beyond this, they identified the benefits of the screening process in terms of raising patients' awareness of their alcohol consumption and motivating change:

. . . a lot of them actually don't realise that they're drinking more than what is recommended, so if you tell them that they are, they'll go, 'Ah!' [gasps], you know, and they're completely in shock. So they want to know more . . .

HCP 5

The HCPs also identified instances when they had been able to assess whether or not the interventions had led to patients changing their alcohol consumption behaviour:

I recognised him the second time so that was quite good because usually I get moved around. So, I think it just being a longer-term thing, it is interesting to see results . . .

HCP 4

These positive appraisals of screening and intervention effectiveness had also led to some of the HCPs changing their usual practice during PA:

I've actually had people, not for orthopaedic surgery . . . they've questioned me on the alcohol and does it, sort of, pose any difference either way. So I've brought it in a little bit there without actually bringing it in, but just saying, 'Well, actually yes, you know, we're running this study for certain ones.'

HCP 5

Communal appraisal

Although HCPs did not specifically discuss participating in communal appraisal of the interventions, two of the interviewees alluded to its occurrence. The first anticipated that interviews with other HCPs would produce similar findings, suggesting that the study processes had been discussed:

I imagine that whoever is doing it has probably got similar things . . . you might get repetition for the same sort of things going on.

HCP 4

Another interviewee explained that, although NHS staff are often averse to change, discussion of positive experiences of delivering the screening and intervention processes had helped to alter this view and that this would, in turn, aid future implementation:

. . . people are reluctant to change and reluctant to change the ways that they do the practice. I think it actually has gone down a lot easier than I thought it was going to and I think it will continue to do that because I think people are now saying it's not as bad as anybody thought it was going to be, it's actually all right, it's quite easy . . .

HCP 4

Reconfiguration

The study processes were formally reconfigured during the course of the feasibility study via the submission of an amendment, which had been informed by the experiences of the HCPs and research team to this point. The positive impact of this was discussed by one interviewee, who felt that the change of the study title and the reduction of the time between initial and follow-up expression of interest were both beneficial:

I think things will go better now with it just being 24 hours . . .

HCP 9

I think now that the titles changed it's a lot better . . .

HCP 9

All three interviewees also pointed to less formal modifications that they made to the delivery of screening and intervention processes with reference to finding 'your own way'. The key here appeared to be rewording questions and amending the terminology used to help improve the acceptability of screening and intervention to patient participants. In some instances it appeared that specific terms could be problematic, regardless of

the individual patient. This specifically related to avoiding any implication that drinking behaviour may be problematic or that patients were being 'accused' of being a dependent drinker:

I perhaps might say pattern for that rather than behaviour because I think that gives a negative vibe to people . . .

HCP 5

I don't know, I think just the wording of those, so it was trying to find a way around wording that so that people didn't feel like they were being, almost accused of being an alcoholic . . .

HCP 5

In other cases, it was important to tailor the phrasing of questions and information to specific patients:

. . . it's trying to get the wording to suit the person in front of you because again, it varies from person to person, not everybody will respond the same way to the same question.

HCP 5

Perception of patient responses

The HCPs' perceptions of alcohol screening were that it was generally acceptable to patients, with very few declining screening and the majority being open to discussion about their alcohol consumption:

. . . good, yeah good ah I've never had one say 'oh no I a can't be bothered with it . . .

HCP 9

However, some demographic characteristics of patients were seen to make certain groups more open to screening and more likely to provide honest responses, with men and younger patients being perceived as more accepting of the screening and more open about their drinking behaviour:

I think the men are they the tend to be a bit more honest than the women erm women get quite a bit more defensive . . .

HCP 9

The HCPs identified once again that patients generally showed a favourable response to the intervention:

. . . the majority of the time it's been really fine, people responded really well.

HCP 5

Nonetheless, specific aspects of both the screening and intervention were identified as potentially leading to adverse responses from patients. The HCPs identified individual questions and phrases as well as a view that individuals were being 'singled out' as potentially making patients more defensive or less open. Each of these issues appeared to relate to a potential implication of judgement that the individual's drinking was problematic:

I think it's just a general issue erm some people get defensive because I think they think you're insinuating that they are drinking too much and I don't think they kinda get that it's for everybody on the list not just a single person . . .

HCP 9

However, it was clear that HCPs felt that the majority of patients were comfortable discussing their alcohol consumption.

Discussion

Although recruitment of patient participants initially proved to be challenging, amendments to the inclusion criteria, study title and period for consideration of participation led to a clear improvement in the percentage of eligible patients consented to the trial. This indicates that the amended study materials and processes were acceptable. Qualitative data from interviews with patient and HCP participants support this as they identify screening and intervention methods as acceptable and the PA as a suitable setting. Further to this, qualitative data provide additional insight into factors that can enhance the acceptability of methods and those that can aid behaviour change.

Qualitative data show that, despite patient participants having little to no knowledge of the association between alcohol consumption and surgical outcomes, screening and intervention in the PAC were acceptable. The finding that alcohol screening is acceptable supports findings from previous quantitative research, which also indicated good patient acceptance.^{57,62,68} Meanwhile, the findings that alcohol interventions delivered in the PA are acceptable mirror those relating to interventions delivered either predominantly¹⁰⁵ or entirely in the postoperative period.¹⁰⁴

This study builds on previous work by providing further detail on factors that contribute to the acceptability of screening and intervention in PA. Specifically, arranging screening and intervention around existing preoperative appointments so that no additional trips to the hospital were required was important, and the perceived normality of screening, along with the non-judgemental approach of staff, contributed to its acceptability. Although both patient and HCP participants identified alcohol as a potentially sensitive subject and suggested that some patients would not be comfortable completing the screening questionnaire, there was no evidence of this being the case even among the heaviest drinkers in our sample.

This work provides some early indications that BBIs may bring about reductions in alcohol consumption in the preoperative period, with half of the participants who received the intervention reporting at least some change to their drinking behaviour. Further to this, the subgroup of participants who did not change still reported receipt of the intervention as acceptable. This work also provides some insight into the components of screening and intervention techniques that were most useful to participants, namely information about the effects of alcohol on recovery, healing and surgical outcomes, along with effects on body weight and medication use and information about the lower-risk guidelines and health benefits of cutting down. However, the small number of patient participants and the variability in the information and advice identified as important highlights the need for interventions and interventionists in the preoperative setting to be sufficiently flexible to allow the tailoring of delivery to the individual patient.^{129,130}

With previous research^{131,132} finding that older adults are one of the least well-informed groups when it comes to alcohol measurement and terminology, it is perhaps not surprising that patient participants in this study were unfamiliar with the term 'standard drink'. Although participants reported being able to understand the screening questionnaires that use this term, their descriptions of standard drinks and units were not always consistent with this and participants consistently reported being more comfortable describing their consumption in terms of pints or glasses. Based on these findings, providing HCPs with adequate training and guidance to ensure that they are confident in converting patient descriptions of alcohol consumed in terms of pints or glasses into standard drinks or units is likely to enhance the accuracy of screening. Further to this, interventions designed for or implemented with older patient populations should seek to include descriptions of units or standard drinks in relation to common beverage servings (e.g. pints of beer, glasses of wine) in order to enhance the interpretation of low-risk drinking guidelines.

Similarly, as participants in this study rejected any categorisation of their drinking as 'risky' and endorsed the 'non-judgemental' approach of HCPs delivering screening and interventions, future screening and intervention work should avoid the use of such categorisations and ensure that the non-judgemental approach is maintained. Furthermore, the tendency for patients to use defensive othering to distance themselves from 'problem drinkers' suggests that interventions that focus on individual-level,

and context-specific (e.g. surgery), risks and benefits are likely to be more acceptable to patients in the preoperative setting.

Some barriers to effective delivery and receipt of screening and intervention methods were identified. Lack of adequate time to deliver screening and intervention to a high standard was identified as a barrier by the HCP participants. Scheduling of intervention sessions appropriately, providing research staff to conduct research-specific tasks (such as consent and randomisation procedures) and including guidance in intervention training that directly addresses how best to deliver intervention sessions if time is limited would go some way to minimising this issue. Nonetheless, unless additional fully trained staff are made available, and adequate space for them to work in is made available, this challenge is unlikely to be fully resolved.

Although removing the term 'risky drinking' from the project title and study materials appears to have aided improvements in patient recruitment, feedback following alcohol screening and information about the low-risk drinking guidelines often draw on this or similar terminology. Therefore, qualitative work in the subsequent pilot RCT sought to explore the preferred terminology in more depth.

Conclusions

The proposed research and intervention methods, once amended, were found to be acceptable to both patient and HCP participants. Although recruitment of patient participants was initially challenging, the changes made during the feasibility study greatly improved the percentage of eligible patients who consented to participate in the study. The planned pilot RCT was therefore considered justifiable.

Changes made prior to pilot randomised controlled trial

With well-documented screening effects and subject reactivity in previous research^{133,134} and some participants in this feasibility study reporting that completion of the screening questionnaire resulted in changes to drinking behaviour, possible changes to the screening and eligibility process were considered. Completion of an initial screen (AUDIT-C) followed by a more in-depth (full AUDIT) screening questionnaire to confirm eligibility at a later date (the method used in this work) may well induce changes in drinking behaviour between the two screens and lead to participants who are motivated, and already acting to reduce consumption, being excluded from intervention delivery. Therefore, the subsequent pilot RCT will assess eligibility relating to drinking behaviour based on the initial AUDIT-C screen. The full AUDIT will then be used at baseline and at follow-up to provide a more detailed assessment of alcohol consumption.

Chapter 4 Pilot randomised controlled trial

Introduction

The feasibility study showed that the screening and intervention methods were broadly acceptable to both patient and HCP participants. A pilot RCT was therefore considered to be justified. Pilot RCTs involve the rehearsal of full trial processes, including randomisation and follow-up, to provide estimations of rates of eligibility, recruitment, retention and data completion that can be used to inform a decision about the feasibility of proceeding to a definitive trial.

The methods of the pilot RCT are reported in the trial protocol.¹

Aims

Primary objective

To assess the feasibility of a definitive RCT by estimating rates of eligibility, recruitment and retention in a pilot RCT.

Secondary objectives

- Assess of completion rates for all data collection tool, including measures of alcohol consumption, quality of life and joint functionality.
- Establish response variability of proposed outcome measures for a definitive trial, which will include drinking status and quality of life.
- Estimate rates of secondary outcomes and perioperative complication rates, including bleeding and infections.
- Explore the acceptability of intervention and research methods with HCPs and patients in qualitative interviews.

Methods

Design

The design was a three-centre, two-arm (TAU vs. BBI), parallel-group, individually randomised pilot trial with an embedded qualitative interview study.

Setting and subject population

The pilot RCT was conducted across three secondary care hospitals in the north of England, one of which was the site of the feasibility study. All three sites have dedicated PACs with surgical care pathways of 6–10 weeks for patients undergoing hip and knee arthroplasty.

Eligible patients were those aged ≥ 18 years who were listed for elective primary hip or knee arthroplasty, met the criteria for increasing risk drinking, had the capacity to provide informed written consent and were able to write and converse in English.

Sample size

Based on recommendations for external pilot trials,¹³⁵ this pilot trial aimed to obtain data from 30 patient participants in each trial arm at 6 months post recruitment. Systematic reviews of alcohol BI trials show

mean follow-up rates of approximately 75%,^{82,136} although rates of follow-up for older adult populations may be higher.¹³⁷ It was therefore decided to allow for a loss to follow-up of 25% providing an initial recruitment target of 80 patients (40 per trial arm).

Progression criteria

The criteria for progression to a definitive trial were recruitment of 40% of patients identified as eligible and retention of 75% of participants at 6-month follow-up.

Procedure

Initial screening for alcohol consumption was conducted by a HCP trained in the use and scoring of the AUDIT-C. This initial screen was conducted after a patient had been listed for elective orthopaedic surgery, either face to face in the outpatient clinic or over the telephone, with the responses immediately assessed for eligibility. Eligibility for the study was confirmed if the patient screened positively for increased risk drinking (AUDIT-C score of ≥ 5) or reported drinking six or more standard drinks in one session at least weekly (identified from question 3 on the AUDIT-C). Patients who scored an AUDIT-C score of < 5 and who consumed six or more standard drinks in a single session less frequently than weekly were thanked for their time and received positive feedback on their low-risk drinking status. Patients were excluded if they were scheduled to undergo sequential joint replacements (bilateral replacement of both joints within a short time) during the study, displayed current (active) withdrawal from alcohol, or had a severe psychiatric disorder requiring medical treatment, cognitive impairment or dementia, affecting their ability to interact with the intervention.

All patients who screened eligible were given a verbal description of the trial and those who expressed interest in participating were provided with a copy of the participant information sheet (see *Appendix 13*) and were asked if they were willing to be contacted about the study. Those willing to be contacted provided either telephone or e-mail contact details (dependent on patient preference), which were recorded on the expression of interest form. Patients were then given a minimum of 24 hours to consider participation. After this time the HCP contacted them by their preferred method to gauge ongoing interest in the trial. When patients expressed ongoing interest, the PAC was informed of their likely participation and arrangements were made for the completion of the consent and randomisation process as well as potential delivery of the BBI.

Patients were met at the PAC by a member of the research team not involved in screening or intervention delivery. The researcher checked that each patient was still interested in participating in the study, confirmed their eligibility, including establishing their capacity to consent, and conducted the informed consent discussion, during which the patient completed the written consent form including indication of their willingness to have their intervention session recorded and to be contacted about participating in the optional booster session and a qualitative interview.

Once informed consent had been obtained, the researcher accessed the electronic randomisation system, which randomised patients to either TAU or BBI on a one-to-one basis. All participants were provided with copies of the WOMAC and EQ-5D questionnaires to complete while they waited to be seen by the PA HCP.

Following consent and randomisation, all participants were seen by a PA HCP. Participants allocated to the control condition received TAU and completed the AUDIT questionnaire. Participants allocated to the intervention condition received TAU and completed the AUDIT questionnaire before receiving BBI.

Brief behavioural intervention

The intervention and its development are described in detail in *Chapter 2* and summarised here. The intervention commenced with completion of the full AUDIT questionnaire. This was followed by the delivery of approximately 5 minutes of structured advice relating to alcohol consumption (based on completion of the AUDIT). The HCPs used the BA tool as a visual prompt and to guide their delivery of advice about alcohol consumption.

Following BA, the BI protocol was used to guide up to 25 minutes of brief behaviour change counselling targeting alcohol reduction or cessation. This aspect of the intervention was designed to be tailored to the individual patient's needs and motivations and could include assessing motivation and confidence to change, pros and cons of changing, goal-setting, problem-solving and identifying of sources of social support. Patients were provided with copies of the intervention tools to take away with them, as well as a copy of the patient leaflet.

Patients who consented to be approached for the second booster session were contacted around 1–2 weeks before surgery to gauge their ongoing interest in the booster session and to arrange this. Where possible, booster sessions were delivered by the HCP who delivered the initial intervention session. If this was not possible, for example because of availability, another appropriately trained HCP delivered the session. Booster sessions were delivered either in clinic or over the telephone according to patient preference. As with the initial intervention session, the booster session began with completion of the full AUDIT tool. The remainder of the 10- to 20-minute session aimed to review or revise behavioural goals, provide feedback on progress and increase self-efficacy. For participants who had expressed interest in changing their drinking behaviour during the initial intervention session, but had not yet set any goals, this session allowed them to set goals and produce action plans to reach these goals and address any potentially 'difficult' times.

Control condition: treatment or care as usual

The comparator condition of TAU is described in detail in *Chapter 2* and summarised here. Patients allocated to the TAU condition did not receive the intervention but did complete all study baseline measures. As part of the standard PA for hip or knee arthroplasty, patients were asked a variety of health-related questions, had blood samples taken and had other observations, including blood pressure and echocardiograms, completed. Patients considered by the PA HCP to be 'heavy drinkers' or those identified as heavy drinkers as a result of LFTs were routinely referred for consideration by a consultant anaesthetist who assessed any potential risk to anaesthesia or surgery itself.

All three sites included in the trial also had specialist alcohol support services available. However, referral of patients from PA to in-hospital alcohol services was reported to be rare, with no standard process for identifying and referring patients (see *Chapter 2* for further detail). Further to this, these services were hospital wide and not designed to provide specific support for preoperative alcohol reduction or cessation.

Follow-up

From screening to final follow-up there were six or seven key points of contact between participants and members of the research team, depending on trial arm. The trial process is summarised in *Figure 4* and the measures and activities completed at study visit are shown in *Tables 13* and *14*.

All baseline measures were completed at visit 1. Follow-up assessments took place 1–3 days preoperatively (either over the telephone or in hospital if admitted the day before surgery); 3–5 days post surgery; at or around the 6-week postoperative outpatient appointment; and at 6 months post intervention.

Data collection

The primary outcomes of this pilot trial were the number of patients screened, the percentage of eligible patients recruited, and the percentage retained at 6-month follow-up. In addition to these outcomes to be utilised in designing a definitive trial, we collected, at the time points shown in *Table 13*:

- alcohol consumption – assessed with the full AUDIT tool⁹
- health-related quality of life – assessed with the EQ-5D^{114,115}
- joint functionality – assessed with the WOMAC.¹¹³

Rates of postoperative complications and length of hospital stay were assessed with the Clavien–Dindo tool¹¹² and POMS.¹¹¹

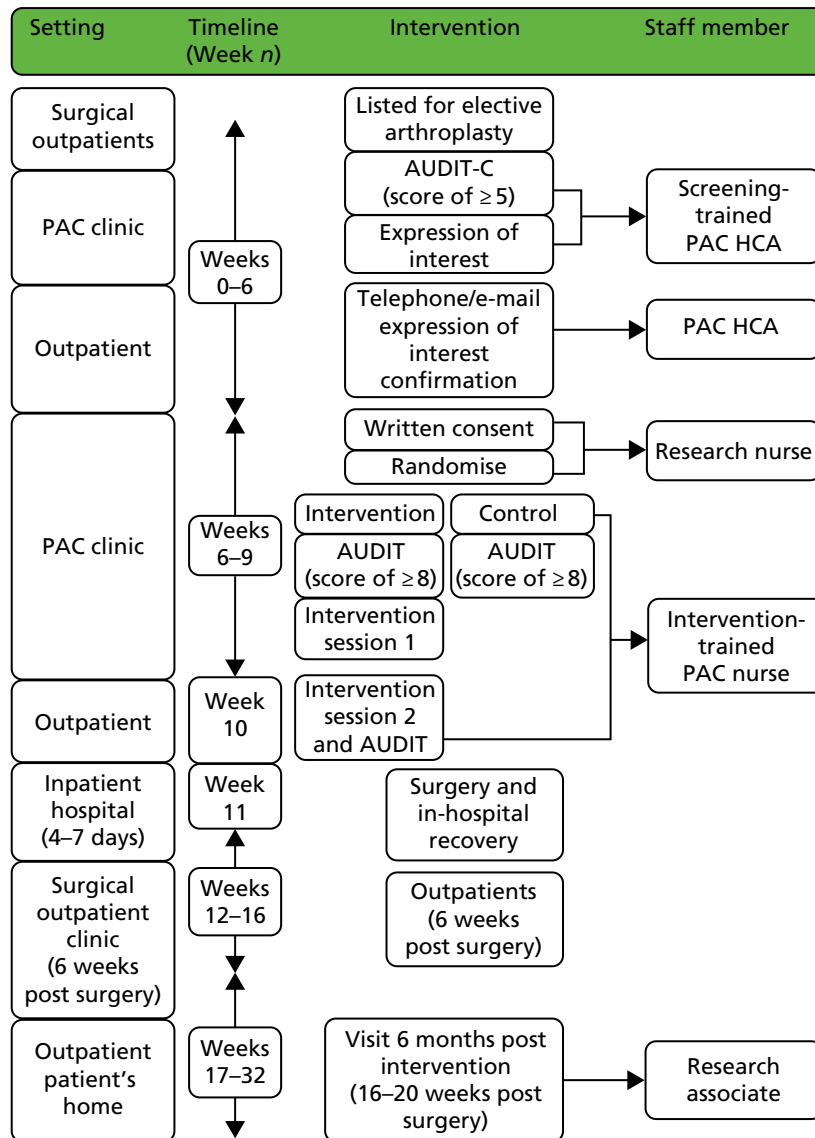


FIGURE 4 Pilot RCT process.

Covariate data relating to health behaviours [smoking, physical activity and body mass index (BMI), which have been shown to be associated with surgical complication rates] routinely captured during PA were also collected at visit 1.

Qualitative methods

Patient interviews

At the point of consent to the pilot RCT, patient participants indicated whether or not they were willing to be contacted about participating in a qualitative interview. At 6 months post intervention, Ellen Lynch contacted participants by telephone to conduct the final follow-up. Participants who had previously provided their consent were asked if they would be willing to take part in an interview. Those who assented were sent a copy of the interview-specific information sheet by e-mail or post (depending on participant preference) and Ellen Lynch made arrangements to conduct the interview at a time and place convenient to the participant.

On the day of the interview, the participant was met by Ellen Lynch, who provided them with a hard copy of the interview-specific patient information sheet and gave them a verbal introduction to the interview process, including ethical considerations. She also gave a verbal summary of her research experience and

TABLE 13 Pilot RCT schedule of events

Time point	Study period					
	Screening	Visit 1: 6–8 weeks pre surgery	Visit 2: 1–2 weeks pre surgery (intervention arm only)	Visit 3: 1 and 3 days pre surgery	Visit 4: up to 5 days post surgery	Visit 5: 6 weeks post surgery
Enrolment						
AUDIT-C	X					
Expression of interest	X					
Consent		X				
Randomisation		X				
Interventions						
Intervention		X				
Booster			X			
TAU		X				
Assessments						
AUDIT baseline		X				
EQ-5D baseline		X				
AUDIT outcome			X	X		X
EQ-5D outcome						X
WOMAC		X			X	
POMS					X	
Clavien–Dindo score					X	
Interview						X

TABLE 14 Pilot RCT patient recruitment and randomisation by arm

Site	Number	Intervention	Control
1	19	11	8
2	34	17	17
3	15	7	8
Total	68	35	33

her role in the project. The participant then had the opportunity to ask any questions before completing the informed consent discussion and signing the interview-specific consent form. Once consent had been gained, Ellen Lynch began the interview by asking the participant what led to them coming into hospital and then utilised the questions and prompts contained within the arm-appropriate (TAU or BBI) interview topic guide (see *Appendix 15*) to structure the interview.

At the end of the session, the participant was thanked for their participation in the interview and in the trial as a whole, and had the opportunity to ask any further questions.

Interviews lasted between 35 minutes and 1 hour 45 minutes and were audio-recorded and transcribed verbatim. Transcripts were anonymised and were then subject to framework analysis.

Health-care professional interviews

Each HCP who consented to take part in the pilot RCT and went on to be involved in delivery of the screening or intervention was offered the opportunity to participate in a qualitative interview regarding their experience of the trial. The research associate contacted HCPs by e-mail asking if they were willing to participate in such an interview.

Those who assented to participate were sent an electronic copy of the HCP interview-specific information sheet and the research associate arranged a time and place convenient to the HCP for the interview to take place. At the beginning of each interview session, the HCP was provided with a hard copy of the interview-specific information sheet. The research associate provided a verbal summary of her research experience, her role in the project and the interview process including ethics considerations. The HCP then had the opportunity to ask any questions before completing the informed consent form. Once consent had been gained, the research associate began the interview by asking the HCP to explain their role in the project and then utilised the questions and prompts contained within the interview topic guide to structure the interview.

At the end of the session, the HCP was thanked for their participation and had the opportunity to ask any questions.

Interviews lasted between 20 minutes and 1 hour 30 minutes, and were audio-recorded and transcribed verbatim. Transcripts were anonymised and then subject to framework analysis.

Analysis

Statistical analysis

The numbers of screened and eligible patients and the rates of recruitment, randomisation and retention were reported, and any reasons for ineligibility and non-participation were summarised. The baseline characteristics and outcomes at follow-up time points were summarised, with descriptive statistics presented by arm or site (means, medians and ranges for continuous data and frequencies and proportions/rates for categorical data). We investigated the data completeness of the study tools by reporting the number of missing data by outcome and arm. This information was then used to identify the primary outcome for a definitive trial and estimate the necessary sample size.

Qualitative analysis

Qualitative data from HCP and patient interviews were analysed using framework analysis.¹²⁶ This is a recommended approach for qualitative health research with objectives linked to quantitative investigation.¹³⁸ As in the feasibility study, patient and HCP participant interviews were analysed separately.

For patient participant interview data, a subset of transcripts were repeatedly read and coded with initial codes used to develop a framework of themes and subthemes. All transcripts were then coded within this framework with additional emergent themes and subthemes added to the framework. Finally, themes relevant to the aim of assessing acceptability and feasibility of study and intervention methods were selected and are discussed here.

For HCP interviews, initial descriptive codes were generated from the transcripts before being grouped into a framework that used the components and constructs of NPT¹²⁸ as themes and subthemes but was left open enough to allow the emergence of additional themes relating to the acceptability of the study research, screening and intervention methods.

Results

Screening, recruitment and retention

The flow of participants through the trial, including screening, recruitment and retention at follow-up, is presented in the CONSORT (Consolidated Standards of Reporting Trials) flow diagram in *Figure 5*. In total, 1117 patients were approached; 866 completed the screening questionnaire (AUDIT-C), 198 were potentially eligible based on the AUDIT-C screen (22.9% of those screened) and 68 (34.3% of those eligible) consented and were randomised (*Figure 6*).

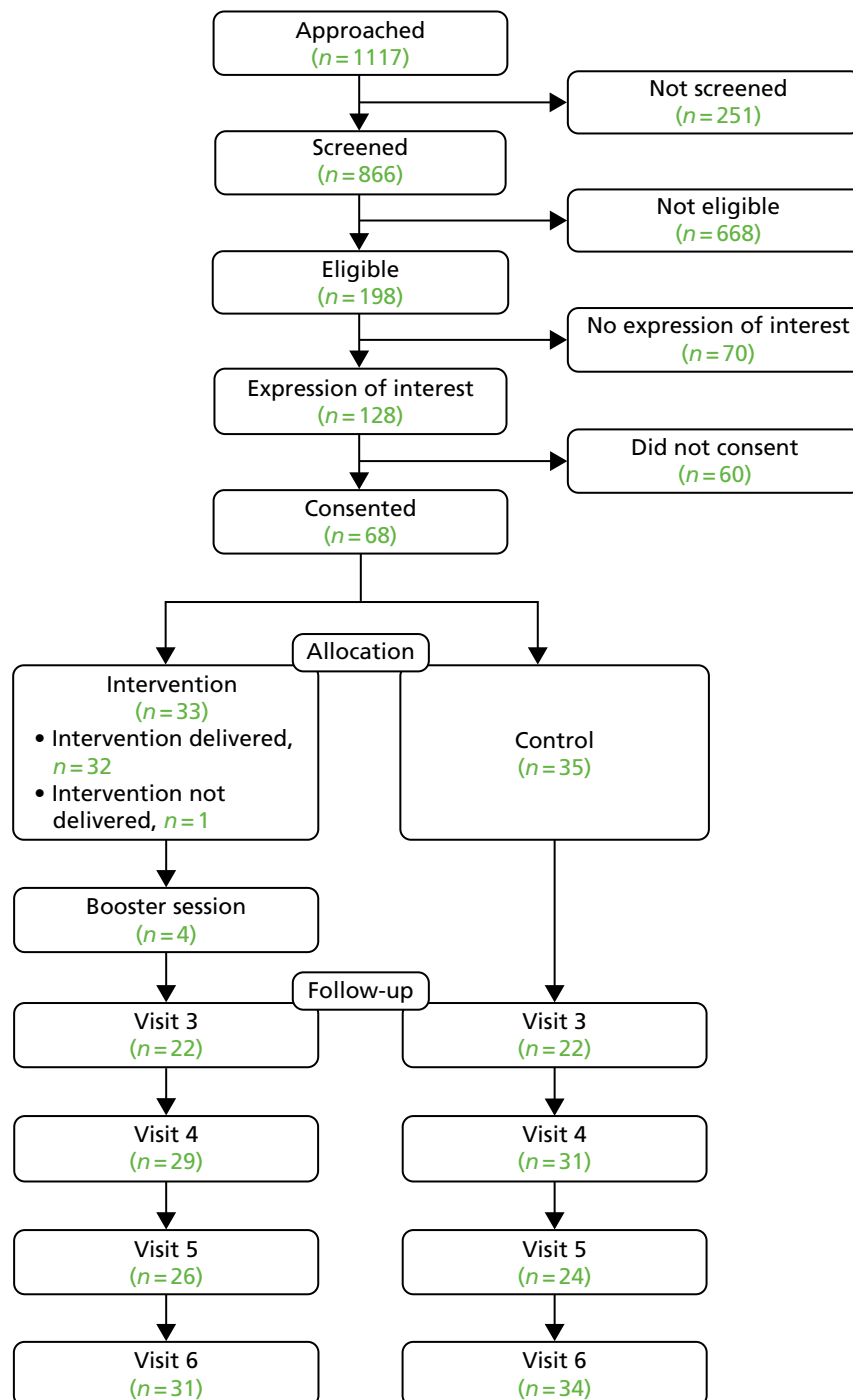


FIGURE 5 Pilot RCT CONSORT flow diagram.

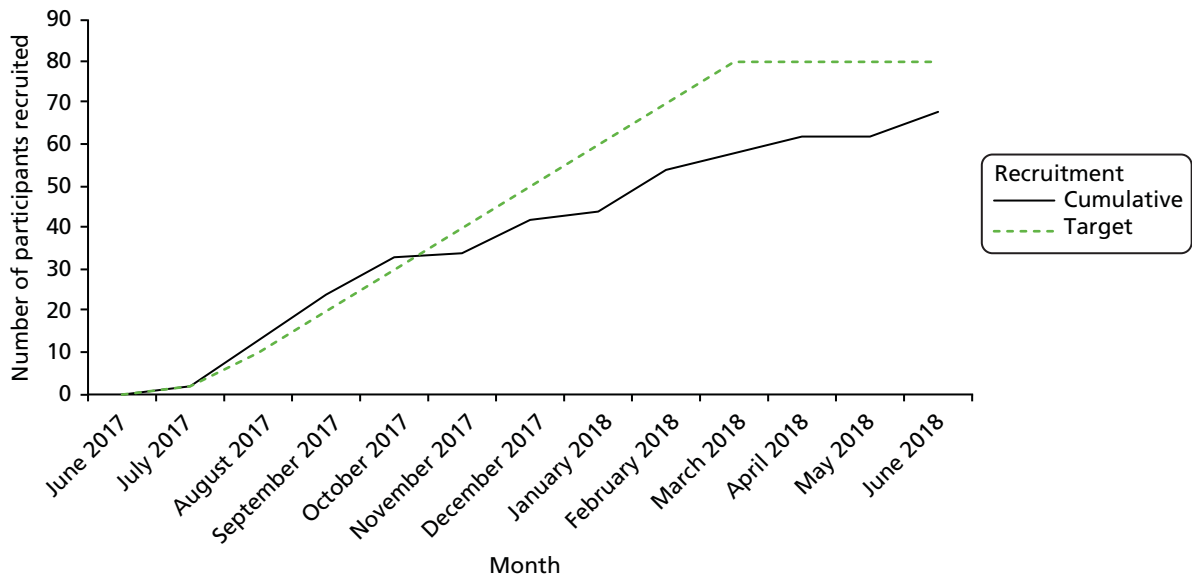


FIGURE 6 Pilot RCT recruitment graph.

Although recruitment of eligible participants fell short of the progression criterion (40%) and the target of 80 patients recruited was not met, retention at final study visit was much higher than estimated, with 65 patients completing the final follow-up. Thus, the subsequent target of follow-up data obtained from 60 patients was exceeded.

Tables 15 and 16 show the reasons patients were found to be ineligible or declined to participate in the trial. Table 17 presents a summary of screening and recruitment data from the feasibility study and pilot RCT to allow direct comparison. Although the percentage of eligible patients expressing interest in the study was 31% lower in the pilot RCT than in the feasibility study, the percentage of eligible patients recruited increased by 20%. The most frequent reasons for ineligibility remained consistent and related to alcohol consumption behaviour, with 88% of ineligible participants scoring < 5 on the AUDIT-C questionnaire and a further 6% reporting that they did not drink alcohol at all. The most frequently cited reasons for non-participation among eligible patients were lack of interest in the study and not having enough time available to participate; 17 eligible patients had no clearly recorded reason for non-participation.

TABLE 15 Reasons that participants did not meet eligibility criteria

Reason	Frequency (%)
AUDIT-C score of < 5	668 (88.1)
Did not drink at all	46 (6.1)
Surgery too soon	24 (3.2)
Psychiatric disorder	6 (0.8)
Possible alcohol dependence	5 (0.7)
Pre-assessment already complete	4 (0.5)
Patient requested rescreen – not eligible	3 (0.4)
Sequential surgeries	1 (0.1)
Did not speak English	1 (0.1)

TABLE 16 Reasons eligible participants declined to participate in the trial

Reason	Frequency (%)
Not interested	44 (42.7)
Unclear	17 (16.5)
Not enough time	12 (15.6)
Unable to contact	9 (8.7)
No staff available	8 (7.8)
Cut down on own	4 (3.9)
Left clinic	3 (2.9)
Did not attend	1 (1.0)

TABLE 17 Comparisons of screening and recruitment rates for feasibility and pilot studies

Recruitment stage	<i>n</i> (%)		% of eligible		
	Feasibility	Pilot	Feasibility	Pilot	Difference
Approached	658 (100)	1117 (100)	–	–	–
Screened	620 (94)	866 (78)	–	–	–
Eligible	105 (16)	198 (18)	100	100	–
Expressed interest	101 (15)	128 (11)	96	65	–31
Consented	15 (2)	68 (6)	14	34	+20

Participant characteristics at baseline

Table 18 summarises the baseline characteristics of the trial participants. The age of the 68 patients recruited ranged from 40 to 85 years (median 67 years); the patients were predominantly male (80.9%), all but one identified as white British, and 66% attended pre-assessment in preparation for knee arthroplasty surgery.

Participant health behaviour at baseline

Table 19 shows the distribution of measures of health behaviours at baseline by trial arm. Participants' weekly alcohol consumption as reported in units at pre-assessment ranged from 1 to 90 units per week, with a median of 18 units. Some participants reduced alcohol consumption between screening and baseline. Although only five participants identified as current smokers, almost 60% were ex-smokers. Forty per cent of patients reported no physical activity and the median BMI identifies the majority of the patient group as falling into the 'obese' category.

The distributions were comparable across trial arms.

Patient follow-up

As seen in the schedule of events (see *Table 13*), follow-up was based around four or five study visits (depending on trial arm). Visit 2 was an optional booster session and therefore available only to those in the intervention condition. All participants were asked to provide data at all other study visits, although the occurrence and timing of visits 3, 4 and 5 were dependent on participants undergoing surgery (eight of the 68 participants recruited did not have surgery during the study period). Rates of completion varied by visit, with the highest rates of completion at visits 1 and 6 and participation in the optional booster session being especially low (4/35).

TABLE 18 Demographic characteristics at baseline by trial arm

Demographic characteristics	Arm		Total (N = 68)
	BBI (N = 33)	TAU (N = 35)	
Age (years)			
Mean	63.8	68.4	66.2
Minimum	40	46	40
Median	64	69	67
Maximum	75	85	85
Missing	–	–	–
Gender, n (%)			
Number	(N = 33)	(N = 35)	(N = 68)
Male	27 (81.8)	28 (80.0)	55 (80.9)
Female	6 (18.2)	7 (20.0)	13 (19.1)
Missing	–	–	–
Ethnicity, n (%)			
Number	(N = 33)	(N = 35)	(N = 68)
White British	33 (100)	34 (97.1)	67 (98.5)
Other	0	1 (2.9)	1 (1.5)
Operation type, n (%)			
Number	(N = 33)	(N = 35)	(N = 68)
Hip	13 (39.4)	10 (28.6)	23 (33.8)
Knee	20 (60.6)	25 (71.4)	45 (66.2)
Missing	–	–	–

TABLE 19 Participant health at baseline by trial arm

Health factor	Arm		Total
	BBI	TAU	
Units of alcohol per week			
Number	(N = 32)	(N = 34)	(N = 66)
Mean	24.6	18.5	21.4
Minimum	1	2	1
Median	20	16	18
Maximum	90	60	90
Missing	1	1	2
Number of days physically active per week			
Number	(N = 18)	(N = 18)	(N = 36)
Mean	5.0	4.6	4.8
Minimum	1	1	1
Median	6	5	5
Maximum	7	7	7
Missing	15	17	32

TABLE 19 Participant health at baseline by trial arm (*continued*)

Health factor	Arm		Total
	BBI	TAU	
BMI (kg/m ²)			
Number	(N = 33)	(N = 34)	(N = 67)
Mean	31.7	31.6	31.7
Minimum	24.6	21.9	21.9
Median	32.2	32.1	32.1
Maximum	44.6	43.6	44.6
Missing	0	1	1
Any physical activity, <i>n</i>			
Number	(N = 31)	(N = 34)	(N = 65)
Yes	20	19	39
No	11	15	26
Missing	2	1	3
Smoking history, <i>n</i> (%)			
Number	(N = 33)	(N = 34)	(N = 67)
Current	2 (6.1)	3 (8.9)	5 (7.5)
Ex	16 (48.5)	23 (67.7)	39 (58.2)
Never	15 (45.5)	8 (23.5)	23 (34.3)
Missing	0	1	1

Time interval between baseline and surgery

It was expected that surgery would take place between 6 and 10 weeks after the baseline visit. *Table 20* and *Figure 7* show the distribution of the time intervals between baseline and surgery observed during the pilot trial.

Eight patients did not undergo surgery before the end of the trial. Two (one in each arm) were removed from the surgical waiting list and six (three in each arm) were awaiting surgery at the close of follow-up. A small number also had the 6-month post-intervention follow-up very shortly after surgery.

TABLE 20 Distribution of time interval between baseline and surgery

Time interval (number of weeks)	Arm		Total (<i>n</i> = 65)
	BBI (<i>n</i> = 32)	TAU (<i>n</i> = 33)	
Minimum	0.7	0.3	0.3
Median ^a	6.6	5.6	5.7
Maximum ^a	> 70.6	> 46	> 70.6

^a For the five participants who were still waiting for surgery at trial close, a proxy measure of time from baseline to trial end has been used. Specifically two participants in the TAU arm waited 28.3 and 46 weeks, and three participants in the BBI arm waited 25.1, 46 and 70.6 weeks.

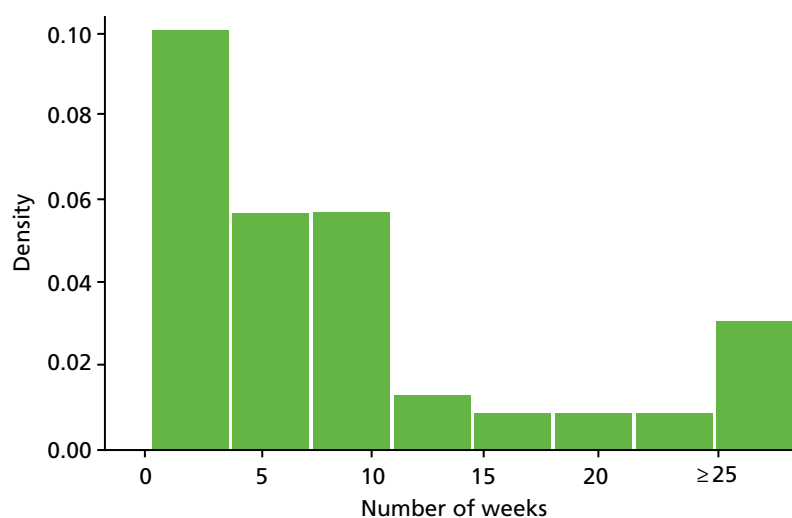


FIGURE 7 Number of weeks between baseline and surgery.

Completion rates for baseline and outcome measures

If patient participants attended a study visit, completion of each questionnaire was high, especially for AUDIT and EQ-5D. The WOMAC questionnaire was less well completed, with five partially complete at visit 1, four partially complete and 18 not completed at visit 4; this instrument required contact with the patient within a short period following surgery. By contrast, measures of complication rates and length of hospital stay could be completed from patient notes by an appropriately trained HCP and did not require patient input (*Table 21*).

TABLE 21 Rates of completion for outcome measures at baseline and follow-up visits by trial arm

Study visit	Measure	Completion	Arm		Total
			BBI	TAU	
1	AUDIT	Complete	32	35	67
		Partially ^a complete	1	–	1
		Missing ^b	–	–	–
	EQ-5D	Complete	33	35	68
		Partially complete	–	–	–
		Missing	–	–	–
	EQ-5D score	Complete	32	35	67
		Missing	1	–	1
	WOMAC	Complete	30	32	62
Partially complete		3	2	5	
Missing		–	1	1	
2 (optional booster 1 week pre surgery)	AUDIT	Complete	4	0	4
		Partially complete	–	–	–
		Missing	5	–	5

TABLE 21 Rates of completion for outcome measures at baseline and follow-up visits by trial arm (*continued*)

Study visit	Measure	Completion	Arm		Total
			BBI	TAU	
3 (1–3 days pre surgery)	AUDIT	Complete	22	22	44
		Partially complete	–	–	–
		Missing	2	6	4
4 (in hospital 3–5 days post operative)	POMS	Complete	29	31	60
		Missing	4	–	–
	Clavien–Dindo	Complete	29	31	60
		Missing	4	–	–
	WOMAC	Complete	20	24	48
		Partially complete	2	2	4
		Missing	7	5	12
	5 (6 weeks post operative)	AUDIT	Complete	26	24
Partially complete			–	–	–
Missing			1	5	6
EQ-5D		Complete	24	24	48
		Partially complete	–	–	–
		Missing	3	5	8
EQ-5D score	Complete	24	24	48	
	Missing	3	5	8	
6 (6 months post intervention)	AUDIT	Complete	31	34	65
		Partially complete	–	–	–
		Missing	–	–	–
	EQ-5D	Complete	31	34	65
		Partially complete	–	–	–
		Missing	–	–	–
	EQ-5D score	Complete	31	34	65
		Missing	–	–	–
	Interview	Consented	7	7	14

a 'Partially complete' refers to those that have missing items but are still usable with the application of particular rules for dealing with missing data for the particular questionnaire.

b Missing refers to questionnaires that either are completely missing or have more than the acceptable number of missing items, and so cannot be used.

Summary statistics for clinical measures across study visits

Tables 22–25 summarise the clinical outcomes by trial arm. Because varying numbers of participants provided data at each study visit, it is difficult to comment on the pattern over time, but typical AUDIT scores decreased in both arms until visit 6. The AUDIT scores were also summarised as whether or not they were in the 'risky drinking' category (AUDIT score of ≥ 8). At baseline, 55% of those in the BBI arm were risky drinkers, compared with 49% in the TAU arm. At visit 6, 45% of those in the BBI arm were risky drinkers, compared with 38% in the TAU arm. Typical EQ-5D visual analogue scale scores increased slightly over time in both arms. Typical WOMAC scores were little changed in either arm.

TABLE 22 The AUDIT scores by arm and study visit

Study visit	Arm		Total
	BBI	TAU	
	(N = 32)	(N = 35)	(N = 67)
1			
Mean	9.7	7.7	8.6
Minimum	3	3	3
Median	9	8	8
Maximum	24	18	24
Missing	1	–	1
	(N = 4)	(N = 0)	(N = 4)
2			
Mean	6.8	–	6.8
Minimum	3	–	3
Median	4	–	4
Maximum	16	–	16
Missing	5	–	5
	(N = 22)	(N = 22)	(N = 44)
3			
Mean	6.3	4.6	5.4
Minimum	0	0	0
Median	5.5	4	5
Maximum	19	15	19
Missing	2	6	8
	(N = 26)	(N = 24)	(N = 50)
5			
Mean	5.5	3.6	4.6
Minimum	0	0	0
Median	5	3	4
Maximum	16	10	16
Missing	1	5	6
	(N = 31)	(N = 34)	(N = 65)
6			
Mean	7.6	6.6	7.1
Minimum	0	0	0
Median	7	7	7
Maximum	17	12	17
Missing	–	–	–

Complication rates for orthopaedic surgery were relatively low, at approximately 4–5%.^{17,22} In this sample, four patients developed at least one postoperative complication. Of these, one patient developed two different complications. Although the numbers are very small, this equates to approximately 6% of the overall sample, and almost 7% of those who completed visit 4. This is in line with evidence from larger trials that complication rates are higher among AUDIT-C-positive patients.

TABLE 23 The EQ-5D visual analogue scale scores by trial arm and study visit

Study visit	Arm		Total
	BBI	TAU	
	(N = 32)	(N = 35)	(N = 67)
1			
Mean	63.0	60.9	61.9
Minimum	20	10	10
Median	65	70	65
Maximum	95	95	95
Missing	1	–	1
	(N = 24)	(N = 24)	(N = 48)
5			
Mean	67.1	76.1	71.6
Minimum	35	35	35
Median	70	80	75
Maximum	90	95	95
Missing	3	4	7
	(N = 31)	(N = 34)	(N = 65)
6			
Mean	73.2	71.3	72.3
Minimum	30	25	25
Median	80	80	80
Maximum	95	100	100
Missing	–	–	–

TABLE 24 The WOMAC scores by trial arm and study visit

Study visit	Arm		Total
	BBI	TAU	
	(N = 30)	(N = 32)	(N = 62)
1			
Mean	55.1	54.3	54.7
Minimum	31	4	4
Median	52.5	51	52
Maximum	86	90	90
Missing	3	3	6
	(N = 20)	(N = 24)	(N = 44)
4			
Mean	54.2	50.3	52.1
Minimum	23	6	6
Median	55	52	53
Maximum	79	89	89
Missing	10	7	17

TABLE 25 Postoperative complication rates and length of stay by trial arm

Visit 4 outcome measure	Arm, n (%)		Total, n (%)
	BBI	TAU	
POMS: morbidity category			
None	26 (89.7)	31 (100.0)	57 (95.0)
Pulmonary	1 (3.5)	–	1 (1.7)
Infectious	2 (6.9)	–	2 (3.3)
Renal	–	–	–
Gastrointestinal	–	–	–
Cardiac	–	–	–
Neurological	–	–	–
Wound	–	–	–
Haematological	–	–	–
Pain	–	–	–
Missing	2	2	4
Any complications (Clavien–Dindo)			
No	27 (93.1)	29 (93.6)	56 (93.3)
Yes	2 (6.9)	2 (6.5)	4 (100.0)
Missing	4	–	4
Clavien–Dindo grade			
1	1 (33.3)	2 (100.0)	3 (60.0)
2	1 (33.3)	–	1 (20.0)
3a	1 (33.3)	–	1 (20.0)
3b	–	–	–
4a	–	–	–
4b	–	–	–
5	–	–	–
Length of stay (days)			
Mean	3.4	3.4	3.4
Minimum	2	1	1
Median	3	3	3
Maximum	13	18	18

In addition to collecting details of postoperative complications, the Clavien–Dindo measure collects data relating to length of hospital stay and length of intensive care unit stay. The national average length of hospital stay is 4.3 days following primary knee arthroplasty and 4.4 days following primary hip arthroplasty. However, length of stay varies from site to site, with hospitals that employ enhanced recovery procedures reporting shorter postoperative hospital stays. This variation is reflected in our data. None of the participants for whom visit 4 was completed was admitted to intensive care following surgery; however, a number of participants had extended hospital stays, with the maximum length of stay being 18 days.

Sample size estimates for a definitive study

After a discussion of the pilot trial results, it was decided that the effectiveness of a preoperative alcohol intervention in a definitive study should have a primary outcome based on alcohol consumption behaviour, and that measures of complications would be a secondary outcome. The primary outcome would be based on AUDIT. This offers the opportunity to use either a continuous (AUDIT score) or a binary (risk group) measure.

A number of considerations led us to select a binary measure of AUDIT score of ≥ 8 or < 8 at 6 months after the intervention. First, the intervals between each point on the AUDIT are not necessarily equivalent. Thus, a reduction of, for example, 2 points for someone originally scoring 20 points does not represent the same level of change or associated benefit as a reduction of 2 points for someone originally scoring 10 points. Second, there is evidence that reduction in risk levels assessed by AUDIT is associated with improvements in physical and mental health and quality of life, as well as reductions in alcohol-related consequences.^{139,140} This is mirrored in the literature about PA, which shows that those drinking at least two standard drinks per day (i.e. the cut-off point for lower-risk drinking) and high but not low to moderate drinkers are at increased risk of experiencing surgical complications.⁵⁸⁻⁶⁰ Meanwhile, no current evidence explicitly identifies what would be a clinically meaningful reduction in either alcohol consumption or AUDIT score in the preoperative setting. Third, employing a dichotomous variable for a sample size calculation will project larger numbers and thus would provide a sample size that would be more than adequate for conducting analysis on a continuous outcome should this be adopted in a future trial. Finally, it was also felt that the binary risk measure would be better understood by those less familiar with alcohol screening tools and the interpretation of screening scores. Studies of other brief alcohol interventions have used an effect size of 13% as the basis of the sample size calculation, when the outcome was whether or not the patient managed to reduce from an AUDIT score of ≥ 8 to that of < 8 over the follow-up period. A study of the PRE-OP BIRDS intervention could not use exactly the same outcome as some of the patients had reduced their alcohol consumption between screening and baseline, meaning that although they were eligible based on the initial AUDIT-C screen, they reported lower-risk drinking at baseline. We have nevertheless used 13% as the effect size, but also shown the sensitivity of the estimates by calculating for an effect size of 10% and 15%. The proportion of patients in the pilot trial with an AUDIT score of ≥ 8 at 6 months was 42%. Because the sample size is largest when the percentages are close to 50%, the differences to be detected have been calculated for 40–50%, 40–53% and 40–55%. Standard sample size calculations to compare proportions will give the number of responses needed at follow-up, using a type 1 error rate of 5% and a power of 90%.

It is also necessary to take into account other estimates from the pilot trial to work out how many patients would need to be screened, approached and recruited to the trial:

- percentage of those screened who are eligible = 23%
- percentage of those eligible who are recruited = 34%
- percentage of responses to primary outcome at follow-up – this was 96% in the pilot study, but a conservative figure of 80% was used for the calculation.

Table 26 shows the total number of patients necessary for a definitive trial. To have 90% power to detect a difference between risky drinking rates of 40% and 53%, it would be necessary to screen 9843 patients, of whom 2264 would meet the eligibility criteria and 770 would be recruited (385 randomised to each arm), to obtain the primary outcome for a total of 616 patients at 6 months. Depending on the number of surgeries undertaken at the sites selected for a definitive trial, it would be possible to achieve such a sample size with 8–10 sites recruiting for between 12 and 18 months.

TABLE 26 Total number of patients needed in definitive trial when outcome is % AUDIT score of ≥ 8 at 6 months

Trial stage	Difference to be detected		
	10%	13%	15%
Number of responses to primary outcome	1038	616	462
Number of recruited patients	1298	770	578
Number of eligible patients	3818	2264	1700
Number of patients screened	16,600	9843	7391

Safety reporting

No serious adverse events were identified during the pilot trial.

Qualitative results

Patient interview results

Fourteen pilot trial patient participants consented to and participated in qualitative interviews about their experience of being involved in the trial. Demographic details of these participants are provided in *Table 27*. Seven themes relating to the acceptability of research, screening and intervention processes were identified from the data and these are presented here.

Acceptability of trial design

Interviews considered the acceptability of the trial as a whole, as well as some specific aspects of the pilot RCT design (time to consider involvement, randomisation and follow-up). Many participants stated that they took part simply because they had been asked to. However, participation in research was also viewed as a way of contributing to something that could help others in the future and was a method of 'giving back' to the NHS both for previous treatment and for the fact that they would be receiving a hip/knee arthroplasty:

I have had two previous involvements with the NHS, both emergencies, one 10 years ago and the other about 20 years ago. On both of those occasions I couldn't speak too highly of the treatment I got. Here you are again and you realise what it's all about. It's up to you to do what you can to play your part and contribute, I think.

Male, knee, 78 years

TABLE 27 Participant characteristics (of those who attended the interview) at baseline by arm

Participant characteristic	Arm		Total (N = 14)
	BBI (N = 7)	TAU (N = 7)	
Age (years)			
Mean	67.7	71.3	69.5
Minimum	60	63	60
Median	67	69	69
Maximum	75	84	84
Missing	–	–	–
Gender, n (%)			
Number	(N = 7)	(N = 7)	(N = 14)
Male	7 (100)	6 (85.7)	13 (92.9)
Female	0 (0)	1 (14.3)	1 (7.1)
Missing	–	–	–
Ethnicity, n (%)			
Number	(N = 7)	(N = 7)	(N = 14)
White British	7 (100)	7 (100)	14 (100)
Other	–	–	–
Operation type, n (%)			
Number	(N = 7)	(N = 7)	(N = 14)
Hip	2 (28.6)	1 (14.3)	3 (21.4)
Knee	5 (71.4)	6 (85.7)	11 (78.6)
Missing	–	–	–

The potential individual benefit of receiving additional information from a HCP and the possibility of reducing the risk of complications arising from surgery or improving recovery time was discussed by only one of the interviewees as a motivation for taking part:

I thought, 'Well, yes'. With initially them saying, 'Well, it could be beneficial for the operation and after the operation—' I've never had an operation like this before. I think, 'Well, if it's going to help, then I'll have a look at that'.

Male, knee, 64 years

Having the necessary free time to participate in the research also appeared to play a role in the decision. However, one participant explained that it was important that patients were not required to take part, and others indicated that there was still a limit to how much time they would be willing to give up in order to participate, which highlights the need to minimise the potential burden of research on participants:

That's fine, you know, you don't mind. It's when it's every week, people are, 'Can we come in?' and I think if that happened, I would just say, 'Sorry, I've had enough' . . .

Male, knee, 70 years

Although participants stated that they were 'quite happy' with the trial, that they understood the questions they were asked and that the study was 'fine' and even 'enjoyable' and one of the 14 interviewees expressed a desire to know more about how the analyses would be completed and what was expected of them in terms of behaviour change:

It was always a bit vague about what the nature of the trial was. Obviously, I know the aim and what it's about, but I didn't know what you were trying to get out of me. I didn't know what you were trying to get from me, so it was always a bit vague, I thought . . .

Male, knee, 61 years

The majority of participants identified their participation in the trial as 'completely independent' from and 'separate' to their treatment but were clear that the trial activities and visits fitted around their existing appointments, with no indication that their participation had any negative impact on the care that they received during the perioperative period:

It's like today, it's fitted in absolutely brilliantly today in the hospital. You're there. It's not as though you've got to put things aside for it. No, it's fine.

Male, knee, 64 years

When asked about particular aspects of the research design that could have influenced participation, interviewees showed little need for a specified amount of time to consider their participation (24 hours), with the majority stating that they had made the decision to participate when they were first approached or contacted:

Well I was happy anyway because when she asked me I said, 'I'll do it anyway'. I was happy just to go ahead with it anyway.

Male, knee, 71 years

Similarly, the randomisation process was found to be acceptable to participants and did not influence their decision to take part. Some participants expanded on this to explain that although there may be some benefit to being allocated to the intervention condition, they did not necessarily feel that they needed that additional information and support; being assigned to the control arm had its own benefits in that it took up less time and that randomisation was an important part of the research method and a

requirement if evidence to inform practice was to be gained. However, one participant did feel that being allocated to the intervention arm may have helped them to further decrease their alcohol consumption:

I didn't object to that because I knew it was a 50/50 thing. If I'm honest, well what did I think? I mean part of me thought, 'Well that's me off the hook. They're not going to probe too deeply'. But on the other hand, I wouldn't have objected to it. I thought, 'Well that might have helped me drink even less'. I just accepted it really because that's the basis on which I went into it.

Male, knee, 85 years

One participant also explained that although the prospect of randomisation did not influence their decision to take part, they did feel that it would be important in the future, should interventions be found to be beneficial, that all patients receive information about alcohol use and surgery:

Personally, I can see why it has to be randomised at the moment, but also I think, longer term, once the research has been pulled together, my view would be it would be great for people to receive it.

Male, knee, 78 years

Trial follow-up methods were also described as acceptable by participants. Specifically, follow-ups were not considered to occur too frequently or to take up too much time, and neither were they described as too intrusive. Participants identified that they never felt pressured to complete the follow-ups and that they felt they could easily request a callback at another time if they were busy:

I didn't think it was too intrusive and it didn't take too long. The questions were pretty straightforward and I gave honest answers. I haven't found it a difficult process.

Male, knee, 85 years

A number of interviewees explained that the follow-ups were fine because they had agreed to them or had been made aware of them when they consented to the trial. One participant went further, identifying that because follow-ups were described in the trial information they would be expected and it was therefore important that they took place:

I think I would have been a little bit frustrated if I hadn't received the 'phone call. So going back, earlier on, you were talking about the process. If somebody said, 'Right, I'm going to ring you in 4 weeks,' and it's gone 4 weeks and 2 days, I'm thinking, 'Why haven't you phoned me?' So I would have been on to them just to say, 'Hang on, you were supposed to ring me'.

Male, knee, 63 years

Acceptability of alcohol screening

In addition to exploring the acceptability of the trial design, the interviews considered the acceptability of the screening and intervention procedures to build on evidence collected in the feasibility study, which found the processes generally acceptable. As in the feasibility study, very few of the participants had identified a link between alcohol use and surgery prior to taking part in the study and thus had not considered that they would be asked about alcohol use as part of the PA:

It never even entered my mind that alcohol would affect the outcome of the operation, the recovery period . . .

Male, knee, 67 years

However, one of the participants identified that a hospital stay could be problematic for 'heavy' drinkers:

If anybody was going in who I knew to be a heavy drinker, I would tell them to come and see me and we'll cut it down. Because it doesn't go hand in hand . . . You're only in hospital for a couple of

nights. If you're a heavy drinker, a couple of night can be a long, long time. I think anybody who was a heavy drinker would get asked a lot more questions.

Male, knee, 70 years

Despite this, four of the interviewees expected to be asked about alcohol at PA either because they considered alcohol consumption to be relevant to health generally or because alcohol use was frequently asked about in health-care settings:

Yes, I suppose so, when I look back, because when you go into hospital, you're always asked about your current health situation, how you are at the minute and how healthy you are. I suppose alcohol would come into that, so, on reflection, possibly, yes, I think it would be part of the standard questionnaire.

Male, knee, 61 years

One participant also identified that he had not expected to be asked about alcohol because he did not consider his consumption to be problematic. However, this participant identified that he was accepting of being asked about alcohol consumption because he recognised that those drinking to excess may present problems for the HCPs:

I don't consider myself a drinker really, so it didn't even cross my mind. It's something that I would never, ever have thought of . . . Doesn't bother me in the least. They've got a right to know because they need to know. If the prospective patient has a problem and makes it cause them a problem. By that I'm talking about somebody who maybe uses a lot of alcohol could cause a problem in the ward . . .

Male, knee, 70 years

Indeed, all of the participants described alcohol screening as acceptable, explaining that they were not 'bothered by it', were 'quite comfortable' and 'didn't object to it'. However, the importance of explaining the relevance of questioning patients about their alcohol consumption in this setting, or at least explaining that it is a standard question, was raised by one interviewee who felt that he had been asked about his alcohol use specifically because he was overweight and expressed a desire to understand why HCPs felt the need to ask about alcohol consumption if the individual was otherwise well:

It's not really an imposition, it seems to be the way slimmer people view older people or people that are overweight, that means they've got to be smokers, drinkers or eaters. Nobody's ever the perfect person.

Male, knee, 71 years

Much of the acceptability of alcohol screening appeared to derive from the fact that participants were generally open to discussing their alcohol consumption and had 'nothing to hide'. As such, they did not have a preference about whether it was a doctor, a nurse or a researcher who asked about their drinking behaviour:

It doesn't really make any difference. No, I'm quite open to whoever it is.

Male, knee, 63 years

Despite the reported acceptability of alcohol screening, the issue of alcohol as a potentially 'sensitive subject' for others was raised by a subset of participants, who explained that some people would not be comfortable answering questions about their alcohol use and as a result would not provide honest answers and would not agree to take part in this type of research. However, this assumption is at least partially contradicted by two of the interviewees who self-identified as drinking more than they should. Although one explained that screening could be awkward, the other was pleased that the issue was being raised:

. . . it's still awkward talking about something which you know is wrong. You're trying to tell somebody that what you're doing is not good for yourself. It's always a bit awkward.

Male, knee, 61 years

I was actually pleased that they were concerned, you know, drinking could be a bit of a problem so I was quite happy that they did . . .

Male, knee, 70 years

Acceptability and effect of the intervention

Interviewees who received the intervention identified it as acceptable and 'great' and that it contained the right amount of information, and one went so far as to say 'I love advice'. Further to this, for one participant the motivational, non-judgemental approach adopted by staff was key as it allowed him to come to his own decision about whether or not he wanted to change their drinking behaviour once he had received the intervention:

I wanted to help, but I didn't want to be preached to when I'd already made these decisions myself . . .

Male, knee, 61 years

In contrast to the fact that very few of the participants were aware of any association between alcohol use and surgery, a number of interviewees explained that the intervention did not include any information that they were not already aware of:

I felt like I, pretty much, knew, anyway, about the drinking. I'm getting on a bit now, and I've seen a lot of it. I didn't feel like I was learning a great lot. You tend to know what's right and wrong, anyway, don't you?

Male, hip, 67 years

Findings regarding the potential effects of the intervention varied, with some participants identifying that they had made significant, long-lasting changes to their drinking behaviour, some saying that they had 'cut down' and others saying that they had not changed their drinking at all. This variation was anticipated and summarised by one participant:

I think that some people would just say, 'I'm going to do what I'm doing. I'm going to have the surgery, then I'm going to do what I'm doing'. I think there are other people who would say, 'Yes, I can see the benefits, fair is fair'.

Male, hip, 67 years

Reasons for changing were similarly varied and included the calorific content of alcohol, the influence of alcohol on weight, interactions with medication, not 'feeling' like drinking in the postoperative period, the intervention confirming existing knowledge and wanting to improve recovery following surgery:

I think it was actually the research which was saying if you cut down on alcohol, you'll recover better. Something like that.

Male, hip, 67 years

There was some indication that the messages of the intervention specifically about when alcohol consumption should be reduced may need further clarification, as four of the participants explained that they had reduced their drinking postoperatively in order to benefit their recovery:

I was still drinking up until I went into hospital, then following the operation I didn't drink for 4 weeks, simply because I'd been told that alcohol could be a factor in how well you recovered.

Male, knee, 67 years

Findings regarding the potential benefit of a booster sessions were similarly mixed, with some participants explaining that additional contact would have been beneficial and others explaining that it would not make any difference because they were confident that they could make the changes they wanted without any further input:

I don't think it would have made much difference to me, personally, simply because I would have said to myself I'd signed up to it or agreed to it pre-op. So I knew it was going to happen, and so I, personally, wouldn't have needed much, perhaps, assistance or reminding of it. I don't think I needed to do that . . .

Male, knee, 63 years

The preoperative setting, optimisation, obligation and opportunity

The PAC was considered to be an acceptable setting for the delivery of alcohol screening and intervention and for some it was simply considered to be part of the PA package:

Just as staff at the hospital talk about, for example, 'These are the tablets you'll need to take. These are the things you need to bring in on the day,' 'This is what you need to think about alcohol.' So I can see it being part of just general, normal routine stuff that is part of that package . . .

Male, knee, 63 years

However, for those participants who did not draw an association between alcohol consumption and surgery, offering an explanation of this prior to screening could influence acceptability of the alcohol screening and intervention:

I was quite surprised because like I say, I didn't have a clue that it would have an effect on the recovery at all until it was explained.

Male, knee, 67 years

Upcoming surgery was identified to act as a motivator for changing alcohol consumption in a number of ways. One participant explained that they had planned to reduce their drinking prior to surgery even before they had received the intervention because they wanted to be 'be fit and right' for surgery. Others explained that they reduced their drinking to enhance their recovery:

. . . it was mainly for the recovery of my knee; I wanted the best outcome possible for my knee. So, that sort of spurred me on just to try and keep off it.

Male, knee, 67 years

Some participants felt that getting surgery presented them with a certain amount of obligation to do their bit to ensure that the operation went well:

There's a lot of time and money going into your hip, or whatever, and you need to play the game.

Male, hip, 67 years

Building on this sense of obligation and the desire to undergo surgery that could lead to improvements in health and quality of life, a number of participants identified that they would cut down or stop drinking if this was a requirement for them to have their surgery:

It's like I said, they told me I couldn't take warfarin, and it'd be exactly the same as saying, 'Before you come in, you mustn't have alcohol for 10 days, but we will test you when you come in'. If you're in pain, you're going to stop.

Male, knee, 73 years

The physical effects of surgery itself and specifically of the early postoperative phase could lead to changes in drinking behaviour because participants were not mobile enough to go out, they were taking medication or they did not feel like drinking:

It didn't occur to me, I wasn't really interested I suppose. I was groggy half the time anyway. I slept a lot, with all this dope inside me.

Male, hip, 67 years

Alcohol health communication

With the feasibility study identifying that terminology concerning 'risky drinking' had a negative impact on recruitment and that the term 'standard drink' was not widely understood by participants, these interviews probed the understanding and acceptability of the key terminology used in health communication about alcohol use. Four participants raised the topic of the low-risk drinking guidelines, which they broadly rejected as 'unrealistic', inconsistent with their normative perceptions of alcohol consumption and 'impossible' to stick to:

Maybe it's just the circles I mix in, I don't know. Maybe people do, by and large, but it doesn't make sense to me, the units. I think they're so low, I'm sure you'd be able to drink more than that safely.

Male, hip, 67 years

Two participants also questioned the motivation and perspective of those behind the low-risk drinking guidelines, stating that these were decided by the 'anti-drink lobby' and those that 'actually have the money'.

A number of participants were able to provide accurate descriptions of a standard drink as being equivalent to a 'unit' and equate a 'standard drink' to servings such as half a pint, a small glass of wine or a single measure of spirits. However, four of the interviewees provided inaccurate descriptions of servings that would equate to a standard drink:

Is a measure where you say 'standard drink'? My standard drink is a pint.

Male, knee, 71 years

Participants identified being more familiar with the term 'unit' than the term 'standard drink', explaining that 'unit' was used in alcohol labelling as well as in health promotion. Indeed, this increased familiarity is demonstrated by the fact that when participants were asked about their understanding of the term 'standard drink', transcripts show that a number immediately interpreted this as referring to 'units':

Interviewer: I wondered what you understood that term to mean, so what a standard drink is?

Participant: I've kind of given up trying to understand what a unit and . . . Personally, I don't think they're realistic.

Male, hip, 67 years

This increased familiarity appeared to equate to a more accurate understanding of the term 'unit', with more than half of participants providing accurate descriptions of servings that equate to 1 unit. However, familiarity was not considered to be universal and could potentially be lower among those who were drinking heavily:

Not everybody is aware of units and not a lot of people that drink a lot care about units.

Male, hip, 67 years

Despite the familiarity with the term 'unit', participants were clear that they were most comfortable talking about alcohol in terms of servings such as pints, half pints and glasses, and that talking in this form allowed them to 'give you quicker answers'. One participant expanded on this, explaining that although they were familiar with 'unit', it required additional work on their part:

I've got to translate. It's using Fahrenheit and celsius or kilos and pounds. You only think in one way. You've got to actually work out the other way.

Male, knee, 61 years

When asked what the terms 'risky drinking', 'hazardous drinking' and 'harmful drinking' meant to them, interviewees provided a range of descriptions relating to volume of alcohol consumed, frequency of drinking, drinking in the morning or before driving, drinking the 'wrong type' of drinks, short-term negative outcomes of drinking, including being involved in accidents and suffering memory loss, and longer-term health outcomes:

Well I mean it means there must be degrees, there is quite low level of risky drinking. I mean you can fall over and injure yourself. I mean any excess drinking can have long-term harm, cancer, heart attack and all this sort of thing but also social effects, domestic effects, driving, just because it frees you from inhibitions. You can act in ways which it would be better that you didn't but it's a matter of degree.

Male, knee, 78 years

Some participants considered the terms to be synonymous and reported no preference about which terms were used in health communication:

I'd know exactly what they were talking about when I saw either, and they would both mean exactly the same.

Male, knee, 61 years

However, others identified distinctions between harmful and hazardous drinking specifically, with hazardous considered to refer to short-term negative outcomes and harmful to longer-term health implications:

I would think hazardous drinking was risk of having an accident or getting in a situation, harmful I would put down to medical. I would just draw that difference for the two terms.

Male, hip, 67 years

Finally, the potential for 'risky' drinking to be interpreted in a positive manner and be something to aspire to was raised by one participant, who explained that this term may be appealing to young people specifically:

No, I don't think it is. Especially for, like, the younger generation, because them, to take a risk is far better than being dull. So, when you say 'risky', they think, 'I'll have a go at that'.

Male, knee, 73 years

By contrast, the term 'harmful' drinking was identified as potentially more effective for use in health communications as it would not have positive implications:

In a way, 'harmful', I think, is the word that hits things home with me, because you can harm yourself in a number of ways, some of which are self-inflicted, some of which you can't do anything about. The idea of if you say to somebody, 'This is harmful to you': that seems to simplify things . . .

Male, knee, 63 years

Although some participants identified that they were drinking ‘too much’, drank in excess of the guidelines, or were ‘heavy’ drinkers, when participants were asked directly whether they would use the terms ‘risky’, ‘hazardous’ or ‘harmful’ to describe their own drinking, they stated they would not. However, one participant explained that the researcher might use that term to describe his drinking:

I don't know what you would class as risky drinking, quantity-wise. It's probably what I'm drinking.

Male, knee, 61 years

Others also explained that, retrospectively, they would describe their previous drinking, specifically their drinking when they were younger, in these terms, although they would not have done so at the time:

In the past. Well yes, that's an honest answer. I mean not all that much but it has happened, I've got to say that.

Male, knee, 78 years

Talking to older patients

Two key factors can be used to broadly characterise the participant population in this trial: they were all ‘patients’ attending for orthopaedic surgery and they were generally in later life. Interviewees were asked if specific considerations should be made when working with older adults and with patients.

Participants raised a number of reasons that older adults may choose to drink alcohol or may increase their alcohol consumption. These reasons predominantly related to changes in circumstances. Retirement was seen to provide an increased opportunity to drink and may lead to people getting ‘carried away’. Similarly, there was an increased chance of boredom, which would act as a motivator to drink. One participant also explained that older adults were less risk-averse and, another pointed to the relatively lucrative financial situation of some retirees, which might facilitate increased drinking:

I think a lot of people our age just think, 'That's it, I've retired, I'm going to enjoy it'. You can get carried away, can't you? . . . And people tend to have a few bob in their pocket, it seems.

Male, hip, 67 years

The issue of death was seen to have the potential to influence drinking behaviour in a number of ways. Loneliness following the death of partners or friends could motivate increased drinking. Meanwhile, the increased salience of death could either lead to a ‘why not’ approach to drinking or motivate individuals to do more to ensure their health:

Loneliness. When you get to the age I'm at and a little bit further on, that's when people die. People do get lonely and it's very, very easy to turn to drink if you're lonely.

Male, knee, 70 years

. . . if you are a heavy drinker you just think well so what, I'm going to die anyway. I might as well go really happy.

Male, knee, 85 years

Consideration of whether or not older adults were an appropriate target for alcohol interventions revealed split opinions. Some interviewees felt that older adults were more likely to be open and honest about their drinking, whereas others explained that older adults would not want to be asked about their alcohol consumption and would not want to be ‘educated’ about alcohol use:

I'm very careful about the words 'educate people' because I'm not convinced that some people like to be educated in this sort of age bracket.

Male, knee, 63 years

Some participants explained that because there was the potential for alcohol use to increase in later life it was appropriate to work with older adults to increase their awareness of alcohol issues and support them in monitoring or changing their behaviour:

It's easy for people to say, 'Oh, we'll go and have a beer or whatever and sit in the garden'. Then one thing leads to another, doesn't it? So I think maybe people our age could be aware of that.

Male, hip, 67 years

In contrast to this, a number of participants felt that alcohol interventions targeting older adults were unlikely to make any difference because the target population would not pay attention or would not be able to change their drinking behaviour:

I think people are set in their ways aren't they? When they get to over 50, they're either drinkers or they're not. Then I think changing someone's habits at my age is really asking a lot.

Male, knee, 67 years

Others pointed to the fact that there was no need to target this population because they did not have the opportunity to drink to excess and their drinking behaviour would already have decreased. One participant went so far as to state that excessive drinkers simply did not live long enough to reach the point of later life:

Big drinkers are not older because well it kills them doesn't it?

Male, knee, 85 years

All participants were directly asked if any specific considerations should be made when working with patients; however, the majority felt that there was nothing additional that should be considered. Five participants did provide specific responses. Once again, opinion was split about whether or not alcohol would be a potentially sensitive subject; two interviewees felt that discussing drinking behaviour would not be a problem and that patients would be honest, whereas two others felt that patients, especially those drinking to excess, were unlikely to tell the truth:

I suppose the more you drink, the less likely you are to tell the truth about what you drink.

Male, knee, 73 years

This difference in opinion was summarised by one patient, who identified that responses were likely to vary from one patient to another depending on the amount of alcohol consumed and that it was important to be aware that some patients would feel less comfortable discussing alcohol use and to take this into account in the way that the subject was approached:

If there's an issue, they probably won't tell the truth. If they're more than happy to say, 'Oh, I have one glass of wine a week,' they'd be proud of it and they'd shout it from the rooftops, but I think it's something that you've just got to bear in mind that not everybody wants to talk about.

Male, knee, 61 years

One participant once again identified that he felt that people were unlikely to act on the advice or information provided:

I don't know what you could say, really. I'm not sure how many people would actually take a great deal of notice, you know.

Male, hip, 67 years

In contrast to this view and the view of other interviewees who felt that little could be done to change the drinking behaviour of older adults, five participants identified that more should be done to address alcohol consumption in general, with a number of diverse approaches suggested. One participant felt that more

should be done to remove high-volume, low-price alcoholic beverages from sale; another felt that drinking to excess should be taxed in some way; another recommended improvements to alcohol labelling to make alcohol content more visible and easier to interpret; and two considered that increasing 'hard-line' health communication messages and fear appeals, especially those involving personalised feedback, was more likely to lead to change:

I don't think that the hospital makes people aware of it, of the damage it could do. Maybe if that could be made a bit more forcefully.

Male, knee, 70 years

Gender differences

With a much greater number of men than women consenting to participate in both the feasibility study and the pilot RCT, participants were asked if they could provide any insight into gender differences that might influence participation. Participants raised the issue of potential gender differences in orthopaedic surgery and in alcohol consumption that would make women less likely to meet the inclusion criteria. However, these opinions were not consistent across interviewees, with some explaining that women drank as much as or as often as men and that from their experience a greater number of women than men were undergoing surgery:

Oh God, this day and age, I don't know. I go out and just see more women out than bloody men.

Male, knee, 64 years

Two participants also explained that women were generally less likely to want to share information about their personal lives. These views suggest that women may decline screening, refuse participation or under-report their alcohol consumption when screened:

I don't think women like being asked invasive questions about themselves. I'm trying to picture my wife being asked the questions and I think you'd be getting a lot of. 'Erm, but, erm'. Maybe she wouldn't quite give you the exact amount.

Male, knee, 70 years

Other participants felt that men would be more open about their alcohol consumption than women, with one suggesting that this might be motivated by seeing friends and family members going through health scares and treatment:

Maybe they've come to their senses and think too much drink is doing too much damage. There are a lot of people, like I've got a couple of friends who are having problems and going through tests on their liver and stuff like that. Maybe it's something to do with that, too much drink, and they realised.

Female, hip, 67 years

One participant also felt that male participants may have been motivated to take part by their female partners:

I don't know. Probably their wives have told them to do it.

Male, knee, 70 years

Health-care professional interview results

Eleven HCPs were recruited during the pilot RCT: four each from sites 1 and 2 and three from site 3. Of these, eight went on to deliver at least one intervention session, one conducted screening only and two had no further involvement. Five HCPs (two from site 1, one from site 2 and two from site 3) consented to and participated in interviews about their experience of being involved in the trial. All five

were female: three conducted both screening and intervention, one conducted the screening only and one conducted the intervention only. Owing to the small number of HCPs involved in the trial and the visibility of their involvement, quotations are identified by site only.

Coherence

Differentiation and individual specification

The HCPs interviewed were asked about both their day-to-day roles and their study-specific roles. The descriptions provided clearly demonstrated that participants had an understanding of their own tasks and responsibilities within the pilot RCT as well as how these differed from their usual preassessment role:

We do the AUDIT, the alcohol questions and then we go through the materials so reasons to cut down, why it's important for surgery and then looking at ways to cut it down . . .

Site 3

I was doing pre-assessments for patients that were going through surgery, minor surgery. Taking heights, weights, blood pressure, bloods, stuff like that.

Site 1

Similarly, when asked how appointments differed for patients involved in the study, HCPs were able to identify key differences between the trial intervention and standard PA processes. They highlighted a focus on taking additional time to complete the AUDIT questionnaire and discuss alcohol consumption as the key aspect of the trial for those involved specifically in intervention delivery. They also mentioned that completion of screening and co-ordination were trial tasks for others:

So it's about we take some extra time to go through the questionnaire and to talk more about alcohol. Sometimes I am doing the pre-assessment as well so I will mention it at the beginning of the assessment and say we will come back to that at the end and I think they have some more questionnaires and forms to fill out for the study . . .

Site 3

There was also some recognition that as the trial participants were taking part in something additional on a voluntary basis it was important to ensure that the experience was as positive as possible for them:

. . . people that are coming in for a booked BIRDS appointment, I never let them wait. So, if their appointment time is 2 o'clock, they won't be in this room any later than 2 o'clock, even if the research team are not here, just give them a cuppa, ask them if they want a cuppa, and let them feel relaxed really. Whereas the other appointments, some people are waiting there a very long time . . .

Site 3

Communal specification

Interview transcripts revealed that the study processes, and specifically screening and intervention, were considered to fit well with existing PA specifically because questions about alcohol use and other health behaviours are already a standard part of PA. Trial processes could be seen to build and expand on these aspects of TAU:

. . . we do already ask about alcohol but we don't really do much with that information. Other than maybe refer the notes to anaesthetist review if they are drinking a lot or maybe do like liver function tests and see how that comes out. So it does fit and it gives a bit something extra that we can do . . .

Site 1

From the patient perspective, the delivery of screening and intervention was also considered to fit well because it was scheduled around times when patients were already attending the hospital for appointments:

So I think it is quite good, the fact of having it in pre-assessment when they come, because they've got to come for their appointment anyway.

Site 3

Because the pilot RCT tasks were additional to TAU, it was considered necessary to have additional time allocated for these sessions in order to allow for implementation:

Although it fitted in well, time is a big thing in this clinic. I think they found it was a bit more time-consuming for them and they were getting held back a little bit. It went OK, just time wise. Some patients like to talk more than others.

Site 1

Further to this, even when adequate time was available to deliver the intervention, there were instances when issues emerged that had to be prioritised over intervention delivery to ensure patient safety:

I think one patient wanted to talk more about something else like they were using some other drugs as well so that was what we talked about that a lot more really but otherwise it was fine with all the others it really was fine.

Site 3

Internalisation

Interviewees identified a number of potential benefits of the trial and intervention at personal, system and societal level. Personal benefits included positive outcomes for professional development, with potential cost-saving benefits for the NHS and wider benefits of addressing alcohol consumption:

I think it will have a positive impact on the NHS. People are taking it in and cutting down on their drinking, it's going to benefit them and us . . .

Site 1

Well, it was to move myself up and get more experience within the NHS. I know the research is a good thing to have on a CV [curriculum vitae].

Site 3

There was a clear indication that many of the potential benefits of screening and intervention were communicated during the trial training suggesting limited understanding of the association between alcohol and surgery:

. . . in the training it said about alcohol making it more likely for the patients to have complications and possibly get infections and things like that and taking longer to recover so if they can cut down then obviously that would help.

Site 3

Cognitive participation

Initiation

Only one of the five participants interviewed directly referred to managerial support of the implementation of the trial process, explaining that one of the consultant anaesthetists was 'keen for us to be involved' and wanted them to 'get to the target'. This was identified as beneficial. In addition, two HCPs described instances when they

discussed difficulties balancing trial work with clinical work and received support to prioritise their trial roles as well as in communicating this prioritisation with the wider clinical team:

I did tell my manager, 'I need you to tell everybody what my priority is and it's the study,' and there was an e-mail sent at one point saying that my job role was the study . . .

Site 3

Despite this support, one of the interviewees identified that it 'didn't really make a difference' to her workload or to others expectations of her in the subsequent weeks.

Enrolment

The HCAs who were responsible for conducting the majority of the screening also took ownership of the study and worked to push it forwards at each of the three sites:

I think I sort of took ownership of it and just went out there and did it.

Site 2

Although this was recognised by other interviewees, one of whom stated that the HCAs' support 'helped a lot' with the co-ordination of study visits, balancing clinical and research work was not always easy and often the research work did not seem to be recognised by other HCPs in the PACs:

I think everybody here thinks you're doing the same as them. They try and get you involved in what they're doing but you don't really have the time.

Site 3

Legitimation

Two of the interviewees clearly expressed the view that nursing staff, and specifically PA nursing staff, were best placed to deliver screening and intervention processes with patients. To some extent this was because of the content of the PAs that they were conducting:

Yes. I think when you're doing a pre-assessment with somebody it is quite in-depth questions, so you have to feel like you've got that bond with the patient for them to be able to tell you things honestly, anyway. So I think if you were to give them a bit of brief advice or brief intervention included in your pre-assessment, then it would be best off a prep nurse.

Site 3

However, one HCP also identified that having nursing staff conduct the interventions would be preferable to doctors doing it as guidance from doctors would be less motivationally focused:

Obviously, a normal person doing it. Not a doctor saying, 'Well, this is what you should be doing, and this, and this, and this'.

Site 2

Similarly, patients were thought more likely to provide truthful, accurate responses to screening questions when screening was conducted by nursing staff rather than by doctors:

I think the problem with doctors [is] that they will say, 'Oh, how many units have you had?' And obviously they will be like, 'Oh, I just have 3 units a week,' or something like that, which you know is totally a lie.

Site 3

Activation

There was limited discussion of how visible the trial was within the PACs. Although there was some indication in interviews that staff were aware of one another's roles, with one of the HCPs describing the supporting role of the screening HCA, there were also instances, as discussed in *Enrolment*, when screening was not recognised as a priority:

It's been hard because you would want to get some of your BIRDS stuff done, but you couldn't because you were being used as a health-care assistant . . .

Site 3

However, the process of randomisation in combination with screening reactivity led to limited involvement of one HCP, despite the fact that she had undertaken training and was scheduled to conduct visit 1 with a number of participants:

I think it has just been by chance but whenever I am going to do the intervention they get allocated to the no intervention or like they are only just on the guidelines or already reduced so there isn't that much to do . . .

Site 1

Collective action

Interactional workability

Interviewees discussed how they interacted with other staff members in the PACs, how they worked with the screening and intervention tools and how patients interacted with these tools.

Regarding interactions with other staff members, it was considered important to maintain positive relationships with PA staff not involved in the trial and to minimise any impact on the day-to-day running of the clinic:

I've always just said to them, 'If you need the patient I'm here all day anyway. You just take them first of all, and I will see them afterwards' . . . obviously you've got to have a good rapport with them, which obviously now we do . . .

Site 2

Both the AUDIT-C and the full AUDIT questionnaires was considered easy to use and fairly self-explanatory, and the infographic detailing standard drinks was seen as beneficial for both the HCPs and the patients:

Yes. The alcohol units are quite good. A lot of patients did like that as well.

Site 2

However, some questions on the full AUDIT questionnaire were considered more likely to generate adverse reactions specifically because they were related to potential dependence. This could in turn hinder the interaction between the HCP and the patient participant:

. . . there was a particular question that had a couple of raised eyebrows. It was, 'How often in the last year have you needed an alcoholic drink to get you going in the morning?' A couple of patients were all right until you got to that question and then they would kind of retract themselves back a bit as if to say, 'Are you calling me an alcoholic?'

Site 1

The BI tools were also considered easy to use and were described as having 'everything that you need', with one HCP explaining 'I don't think they need to change'. However, familiarity with these tools and

practice using them was considered important both for the effective delivery of the intervention and for assessing their benefit:

... there is a lot of information like they have all the things you would need I suppose I just I can't really say more than that I don't know what it's like really to go through it all with a patient ...

Site 1

Skill set workability

In terms of delivering the screening and intervention, HCPs considered themselves to be experienced in asking about alcohol use and, therefore, well placed to conduct the screening:

... it's just about how you say it and you know we ask about alcohol all the time so I'm used to it and I don't it's not about judging them it's about making sure they are safe for their surgery so that can help too.

Site 1

However, training was considered necessary to develop the additional knowledge and skills required to deliver the intervention, with practice needed to ensure effective delivery:

I don't think that you could do it without having the training. I don't think that you could just go and just reel off what was on there, because obviously there are different crib sheets that you go off.

Site 2

Additionally, one of the interviewees identified that those who were interested in and enjoyed delivering the interventions were best placed to deliver them:

I think there were a few of us doing it at the beginning but I am the only one really now doing the interventions. I enjoyed doing it so I suppose it just makes sense because some of the others they were quite nervous about it ...

Site 3

Contextual integration

Consideration of the interview transcripts identified a number of issues relating to the allocation of resources, specifically in terms of staff and time allocation. As discussed in *Chapter 3, Communal specification*, the allocation of adequate time to deliver the intervention was important. However, there was a potential downside to this. Even with the work of HCAs to co-ordinate the pilot RCT, there were times when staff time was allocated to deliver sessions but the session was delayed, the participant was allocated to the TAU condition or the patient did not turn up:

It is a bit frustrating because you set the time aside and you know you've done the training and then you set the time aside and it's a lot of standing around and waiting while they do the like the consent then at the end of it they don't go in the intervention so you just do the preassessment ...

Site 1

When staff had both clinical and research responsibilities, this could also lead to issues with HCAs having to remind other staff to complete the AUDIT screening questionnaires and return them in a timely manner to ensure that expressions of interest could be completed for eligible patients:

A lot of the nurses do forget to give us them and I had a lot of patients that were missed, because if I was working in the investigation suite the AUDITs would be popped on this desk and then I would come in and they had scored over five, but they had left the department ...

Site 3

Reflexive monitoring

Systematisation

There was that the effectiveness of screening and intervention was formally assessed. One interviewee, however, did express a desire to see the final results of the pilot trial, although she did not demonstrate a clear understanding of the fact that a pilot trial would not be powered to detect between-group differences:

... it would be good to see the results because some of them they do seem positive but it would be really nice to know if it helped and if it did make a difference.

Site 3

Communal appraisal

Discussion of communal engagement in assessing of the effectiveness of research, screening and intervention processes was also limited. Although there was some evidence of HCPs discussing the trial and assessing issues around implementation, there was no suggestion that such conversations had considered the potential benefits or effectiveness of the work:

... other people I know had a patient booked in but then they didn't turn up or cancelled at the last minute and that is annoying ...

Site 1

Individual appraisal

In contrast to the limited evidence of systematisation and communal appraisal, there were numerous examples of how individuals had collected anecdotal evidence of effectiveness. Some of these related specifically to completion of the screening questionnaires, which was seen to increase patients' awareness of their alcohol consumption:

The patients that I've talked to have said, 'Actually, I didn't realise how much I was drinking' ...

Site 2

Others thought that the intervention would lead to more changes in drinking behaviour than screening alone:

... they want the surgery and they want to get better more quickly and then like the questions they realise that maybe they are drinking more than they thought so we can then we look at cutting it down and they are quite positive so I think that some of them they will change for the surgery.

Site 3

In addition, the fact that the trial involved multiple contact points across the full course of the surgical pathway not only offered HCPs the opportunity to get an idea about whether or not the intervention was having a positive impact on patients' alcohol consumption but was also seen as beneficial to the patient experience:

I think it was just the fact as well of having that extra bit of contact that actually made it enjoyable. Within the trust more. The patient experience was a bit better.

Site 2

The HCPs also identified a number of benefits to themselves as individuals from being involved in the trial. In addition to the anticipated benefits for their own professional development, being involved was described as 'interesting' and 'enjoyable' and for some had led to a change in their own drinking behaviour:

I know my drinking habit has changed since doing it completely. And it still has changed now. We will just have alcohol if we go out. Which is very rarely, obviously, with a young child. But we don't have alcohol in the house anymore ... The whole family has reduced alcohol intake, which I think has been a good thing.

Site 2

Reconfiguration

The HCPs described tailoring the delivery of the screening questionnaire to help ensure positive interactions with patients when completing them. For some, this involved 'forewarning' patients that some of the questions might or might not apply to them:

People do adapt a little bit to their own style, but you still have to ask them questions and get them answers.

Site 2

However, HCPs also made some suggestions about how the trial could be improved, with a recommendation to use the term 'units' instead of 'standard drinks':

... as a pre-assessment nurse you go by units, whereas the auditing is by standard drinks and people will get a bit confused about a unit or a standard drink.

Site 3

Conclusions

The pilot trial identified that a definitive trial is feasible. We aimed to recruit 80 patient participants to allow the collection of outcome data from a total of 60 patient participants at 6 months post recruitment. Sixty-eight patient participants were recruited (86% of target) but data were collected from 65 participants (96% of target) at 6 months post recruitment. There were very small numbers of missing data at baseline and at 6 months post recruitment in both trial arms. Therefore, the very high retention rate and high levels of data completion mitigated the fact that the initial recruitment target was not met.

To detect a between-group difference of 13% in the number of participants identified as lower-risk drinkers at 6 months post recruitment follow-up (AUDIT score of 0–7), just less than 10,000 patients would need to be screened to recruit 770 patients to the trial. With approximately 160,000 patients undergoing hip or knee arthroplasty in the UK annually²⁴ and the majority of sites employing some form of assessment of preoperative alcohol consumption,¹¹⁶ this level of screening and recruitment is considered to be achievable.

Further to this, qualitative findings identified the proposed screening, intervention and research processes as broadly acceptable to both HCPs and patient participants. The randomisation process was shown to have little influence on patient participants, although, as we did not interview decliners, it is possible that they hold different views. Similarly, the burden of participation was also acceptable, with patient participants identifying themselves as having the necessary free time to participate.

The amendment of the inclusion criteria so that patients were not required to report regular high-intensity consumption (consumption of six or more standard drinks on a single occasion at least weekly) and to judge eligibility on the initial AUDIT-C screen rather than the completion of full AUDIT at baseline led to the identification of 23% of patients screened as being eligible. This also ensured that reductions in alcohol consumption following screening and invitation to participate did not lead to the exclusion of patients who were potentially eligible at initial screening.

Just over one-third of eligible patients were recruited to the pilot trial. With higher rates of recruitment seen in RCTs that conduct screening, consent and intervention on a single occasion,¹⁴¹ further streamlining of the trial processes may enhance recruitment rates.

A total of 68 patient participants were randomised to the BBI or TAU. Of the 33 patient participants allocated to the BBI arm, 32 (97%) received the intervention as intended and all received a copy of the patient information leaflet. However, delivery rates of the optional booster intervention session was very low, with only four out of 33 participants (12%) allocated to the intervention receiving this session. With such low rates of delivery and limited indications of any additional benefit or potential benefit of this session in qualitative data from patient participants, it is considered neither feasible nor necessary to employ a booster session in a definitive trial.

Very few problems were identified with the proposed follow-up measures, although length of hospital stay could limit collection of self-reported patient data at the in-hospital (visit 4) follow-up. Rates of completion of the AUDIT tool, the proposed primary outcome measure, were consistently high. Although qualitative interview data from HCP participants identified that some of the wording and terminology in the AUDIT tool could lead to adverse reactions among patient participants, something that they acted to mitigate by tailoring delivery, this was not something that emerged from interviews with patient participants.

The proportion of missing data was higher at interim study visits, although this never fell below 65% for required follow-up points (i.e. excluding the optional booster session). Rates of completion were lowest for visit 3, which was designed to be conducted over the telephone 1–3 days before surgery. Scheduling this visit to occur on the day of surgery, when patients present at the hospital, may improve rates of completion, but the acceptability of this should be further explored.

Alcohol use at baseline, as assessed by AUDIT and self-reported units of alcohol consumed per week, was observed to be lower in the BBI arm than in the control arm. Although no inferential statistics were conducted to assess the significance of this difference, a definitive trial may need to assess and control for such differences.

Chapter 5 Discussion

This chapter draws together and discusses the findings from the three key phases of the project (feasibility, pilot RCT and characterising TAU). Findings are discussed in order of trial processes (screening and recruitment, intervention compliance, retention and follow-up) followed by additional findings related to the implementation of trial processes and variation in perioperative pathways and TAU. Key findings and their implications for future research are summarised in *Table 28*.

TABLE 28 Summary of findings and implications

Issue	Findings	Implications for future research
Identifying potential participants	Screening for AUDIT-C score of ≥ 5 or consumption of six or more standard drinks weekly increased the number of eligible patients. Initial screening and study invitation can lead to reductions in alcohol consumption prior to intervention. Waiting time between listing for surgery and attendance at the PAC (≥ 3 months) could create a lag between screening and recruitment	Use revised screening criteria. Inclusion should be based on initial screening to avoid excluding patients who are highly motivated to change. Consider postal invitation and telephone screening
Consenting eligible participants	Removal of the term 'risky drinking' from the study title and a reduction in the period of time before expression of interest was followed up increased the proportion of patients consenting. In the pilot RCT, 34% of eligible participants were consented to the trial. The most common reasons for declining participation were lack of interest and not having enough time	Future trials must avoid any pejorative terminology in recruitment materials and streamline trial visits. Improve appeal of initial approach by including information on the potential benefits of the trial
Meeting recruitment target	Recruitment fell short of target, with 68 patient participants recruited against a target of 80 (85%)	Recruitment of preoperative patients to alcohol intervention trials is challenging
Compliance with intervention	In total, 32 out of 33 patient participants allocated to the intervention arm received the intervention and all 33 received a copy of the patient information leaflet. Only 4 out of 33 received the optional booster intervention	Delivery of BI in the PAC is feasible. Future trials need not include a booster session
Fidelity of delivery	Fidelity of delivery improved between the feasibility study and the pilot RCT. Motivational BCTs were well delivered but volitional ones less so	Additional training may be required for HCPs to effectively deliver volitionally focused BCTs. Alternatively, the adoption of an advice-focused intervention could be adopted to ensure consistent delivery
Characterising TAU	TAU relating to alcohol screening, availability of advice and availability of referral was found to vary between individuals and between sites	TAU at trial sites should be considered during selection. Standardisation of TAU across sites may also be necessary
Retention	Retention at 6 months post recruitment was very high (96%)	Retention unlikely to be a concern for future trials
Outcome assessments	There were few missing data on AUDIT and EQ-5D. WOMAC was less well completed	AUDIT and EQ-5D are acceptable outcome measures. Consider when WOMAC is completed and how patient participants are instructed to complete it
Safety issues	No serious adverse events were reported	No safety issues for future trials

continued

TABLE 28 Summary of findings and implications (*continued*)

Issue	Findings	Implications for future research
Sample size calculation	Sample size calculation feasible	Indicated that 385 participants per arm to be recruited for definitive trial
Communication of alcohol health messages	There was limited understanding of associations between alcohol and surgical risk, as well as of the term 'standard drink' and to a lesser extent 'unit'	HCPs need adequate training to conduct screening and intervention. Training and interventions should adopt the term 'unit' and better explanations of alcohol use

Screening and recruitment

Findings from the feasibility study and comparison of screening and recruitment rates from the feasibility and pilot RCT clearly demonstrate the importance of working with end-users (both HCPs and patients) to refine study processes and materials to ensure and enhance acceptability before attempting to recruit to a definitive RCT. Specifically, amendments made during and following the feasibility study led to a 20% increase in the percentage of eligible patients recruited. As a result, four times as many patient participants were recruited from screening only twice as many patients.

Initial results of screening in the feasibility trial identified that a large proportion of patients who screened AUDIT-C positive (score of ≤ 5), indicating increased risk from drinking, were judged ineligible because they did not report consumption of six or more standard drinks on a single occasion at least weekly. Amending the screening criteria to include both regular and high-intensity drinking (AUDIT-C score of ≤ 5 or consumption of six or more standard drinks on a single occasion at least weekly) increased eligibility rates from 16% to 20%. In the pilot RCT, the rate of eligibility based on alcohol screening with the AUDIT-C was approximately 34% when the criteria were set as AUDIT-C score of ≤ 5 or consumption of six or more standard drinks on a single occasion at least weekly. Taking into consideration the fact that one site employed pre-screens to avoid screening those already documented as abstainers, this is reflective of overall population rates of exceeding the lower-risk guidelines.¹⁰ Although this means that a large number of patients (approximately five) have to be screened to identify one eligible patient, it is these patients who are most at risk of developing alcohol-related complications. Further to this, assessment of alcohol consumption is already part of the standard preoperative care pathway, and the use of validated tools is becoming more common, especially with the advent of the CQUIN programme.

Although the number of patients who declined participation is much smaller than the number of those found to be ineligible, the recruitment of eligible patients (34%) fell short of the predefined progression criteria. Taking into account the high retention rate, which indicates that progression to full trial would be feasible, it is important to consider if and how further improvements can be made to recruitment. With over 40% of those declining doing so because they were not interested in the trial, future trials should ensure that the initial approach to patients is appealing and clearly sets out the possible benefits of involvement to health and postoperative recovery.

The percentage of eligible patients who did not express an interest in being involved in the trial was higher in the pilot RCT than in the feasibility study (35% vs. 4%). This is interpreted as either resulting from the addition of the randomisation process or resulting from the increased number of study visits in the pilot RCT. This points to a need to ensure that study visits are kept to a minimum. This issue is further highlighted by the fact that 15% of participants who declined participation did so on the basis that they did not have enough time to take part or to attend the intervention session. In addition, the findings of qualitative interviews with patient participants identified that even among those who considered themselves to have a large amount of free time there was a limit to the frequency of contact that would be acceptable. Minimising the time burden placed on patients by ensuring that the number of study visits are kept to a minimum, that the

intervention itself and any required research processes are as succinct as possible and that study visits are arranged around existing hospital appointments or over the telephone will be key for a successful full trial. Possible streamlining of study visits is discussed in more depth in *Follow-up and retention*.

Participants in qualitative interviews were specifically asked about the acceptability and importance of the number of study visits. Although time is required for all participants to consider entry into any study, many patients indicated that offering a minimum of 24 hours following screening was not necessary. This information lends itself to the possibility of conducting same-day screening, consent and randomisation. Indeed, this pragmatic approach would be more consistent with how screening and intervention would occur if the intervention were implemented as part of standard care. It would also minimise the number of ineligible patients who had already been through PA or for whom the date of surgery would not have allowed adequate time for behaviour change (the third most frequent reason for non-eligibility). However, it would also require consistent availability of staff for consent and intervention delivery and, therefore, may not be practical in the research trial.

A final point to consider concerning patient eligibility and recruitment is that there was no clear reason recorded for 16.5% of the patients who declined to participate. This points to the need to ensure accurate recording of the outcomes of all patient contact while protecting patients' right to decline or withdraw from participation without giving a reason.

Intervention compliance and fidelity of delivery

Findings from the pilot RCT show a high level of compliance to allocation, with 96% of patient participants allocated to the intervention receiving the BA and BI elements and all receiving a copy of the patient information leaflet. However, the specific content of the intervention sessions, as documented by assessments of fidelity of delivery, showed more variability.

The AUDIT questionnaire was found to be acceptable to both patients and HCPs in the feasibility study and pilot RCT. However, some of the questions designed to assess harm experienced as a result of drinking behaviour were identified by HCPs as potentially more likely to provoke adverse reactions. This reflects early feasibility findings that the term 'risky drinking' was not acceptable to potential participants. BIs emphasise a non-judgemental, positive, motivational approach that can be seen to be inconsistent with some of the terminology routinely included in alcohol screening and alcohol-related health communication. Therefore, qualitative interviews conducted as part of both the feasibility study and the pilot RCT were used to further explore the issue of appropriate terminology. Findings from the pilot RCT show that although interviewees demonstrated a large amount of variation in how they interpreted the terms risky, harmful and hazardous drinking, none considered these terms to be applicable to their own current drinking behaviour. Indeed, the majority of participants identified their drinking as acceptable or moderate even if it was in excess of the low-risk drinking guidelines. Even the two participants who self-identified as 'heavy' drinkers did not relate to these terms. Similarly, findings from the feasibility study point to the use of 'defensive othering' as a technique to distinguish own drinking from the 'problematic' drinking of others. In combination, these findings point to a need to avoid the use of any language that categorises participants' drinking behaviour in a negative manner (e.g. 'risky drinking'), even when providing feedback on screening.

Fidelity of intervention delivery was low in the feasibility study but improved in the pilot RCT. This change is likely to have resulted from a combination of two factors: first, the work to optimise the training package between the feasibility and pilot RCT and, second, the greater number of patients recruited to the pilot trial. The resulting increase in frequency of intervention delivery offered HCPs the opportunity to gain additional experience of delivering the intervention and enhanced their familiarity with the intervention tools, two factors that the HCP qualitative interview data identified as contributing to the effective delivery of interventions. Nonetheless, in both phases of the study, although motivationally focused BCTs, especially those related to communicating the health, social and emotional consequences of alcohol consumption,

were consistently delivered, volitionally focused BCTs such as problem-solving and pros and cons were less consistently delivered. This suggests that further refinement of the training package, and possibly a longer period of time dedicated to training, may be required to enable PA HCPs to deliver these BCTs.

Although HCPs identified alcohol consumption as a priority for health care, awareness of the link between alcohol consumption and surgery was low among both patient and HCP participants. The training was identified as increasing HCPs' knowledge in this area and thus increasing the perceived benefit of delivering alcohol screening and BI in this setting. Similarly, findings from patient interviews identified that messages around alcohol and surgical risk are most relevant to screening and intervention in the preoperative setting, with issues regarding weight loss and medication management also considered relevant. Therefore, further amendments to the intervention to increase the focus on the perioperative setting may be beneficial.

There was very low uptake of the optional booster intervention session planned to be delivered approximately 1 week before surgery. Findings from qualitative interviews regarding the potential benefit of this session were mixed, with no clear indication that it was considered necessary or beneficial. This is in line with previous trials that have found no additional benefit from offering more extended interventions and lower rates of compliance when interventions require multiple sessions.⁷⁵

Follow-up and retention

Follow-up data from the pilot RCT demonstrate that this population is highly amenable to follow-up, with a very high retention rate (96%) at 6 months post recruitment. This means that provision for a 25% loss to follow-up rate in the setting of recruitment targets was not necessary to allow adequate data at outcome. This compares favourably with a previous trial of alcohol interventions in the preoperative setting⁹⁵ and trials from primary⁸⁴ and emergency⁸⁴ care, which report lower but still acceptable retention rates at 6-month follow-up (72–88%). With variation in retention rates for other alcohol intervention trials, and lower completion of interim follow-ups in this pilot trial, a retention rate of 80% was employed for the sample size calculation necessary for a definitive trial. This will produce more conservative recruitment targets.

The proportion of missing data was higher at interim study visits, although it never fell below 65% for required follow-up points (i.e. excluding the optional booster session). Rates of completion were lowest for visit 3, designed to be conducted over the telephone 1–3 days before surgery. Completion of this measure face to face when patients present at the hospital prior to surgery could improve rates of completion. However, the acceptability of this to patient participants has not yet been considered and thus would need to be explored prior to implementation.

The average length of hospital stay in our study of 3–4 days is in line with national data available from Scotland.¹⁴² Given this information, and the fact that eight patient participants did not undergo surgery during the study, the low completion rate for visit 4 (planned to take place 3–5 days postoperatively) is unsurprising. Any future trial should aim to conduct post-surgical follow-up on or before 3 days post surgery in order to maximise opportunities for measure completion. Further to this, completion of the WOMAC questionnaire at visit 4 was additionally complicated by the nature of the questionnaire. Triangulation with qualitative data shows that some items in the WOMAC require respondents to have completed certain activities (e.g. climbing the stairs) before being able to accurately assess their ability to complete these activities. Providing guidance on how to manage situations when accurate assessments cannot be made may be helpful in this regard. However, it would be more appropriate to address these issues (variation in length of stay, minimising of participant burden and lower completion rates of the WOMAC questionnaire) by ensuring that visit 4 is focused primarily on postoperative complications that could be mainly accessed from patient notes, thereby reducing patient contact.

If these changes were made, along with the completion of screening, recruitment and intervention on a single occasion, it could reduce the current seven-visit trial design to four visits.

Surgical care pathway variation

Although many hospitals have a standard care pathway of 6–10 weeks from PA, variation in pathways, even in this pilot study, was notable. Some eligible patients when identified had < 7 days before their operation, whereas eight of the 68 patients recruited to the pilot RCT had not undergone surgery before the end of the study. This variation would be difficult to control without having an adverse impact on patient care. Nevertheless, some considerations may be relevant to minimise the impact of such variation.

First, identifying and intervening with patients as early as possible in the preoperative care pathway remains a priority for preoperative intervention trials. Second, tailoring interventions to individual preoperative pathways will be important in facilitating both shorter- and longer-term behaviour change. Finally, it may be appropriate to consider including a trial follow-up visit to occur a specified length of time after surgery.

Both the focus groups and the survey responses demonstrate a large amount of variation in day-to-day practices between individuals and between sites, as well as over time. This variation was seen across processes for alcohol screening, the identification of patients whose drinking represented a potential surgical risk, the management of patients following assessment of alcohol consumption and the availability of alcohol specialist services. Despite previous research demonstrating that applying validated screening tools in PA improves the identification of both dependent and increased risk drinkers,⁶⁷ findings from this work indicate that such tools remain infrequently adopted in PA, although the CQUIN initiative may change this. This is in line with a previous survey of PA leads.¹⁰

Although many respondents identified the availability of support and potentially interventions for dependent drinkers, including anaesthetic review and referral to alcohol specialist nurses, limited options were available to address increased risk drinking either specifically in relation to surgery or more generally. However, the availability of generalised interventions may increase for sites participating in the CQUIN initiative as the second phase of this focuses on delivery of appropriate interventions. Further to this, some HCPs indicated that they provide simple advice to reduce drinking or avoid alcohol consumption prior to surgery or that such a recommendation was included in the information leaflets provided to patients. Overall, this variation points to a need for high-quality evidence to inform policy and practice around alcohol consumption and surgery. However, this very same variation means that the selection of trial sites for a future definitive trial will need to involve consideration of the method of alcohol screening, level of information and available alcohol specialist support. Work to standardise the TAU condition would also be beneficial to ensure consistency in its delivery.

Implementation of trial processes

Qualitative interviews with HCP participants identified a number of factors that could act as barriers to or facilitators of the implementation of trial processes.

It was clear that initial knowledge of associations between alcohol consumption and surgical outcomes was limited and that knowledge of the potential benefits of the research predominantly derived from the training provided. Without this understanding, it is unlikely that HCPs would volunteer to participate in the trial. Having the required time to complete trial activities, including screening, intervention, co-ordination and follow-up, was important as PACs were considered to be busy and individual appointments included a relatively extensive assessment. Having adequate staff time allocated for intervention delivery was considered vital to the effective delivery of intervention sessions but could present a problem if patients failed to attend or declined to participate on the day. Furthermore, HCPs based in PACs often struggled to balance research tasks against PA roles. In addition to having the necessary training to deliver screening and intervention, gaining 'real-life' experience of delivery and becoming familiar with the tools were highlighted as important to effective delivery and to maintaining a sense of professionalism. This was not considered to be possible

through training or role-play activities but required experience with actual patients and within the day-to-day clinic. The application of NPT allowed further identification of issues specifically related to the implementation of trial activities. These included limited higher-level management support for trial activities, infrequent intervention delivery and limited visibility of the research within the PAC.

Chapter 6 Conclusions and recommendations

Conclusions

This work finds that preoperative alcohol screening using the AUDIT-C and full AUDIT is acceptable to patients and HCPs. Similarly, delivering BBI in the PAC is possible and the intervention methods adopted were acceptable to patients and HCPs. The evidence supports the feasibility of a definitive trial to assess the effectiveness of these methods in bringing about reductions in preoperative alcohol consumption and secondary outcomes of surgical complications if recommendations to enhance recruitment are adopted.

Recommendations

The primary recommendation from this project is that a definitive RCT is feasible. The very high levels of retention in the pilot RCT and data completion at baseline and follow-up mitigate the fact that recruitment fell slightly short of the initial target. With the background literature identifying a wealth of evidence on the associations between preoperative alcohol consumption and surgical outcomes, but a sparsity of evidence regarding the effectiveness of behavioural interventions in reducing preoperative alcohol consumption, such a definitive trial is also considered to be appropriate.

A number of secondary recommendations for the design and conduct of a definitive trial can also be made. These are arranged in priority order.

1. Evidence from both the feasibility study and the pilot RCT shows that avoiding potentially pejorative terminology in any recruitment materials and the adoption of a non-judgemental approach throughout are vital for recruitment to be successful. Specifically, a future trial should:
 - avoid any categorisation of drinking as ‘risky’, ‘harmful’ or ‘hazardous’
 - communicate that all patients are being invited to complete screening.
2. Qualitative evidence shows limited understanding of, and low familiarity with, the term ‘standard drink’; it is therefore recommended that:
 - the term ‘units’ be adopted in all trial materials
 - HCPs be trained and prepared to ensure that they are confident in converting patient descriptions of alcohol consumed in terms of pints or glasses into units in order to enhance the accuracy of screening
 - interventions include a description of units to enhance interpretation of the lower-risk drinking guidelines and increase the accurate monitoring of alcohol.
3. Although qualitative evidence from trial participants identified that the burden of participation was acceptable, the rate of eligible participants (34%) consented may be further improved by streamlining the trial visits. Specifically:
 - with the very low delivery of the optional booster session, this visit should be excluded from any future trials
 - with low completion rates of visit 3 (1–3 days pre surgery), this visit could be scheduled to take place when patients arrive at the hospital on the day of surgery.

- with variable length of stay and some difficulties completing the WOMAC questionnaire at visit 4 (in-hospital follow-up 3–5 days post surgery), a future trial should consider either conducting this visit 1–3 days post surgery or amending it to focus only on postoperative complications that can be collected from patient notes
 - as in this pilot RCT, all study visits should be arranged to either take place around existing hospital appointments or be conducted over the telephone or at the patients' home in order to minimise burden and remove any requirement for additional travel to the hospital site.
4. With 40% of eligible patients who declined participation in the trial stating that they did so because they were 'not interested', future trials should ensure that the initial approach and introduction to the study is appealing and clearly sets out potential health benefits of participation.
5. With HCP interviews identifying difficulties in balancing research roles with clinical demands in busy PACs, it is recommended that future trials:
- arrange for all follow-ups to be conducted by research-specific staff while PA staff maintain the role of intervention delivery
 - work with PA leads throughout the trial to raise the profile of the research in the clinic, track progress against targets and identify any issues.
6. With evidence from the focus groups and HCP survey showing that PA frequently involves the assessment of alcohol consumption and may include a brief recommendation to reduce drinking prior to surgery alongside qualitative evidence that some participants in both the feasibility study and pilot trial report reducing their alcohol consumption following initial screening and invitation to participate, future trials should:
- assess eligibility in terms of alcohol consumption based on initial screening
 - carefully consider and characterise the comparator condition.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to data may be granted following review.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: <https://understandingpatientdata.org.uk/data-citation>.

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Appendix 1 Behaviour change techniques present in intervention materials

TABLE 29 Behaviour change techniques present in BA and BI tools

Intervention tool	BCT
BA	5.1 Information on health consequences 5.1 Information on health consequences 2.2 Feedback on behaviour 2.7 Feedback on outcomes of behaviour 6.2 Social comparison 5.1 Information on health consequences 5.3 Information on social and environmental consequences 5.6 Information on emotional consequences 8.2 Behaviour substitution 12.1 Restructuring the physical environment 12.2 Restructuring the social environment 12.3 Avoidance/reducing exposure to cues for behaviour
BI	1.1 Goal-setting behaviour 9.2 Pros and cons 9.2 Pros and cons 1.1 Goal-setting behaviour 1.2 Problem solving 3.1 Social support unspecified

TABLE 30 Behaviour change techniques present in patient information leaflet

Intervention tool	BCT
Patient information leaflet	5.1 Information on health consequences 5.3 Information on social and environmental consequences 9.2 Pros and cons 2.3 Self-monitoring of behaviour 1.2 Problem-solving 8.2 Behaviour substitution 12.3 Avoidance/reducing exposure to cues for behaviour 12.1 Restructuring the physical environment 12.2 Restructuring the social environment 1.2 Problem-solving 3.1 Social support unspecified 2.3 Self-monitoring of behaviour

Appendix 2 Capability, Opportunity and Motivation to perform a particular Behaviour questionnaire

COM-B Self-Evaluation Questionnaire (COM-B-Qv1)

When it comes to you personally providing a brief intervention that targets alcohol reduction or cessation to patients during pre-assessment, what do you think is needed for you to do it?

Please circle any of the items on the list that you think apply to you. You can circle as many or as few as you think appropriate. Some of the items may look strange, but that is just because we need to cover all areas – some which may not apply to you.

For each item you circle could you also say why you think it might be important for you in the free text box provided beneath.

I would have to....

Capability

- | | | |
|----|--------------------------------------|---|
| 1. | Know more about why it was important | e.g. have a better understanding of the benefits of providing a brief intervention targeting alcohol reduction and cessation prior to surgery to my patients. |
| 2. | Know more about how to do it | e.g. have a better understanding of how to effectively deliver a brief intervention targeting alcohol reduction and cessation to my patients. |
| 3. | Have better physical skills | e.g. acquire/develop new skills to effectively deliver a brief intervention targeting alcohol reduction and cessation to my patients. |
| 4. | Have better mental skills | e.g. learn how to reduce the likelihood that patients go off on tangents during discussions about alcohol reduction or cessation |
| 5. | Overcome physical limitations | e.g. proceed to deliver a brief intervention targeting alcohol reduction and cessation effectively to patients when feeling tired. |

- | | | |
|----|----------------------------|--|
| 6. | Overcome mental obstacles | e.g. overcome the urge to avoid delivering the intervention to a patient who has previously been resistant to changing their alcohol consumption. |
| 7. | Have more physical stamina | e.g. develop greater capacity to maintain physical effort, particularly following delivery of an intervention to a challenging patient. |
| 8. | Have more mental stamina | e.g. increase mental capacity to discuss alcohol reduction and cessation with patients, particularly following delivery of an intervention to a challenging patient. |

I would have to....

Opportunity

- | | | |
|-----|--|---|
| 9. | Have more time to do it | e.g. dedicate time to provide an intervention to patients targeting alcohol reduction or cessation. |
| 10. | Have the necessary materials | e.g. have materials available to me to help target alcohol consumption or cessation in my patients |
| 11. | Have colleagues around me doing the same thing | e.g. be part of a group of colleagues who are also providing the intervention to patients. |
| 12. | Have triggers to prompt me | e.g. have reminders at strategic times to prompt me to use specific parts of the intervention. |
| 13. | Have support from others | e.g. have colleagues/supervisors supporting me to provide the intervention. |

I would have to....

Motivation

- | | | |
|-----|---------------------------------------|---|
| 14. | Feel that I want to do it enough | e.g. feel a sense of pleasure or satisfaction from using/providing the intervention to patients to target alcohol reduction or cessation. |
| 15. | Feel that I need to do it enough | e.g. care more about the negative consequences of not providing the intervention to target alcohol reduction or cessation. |
| 16. | Believe that it would be a good thing | e.g. have a strong sense that I should provide the intervention. |
| 17. | Develop better plans for doing it | e.g. have clearer and well-developed plans for providing the intervention. |
| 18. | Develop a habit of doing it | e.g. getting into a pattern of providing the intervention without having to think too much about it. |
| 19. | Something else (please specify): | |

Thank you for taking the time to respond to this questionnaire.

Appendix 3 Capability, Opportunity and Motivation to perform a particular Behaviour questionnaire responses

TABLE 31 The COM-B questionnaire responses from HCPs

Category	Item	Summary of free-text responses	Number of responses
Capability	Know more about why it was important	Have better understanding of postoperative risks to explain to patients why they should do it. Facts and figures to back up	9
		To have a better understanding of risks related to surgery in order to allow an explanation of why it would benefit the patient(s) and encourage them to try to cut down/quit	
		Important to understand why the intervention is targeting alcohol reduction	
	Know more about how to do it	No previous experience in this area so increased knowledge and training are required	1
		A structured pathway for patients to be able to follow to reduce alcohol intake would help	
		Need a guide including precise facts and information to provide to patients	
		Can be a difficult subject to approach especially if the patient feels that their alcohol intake is not high/problematic	
	Have practical skills to adequately deliver each part of the intervention	Guidance on what should be covered	6
	Have skills to navigate the intervention in the way that is required	Training required to enable delivery of deliver a positive/effective intervention without it being too time-consuming	8
	Have the ability to keep going despite physical barriers		5
Have the ability to keep going despite lacking in determination/motivation	Can be difficult to encourage patients when they lack interest or are resistant to change or accepting help	6	
Have more physical stamina	Could be a challenging role especially for patients who have had habits for a number of years	1	
	I think we have to do this anyway on lots of things and is part of working in NHS		
Have more mental stamina		2	

continued

TABLE 31 The COM-B questionnaire responses from HCPs (*continued*)

Category	Item	Summary of free-text responses	Number of responses	
Opportunity	Have more time to do it	Time is short and may neglect other issues if spending time on the intervention	8	
	Have the necessary materials	Need longer appointment times if to deliver more interventions	7	
		Protocols and guidelines as to who you want targeted and key things to cover		
	Have colleagues around me doing the same thing	Visual aids often good at helping patients understand the importance of reducing alcohol/smoking from my experience	6	
		Everyone working towards the same goal and outcome		
	Have reminders in place to deliver the intervention	Working as a team advice from colleagues how they managed certain situations/support	4	
Working as team – can bounce ideas off each other/help motivate				
Motivation	Have support from others	Very basic forms would be good due to time limits	3	
	Feel that I want to do it	These patients will hopefully be identified on set lists	2	
	Feel that I should do it		2	
	Believe that it would be a good thing		5	
	Develop better plans for doing it	Time allocated		9
		Need to be clear, concise, easy to follow		
		I believe in it if it's done properly with time planning ahead		
	Develop a habit of doing it	Need a structured plan to feel confident in talking to patients about it		
		Would need some continuity, not 'one-off' sessions		6
	Something else (please specify)	Set time/follow on from a questionnaire in PAC, which would automatically trigger if needed intervention		
Increase PAC time			2	
		Needs to work where patients do not feel judged – patients should not be dictated to		

Appendix 4 Affordability, Practicability, Effectiveness, Acceptability, Safety and Equity questionnaire

Pre-ops Bird Training Program Design

Dear x,

Thank you very much for agreeing to assist us with the development of the Pre-ops Bird Training Program. The training program is targeted at practice nurses who will be delivering a screening and short intervention for risky drinking to pre-operative patients.

To support nurses with the delivery of the intervention we have designed an outline for a 2, 5 hour training program that aims to provide nurses with the necessary knowledge and skills to effectively deliver the intervention. Given your experience in pre-operative care we would like to involve you in the design of this training to make it as appealing and relevant as possible for the nurses.

The following questionnaire provides an outline of the preliminary components of the training. Could we please ask you to look at each individual component and rate each in terms of:

- Effectiveness (Will the component help nurses gain necessary knowledge and skills to effectively deliver the intervention?)
- Acceptability (Is the intervention component appropriate for the nurses?)
- Side-effects (Are there any potential negative side-effects of the component? E.g. nurses might feel uneasy or distressed to do an exercise)

Please respond to each item with Yes or No in the third column. If you feel like a specific component doesn't fit any of the criteria (effectiveness, acceptability, or side-effects) could you provide a short description of your rationale?

Intervention function	Individual training components	Does the intervention function meet the following criteria (effectiveness, acceptability, side-effects, equity)?	Why no?
Education	Providing information/ education regarding risks associated with risky drinking behaviour	Effectiveness: Acceptability: Side-effects:	
Education	Providing information about what constitutes normal/abnormal drinking behaviour	Effectiveness: Acceptability: Side-effects:	
Persuasion	Scientific evidence will be used to strengthen the credibility of the intervention package	Effectiveness: Acceptability: Side-effects:	
Incentivisation	Nurses will be quizzed about their knowledge regarding the intervention package and a prize will be given	Effectiveness: Acceptability: Side-effects:	

Education, Training	Instructions on how to complete the intervention package with the patient	Effectiveness: Acceptability: Side-effects:
Modelling	Short video demonstrations of the delivery of the individual intervention package	Effectiveness: Acceptability: Side-effects:
Training	Nurses will be prompted to practice delivering the brief intervention to each other	Effectiveness: Acceptability: Side-effects:
Training	Intervention deliverers will provide feedback to the nurses on how they delivered the intervention	Effectiveness: Acceptability: Side-effects:
Enablement	Nurses will be prompted to come up with a plan on how to deal with difficult/challenging situations	Effectiveness: Acceptability: Side-effects:
Enablement	Nurses will be encouraged to form 'supportive couples' or groups in which they can discuss their experiences and address any concerns	Effectiveness: Acceptability: Side-effects:

Thank you very much for completing this questionnaire. We will have a look at your responses and integrate your feedback in the final version of the Pre-ops Bird Training program.

Kind Regards,

Your Pre-ops Bird Research Team

Appendix 5 Training feedback form

Preoperative Behavioural Intervention for Risky Drinkers before elective orthopaedic Surgery (Pre-Op BIRDS)

Training Intervention Evaluation

Name (optional):

We are keen to find out whether you found the training intervention we delivered both informative and practically useful (i.e. whether you felt it equipped you with the knowledge and skills required to deliver a brief behavioural intervention to your patients). You will be presented with a series of statements for which you will be asked to circle a response that most closely matches how you feel about the session. If you have any additional comments to make about the session generally, or those delivering it (Ellen Lynch, Leah Avery, and Sebastian Potthoff), then those will be gratefully received in the free text box at the end of this form.

The objectives of the session were clearly stated and appropriate

Strongly agree Agree Disagree Strongly Disagree N/A

The session was well structured and relevant

Strongly agree Agree Disagree Strongly Disagree N/A

The content of the session was appropriately related to the overall outcomes

Strongly agree Agree Disagree Strongly Disagree N/A

The session was appropriately timed and delivered at an satisfactory pace

Strongly agree Agree Disagree Strongly Disagree N/A

The session was delivered with interest and enthusiasm

Strongly agree Agree Disagree Strongly Disagree N/A

I was invited to ask questions and participate in discussions

Strongly agree Agree Disagree Strongly Disagree N/A

Appropriate practical examples were used to illustrate theoretical points

Strongly agree Agree Disagree Strongly Disagree N/A

The content was made relevant to my practice

Strongly agree Agree Disagree Strongly Disagree N/A

The training accommodation was suitable

Strongly agree Agree Disagree Strongly Disagree N/A

Audio-visual aids (e.g., PowerPoint) intervention materials and handouts were used effectively to deliver/support the session

Strongly agree Agree Disagree Strongly Disagree N/A

The individuals delivering the session were approachable and non-judgemental

Strongly agree Agree Disagree Strongly Disagree N/A

Having attended the above session, I feel I left with a good knowledge of the topic delivered

Strongly agree Agree Disagree Strongly Disagree N/A

The knowledge gained from the session will assist me further in my clinical practice

Strongly agree Agree Disagree Strongly Disagree N/A

The skills gained from the session will assist me further in my clinical practice

Strongly agree Agree Disagree Strongly Disagree N/A

Overall I enjoyed the session

Strongly agree Agree Disagree Strongly Disagree N/A

If you have any additional comments you would like to make, please write them in the space below:

Signed:

Date:

Thank you for completing this evaluation questionnaire.

Appendix 6 Focus group participant information sheet

Feasibility Study: Pre-Operative Behavioural Intervention to Promote Responsible Drinking before elective orthopaedic Surgery

(PRE-OP BIRDS)

Participant Information Sheet

Health Care Professionals Focus Groups

We would like to invite you to take part in a focus group discussion as part of the PRE-OP BIRDS research study. Before you decide you need to understand why the research is being done and what taking part would mean for you. Please take time to read the following information carefully, and feel free to talk to others about the study, if you wish. Take some time to consider it carefully before you decide.

Please ask us if there is anything that is not clear.

What is the purpose of the study?

Alcohol consumption is known to be associated with increased complications after surgery, which prevent early recovery and prolong rehabilitation times. It is therefore important that we are able to detect increased alcohol intake by patients much better than we currently do.

This study aims to test a revised screening and behavioural intervention which will be used with patients being referred for surgery. The behavioural intervention will help you to provide simple advice and guidance to patients on how reducing alcohol consumption prior to surgery could improve recovery time and reduce the amount of time spent in hospital after an operation.

In order to fully understand if the new intervention is successful we will need to test it against the standard treatment provided to these patients. These focus groups will therefore be used to gather information regarding what is standard practice in local NHS Trusts. The information provided will be used to inform a larger pilot trial that will run straight after this feasibility study and will compare the new intervention against standard practice, as identified during the focus groups.

Why have I been invited to take part in PRE-OP BIRDS?

You have been invited to participate as you currently work within or alongside a Preoperative Assessment Clinic and are involved in the development, organisation or delivery of the elective surgical patient pathway.

Do I have to take part?

You do not have to take part, and it is up to you to decide. If you do agree to take part, you can withdraw without giving a reason.

Once the Focus Group has started you are also free to leave at any point but data collected up to that point will be retained for use in the study.

What will I have to do?

After you have signed the study consent form you will take part in a focus group that will last approximately one hour. The focus group will involve approximately 6-8 staff members per group and will involve a mix of healthcare professionals involved in the orthopaedic surgery patient pathway. This will take place at a time and location convenient for you. The aim of the focus group is to explore current views of preoperative alcohol screening and behavioural intervention in older orthopaedic patients. We also aim to clarify and understand what defines usual practice in preoperative assessment clinics particularly with regard to screening patients for high-risk alcohol consumption.

The focus groups will be audio recorded and transcribed verbatim. This data will then be analysed by a researcher and will assist the research team in defining the comparator or treatment as usual group for the pilot trial.

What are the possible benefits of taking part?

Taking part in the focus group will not benefit you directly but the information we gather from these focus groups will help inform a larger pilot trial and may help patients and Health Care Professionals in the future.

Will my taking part in this study be kept confidential?

All study information, including personal details, will be kept confidential and will not be made public. The study data may be looked at by people who are monitoring or auditing the study, a Research Ethics Committee (REC) or other regulatory authorities, or the hospital Trusts involved in the study, to make sure that the study is being run correctly. By signing the consent form, you are giving your permission for this to happen.

Everyone involved in this study has a duty of confidentiality to the participants and this will be maintained throughout the session. If however, during the course of the focus group any abusive and/or unprofessional behaviours and/or actions are disclosed by staff this will need to be reported to the study Chief Investigator. It will also be reported to their line manager and, if applicable, through the appropriate NHS safeguarding process.

Who is organising and funding the research?

This study is being funded by the NIHR Health Technology Assessment programme. This body is funded by the UK government to carry out research for the benefit of the NHS and its patients. It is being organised and carried out by a team of researchers based in Newcastle upon Tyne.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by Newcastle & North Tyneside 2 Research Ethics Committee.

What will happen to the results of this study?

Data from this study will be used to improve the behavioural intervention and the next phase of the research. Data from your focus group may be used, anonymously, in the study report and publications from the research.

Further information and contact details

These are the key contacts for this study. If you have any further questions or would like any further information about the study or the rights of participants, please feel free to contact them.

[insert local details here]

Appendix 7 Focus group consent form

Patient Identification Number for this trial:

CONSENT FORM

Health Care Professionals Focus Group

Title of Project: Preoperative Behavioural Intervention to promote Responsible Drinking before elective orthopaedic Surgery (PRE-OP BIRDS) – Feasibility Study

Chief Investigator: Dr Chris Snowden

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated [] version [] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.
3. I understand that data collected during the study, may be looked at by individuals from Newcastle University, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.
4. I give my permission for the focus group to be audio recorded and for these recordings to be saved by the research team
5. I agree to take part in the above study.

Name of Participant	Date	Signature

Name of Person	Date	Signature

taking consent.

When completed - 1 copy for participant and 1 original copy for Investigator Site File

Appendix 8 Focus group discussion guide

Before commencing Interview:

Ensure have completed consent forms, discussed recording interview and anonymisation of data.

Check staff members are happy to start focus group and inform you will turn audio recorder on.

Introductions:

I'm sure some of you know each other already but it would be really beneficial for me if you could introduce yourselves, give your job title and a brief description of your role in preoperative assessment.

Usual Care Questions:

1. Could you talk me through the preoperative care pathway for individuals undergoing primary hip or knee arthroplasty?

Prompts:

Is that right from the first contact with the patient?

Is there anything that any of you do with or for patients that hasn't been covered?

2. Do you do any kind of preoperative alcohol screening, if so can you tell me about it?

Prompts:

when/how?

How do patients respond to being asked about alcohol?

What about other health behaviours?

Are there any specific issues or concerns about conducting such screening with older orthopaedic patients?

3. What happens as a result of screening, for example if a patient screens positive?

Prompts:

Do they get given any information?

What about if they screen negative?

Perceptions of Current Status Questions:

1. How do you feel about the current approach to preoperative alcohol screening?

Prompts:

Is screening important? If so why?

Should we be doing more?

Is this the right time to be asking about alcohol use?

Are there any specific issues or concerns about conducting such screening with older orthopaedic patients?

2. What are your thoughts about conducting behavioural interventions as part of preoperative assessment?

Prompts:

Is that specific to alcohol interventions or any intervention?

From your experience would you expect any differences when dealing with older orthopaedic patients compared to other patient groups?

3. Have any of you been involved in any behavioural interventions during preoperative care?

Prompts:

If so what for/how did you find that?

Closing Questions

1. Is there anything else that we should consider when looking at alcohol screening and behavioural interventions with older orthopaedic populations?
2. Does anyone have anything that they would like to add or anything that you think we should have talked about today?

To close the session:

Turn off recorder.

Thank the staff members for giving up their time to take part and for providing useful insight.

Remind that data will be used to inform future trial and may be used in publications but will be transcribed and anonymised so they are unidentifiable

Ask if they have any questions

Appendix 9 Treatment-as-usual survey

Age:

Gender

- Male
- Female
- Other (please specify)

Please indicate your current job role in the preoperative care pathway

Please note: this survey is specifically aimed at individuals currently employed in preoperative assessment. If you are not currently employed in preoperative assessment please tick this box and end the survey here.

- Healthcare Assistant
- Senior Healthcare Assistant
- Band 4 Nurse
- Band 5 Nurse
- Band 6 Nurse
- Band 7 Nurse
- Team Leader
- Manager
- Sister
- Senior Sister
- Matron
- Anaesthetist
- Consultant Anaesthetist
- Prefer not to say
- Other (please specify)

How long have you:

	Years	Months
Held your current post?	<input type="text"/>	<input type="text"/>
Worked in pre-assessment?	<input type="text"/>	<input type="text"/>

In your department, approximately how long does a preoperative assessment appointment last for patients undergoing primary knee arthroplasty?

In your department, approximately how long does a preoperative assessment appointment last for patients undergoing primary hip arthroplasty?

As part of preoperative assessment for hip and knee arthroplasty are patients asked about their alcohol consumption?

- Yes as part of formal pre-operative assessment procedure
- Yes patients are asked but this is not part of formal preoperative assessment procedure
- No
- Don't Know
- Prefer not to say

How (in what form) are patients asked about their alcohol use? (please respond yes, no or don't know to each option)

	Yes	No	Don't know	Prefer not to say
A simple yes or no indication of alcohol consumption	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients are asked 'how much do you drink'	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients are asked 'how often do you drink'	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients are asked how many units/standard drinks they consume per week	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients are asked 'how many units/standard drinks they consume per day	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Completion of a screening tool or questionnaire (please give details below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please provide details of screening tools used or specify any other method of questioning not covered above

As part of preoperative assessment for hip and knee arthroplasty are patients provided with any information about alcohol use?

- Yes, this is part of formal pre-operative assessment procedure
- Yes patients are given information but this is not part of formal preoperative assessment procedure
- No
- Don't know
- Prefer not to say

What form does this information take? (please indicate yes, no or don't know for each option)

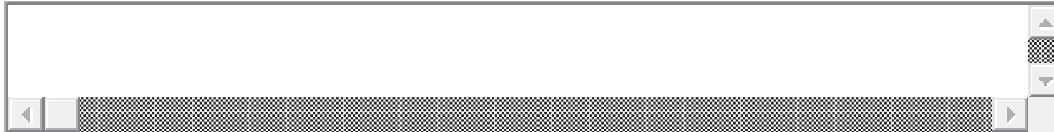
	Yes	No	Don't know	Prefer not to say
Information leaflet/booklet about alcohol in general	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Information leaflet/booklet about alcohol use in relation to surgery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Face to face information about alcohol in general	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Face to face information about alcohol use in relation to surgery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Websites to access information online in their own time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Contact numbers for telephone information/support lines to use in their own time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patient is told to contact their GP surgery for information	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other (please specify)

Which patients are given this information about alcohol use? (please indicate yes, no or don't know for each option)

	Yes	No	Don't know	Prefer not to say
All patients (regardless of whether they drink alcohol) receive advice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
All patients who report drinking alcohol receive advice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
All patients who request information	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients who consume over a specified number of units/standard drinks receive information (please provide details below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients who state, when asked, that they would like to cut down their alcohol consumption receive information	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients identified through liver function tests receive information (please give details below of who interprets liver function tests and follows up if abnormal)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients identified through other blood test receive information (please give details below of who interprets blood tests and follows up if abnormal)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please give details below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please give details here



Are you able to refer patients for additional advice or support related to alcohol consumption?

- Yes, this is part of standard practice
- Yes, but this is not part of standard practice
- No
- Don't know
- Prefer not to say

To whom can patients be referred? (please indicate yes, no or don't know for each option)

	Yes	No	Don't know	Prefer not to say
Referral to consultant anaesthetist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Referral to GP	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Referral to in-hospital alcohol liaison nurse or nurse specialist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Referral to in-hospital addiction psychiatrist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Referral to Alcoholics Anonymous (AA) groups	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Referral to other external organisation (please give details below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please give details below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please give any details here:

Which patients are identified for referral? (please indicate yes, no or don't know for each option)

	Yes	No	Don't know	Prefer not to say
All patients are referred regardless of whether they report alcohol consumption or not	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
All patients who report drinking alcohol receive referral	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients who consume over a specified number of units/standard drinks receive referral (please give details below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients who state, when asked, that they would like to cut down their alcohol consumption receive referral	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients identified through liver function tests receive referral	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients identified through other blood test receive referral	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
patients who ask to be referred receive referral	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients who show signs of alcohol dependence receive referral	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patients who are already identified as alcohol dependent receive referral	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please give details

As part of routine pre-operative assessment does your department currently provide interventions (term described above) for any of the following health behaviours? (please indicate yes, no or don't know for each option)

	Yes	No	Don't know	Prefer not to say
Alcohol use	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Smoking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Physical activity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diet/nutrition	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please give details below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please give details here

As part of routine pre-operative assessment do you personally currently provide interventions (term described above) for any of the following health behaviours? (please indicate yes, no or don't know for each option)

	Yes	No	Don't	Prefer not to say
Alcohol consumption	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Smoking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Physical activity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diet/nutrition	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please give details below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please give details

As part of routine pre-operative assessment have you personally ever provided interventions (term described above) for any of the following health behaviours? (please indicate yes, no or don't know for each option)

	Yes	No	Don't Know	Prefer not to say
Alcohol consumption	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Smoking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Physical activity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diet/nutrition	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please give details below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please give details here

Appendix 10 Feasibility study health-care professional interview participant information sheet

Feasibility Study: Preoperative Behavioural Intervention to promote Responsible Drinking before elective orthopaedic Surgery (PRE-OP BIRDS)

Participant Information Sheet Health Care Professional Interviews

We would like to invite you to take part in an interview as part of the PRE-OP BIRDS study. Before you decide you need to understand why the research is being done and what taking part would mean for you. Please take time to read the following information carefully, and feel free to talk to others about the study if you wish. Take some time to consider it carefully before you decide.

Please ask us if there is anything that is not clear.

What is the purpose of the study?

Alcohol consumption is known to be associated with increased complications after surgery, which prevent early recovery and prolong rehabilitation times. It is therefore important that we are able to detect increased alcohol intake by patients much better than we currently do.

This feasibility study aims to test a revised screening and behavioural intervention which will be used with patients being referred for surgery. The behavioural intervention will help nurses to provide simple advice and guidance to patients on how reducing alcohol consumption prior to their surgery, which could in turn improve their recovery time and reduce the amount of time they have to spend in hospital after their operation.

As part of this study we have trained pre-operative assessment clinic staff, to deliver the AUDIT C and AUDIT screening tools and have also trained some of them to deliver the intervention. We are now inviting all those trained to take part in interviews to find out how acceptable this screening procedure and the new intervention is and how easily these procedures can be embedded as standard practice during pre-operative assessment clinics.

Why have I been invited to take part in PRE-OP BIRDS?

You have been invited to participate as you have received training on the use of the AUDIT C and AUDIT screening tools and/or the intervention and have been using them in the preoperative assessment clinic.

Do I have to take part?

You do not have to take part, and it is up to you to decide. You can withdraw from the study at any time, without giving a reason.

What will happen to me if I take part?

Members of staff from both groups (those trained in screening only and those trained in both screening and behavioural intervention) will be asked to take part in a one-to-one interview with the researcher. This will last approximately one hour and will take place at a time and location convenient for you. The interview will explore your views on the feasibility of the new screening and behavioural intervention, any factors that may affect the delivery of the intervention and the acceptability of the intervention.

With your permission, interviews will be audio recorded and transcribed verbatim. This data will then be analysed and will assist the research team in designing a larger pilot trial.

What are the possible benefits of taking part?

Taking part in an interview will not benefit you directly but the information we gather from this feasibility study will help inform a larger pilot trial and may help patients in the future.

Will my taking part in this study be kept confidential?

All study information, including personal details, will be kept confidential and will not be made public. The study data and patient medical records may be looked at by people who are monitoring or auditing the study, Research Ethics Committee (REC) or other regulatory authorities, or the hospital Trusts involved in the study, to make sure that the study is being run correctly. By signing the consent form, you are giving your permission for this to happen.

Everyone involved in this study has a duty of confidentiality to the participants and this will be maintained throughout the session. If however, during the course of the interview any abusive and/or unprofessional behaviours and/or actions are disclosed by staff this will need to be reported to the study Chief Investigator. It will also be reported to their line manager and, if applicable, through the appropriate NHS safeguarding process.

Who is organising and funding the research?

This study is being funded by the NIHR Health Technology Assessment programme. It is being organised and carried out by a team of researchers based in Newcastle upon Tyne.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by Newcastle & North Tyneside 2 Research Ethics Committee.

What will happen to the results of this study?

Data from this study will be used to improve the behavioural intervention and the next phase of the research. Data from your interview may be used, anonymously, in the study report and publications from the research.

Further information and contact details

These are the key contacts on this study. If you have any further questions or would like any further information about the study or the rights of participants, please feel free to contact them.

[insert local details here]

Appendix 11 Feasibility study health-care professional interview topic guide

HCP Interviews Discussion Guide

Before commencing Interview:

Ensure have completed consent form, discussed recording interview and anonymisation of data.

Check staff member is happy to start interview and inform you will turn audio recorder on.

Check we have access to Age and Gender

Introduction:

1. To start with could you tell me about your experience of the study to date?

Prompts:

What was your role?

What motivated you to take part?

Where you happy to be involved?

2. How have you found using the AUDIT to screen patients for alcohol use?

Prompts:

have you used it before?

was it easy to score?

were you comfortable asking all the questions?

3. And what about the intervention?

Prompts:

Have you used these material before?

Have you used another intervention (other materials before) – if so what?

How did you feel about talking to your patient about alcohol?

How did the patient react?

Feasibility Questions:

1. How did you find the screening fit in with usual preoperative assessment procedures?

Prompts:

What worked well?

What didn't work well?

Suggestions for improvements?

2. Do you think it is practical to conduct screening during preoperative assessment?

Prompts:

Why is that?

Can you expand on that?

- How did you find the intervention fit in with usual preoperative assessment procedures?

Prompts:

What worked well?

What didn't work well?

Was there enough time to deliver the intervention?

Can you expand on that?

- Do you think it is practical to deliver an intervention during preoperative assessment?

Intervention Materials:

- We've got the study materials here, could you tell me what you thought of them?

Prompts:

Do you have any suggestions about how we could improve the materials?

Where there any aspects that you thought were particularly good or bad?

- Where you able to link these materials to the theories covered in the training you received?

Prompts:

Could you give me some examples of the key components of the intervention and where they appear in the materials?

- How did patients react to the study materials?

Prompts:

Were they well received?

Were there any negative comments or reactions?

Procedure Questions

- How did you find the overall procedure?

Prompts:

So things like gaining consent, screening patients, conducting the intervention and the booster?

Can you think of any way the procedure could be improved?

Fidelity Questions:

- Did you find it easy enough to stick to the intervention?
- Were there any factors that influenced how you delivered the intervention?

Prompts:

Can you think of any that would?

Acceptability:

- How did you feel talking about alcohol with patients during preoperative assessment?

Prompts:

Did you feel you had the necessary skills and understanding to do this?

- How did patients react to talking about their alcohol use in this setting?

Prompts:

Do you think that's specific to older orthopaedic patients?

Closing Questions:

1. Is there anything that you think we should have talked about that we haven't?
2. Is there anything that you would like to add?

To Close the Interview:

Turn off recorder.

Thank the staff member for giving up their time to take part and for providing useful insight.

Remind that data will be used to inform future trial and may be used in publications but will be transcribed and anonymised so they are unidentifiable

Ask if they have any questions

Appendix 12 Feasibility study patient interview information sheet

Feasibility Study: Preoperative Behavioural Intervention to promote Responsible Drinking before elective orthopaedic Surgery (PRE-OP BIRDS)

Participant Information Sheet

Patient Interviews

We would like to invite you to take part in an interview as part of the PRE-OP BIRDS research study. Before you decide you need to understand why the research is being done and what taking part would mean for you.

Please take time to read the following information carefully, and feel free to talk to others about the study, if you wish. Take some time to consider it carefully before you decide.

Please ask us if there is anything that is not clear.

Why have I been invited to take part in an interview?

You have been invited to take part in an interview because you have recently attended an appointment with a pre-operative assessment nurse using the behavioural intervention. As such, we are interested in hearing your thoughts on this experience and how useful the newly developed intervention was for you.

What is the purpose of the study?

Alcohol consumption is known to be associated with increased complications after surgery, which prevent early recovery and prolong rehabilitation times. It is therefore important that we are able to detect increased alcohol intake by patients more accurately than we currently do.

This study aims to test a revised screening and behavioural intervention, which will be used with patients being referred for surgery. The behavioural intervention will help healthcare professionals provide simple advice and guidance to patients on how reducing alcohol consumption prior to surgery could improve recovery time and reduce the amount of time spent in hospital after an operation.

As well as asking patients to take part in two sessions using this behavioural intervention, we are also asking if they would be willing to take part in an interview once the sessions have been completed. This is to gather the thoughts and feelings of those that will actually be using the advice to see how they felt about it.

Do I have to take part?

You do not have to take part, and it is up to you to decide. You can withdraw from the study at any time, without giving a reason, and this will not affect the care that you receive.

What will happen if I take part?

After you have signed the consent form you will take part in an interview with a member of the research team. The interview will take place after you have received your operation and have been discharged from hospital. It will last approximately one hour and will take place at a time and place convenient for you. The interview will explore your thoughts regarding the intervention and how acceptable you found it.

The interview will be audio recorded. This is to make sure that the researchers have access to the information that you provide. This helps them make any changes needed to the intervention and improve how it works in the future. By recording the interview, they can concentrate on what you are saying, rather than being distracted by taking notes.

Expenses and payment

You will not receive payment or reimbursement of expenses for taking part in this study. However the interview can be conducted when you attend your 6 week post-operative follow up appointment or in your home, at a time convenient to you. This ensures that you won't incur any additional costs as a result of taking part in this study.

What are the possible benefits of taking part?

By taking part in an interview you are providing valuable information that will help us to further develop the screening and behavioural intervention used as part of this study. We cannot promise the study will help you directly but the information we get from this study may help other patients in the future.

Will my taking part in this study be kept confidential?

All study information, including personal details, will be kept confidential and will not be made public. The study data and your original medical records may be looked at by people who are monitoring or auditing the study, a Research Ethics Committee (REC) or other regulatory authorities, or the hospital Trusts involved in the study, to make sure that the study is being run correctly. By signing the consent form, you are giving your permission for this to happen. Everyone involved in this study has a duty of confidentiality to the participants and this will be maintained.

What will happen if I don't want to carry on with the interview?

You have the right to withdraw at any time for any reason, and without giving a reason. But we might ask you to allow us to record why you have decided to withdraw. We will also keep the data we have collected from you up to the point of withdrawal if you agree for us to do so.

What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the researcher who will do their best to answer your questions: [insert staff details here]

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against The Newcastle upon Tyne Hospitals NHS Foundation Trust but you may have to pay your legal costs. NHS indemnity does not offer no-fault compensation (for harm that is not anyone's fault).

If you are still unhappy and wish to complain formally, you can do so through the hospital's procedure Patients Complaints Service (PALS) [insert details here]

Who is organising and funding the research?

This study is being funded by the NIHR Health Technology Assessment programme. This body is funded by the UK government to carry out research for the benefit of the NHS and its patients. It is being organised and carried out by a team of researchers based in Newcastle upon Tyne.

Who has reviewed the study?

To protect your interests, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This study has been reviewed and given favourable opinion by Newcastle & North Tyneside 2 Research Ethics Committee.

How have patients and the public been involved in this study?

Members of Voice North have been involved in the design of this study. Voice North is a voluntary organisation that includes members of the public. Members actively volunteer to assist researchers with the design of research studies to improve the quality of the research and make sure it fits with what is important for both patients and the public. You can find out more about Voice North at: <http://www.ncl.ac.uk/ageing/partners/voicenorth/#about>

What will happen to the results of this study?

Data from this study will be used to improve the behavioural intervention and the next phase of the research. Data from your interview may be used (anonymously) in the study report and in other publications from the research.

Further information and contact details

These are the key contacts for this study. If you have any further questions or would like any further information about the study or the rights of participants, please feel free to contact them.

[insert local details here]

Appendix 13 Feasibility study patient interview discussion guide

Before commencing Interview:

Ensure have completed consent form, discussed recording interview and anonymisation of data.

Check participant is happy to start interview and inform you will turn audio recorder on.

Check we have access to Age, Gender, Audit Score

Introduction Questions:

1. Could you tell me what led to you coming into hospital for surgery in the first place?
2. Before coming in to hospital did you expect to be asked about alcohol use? Why?
3. Would you link alcohol use and surgery in anyway?

Experience of the study

1. So, moving on, can you tell me about your experience of being involved in the study?

Prompts:

Could you tell me what motivated you to take part?

Who did you speak to about the study?

How did you feel about being involved?

2. Next I'd like to know about the process of the study so could you start by taking me through step by step what the study involved?

Prompts:

What parts of the process could be improved?

Did you feel comfortable with all parts of the process?

Where there any parts that were unclear?

Acceptability Questions:

1. How did you feel being asked about alcohol use by a nurse?

Prompts:

Were you comfortable talking about your drinking?

2. We used the pre-operative assessment as an opportunity to talk about your alcohol use: how did you feel about that?

3. This is the tool or questionnaire (present AUDIT) that we used to assess your alcohol use which you have completed a few times now, can you tell me what you thought of it?

Prompts:

Were the questions acceptable?

Did you understand them all?

How easy was it to complete?

4. Focusing on the advice you received: how did you feel about that?

Feasibility Questions:

1. How did you find the questions and discussion about alcohol fit in with your care?

Prompts:

Do you think it influenced the rest of your care?

If so was this in a good or bad way?

2. I'm not sure if you know this already but this was a feasibility trial which means we work with a small number of staff and patients to assess if these methods are practical and the findings then inform a larger study. With that in mind there are a few things which didn't happen in this study but would in a larger trial that I'd like to ask you about. Firstly in a full trial we would want to contact participants 6 months after the intervention session to ask them some more questions. How would you have felt about doing that?

Prompts:

Specifically we'd ask you the AUDIT (show AUDIT) questions again, to look at alcohol use and these questions about your health (show EQ-5D). Would you have been happy to complete those?

Also in this study everyone who wanted to take part received information about alcohol use but in a full trial only half the participants would be randomly selected to receive information the other half would just get standard treatment. How would you have felt about that?

Prompts:

Would it have influenced your decision to take part?

Intervention materials:

1. We have the study materials here in front of us, the ones you were given by the nurse, and I wondered what you thought of them?

Prompts:

Is there any way we could improve the materials?

Did you find some of these more useful than others?

Was it too much information, not enough information or about right?

2. You'll notice the term standard drinks is used quite a bit in the materials. Did you understand this?

Prompts:

Sometimes people use the term 'unit' or 'units' rather than 'standard drink' would you prefer that?

3. If I could get you to look at the Brief Advice sheet – we had quite a few lists of benefits from reducing alcohol intake and risks associated with higher alcohol intake did you think we had the most important or most relevant points at the top of each list?

Prompts:

Did you think there was anything missing from these lists?

4. Is there anything we should know about talking to people your age about alcohol use?
5. What about talking to patients about alcohol use?

Closing Questions

1. Is there anything that you think we should have talked about that we haven't?
2. Is there anything you would like to add before we finish?

To Close the Interview:

Turn off the recorder.

Thank the participant for giving up their time to take part and for providing useful insight.

Remind that data will be used to inform future trial and may be used in publications but will be transcribed and anonymised so they are unidentifiable

Ask if they have any questions

Appendix 14 Pilot randomised controlled trial patient participant information sheet

Pre-Operative Behavioural Intervention to Reduce Drinking before elective orthopaedic Surgery (PRE-OP BIRDS): A Pilot Randomised Controlled Trial

Participant Information Sheet

We would like to invite you to take part in a research trial. Before you decide you need to understand why the research is being done and what taking part would mean for you.

Please take time to read the following information carefully, and feel free to talk to others about the trial if you wish. Take some time to consider it carefully before you decide.

Please ask us if there is anything that is not clear.

Why have I been invited to take part in PRE-OP BIRDS?

You have been invited to take part because you have recently been placed on the waiting list for elective hip or knee replacement surgery. As part of your pre-operative care you will be asked to complete a questionnaire called AUDIT C. This questionnaire is routinely used before a patient has surgery in order to find out how much alcohol the patient consumes on a regular basis. Once completed this questionnaire will be reviewed by the PRE-OP BIRDS study team to see if you are eligible to take part in this trial.

What is the purpose of the trial?

Alcohol consumption is known to be associated with increased complications after surgery, which can prevent early recovery.

This trial aims to test a method which aims to reduce alcohol intake in patients known as a 'behavioural intervention'. This will be used with patients being referred for surgery. The behavioural intervention will be used by healthcare professionals to provide simple advice and guidance to patients on how they can reduce their alcohol consumption should they want to and what benefits this could bring.

Do I have to take part?

It is up to you to decide whether you want to take part or not. You can withdraw from the trial at any time, without giving a reason, and this will not affect the care that you receive.

What will happen if I take part?

Taking part in the trial will not influence if or when you receive your surgery. If the AUDIT C shows that you are eligible and you decide to take part you will be asked to complete and sign a consent form. After which you will be asked to complete the AUDIT questionnaire, which is a slightly longer version of the AUDIT C questionnaire that you previously completed. You will then be randomly allocated to one of two groups:

- Behavioural intervention plus treatment as usual

Or

- Treatment as usual only

You will have a 50-50 chance of being allocated to one of the groups. Your group will be randomly picked by a computer. Neither you nor the trial team will have a say on which group you are put in, but you will be told straight away which group you have been allocated to. You will then attend your pre-assessment appointment, receiving your usual care.

What will I have to do?

As part of this trial there are some visits that you will be required to attend/take part in. In this trial all visits to the hospital have been scheduled to take place either when you are already at hospital (for example during routine appointments or whilst you are an in-patient around the time of your surgery) or at your home/by telephone. This is to ensure you do not have to make additional trips to hospital.

Once you have been randomised you will be informed straight away which group you have been allocated to either (a) behavioural intervention or (b) usual care.

(a) Behavioural intervention

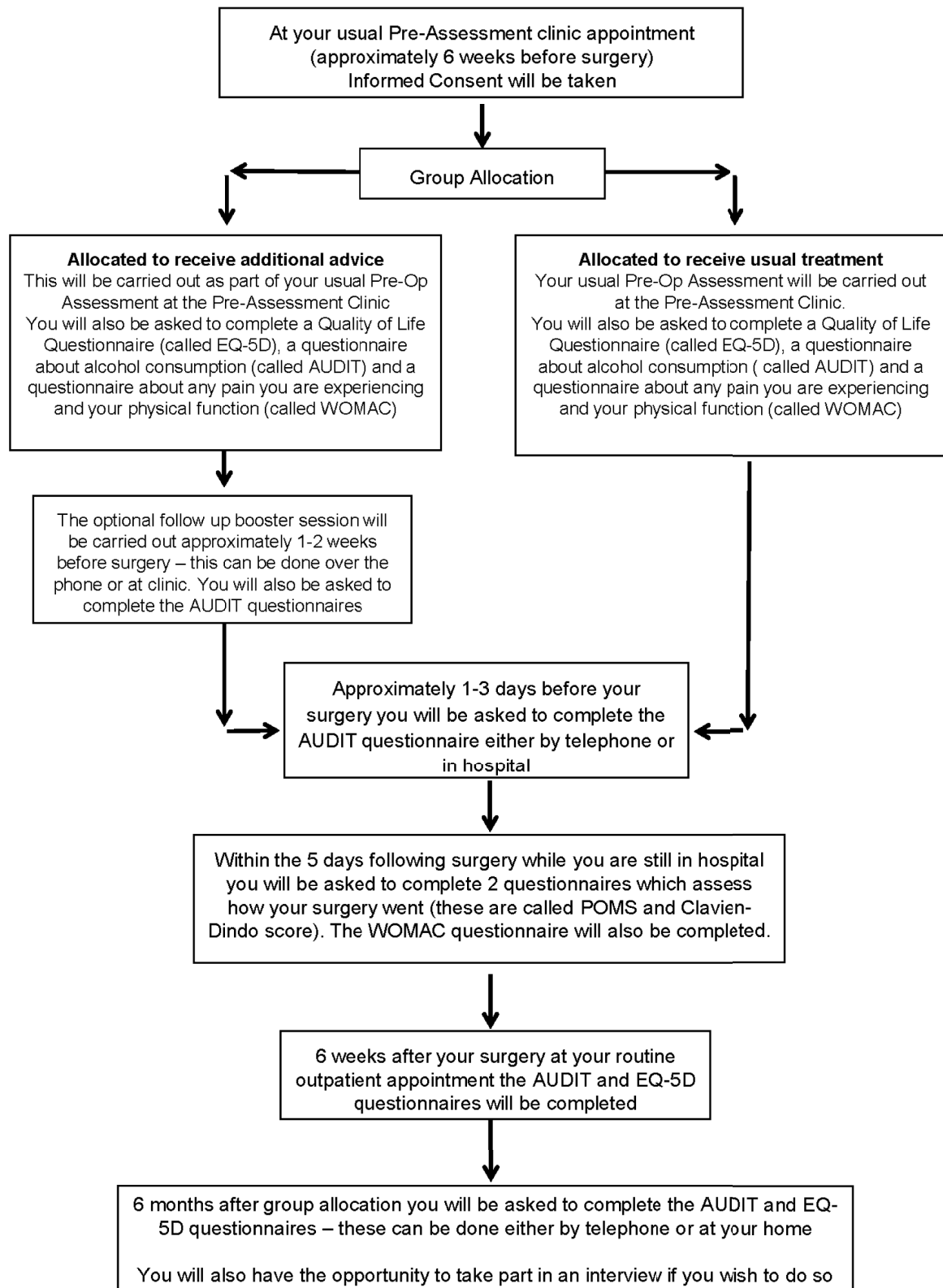
If you are allocated to receive the behavioural intervention, the trial team will go through the intervention with you as part of your pre-assessment appointment. As part of the behavioural intervention you will be provided with brief advice on alcohol intake and support to reduce your alcohol consumption before surgery should you want to. The team will also ask you some questions about your alcohol use and feelings of wellbeing. The behavioural intervention session will last approximately 30 minutes which means your pre-assessment appointment will last approximately 30 minutes longer than usual. Approximately one to two weeks before your surgery the research team will contact you (by telephone) to ask you a few more questions and to offer you a second intervention session. This session will last approximately 10 to 20 minutes and can be delivered by telephone if it is easier for you. During this second session you will be asked to complete the AUDIT tool and receive the behavioural intervention which will involve some feedback and support. The aim of this session is to provide a refresher of the advice and guidance you received during the first session and to provide you with an opportunity to receive feedback and ask any questions. This second session is optional and you will be asked when signing the consent form to indicate if you are willing to take part in a second session and this will be confirmed with you again when you are contacted by the team one to two weeks before surgery.

We would like to make an audio recording of the behavioural intervention sessions in order to help with the training of staff delivering the intervention. For example, researchers will listen to the recording and make a note of whether the nurse delivering the session is covering everything they need to. The recordings will also ensure that the behavioural intervention is being delivered correctly and delivered in the same way each time. The recorded data will be anonymised and then analysed by a researcher to assist the research team in improving the intervention content for future use. The attached consent form will ask you to indicate whether or not you are willing to have your intervention sessions recorded. The recording will only be listened to by members of the research team.

(b) Usual Care

If you are allocated to receive treatment as usual you will not receive the intervention sessions and your consultations will not be audio recorded, but you will be asked some questions about your alcohol use and quality of life at the trial visits. These will only take a few minutes to complete.

Regardless of which group you are randomised to, you will be followed up for 6 months after randomisation. A schedule of the trial visits are listed in the diagram below along with what information will be collected:



When you come in for your surgery you will be asked if you would like to take part in the National Joint Registry. This is national registry which collects information on all hip, knee, ankle, elbow and shoulder replacement operations and you will be provided with a separate information sheet which will contain much more detailed information about the National Joint Registry and what it does. The WOMAC questionnaire mentioned in the table above is collected as part of the National Joint Registry and therefore if you agree to take part in the registry we will be able to use the WOMAC questionnaires completed as part of that (with your permission) and you will not have to complete them again as part of this trial. If however you decide not to take part in the registry we will need to go through these questionnaires with you as part of the PRE-OP BIRDS trial.

You will also be offered the opportunity to take part in an interview after you have completed the trial. The interview will last around 60 minutes and will ask you how useful you found this trial. Again this is entirely optional and you do not have to take part in an interview if you don't want to. If you are interested in taking part we will provide you with an additional information sheet that provides more information on what the interview will involve.

Expenses and payment

As part of this trial you should not have to attend hospital for any additional visits outside of your routine appointments. However, in the unlikely event that you do have to attend an additional visit at hospital in order to complete a trial visit, reasonable travel expenses will be reimbursed.

What are the possible benefits of taking part?

By taking part in this trial and following advice provided it is possible that you may recover more quickly following your operation and you may not have to spend as much in time in hospital afterwards. We cannot promise that the trial will help you directly but the information we gain from this trial will inform future research and may help other patients in the future.

What are the possible disadvantages of taking part?

There are no direct risks involved in taking part in this study and the standard of care you receive will not be affected whether you decide to take part or not. If you do agree to take part in the study you will be required to give up a small amount of your time to complete the study visits, however we will ensure that you do not have to attend hospital for additional visits outside of routine appointments wherever possible.

You may be asked some potentially sensitive questions regarding your use of alcohol. These questions are asked routinely, as part of standard clinical practice, in the pre-assessment clinic prior to any surgery.

Will my taking part in this trial be kept confidential?

All trial information, including personal details, will be kept confidential and will not be made public. With your permission, we will let your family doctor (GP) know that you are taking part. The trial data and your original medical records may be looked at by people who are monitoring or auditing the trial, a Research Ethics Committee (REC) or other regulatory authorities, or the hospital Trusts involved in the trial, to make sure that the trial is being run correctly. It is possible that the trial team might share anonymous information collected with other researchers in the future. Sharing trial information with other researchers is very important as it helps us to make sure that we are running a trial in the best possible way and it means that we can make the most of the information collected during a trial. Any information that is shared

will contain none of your personal details and will be fully anonymised. By signing the consent form, you are giving your permission for this to happen. Everyone involved in this trial has a duty of confidentiality to the participants and this will always be maintained. The Newcastle Clinical Trials Unit would like to receive a copy of your consent form for safety purposes. This will be confidentially destroyed once it has been reviewed.

What will happen if I don't want to carry on with the study?

You have the right to withdraw from the trial at any time for any reason, and without giving a reason. But we might ask you to allow us to record why you have decided to withdraw. We will also keep the data we have collected on you up to the point of withdrawal.

What if there is a problem?

If you have a concern about any aspect of this trial you should ask to speak to the researcher who will do their best to answer your questions: [insert staff details here]

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against The Newcastle upon Tyne Hospitals NHS Foundation Trust but you may have to pay your legal costs. NHS indemnity does not offer no-fault compensation (for harm that is not anyone's fault).

If you are still unhappy and wish to complain formally, you can do so through the hospital's procedure Patients Complaints Service (PALS) [insert details here]

Involvement of the General Practitioner/family doctor (GP)

With your permission, we will let your family doctor (GP) know that you are taking part. Participation in the trial will also be noted in your hospital records so that anyone who treats you will know you are taking part in the trial.

Who is organising and funding the research?

This trial is being funded by the NIHR Health Technology Assessment (HTA) programme. This body is funded by the UK government to carry out research for the benefit of the NHS and its patients. It is being organised by a team of researchers based in Newcastle upon Tyne.

Who has reviewed the trial?

To protect your interests, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This trial has been reviewed and given favourable opinion by [insert name of REC].

How have patients and the public been involved in this trial?

Members of Voice North have been involved in the design of this trial. Voice North is a voluntary organisation that includes members of the public. Members actively volunteer to assist researchers with the design of research studies to improve the quality of the research and make sure it fits with what is important for both patients and the public. You can find out more about Voice North at: <http://www.ncl.ac.uk/ageing/partners/voicenorth/#about>

Patients have also been involved in a feasibility study as part of this project to help inform the design of the screening and intervention materials as well as the development of this pilot trial.

What will happen to the results of this study?

Data from this trial will be used to inform future research. Data may be used, anonymously, in the trial report and publications from the research.

Further information and contact details

These are the key contacts on this trial. If you have any further questions or would like any further information about the trial or the rights of participants, please feel free to contact them.

[insert local details here]

Appendix 15 Pilot randomised controlled trial patient participant interview topic guides

Pre-op BIRDS pilot RCT Patient Interview Topic Guide – Control Condition

Ensure have completed consent form, discussed recording interview and anonymization of data.

Check participant is happy to start the interview and inform you will turn the audio recorder on.

Check we have access to age, gender and AUDIT scores.

Introduction Questions

1. Could you tell me what led to you coming in to hospital for surgery in the first place?
2. Before you came into hospital did you expect to be asked about alcohol use?
Prompts:
Why?
3. Before you became involved in the research would you have linked alcohol to surgery in any way?
4. Would you mind telling me about your alcohol consumption before you took part in the trial?

Change Questions

5. And did you feel that your alcohol use changed at all over the course of the research?
Prompts:
Would you say that's because of the surgery itself or being involved in the research?
6. Were there specific aspects of the trial that motivated you to change your drinking?
7. Do you remember if you set yourself any specific goals in terms of the change you wanted to achieve?

Experience of the Trial

1. Could you tell me what motivated you to take part in the trial?
2. I'd like to know about the process of the trial, could you start by talking me through step by step what the study involved?
Prompts:
Who did you speak to about the trial?
Did you feel comfortable with all parts of the process?
Where there any parts that were unclear?
What parts of the process could be improved?
3. At the beginning of the trial you may remember that you were contacted about the trial and then given time to think about your involvement before coming back to be consented into the trial. Was it important to you to have this time to consider whether or not you wanted to take part?
4. I'm not sure if you remember but at the beginning of the trial you were told you had a 50/50 chance of receiving the information about alcohol use or treatment as usual. How did you feel about that?
Prompts:
Did it have any influence on your decision to take part?

5. How did you feel about being asked some questions while you were in hospital recovering from your surgery?
6. How did you feel about being followed up at six weeks post-surgery and six after joining the trial?

Acceptability Questions

8. How did you feel being asked about alcohol use by a nurse?

Prompts:

Are you generally comfortable talking about your alcohol use?

Are you more/less comfortable talking to a nurse?

Feasibility Questions

1. How did you find the questions and discussion about alcohol fit in with your care?

Prompts:

Do you think it influenced the rest of your care?

If so was this in a good way or a bad way?

2. How did you find completing the different study questionnaires fit in with your care?

Prompts:

Do you think it influenced the rest of your care?

If so was this in a good way or a bad way?

3. You'll notice the term standard drink is used quite a bit in the materials. Did you understand that term?

Prompts:

Sometimes people use the term units or units instead of standard drink. Would you have preferred that?

1. We used the term risky drinking in the intervention materials, could you tell me what you thought of this term?

Prompts:

What did you think was meant by the term risky drinking?

Sometimes the terms hazardous or harmful drinking are also used. Would you have preferred this?

How would you feel if those terms were used to describe your drinking behaviour?

4. Is there anything you think we should know about talking to people your age about alcohol use?

5. What about talking to patients about alcohol use?
6. We have noticed that a lot more men than women have agreed to take part in the trial. Can you think of any reasons why that might be the case?

Closing Questions

1. Is there anything that you think we should have talked about today that we haven't?
2. Is there anything you would like to add before we finish?

To Close the Interview

Turn off the recorder.

Thank the participant for giving up their time to take part and for providing useful insight.

Remind that data will be used to inform future research and may be used in publications but will be transcribed and anonymised so that they won't be identifiable.

Ask if they have any questions.

Pre-op BIRDS pilot RCT Patient Interview Topic Guide – Intervention Condition

Ensure have completed consent form, discussed recording interview and anonymization of data.

Check participant is happy to start the interview and inform you will turn the audio recorder on.

Check we have access to age, gender and AUDIT scores.

Introduction Questions

Could you tell me what led to you coming in to hospital for surgery in the first place?

Before you came into hospital did you expect to be asked about alcohol use?

Prompts:

Why?

Before you became involved in the research would you have linked alcohol to surgery in any way?

Would you mind telling me about your alcohol consumption before you took part in the trial?

Change Questions

And did you feel that your alcohol use changed at all over the course of the research?

Prompts:

Would you say that's because of the surgery itself or the information you received?

Were there specific aspects of the information and advice that motivated you to change your drinking?

Do you remember if you set any specific goals in terms of the change you wanted to achieve?

Experience of the Trial

Could you tell me what motivated you to take part in the trial?

I'd like to know about the process of the trial, could you start by talking me through step by step what the study involved?

Prompts:

Who did you speak to about the trial?

Did you feel comfortable with all parts of the process?

Where there any parts that were unclear?

What parts of the process could be improved?

At the beginning of the trial you may remember that you were contacted about the trial and then given time to think about your involvement before coming back to be consented into the trial. Was it important to you to have this time to consider whether or not you wanted to take part?

I'm not sure if you remember but at the beginning of the trial you were told you had a 50/50 chance of receiving the information about alcohol use or treatment as usual. How did you feel about that?

Prompts:

Did it have any influence on your decision to take part?

Were you offered an optional second session of advice about 1-2 weeks before surgery?

Prompts:

Did you take part in this session?

Why?

Did you choose to have the session delivered over the phone or face to face?

Was the session useful?

How did you feel about being asked some questions while you were in hospital recovering from your surgery?

How did you feel about being followed up at six weeks post-surgery and six after joining the trial?

Acceptability Questions

How did you feel being asked about alcohol use by a nurse?

Prompts:

Are you generally comfortable talking about your alcohol use?

Are you more/less comfortable talking to a nurse?

We used the pre-operative assessment as an opportunity to talk to you about your alcohol use. How did you feel about that?

Thinking about the information and advice that you received from the nurse. How did you feel about that?

Prompts:

Was it about the right amount of information?

Did you understand it all?

Feasibility Questions

How did you find the questions and discussion about alcohol fit in with your care?

Prompts:

Do you think it influenced the rest of your care?

If so was this in a good way or a bad way?

How did you find completing the different study questionnaires fit in with your care?

Prompts:

Do you think it influenced the rest of your care?

If so was this in a good way or a bad way?

Intervention Materials

You'll notice the term standard drink is used quite a bit in the materials. Did you understand that term?

Prompts:

Sometimes people use the term units or units instead of standard drink. Would you have preferred that?

We used the term risky drinking in the intervention materials, could you tell me what you thought of this term?

Prompts:

What did you think was meant by the term risky drinking?

Sometimes the terms hazardous or harmful drinking are also used. Would you have preferred this?

How would you feel if those terms were used to describe your drinking behaviour?

Is there anything you think we should know about talking to people your age about alcohol use?

What about talking to patients about alcohol use?

We have noticed that a lot more men than women have agreed to take part in the trial. Can you think of any reasons why that might be the case?

Closing Questions

Is there anything that you think we should have talked about today that we haven't?

Is there anything you would like to add before we finish?

To Close the Interview

Turn off the recorder.

Thank the participant for giving up their time to take part and for providing useful insight.

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Ask if they have any questions.

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