Supportive exercise programmes for accelerating recovery after major abdominal cancer surgery

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

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

Contact information

Type(s)

Public

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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 TypeBehavioural

Primary outcome(s)

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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Scotland

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

United Kingdom NW3 2QG

Study participating centre Raigmore HospitalNHS 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

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes