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Home based internet supervised exercise for people with liver cancer

Submission date
23/06/2021

Recruitment status
No longer recruiting

Registration date
25/06/2021

Overall study status
Completed

Last Edited
13/06/2024

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
Liver cancer is generally diagnosed at an advanced stage. Patients with liver cancer are often elderly, frail, with other chronic health conditions. Structured exercise can bring various health benefits to people living with liver disease or cancer, including improved quality of life, physical fitness, and life-expectancy. However, barriers to these patients taking part in structured exercise include costs, lack of access/transport, and lack of confidence. Advances in technology mean that exercise sessions can now be delivered online in real-time, allowing patients to exercise at home in a 'virtual' group setting under the supervision of a physiotherapist.
Aims: Our main aim is to see whether it is feasible to deliver online, live, home-based exercise to older patients with liver cancer. Another aim is to see whether online exercise can improve quality of life, fatigue, and physical function. We will also use patient feedback on the exercise programme to improve how it is delivered.
Our findings will tell us whether delivering online exercise to liver cancer patents is feasible and acceptable. This information will help us design a larger study that can confirm the health benefits of virtually-delivered exercise. We hope that this eventually leads to online exercise being part of standard NHS care for liver cancer survivors.

Who can participate? Patients with a diagnosis of primary liver cancer, under follow-up at Newcastle University NHS Foundation Trust. These will be patients who have received some treatment and whose cancer is regarded as stable. These will be patients fit enough to take part, in either chair based or exercise based exercises, expected to survive at least 6 months.

What does the study involve?
We will deliver live, online, group exercise sessions to 20 patients with liver cancer (aged 60+ years). This will be twice-weekly, seated or standing, tailored to ability, for 10 weeks. Sessions will last for 45-minutes and be supervised 'virtually' by a physiotherapist using online videoconferencing. We will assess physical function and self-reported outcomes (e.g. quality of life) before and after the exercise programme. We will also use surveys and interviews to ask patients what they thought of different aspects the exercise programme.

What are the possible benefits and risks of participating? The benefits may be improved quality of life and possibly also improved fitness and survival. There may be anxiety about using the

internet for a class with other people. Computor tablets pre-loaded with internet access will be provided to those who need them, with one – to – one set up sessions in advance of a class. There may be a small risk of injury, taking part in exercise – but risks will be carefully assessed by experienced staff, with exercise tailored to individuals ability.

Where is the study run from?
The study will be 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?
April 2021 to November 2022

Who is funding the study?
Newcastle NIHR Biomedical Research Centre (UK)

Who is the main contact?
Dr Kate Hallsworth, kate.hallsworth@newcastle.ac.uk
Professor Helen Reeves, h.l.reeves@ncl.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
300809

Study information

Scientific Title
Telehealth exercise for patients with primary liver cancer

Acronym
TELEX-Liver Cancer

Study objectives
Patients with primary liver cancer will be able to (1) take part in remotely supervised exercise classes designed to suit their ability and (2) this will have a positive impact on their quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/08/2022, North East - Newcastle & North Tyneside 2 Research Ethics Committee (NHS BT Blood Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear NE2 4NQ; +44 (0)207 104 8233; newcastlenorthtyneside2.rec@hra.nhs.uk) ref: 21/NE/0145

Primary study design
Interventional

Study design
Single-group feasibility trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Quality of life in patients with liver cancer

Interventions
The intervention will be twice weekly home-based exercise for three months. The follow-up will be complete within 3 months.

The feasibility and acceptability of the intervention and study procedures will be assessed using a mixed-methods approach. Measures of physical function, quality of life, fear of falling, fatigue, and anxiety/depression will be taken before and after the 10-week exercise intervention.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rate will be recorded as the number of eligible participants who consent to participate in the study within 4 months of it opening
2. Retention rate will be recorded as the proportion of patients who complete the study, including attending a follow-up visit 1 month after the exercise intervention ends.
3. Intervention adherence will be determined assessing the proportion of exercise sessions attended by patients, as well as assessing the intensity of exercise achieved – using an accelerometer and recorded exercise repetitions..
4. Fidelity of the intervention will be assessed by a research team member attending a 10% sample of the virtual sessions, with a checklist to record the expected verses delivered exercise repetitions.
5. Safety will be recorded as the number, type, attribution, and severity of adverse events in accordance with Common Terminology for Adverse Events (CTCAE) criteria

Key secondary outcome(s)

Physical function and self-reported outcomes assessed at baseline and the 10-week follow-up:
1. 5-repetition sit-to-stand (seconds)
2. Isometric handgrip strength (kg)
3. Standing balance in a side-by-side, tandem, and semi-tandem stance (seconds)
4. 4-meter usual gait speed (seconds)
5. Mid-arm circumference (cm)
6. Objectively-measured physical activity over 7 days (accelerometer counts)
7. Functional Assessment of Chronic Illness Therapy - Fatigue (total score)
8. The Functional Assessment of Cancer Therapy – Hepatobiliary (total score)
9. Activities-Specific Balance Confidence Scale (total score)
10. Hospital Anxiety and Depression Scale (total score)
11. Godin leisure-time exercise questionnaire (total leisure activity score)

12. Acceptability will be assessed by brief online surveys to patients within one-hour of their last exercise session in weeks 2, 4, 6, 8, and 10 via Google forms. A link to the survey will be distributed via the chat function in Zoom or via email. The survey will include items related to satisfaction with the technology and exercise sessions, using a Likert-like 5-point scale, as well as an open-ended section.
13. Acceptability will also be assessed qualitatively with in-depth, semi-structured exit interviews using a random sample of at least 10 patients, within 1 - 4 weeks after completion of the final follow-up assessment.

Completion date
30/11/2022

Eligibility

Key inclusion criteria
1. Patients aged ≥60 years with a clinical diagnosis of HCC
2. Have received NHS standard treatment for HCC (determined by stage of disease), with post-treatment imaging reporting a complete/partial response or stable disease. These will be patients undergoing ‘active monitoring’ with routine scans and outpatient visits every 3-6 months
3. Receiving ongoing care at Newcastle upon Tyne Hospitals NHS Foundation Trust
4. Childs Pugh of B7 or lower (i.e. preserved liver function)
5. WHO performance status 0 or 1 (i.e fit patients)
6. Minimum life expectancy of 6 months
7. Willing and able to give written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
60 Years

Sex
All

Total final enrolment
19

Key exclusion criteria
1. Uncontrolled cardiovascular or metabolic disease
2. Breathlessness at rest or with mild exertion
3. Inability to understand written and verbal instructions in English
4. Physical disability or mental impairment that precludes safe and adequate participation in the study

Date of first enrolment
01/07/2021

Date of final enrolment
31/05/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newcastle upon Tyne Hospitals NHS Foundation Trust
Newcastle Joint Research Office
Level 1, Regent Point
Regent Farm Road
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Not defined

Funder Name
NIHR Newcastle Biomedical Research Centre

Alternative Name(s)
Newcastle Biomedical Research Centre, Newcastle NIHR Biomedical Research Centre, NIHR Newcastle BRC, Newcastle Biomedical Research Centre - NIHR

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. Patient-identifiable data will be stored in an intranet secure database in the Newcastle upon Tyne NHS Trust, including a code-linked anonymised identifier. Name and home contact details will be held by the study team supervising the interventions, on university secure password-protected devices. All patient study data will be stored in a code-linked anonymised form, on university secure password-protected computers. There will not be a weblink or public access to this dataset, which will include baseline and follow-up parameters measured (demographic data, disease stage, baseline physical and questionnaire/qualitative response assessments). Only consenting patients will be recruited.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/06/2024	13/06/2024	Yes	No
Protocol article		27/05/2022	10/05/2023	Yes	No
HRA research summary			28/06/2023	No	No