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Pre-operative behavioural intervention for risky drinkers before elective orthopaedic surgery

Submission date
06/01/2016

Recruitment status
No longer recruiting

Registration date
06/01/2016

Overall study status
Completed

Last Edited
20/05/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The National Institute for Health and Care Clinical Excellence (NICE) recognises that major surgery often represents the only treatment for worsening arthritis. The majority of patients undergoing knee and hip replacement surgery are over 65 years of age. Unfortunately, older patients are more at risk of developing complications following surgery when compared to younger patients. The reasons for this are unclear but age should not in itself be a barrier to performing surgery. Detecting and reducing factors known to put a patient more at risk of developing complications after surgery, especially in older patients, is becoming increasingly important. For this reason, preoperative (before surgery) assessment clinics are becoming common in the UK. These clinics provide an underutilised, early opportunity to develop interventions (i.e. treatments) that reduce the risks associated with surgery and ultimately improve outcome. Drinking excessive amounts of alcohol is associated with an increased risk of complications after surgery, preventing early recovery and prolonging rehabilitation. Therefore any therapy that successfully the amount of alcohol a person drinks before surgery is likely to be very beneficial. Being able to detect a patient that drinks a lot of alcohol, followed by techniques that aim to support them to reduce their intake of alcohol through changing their attitudes and behaviours, have been successful in reducing the amount that is consumed in other clinical situations; this includes accident and emergency, general practice and some hospital wards. These techniques therefore have considerable potential in reducing alcohol consumption before surgery. This study aims to tailor a detection and brief behaviour-change intervention to patients being referred for major joint surgery. Use of the preoperative assessment clinic will provide a dedicated workforce applying the process at a much earlier stage than would be otherwise, thereby hoping to maximise the potential benefit of the intervention.

Who can participate?
Adults aged at least 18, about to have a hip or knee replacement and identified as heavy drinkers.

What does the study involve?
The study is split into two phases. The first phase takes place in a preoperative assessment clinic in the North East of England. The first objective is to establish a nurse-administered preoperative screening tool, to identify those patients that drink a lot of alcohol. Any patients

detected as heavy drinkers are then invited to discuss this, over one or two sessions, with dedicated preoperative assessment nurses, with the aim of motivating and supporting the patient to think about and plan a change in drinking habits before surgery. The ease with which this process is integrated into the surgical pathway (the steps that are taken when someone is having surgery) and how acceptable it is to both patients and nurses is then assessed. In phase 2, the now optimised screening and behavioural intervention is tested in a study that takes place in up to three hospitals in the Tyne and Wear area. Patients are randomly allocated into one of two groups. Those in group 1 are given the usual care before surgery. Those in group 2 receive the intervention before surgery. It is hoped that this phase of the study will provide information that will help in developing a much larger study to promote cutting down on the amount of alcohol a person drinks before surgery in the orthopaedic population (patients about to have joint replacement surgery, for example).

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2016 to July 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Miss Nicola Goudie

Contact information

Type(s)
Public

Contact name
Miss Nicola Goudie

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 14/42/01

Study information

Scientific Title
PRE-OPerative Behavioural Intervention for Risky Drinkers before elective orthopaedic Surgery

Acronym
PRE-OP BIRDS

Study objectives
This study aims to develop a screening and behavioural intervention tool related to the specific issue raised by preoperative alcohol consumption. If successful, this approach aimed specifically at the surgical population, will have significant benefit in the early postoperative phase by:
1. Reducing deleterious effects on wound healing, infection and bleeding episodes
2. Preventing an escalation of complications, which will prevent early mobilisation, further impair physical functional return and prolong hospital stay. This is particularly relevant to the elective orthopaedic population where patient recovery times rely heavily on the promotion of early mobilisation
3. Ensuring a more timely return to functional independence with less reliance on family and community social support
and late postoperative phase by preventing postoperative complications that reduce longevity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Newcastle & North Tyneside 2 Research Ethics Committee, 16/12/2015, ref: 15/NE/0419

Study design
1. Feasibility single centre study
2. Pilot multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Risky drinking

Interventions
Behavioural Intervention. The intervention will be delivered over two sessions – the first session will last approximately 30 minutes, while the second session will be an optional, booster session and will last approximately 20 minutes. The first intervention session will provide patients identified as increased or high risk drinkers with five minutes of simple, structured advice regarding alcohol consumption including specific feedback on risk, normative comparison, the benefits of reducing alcohol intake strategies that could be used to reduce drinking and a personal target for reduced drinking. This will be followed by 15-25 minutes of behaviour change intervention targeting alcohol reduction and cessation. Two intervention tools will be utilised: a Brief Advice (BA) tool will act as a visual aid for communicating information and will provide participating healthcare professionals with prompts on how to structure and deliver this advice to participating patients. A brief behaviour change intervention tool will be used by healthcare professionals to guide discussion, goal setting and problem solving with participating patients and to record aspects of the intervention (e.g., goals and plans) to prompt behaviour outside of the clinical setting. Participants will be given both intervention tools to take away with them. They will also be given a copy of the Department of Health's information leaflet 'How much is too much?'

The optional booster session will aim to review or revise behavioural goals, provide feedback on performance and increase self-efficacy. This sessions will also allow those individuals who have showed an initial intention to make changes, but who have not formally set a goal and action plan to move forward.

This intervention will be compared against standard care in the second phase of the study (the pilot RCT) - A purposive sample of healthcare professionals including lead clinicians and nurses from across all three centres that will participate in the pilot RCT, will be selected to take part in focus group discussions. The aim is to explore perceptions about the current status of preoperative alcohol screening and behavioural intervention in the older orthopaedic population and to understand what defines usual practice in preoperative assessment, particularly in respect of screening for risky drinking in the three centres. The focus group discussions will assist the team to define the comparator group for the pilot RCT trial.

Intervention Type
Behavioural

Primary outcome measure
Feasibility Study (Phase 1):
1. Acceptability and feasibility assessment of themes identified in Framework analysis of staff and patient interview transcripts.

External Pilot RCT (Phase 2):
Primary outcome measures to judge the success of the external pilot:
Recruitment and randomisation rates defined by;
1. Proportion of eligible patients who agree to participate in the trial and
2. Proportion of enrolled patients successfully followed up 6 months after baseline assessment

Secondary outcome measures
Feasibility Study (Phase 1):
1. Fidelity of delivery assessment via audio recordings of interventions delivered
2. Characterisation assessment of themes identified in Framework analysis of focus group transcripts

External Pilot RCT (Phase 2):
1. Rates of eligibility and reasons for ineligibility (captured through screening logs)
2. Acceptability of the study design including attendance rates at the second session, completion of outcome measures, retention and reasons for drop-outs; as well as via qualitative work
3. Alcohol consumption as measured by AUDIT score at preoperative assessment (baseline), before surgery (night before or day of surgery), at 6 weeks post-surgery and at 6 months after preoperative assessment

Overall study start date
01/02/2016

Completion date
31/01/2019

Eligibility

Key inclusion criteria
Screening and Intervention Health Care Professionals:
1. Currently employed in the primary centre as a preoperative assessment nurse
2. Willing and able to attend study specific training

Health Care Professionals Focus Groups:
1. Currently involved in the orthopaedic patient pathway in one of the three centres identified for the RCT

Patient Participants:
1. Adults aged ≥ 18 years listed for elective primary hip or knee arthroplasty
2. Patients scoring ≥ 8 on AUDIT and at least weekly drinking of 6 units or more in one session
3. Capacity to provide informed written consent
4. Ability to write and converse in English (able to understand English sufficiently to complete the study questionnaires without the need for an interpreter)

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Feasibility: 42 - Pilot RCT: 80

Total final enrolment
122

Key exclusion criteria
Health Care Professionals:
1. Those not willing to consent to audio recordings of intervention sessions which are required for fidelity assessment

Patient Participants:
1. Patients scoring <8 on AUDIT
2. Patients who do not consume 6 units of alcohol or more in one session at least weekly
3. Patients likely to undergo sequential (on different dates) joint replacements (for bilateral disease) within the scope of the proposal (due to reduced availability for 6 month follow up)
4. Patients displaying current (active) withdrawal from alcohol; these individuals will be referred for review by an addiction psychiatrist
5. Severe psychiatric disorder requiring medical therapy and severe cognitive impairment /dementia impacting on ability to interact with intervention and increasing likelihood of postoperative delirium

Date of first enrolment
01/03/2016

Date of final enrolment
28/06/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
The Newcastle upon Tyne Hospital NHS Foundation Trust

Sponsor details
Freeman Hospital
Freeman Road
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England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Study team members will be committed to disseminate the findings through local and national presentations to varying clinical groups. Furthermore, study team members have delivered numerous lectures and presentations at national and international meetings especially

regarding the use of preoperative assessment clinics in the optimisation of patients prior to surgery, behavioural interventions and screening and behavioural interventions targeting alcohol consumption. This will be continued in light of the findings of the present proposal. Relevant findings will be published in open access medical and scientific peer reviewed journals such as Health Technology.

2019 final report in https://www.journalslibrary.nihr.ac.uk/hta/hta24120/#/full-report

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2018		Yes	No
Results article	results	01/03/2020	10/03/2020	Yes	No
HRA research summary			28/06/2023	No	No