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Supportive exercise programmes for accelerating recovery after major abdominal cancer surgery

Submission date 07/07/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 07/07/2016	**Overall study status** Completed	
Last Edited 12/08/2025	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-exercise-to-help-recovery-after-bowel-cancer-surgery-prepare-abc

Study website
http://www.uea.ac.uk/prepare-abc

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
30965

Study information

Scientific Title
SupPoRtive Exercise Programmes for Accelerating REcovery after major ABdominal Cancer surgery (PREPARE-ABC) – A multicentre, 3 arm, parallel randomised controlled trial of standard care alone versus standard care plus supervised hospital based exercise and standard care plus supported home-based exercise pre and post hospital discharge in cancer patients awaiting curative colorectal cancer surgery

Acronym
PREPARE-ABC

Study objectives
The aim of this study is to investigate whether an exercise intervention would be beneficial to patients pre and post hospital discharge when undergoing curative colorectal surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
22/06/2016, ref: 16/EE/0190

Study design
Randomised; Interventional; Design type: Treatment, Prevention, Psychological & Behavioural, Physical

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions

Current interventions as of 19/08/2019:
Control arm:
Treatment as Usual (TAU) comprising the patient information leaflet and study follow-up visits only. No other information relating to peri-operative exercise will be offered outside of what constitutes current standard practice for each recruiting centre.

Intervention arm A (hospital-based supervised exercise):
Pre-surgery, participants receive an initial 45 min exercise counselling incorporating behaviour modification techniques. Patients will be offered up to three sessions per week of aerobic interval exercise on a cycle ergometer prior to their procedure. Patients are encouraged to attend as many pre-operative supervised exercise sessions as possible. In addition, patients will undertake twice-weekly resistance exercise. Exercise programmes will be tailored to each patient, taking the previous level of activity, mobility and any barriers to exercise into consideration. Until the end of the study (12 months post-randomisation), patients will be encouraged to comply with current physical activity recommendations: 150 min of moderate-intensity aerobic exercise per week (brisk walking/cycling) and two sessions of resistance exercise per week. They will also be signposted to local exercise facilities and receive monthly supervised exercise sessions.

Intervention arm B (supported home-based exercise):
Participants receive an initial 45 min exercise counselling incorporating behaviour modification techniques. Patients will then be encouraged to comply with current physical activity recommendations, which will form the basis of the home exercise programme: a minimum of 150 min of moderate-intensity aerobic exercise per week (brisk walking/cycling) and two sessions of resistance exercise. Exercise programmes will be tailored to each patient, taking the previous level of activity, mobility and any barriers to exercise into consideration. Patients will receive weekly 15 min telephone support from a Trial Physiotherapist to encourage compliance with the exercise programme. Until the end of the study (12 months post-randomisation), patients will be encouraged to comply with current physical activity recommendations and sign posted to local exercise facilities and receive monthly 15 min motivational telephone calls from a Trial Physiotherapist.

Previous interventions:
Participants are randomly allocated to one of three groups.

Control arm: Treatment as Usual (TAU) comprising the patient information leaflet only. No other information relating to peri-operative exercise will be offered, consistent with current practice.

Intervention arm 1 (Hospital-Based Supervised exercise programme): Pre-surgery, participants receive an initial 45 min exercise counselling incorporating behaviour modification techniques. Patients will be offered three sessions per week of aerobic interval exercise on a cycle ergometer over 3-4 weeks prior to their procedure (aim is to achieve 12 sessions). In addition, patients will undertake twice-weekly resistance exercise. Exercise programmes will be tailored to each patient, taking the previous level of activity, mobility and any barriers to exercise into consideration. Until the end of the study (12 months post-randomisation), patients will be encouraged to comply with current physical activity recommendations: 150 min of moderate-intensity aerobic exercise per week (brisk walking/cycling) and two sessions of resistance exercise per week. They will also be signposted to local exercise facilities and receive monthly supervised ‘booster’ exercise sessions.

Intervention arm 2 (Supported Home-Based exercise): Participants receive an initial 45 min exercise counselling incorporating behaviour modification techniques. Patients will then be encouraged to comply with current physical activity recommendations, which will form the basis of the home exercise programme: a minimum of 150 min of moderate-intensity aerobic exercise per week (brisk walking/cycling) and two sessions of resistance exercise. Exercise programmes will be tailored to each patient, taking the previous level of activity, mobility and any barriers to exercise into consideration. Patients will receive weekly 15 min telephone support from a Trial Physiotherapist to encourage compliance with the exercise programme. Until the end of the study (12 months post-randomisation), patients will be encouraged to comply with current physical activity recommendations and signposted to local exercise facilities and receive monthly 15 min motivational telephone calls from a Trial Physiotherapist.

Intervention Type
Behavioural

Primary outcome measure
Health-related quality of life is measured using the Study Short-Form Health Questionnaire (SF-36) at baseline and 12 months post-randomisation.

Secondary outcome measures
1. Post-operative morbidity is measured 30 days post-surgery
2. Cardiopulmonary fitness
3. Grip strength
4. Length of hospital stay is recorded at discharge following operation
5. Fitness for discharge is recorded at discharge following operation
6. Re-admission rate is determined 90 days post-surgery
7. Post-operative mortality is measured 90 days post-surgery
8. Physical activity behaviour is measured 6 and 12 months
9. Psychological health status is measured 6 and 12 months

Overall study start date
01/11/2016

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Male and female participants ≥ 18 years old
2. Awaiting a curative elective colorectal resection for cancer
3. American Society of Anaesthesiologists physical status I-III (ASA, 2014)
4. Able and willing to provide informed consent
5. Understand verbal and written instructions in English
6. Patients who are already participating (or have participated) in other trials may be eligible, but this must be agreed in advance by the relevant trial teams

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 1146; UK Sample Size: 1146

Key exclusion criteria
1. Contra-indications to exercise (e.g. lower limb amputation without prosthesis, orthopaedic disorder exacerbated by exercise, chronic lung disease causing desaturation with exercise or shortness of breath at rest, severe psychiatric health problems)
2. Cardiovascular contraindications (e.g. unstable angina, acute left ventricular failure, uncontrolled cardiac arrhythmias, uncontrolled hypertension, cardiac event in the previous 6 weeks, cerebral vascular disease resulting in transient ischaemic attacks)
3. Participation in other treatment trials, where this has not been agreed in advance with both trial teams

Date of first enrolment
01/11/2016

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Norwich Medical School
University of East Anglia
Norwich Research Park
Norwich
United Kingdom
NR4 7TJ

Study participating centre

Norfolk and Norwich University Hospitals NHS Foundation Trust
Norwich
United Kingdom
NR4 7UY

Study participating centre
University Hospital Birmingham NHS Foundation Trust
Birmingham
United Kingdom
B15 2WG

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
University Hospitals of Derby and Burton NHS Foundation Trust
Derby
United Kingdom
DE22 3DT

Study participating centre
Imperial College Healthcare NHS Trust
London
United Kingdom
W2 1NY

Study participating centre
Northumbria Healthcare NHS Trust
North Shields
United Kingdom
NE29 8NH

Study participating centre

Royal Devon and Exeter NHS Foundation Trust
Exeter
United Kingdom
EX2 5DW

Study participating centre
North West Anglia NHS Foundation Trust
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Western General Hospital
NHS Lothian
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Manchester Royal Infirmary
Manchester University NHS Foundation Trust
Manchester
United Kingdom
M13 9WL

Study participating centre
Torbay and South Devon NHS Foundation Trust
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Harrogate and District NHS Foundation Trust
Harrogate
United Kingdom
HG2 7SX

Study participating centre

Glasgow Royal Infirmary
NHS Greater Glasgow and Clyde
Glasgow
United Kingdom
G4 0SF

Study participating centre
Nottingham University Hospitals NHS Trust
Nottingham
United Kingdom
NG7 2UH

Study participating centre
South Tyneside District Hospital
South Tyneside and Sunderland NHS Foundation Trust
South Shields
United Kingdom
NE34 0PL

Study participating centre
West Suffolk NHS Foundation Trust
Bury St Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Ipswich Hospital
East Suffolk and North Essex NHS Foundation Trust
Ipswich
United Kingdom
IP4 5PD

Study participating centre
St Mark's Hospital
London North West University Healthcare NHS Trust
London
United Kingdom
HA1 3UJ

Study participating centre
Royal Free London NHS Foundation Trust
London
United Kingdom
NW3 2QG

Study participating centre
Raigmore Hospital
NHS Highland
Inverness
United Kingdom
IV2 3UJ

Study participating centre
University Hospital Crosshouse
NHS Ayrshire and Arran
Kilmarnock
United Kingdom
KA2 0BE

Study participating centre
Furness General Hospital
University Hospitals of Morecambe Bay NHS Trust
Lancaster
United Kingdom
LA14 4LF

Sponsor information

Organisation
Norfolk and Norwich University Hospitals NHS Foundation Trust

Sponsor details
Colney Lane
Norwich
England
United Kingdom
NR4 7UY

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01wspv808

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
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/04/2025

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown.

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		23/10/2021	01/11/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Internal pilot	06/08/2021	12/08/2025	Yes	No
Other publications	Process evaluation	23/10/2024	12/08/2025	Yes	No