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ACTIOHN: Activity as medicine in oncology for head and neck

Submission date
22/08/2022

Recruitment status
No longer recruiting

Registration date
23/08/2022

Overall study status
Completed

Last Edited
29/07/2025

Condition category
Cancer

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

Plain English summary of protocol
Background and study aims
We aim to increase head and neck cancer (HaNC) patients' engagement in physical exercise. There are many proven benefits of exercise following cancer treatment, aiding recovery, reducing risk of cancer returning, improving physical and psychological well-being and quality of life (QOL). However, the vast majority of HaNC patients have low levels of physical activity both pre- and post-treatment. There are multiple reasons for this; HaNC treatment is often aggressive with severe side-effects e.g. profoundly dry mouth, breathing through a hole in the neck, shoulder dysfunction, poor swallowing making it difficult to exercise; apprehension about participating in groups due to altered facial appearance; many are from low socio-economic areas, with high risk smoking and alcohol behaviours and other health problems; HaNC services are regional, requiring long journeys to access specialist support. Our survey of 400 HaNC patients found a desire to participate in an exercise programme, if tailored to individual needs and preferences. We will develop a collaborative, flexible, patient-centred personalised programme, with tools to support HaNC-specific barriers to exercise, and test whether this is feasible and
acceptable.

Who can participate?
We will recruit 70 HaNC patients aged 16 years or older, pre-treatment and up to 2 months post-treatment, across two large HaNC units in NW and NE England.

What does the study involve?
In consultation with a HaNC Physiotherapist, patients will work with a local Cancer Exercise Specialist to devise a personalised exercise programme (including options for time, frequency, intensity, type, location, remote delivery), using support tools to overcome HaNC-specific barriers, with weekly virtual support, delivered over 8-weeks. We will assess; rates of uptake, retention and exercise completion; patient reported symptoms and QOL; physical fitness. We will interview patients and healthcare professionals to understand how acceptable they found the programme and explore any issues with integrating it into HaNC care.
Our study will determine whether further research into personalised exercise programmes is feasible and worthwhile for HaNC patients.

What are the possible benefits and risks of participating?
Introducing a personalised physical exercise programme early in the cancer care pathway encourages healthy behaviours and patients taking an active role in their recovery. In terms of short-term impact, this study will increase awareness amongst patients and staff about the general importance of physical exercise in cancer care and its potential benefits. It will aid decision-making regarding whether / how to proceed with testing for effectiveness, enhancing the likely success of a future trial. The essential components required to engage HaNC patients in exercise will be identified. It will provide a roadmap of how to integrate this intervention into HaNC care, overcome barriers and identify ways of promoting adherence and compliance.

Building on the current study, we would propose to apply for follow-on funding to test the effectiveness, cost and cost-effectiveness of a personalised physical exercise programme in HaNC, via a RCT. If effective, this intervention, has the potential to reduce high symptom-burden and low mood, prevent and reduce co-morbidities, attenuate treatment toxicity, improve QoL and ultimately reduce mortality in HaNC – a group in high need, with significant treatment side-effects. An improvement in these outcomes could lower costs to the NHS and societal benefits in terms of reduced lost productivity costs due to chronic treatment side-effects. Thus, the potential long-term impacts of the project are extensive.

Videos via a commercially available app (Physitrack, UK) will be used to show participants how to perform exercises safely and effectively. Where participants do not have access to apps, paper copies of exercise instructions printed from Physitrack will be supplied. Although all exercise will be performed by participants unsupervised, the cancer exercise specialist will check on resistance training and stretching technique during weekly telephone or video consultations. Each participant will be given a 'physiotherapy advice and information sheet' that provides safety information. This includes circumstances when not to start exercising, recognising adverse symptoms during exercise for which exercise should be immediately terminated, and information on what the participant should do if he or she experiences any of these symptoms. The physiotherapists will be the main contact for participants to report adverse symptoms, however, out-of-office hours contact details also will be provided. A traffic light system will be used by clinicians to flag any deterioration of participants during the exercise programme that may necessitate extra precautions, or temporary or complete cessation of exercise. This information will be communicated to the cancer exercise specialist. Assessments have been selected and discussed with the PPI group to ensure adequate data is collected, balanced with the burden for patients completing them.

Where is the study run from?
University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
October 2021 to February 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
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Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
310827

ClinicalTrials.gov (NCT)
Nil known

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CPMS 52727, NIHR202773, IRAS 310827

Study information

Scientific Title
Activity as medicine in oncology for head and neck

Acronym
ACTIOHN

Study objectives
We aim to increase head and neck cancer (HaNC) patients' engagement in physical exercise.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/05/2022, West of Scotland Research Ethics Committee 1 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 3140213; WoSREC1@ggc.scot.nhs.uk), ref: 22/WS/0058

Study design
Interventional non-randomised

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Head and Neck Cancer

Interventions
This is a multi-centre (Liverpool and Sunderland Head and Neck Cancer Centres) feasibility and acceptability study. The MRC framework for Developing Complex Interventions has informed the methods. It is a prospective, single armed, unblinded, mixed methods design.

INTERVENTION
The intervention is a personalised, collaborative, and flexible 8-week exercise programme, and will be delivered remotely by a cancer exercise specialist, employed by the study. The step-by - step process is as follows:

1. The cancer exercise specialist will receive the following information from the head and neck cancer (HNC) specialist physiotherapists regarding each participant:
• Current clinical status and medications
• Pre-intervention assessment results (listed below)
• Any exercises, modifications, or precautions that should be incorporated into the exercise programme to address any musculoskeletal or other clinical issues, such as the patient having a

feeding tube.
The information will be anonymised by using patient study identification codes and emailed to the cancer exercise specialist. Each patient's name, contact details, and study identification code will be given to the cancer exercise specialist by telephone so the cancer exercise specialist can then contact the patient to arrange their first meeting.

2. Development of an exercise programme that will be co-designed by the participant and the cancer exercise specialist, at their first meeting, based on a comprehensive individual needs analyses that considers information obtained from the head and neck cancer specialist physiotherapists and the participant's exercise history, exercise preferences, perceived barriers to exercise, and personal goals.

3. During the 8-week exercise programme, participants will complete a daily log that includes details of the intensity, duration, and type of exercise, including the resistance and number of sets and repetitions where resistance training has been prescribed. Patients also will log reasons for any non-adherence such as not initiating, modifying, or early termination of an exercise session.

4. The cancer exercise specialist will undertake a weekly individual consultation by video (or telephone call if necessary) with each participant during the 8-wk programme. Consultations will provide patient education, resolution of perceived exercise barriers, ask about and promote exercise adherence, and encourage timely and accurate completion of daily logs.

5. The cancer exercise specialist or research associate will send two texts per week to each participant to further encourage timely and accurate completion of daily logs and provide a motivational message to promote programme adherence.

6. Patient support to continue with exercises will include 'top tips' information and 'exercise stories' of how to best manage specific HNC symptoms and overcome exercise barriers, developed through collaboration between clinicians and the PPI group. Participants will be encouraged to voluntarily share their stories, challenges, and tips via a Twitter account. In addition, the CancerFit website (http://www.cancerfit.me/site/), the Macmillan website (https://www.macmillan.org.uk/cancer-information-and-support/trea tment/preparing-for-treatment/eating-well-andkeeping-active), and our Twitter feed will provide online resource support.

7. Patients will hand in their daily logs during their next routine clinical appointment.

8. After post-intervention assessments with the HNC specialist physiotherapist, the participant will meet with the cancer exercise specialist for a final time to develop and agree a personalised exit strategy from the exercise intervention to facilitate transition to independent long-term exercise. This will involve discussing and formalising the patients' goals over the next 12 months, how the current exercise programme can be progressed, and a list and explanation of appropriate behaviour change techniques that the participant can apply.

Exercise programme design
Exercise programmes will be prescribed within the framework of current cancer physical activity guidelines and will include aerobic, resistance, and flexibility training. However, patient needs and preferences will take precedence if these are not congruent with recommendations. This is in accordance with the premise that the best exercise is the one the person will actually do. Details of the exercise programme design process will be recorded in the Cancer Exercise Specialist's notes as part of a needs analysis documentation.

Personalisation of exercise programmes will include appropriate manipulation of acute training variables (frequency, intensity, time, type, volume, and progression of exercise), and the location of the exercise. This will be based on the clinical status, physical activity history, exercise preferences, perceived barriers to exercise, and personal goals of each participant. A menu of no-cost, convenient, locally available, or virtual exercise options, will be used to help patients choose their preferred exercise mode and location. The menu will initially be created by members of the research team and expanded by the cancer exercise specialist via his or her own experiences. However, participants will be encouraged to suggest alternatives based on preferences and any past successes at adhering to exercise and these will be added to the menu where appropriate as the study progresses. Participants will have the option to perform the exercise programme within their homes, in outside spaces, in other locations, or a combination of locations, exercising alone or with other people, depending on preference and perceived barriers. Advice on social distancing during exercise relating to Covid-19 will be given if applicable. Resistance bands will be given to participants for performing resistance exercises where appropriate. Resistance bands have been shown to be a versatile and effective method for developing muscular strength and endurance.
Flexibility will be embedded and formally written into each participant's exercise programme in the form of alternative exercise options, so participants can immediately respond to foreseeable emerging exercise barriers, such as indoor exercise for when outdoor exercise proves to be a barrier due to poor weather.

Exercise progression and regression
Exercise programmes will be progressed towards meeting the minimum recommended amount of physical activity for cancer patients. The focus, however, will be on avoiding inactivity and promoting exercise adherence rather than meeting the physical activity guidelines as a primary outcome goal. Exercise programmes will be progressed by manipulating only one acute training variable at a time. Where appropriate, the duration of aerobic exercise bouts will be increased by 5-10 min every 1-2 weeks until the participant can perform 30 min of continuous exercise at a particular intensity, after which exercise intensity will be progressively increased. Aerobic exercise intensity will be progressed by moving through the exercise intensity domains for ratings of perceived exertion proposed by the American College of Sports Medicine. Resistance training will be progressed using a tried and tested method, increasing the number of repetitions within the target repetition range and then changing to the resistance band with the next highest resistance when the upper value of the target repetition range can be performed with good form in all sets for a given exercise.

Flexibility will be embedded and formally written into each participant's exercise programme so that they can regress the exercise sessions in response to changes in adverse symptoms such as fatigue. This type of day-to-day 'autoregulation' will include manipulation of the programme's acute training variables such as completing only 50% of the training volume in a session where the participant perceives the full prescribed training volume is unachievable on that particular day.

ASSESSMENTS
Assessments will be conducted to coincide with routine standard of care visits immediately before and after the 8-week intervention and will consist of patient-reported outcome measures via questionnaires and objective measures.
The fitness tests will be undertaken by the specialist physiotherapists.
Pre- and post-intervention measures of physical fitness:
• Aerobic endurance (6-Minute Walk Test),
• Lower body muscular strength and endurance (30-Second Chair Stand Test)

• Upper body muscular strength and endurance (Arm Curl Test)
• Agility and dynamic balance (8-Foot Up-and-Go Test)
• Shoulder and neck range of motion (goniometric measurements)
Pre- and post-intervention patient-reported measures
• Fatigue (Multidimensional Fatigue Symptom Inventory - Short Form)
• Quality of life (SF-36)
• Physical activity levels (International Physical Activity Questionnaire - Short Form)

The ACTIOHN PPI group have been central to the development of the intervention and assessment protocol. The group felt it important that any exercise programme should be personalised and flexible in approach as well as finding ways to overcome significant barriers, particularly treatment side-effects. They were uncertain as to what the best time point might be to introduce a physical exercise programme. They have reviewed the proposed assessments (ensuring these are not too burdensome) and delivery of the intervention, and have deemed it acceptable and potentially achievable.

DATA COLLECTION TIME POINTS
Baseline
Demographics, patient characteristics, MFSI-SF; SF-36; IPAQ-SF; Fitbit accelerometer outcomes; 30-Second Chair Stand Test; 30-Second Arm Curl Test; goniometric measurements of shoulder and neck function; 8-Foot Up-and-Go Test; 6-Minute Walk Test.
During intervention
Patients will complete a simple exercise log sheet for every day during the 8-week exercise programme that they exercise. The log sheets will allow the determination of the frequency, intensity, duration, and type of exercise, and the different measures of exercise adherence. Any adverse events and reactions also will be recorded by patients in their log sheets.
End of intervention
MFSI-SF; SF-36; IPAQ; Fitbit accelerometer outcomes; 30-Second Chair Stand Test; 30-Second Arm Curl Test; goniometric measurements of shoulder and neck function; 8-Foot Up-and-Go Test; 6-Minute Walk Test; Adverse events.

SAMPLE
Sample size has been determined pragmatically using feasibility study conduct guidance that recommends a sample size of between 24 and 50. The HNC exercise literature suggests a sample size of 40 sufficient to estimate effect size for a full trial. Rates of attrition are reported to be between 12-40%. This study will identify 70 eligible patients, estimating a conservative retention rate of 60%, this will provide us with a minimum of 42 patients on study completion, and allows an estimation of the retention rate with an accuracy of 11.5%. For the recruitment period, for each month our target is: 1.5 patients per site, months 0-3 (n=9); 2.5 per site months 4-7 (n=20), 4 per site months 8-12 (40). The annual referral rate of newly diagnosed HaNC patients is approximately Liverpool n=800 and Sunderland n=220.

QUALITATIVE INTERVIEWS
Interviews with patients and staff (members of the HNC multi-disciplinary team and the cancer exercise specialist) will be conducted by the Research Associate with experience in qualitative research and skills in interviewing vulnerable populations around sensitive topics. They will use a topic guide developed from discussions with the wider team, including the patient panel and from literature around exercise participation. The topic guide will be used in the interviews but interviewees will be encouraged to speak freely about any other issues relating to the feasibility and acceptability of the study. The guide will be revised as new issues emerge in each interview.

The location of interviews will be mutually agreed between the Research Associate and participant, at a time and place as convenient for them as possible, including the option to use telephone or video-calls.

TIMETABLE
An estimated timeline for the project is below
Months 0-4 Ethical approval / development of study materials, set-up and site initiation
Months 5-17 Participant recruitment
Months 7-19 Intervention delivery
Month 20 Data collection complete
Months 20-24 Complete analysis, write-up final report, dissemination

Intervention Type
Behavioural

Primary outcome(s)
1. Exercise uptake: percentage of eligible patients that agreed to participate. Reasons for refusal also will be sought. At 8 week post intervention
2. Exercise adherence:
2.1. Exercise programme adherence: Percentage of the total prescribed exercise sessions completed. At 8 week post intervention
2.2. Permanent treatment discontinuation: permanent discontinuation of the exercise programme before the end of week 8;
2.3. Treatment interruption: percentage of participants that missed at least three continuous scheduled training sessions; At 8 week post intervention
2.4. Dose modification: number of exercise sessions where the prescribed exercise was reduced by the participant, or reduced according to the exercise regressions embedded in each participant's exercise programme; At 8 week post intervention
2.5. Early session termination: number of sessions terminated early by the participant. At 8 week post intervention

Key secondary outcome(s))
Pre- and post-intervention measures of physical fitness:
1. Aerobic endurance (measured using 6-Minute Walk Test) baseline and 8-week post intervention
2. Lower body muscular strength and endurance (measured using 30-Second Chair Stand Test) baseline and 8-week post intervention
3. Upper body muscular strength and endurance (measured using the Arm Curl Test) baseline and 8-week post intervention
4. Agility and dynamic balance (measured using 8-Foot Up-and-Go Test) baseline and 8-week post intervention
5. Shoulder and neck range of motion (measured using goniometric measurements) baseline and 8-week post intervention

Pre- and post-intervention patient-reported measures
6. Fatigue (Multidimensional Fatigue Symptom Inventory - Short Form) baseline and 8-week post intervention
7. Quality of life (SF-36) baseline and 8-week post intervention
8. Physical activity levels (International Physical Activity Questionnaire - Short Form) baseline and 8-week post intervention

Completion date
01/02/2024

Eligibility

Key inclusion criteria
1. >= 16-year-old.
2. Able to provide informed consent.
3. Diagnosed with HaNC for treatment with curative intent.
4. Between time of diagnosis and up to 8 weeks post-treatment.
5. Classified as low-medium risk according to an exercise risk stratification tool.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Total final enrolment
76

Key exclusion criteria
1. Treated with palliative intent, as decided by the HNC multidisciplinary team.
2. Classified as high risk according to an exercise risk stratification tool, or has any other unstable or uncontrolled medical condition associated with increased risk during exercise.
3. Unable to provide informed consent.

Date of first enrolment
12/09/2022

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South Tyneside and Sunderland NHS Foundation Trust
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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?
Results article		11/07/2025	29/07/2025	Yes	No
Protocol article		25/08/2023	29/08/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	interview version 1.1	09/06/2022	23/08/2022	No	Yes
Participant information sheet	main version 3.2	08/06/2022	23/08/2022	No	Yes
Participant information sheet	staff version 2.2	08/06/2022	23/08/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.19	19/05/2022	23/08/2022	No	No