Changing health behaviours prior to surgery: What are your views?

Submission date 24/07/2015	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 19/10/2015	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 02/07/2020	Condition category Surgery	Individual participant data

Plain English summary of protocol

Background and study aims

Complications such as wound infections, chest infections and heart problems are common after major surgery. Up to half of all patients having a major operation experience complications and even though the vast majority of those patients get better and subsequently go home, their quality of life and ability to function as well as they did before their operation can be seriously affected. Hospital based preoperative assessment clinics allow healthcare professionals to detect chronic health conditions such as heart disease and diabetes, which, if not managed properly, can lead to increased death and complication rates. It is now well established that, like these chronic health conditions, certain lifestyles make complications after surgery more likely. These behaviours include: being less active and having poor physical fitness, being underweight or severely obese, smoking and drinking too much alcohol. It is common for patients to have more than one of these factors (e.g. smoking and alcohol excess) with the impact on risk of complications following surgery frequently underestimated by the medical profession. For example, patients who drink even a small amount more than the Government recommended alcohol limit have a 50% increase in the chance of suffering a complication after surgery. Despite this knowledge patients are rarely told to cut down their alcohol consumption before their operation. The prospect of surgery itself provides healthcare professionals a unique opportunity to discuss, and counsel patients about, these adverse behaviours at a time when they are likely to be focused on their health. It may be possible to use this increased focus on health, and frequent contact with healthcare professionals around this time, to help patients make lifestyle behaviour changes that will benefit not only their short-term surgical outcome, but also their long-term health. This research project aims to investigate the attitudes, beliefs and motivations of patients about to undergo major surgery with regards to making changes to their lifestyle before surgery.

Who can participate?

Adult patients (aged at least 18) attending the pre-operative assessment clinic prior to undergoing any operative procedure.

What does the study involve?

Patients are given a questionnaire exploring views about behaviour change prior to major surgery. The questionnaire investigates patient's ratings of motivation, confidence and

perceptions on short and long-term behavioural changes and perceptions about multiple behaviour change. The questionnaire also asks the patient their views about the acceptability of different weight loss/gain, physical activity, alcohol reduction and smoking cessation interventions (programs or treatments).

What are the possible benefits and risks of participating?

There are no immediate benefits or risks to participants. However, information gleaned from the study may influence preoperative practice in the future and benefit future patients undergoing surgery.

Where is the study run from?

The questionnaire is run in the pre-operative assessment clinic across 3 different NHS Hospital sites (James Cook University Hospital, York Teaching Hospitals NHS Foundation Trust and Leeds General Infirmary).

When is the study starting and how long is it expected to run for? August 2015 to March 2016

Who is funding the study? South Tees Hospitals NHS Foundation Trust (UK)

Who is the main contact? Dr Elke Kothmann

Contact information

Type(s) Scientific

Contact name Dr Elke Kothmann

Contact details

Department of Academic Anaesthesia James Cook University Hospital Marton Road Middlesbrough United Kingdom TS4 3BW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1.0

Study information

Scientific Title

Changing health behaviours prior to surgery: an observational study

Study objectives

The aim of this study is to explore attitudes, barriers and facilitators to implementing evidence based behaviour change to optimise patients health before major elective surgery.

Ethics approval required Old ethics approval format

Ethics approval(s) The proportionate review sub-committee of the Wales, 08/07/2015, ref: REC 7. 15-WA-0255

Study design Observational study

Primary study design Observational

Secondary study design

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

Improving patient fitness prior to major elective surgery (prehabilitation).

Interventions

A nurse administered patient questionnaire to explore attitudes, barriers and facilitators to implementing evidence based behavioural change to optimise patients health before major surgery. Responses to questions will be rated on a visual analogue scale.

Intervention Type

Behavioural

Primary outcome measure

Visual analogue scale score in response to the questions asked exploring the attitudes, barriers and facilitators to implementing evidence based behavioural and non-behavioural interventions before surgery. It will be to determine patient opinion about behavioural change prior to surgery.

Secondary outcome measures

Descriptive analysis of subgroups of interest e.g. type of surgery, age, socio-economic status and baseline behaviours to look at moderators of response to individual questions.

Overall study start date 03/08/2015

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Completion date 01/03/2016

Eligibility

Key inclusion criteria

All adult patients (minimum 18 years of age) attending the preoperative assessment clinic prior to undergoing any operative procedure.

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants 100-150

Total final enrolment 299

Key exclusion criteria1. Patients aged 18 years and under2. Patients lacking capacity to consent and complete questionnaires

Date of first enrolment 03/08/2015

Date of final enrolment 01/03/2016

Locations

Countries of recruitment England United Kingdom

Study participating centre James Cook University Hospital Marton Road Middlesbrough United Kingdom TS4 3BW

Study participating centre York Teaching Hospitals NHS Foundation Trust Wigginton Road York United Kingdom YO31 8HE

Study participating centre Leeds General Infirmary Great George Street Leeds United Kingdom LS1 3EX

Sponsor information

Organisation South Tees Hospitals NHS Foundation Trust

Sponsor details James Cook University Hospital Middlesbrough England United Kingdom TS4 3BW

Sponsor type Hospital/treatment centre

Website southtees.nhs.uk

ROR

Funder(s)

Funder type Hospital/treatment centre

Funder Name South Tees Hospitals NHS Foundation Trust

Results and Publications

Publication and dissemination plan

We anticipate that we will publish our findings in an appropriate peer reviewed journal and present our findings at a national presentation. We expect to achieve this in the summer /autumn 2016.

Intention to publish date

01/07/2016

Individual participant data (IPD) sharing plan

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?
<u>Results article</u>	results	21/10/2019	02/07/2020	Yes	No