ISRCTN17883425 https://doi.org/10.1186/ISRCTN17883425

BT-LIFE: Brain tumours, lifestyle interventions and fatigue evaluation

Submission date
24/09/2018

Recruitment status
No longer recruiting

Registration date
02/10/2018

Overall study status
Completed

Last Edited
01/11/2022

Condition category
Cancer

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

Plain English Summary
Background and study aims
The aim of this study is to see if it is feasible to treat fatigue without using drugs, in people who have (or have had) a brain tumour. The study tests two non-drug treatments. The first treatment involves improving lifestyle factors with an intervention called “Health Coaching”. The second treatment involves interviews with a trained life coach, called “Patient Activation”. These new approaches have a lot of potential to change how fatigue is managed in clinic, if they are feasible to deliver.

Who can participate?
Patients aged 18 and over with a brain tumour who have moderate or severe fatigue

What does the study involve?
Participants are randomly allocated to one of three groups. Patients in the control group are given high-quality written advice on how to manage fatigue, and continue to receive care and support as standard from their neuro-oncology team. They are contacted again 10 and 16 weeks later and invited to complete follow-up study questionnaires. This group is important for the study because it helps us understand what happens to fatigue as it is currently managed. Patients in the 'Health Coaching' group receive an information leaflet and Health Coaching. First they are given some forms to complete at home. They then have a clinic appointment with a Health Coach (a trained personal trainer or a physiotherapist). They do some routine physical measurements such as heart rate and blood pressure. The patient receives a “fitbit”-style monitor to wear while they are in the study. They are then asked to record information each day using a paper diary form. The type of information collected includes what they drink, what they eat, how many hours they sleep, how active they are, and what their stress levels are like. Over the next eight weeks they are offered up to five more sessions with the Health Coach, lasting up to 45 minutes. To minimise the burden to participants they are offered these sessions by Skype, telephone, or FaceTime, or alternatively in clinic, as the patient prefers. The Health Coach helps them set personal goals to change lifestyle areas that may help reduce fatigue. Patients do not have to use all the sessions offered, nor complete all the information asked, if they find it too difficult. Patients in the 'Health Coaching plus Patient Activation' group are treated in the same way as the 'Health Coaching' group and also receive Patient Activation. For this, a trained life coach meets patients at a time and place that suits for an interview. These coaches are supplied

by brainstrust, an established UK brain tumour charity with long experience in the field of personal coaching. At the interview patients are given a short questionnaire measuring how much they feel able to manage fatigue themselves. Their coach then talks with the patient for up to one hour, helping them find ways to improve their own approach to fatigue. They are offered a second interview identical in structure to the first after a further four weeks. Each participant spends 16 weeks in total in the study.

What are the possible benefits and risks of participating?
The treatments are new and innovative. It is hoped that this study will teach us more about how to manage fatigue in people with a primary brain tumour. It may enable us to improve the standard of treatment to help other patients in the future. It is also hoped that the treatments being tested in this study might help improve patients' own fatigue, although we are not testing this directly. Health Coaching involves making simple changes to improve health. Patients might find it hard to record aspects of their lifestyle every day. The initial Health Coaching appointment will be in a dedicated clinic, so patients will have to travel to it. Follow-up sessions can be given by phone or Skype, or in clinic as the patients choose. For clinic sessions patients may incur expenses such as travel and parking. Patients will be advised of this before they consent, and these costs will be refunded so they are not out of pocket. Patient Activation involves a personal coach meeting with patients for an hour, twice in four weeks. Although this can happen in a mutually agreed location, they might be tired or not want to talk. Interviews will be scheduled at a time that suits the patient. Similar comments apply to the interview.

Where is the study run from?
1. Western General Hospital (UK)
2. Beatson West of Scotland Cancer Centre (UK)
3. Christie Hospital (UK)
4. Queen Elizabeth University Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2017 to September 2019

Who is funding the study?
Brain Tumour Charity (UK)

Who is the main contact?
1. Michelle Welsh
Michelle.Welsh@phs.scot
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38936

Study information

Scientific Title
Brain tumours, lifestyle interventions and fatigue evaluation: a multi-centre feasibility randomised controlled trial

Acronym
BT-LIFE

Study hypothesis
The aim of this study is to see if it is feasible to treat fatigue without using drugs, in people who have (or have had) a brain tumour. The trialists are testing two non-drug treatments. The first treatment involves improving lifestyle factors with an intervention called “Health Coaching”. The second treatment involves interviews with a trained life coach, called “Patient Activation”. These new approaches have a lot of potential to change how we manage fatigue in clinic, if they are feasible to deliver. To answer the question of feasibility the trialists will conduct a feasibility

randomised controlled trial in three UK neurooncology centres. They will monitor recruitment and retention, administer questionnaires, and develop systems that they may use in a future, definitive trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland REC 02, 27/03/2018, ref: 18/SS/0025

Study design
Both; Design type: Process of Care, Education or Self-Management, Dietary, Psychological & Behavioural, Physical, Active Monitoring, Qualitative

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 to request a patient information sheet

Condition
Fatigue in people with brain cancer

Interventions
Patients will be randomised to one of the three study arms through minimisation to ensure balance, with the minimisation factor being recruiting site.

Group 1:
This is a 'Control' group and will consist of ~20 patients. Patients in the Control group will be given high-quality written advice on how to manage fatigue, and will continue to receive care and support as standard from their neuro-oncology team. They will be contacted again 10 weeks and 16 weeks later and invited to complete follow-up study questionnaires. This group is important for the study because it helps us understand what happens to fatigue as it is currently managed.

Group 2:
This is a 'Health Coaching' group and will consist of ~20 patients. Patients in this group will receive an information leaflet and Health Coaching. First they will be given some forms to complete at home. They will then have a clinic appointment with a Health Coach (a trained personal trainer or a physiotherapist). They will do some routine physical measurements such as heart rate and blood pressure. The patient will receive a “fitbit”-style monitor to wear while they

are in the study. They will then be asked to record information each day. They will be able to do this using paper diary form. The type of information collected will include:
-What they drink
-What they eat
-How many hours they sleep
-How active they are
-What their stress levels are like

Over the next eight weeks they will be offered up to five more sessions with the Health Coach, lasting up to 45 minutes. To minimise the burden to participants they will be offered these sessions by Skype, telephone, or FaceTime, or alternatively in clinic, as the patient prefers. The Health Coach will help them set personal goals to change lifestyle areas that may help reduce fatigue. Patients will not have to use all the sessions offered, nor complete all the information asked, if they find it too difficult.

Group 3:
This is a 'Health Coaching plus Patient Activation' group and will consist of ~20 patients. Patients in this group will be treated in the same way as Group 2 and will also receive Patient Activation. For this, a trained life coach will meet patients at a time and place that suits for an interview. These coaches will be supplied by brainstrust, an established UK brain tumour charity with long experience in the field of personal coaching. At the interview patients will be given a short questionnaire measuring how much they feel able to manage fatigue themselves. Their coach will then talk with the patient for up to one hour, helping them find ways to improve their own approach to fatigue. They will be offered a second interview identical in structure to the first after a further four weeks.

Each participant will spend 16 weeks in total in the study.

Intervention Type
Behavioural

Primary outcome measure
The feasibility of delivering Health Coaching and Patient Activation to fatigued patients with a primary brain tumour.
Feasibility will be assessed by meeting a priori defined standards for recruitment and retention as follows:
1. Recruitment will be feasible if 20 fatigued brain tumour patients can be recruited per centre over 12 months
2. Retention will be feasible if total attrition at T2 (endpoint) is less than or equal to 40%

Secondary outcome measures
1. The acceptability of the interventions to patients
2. The manageability of the interventions for professionals
3. The development of systems and piloting outcome measures for future definitive RCTs of the interventions for fatigued brain tumour patients, including determination of mean change in outcome scale scores in each arm

Overall study start date
02/06/2017

Overall study end date

06/09/2019

Eligibility

Participant inclusion criteria
1. Patients aged 18 and above
2. Diagnosed with any primary brain tumour
3. >3 months post-completion of chemotherapy/radiotherapy
4. Clinically and radiologically stable, as defined by no evidence of disease progression at most recent clinic appointment
5. Moderate or severe fatigue (Brief Fatigue Inventory score ≥4/10, indicating at least 'moderate' severity of fatigue over the previous week)
6. Participants can be male or female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
46

Participant exclusion criteria
1. Patients unable to give informed consent, or are unable or unwilling to comply with interventions
2. Patients with significant cognitive or sensory impairment (e.g. severe dysphasia or severe visual impairment)
3. Patients who are clinically unstable
4. Radiological or clinical concern at most recent appointment over disease progression

Recruitment start date
15/10/2018

Recruitment end date
17/05/2019

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Western General Hospital (lead site)
Crewe Road
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Beatson West of Scotland Cancer Centre
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN

Study participating centre
Christie Hospital
Wilmslow Rd
Manchester
United Kingdom
M20 4BX

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Rd
Glasgow
United Kingdom
G51 4TF

Sponsor information

Organisation
NHS Lothian

Sponsor details

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Charity

Funder Name
Brain Tumour Charity; Grant Codes: 2018/0113

Alternative Name(s)
The Brain Tumour Charity

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists will publish their findings in peer review journals. They will pay for open access, so that everyone has access. If appropriate they may seek the opportunity to issue a public announcement on any impactful study findings. Study results will also be publicised by the funding Brain Tumour Charity at their discretion. They intend to publish around one year after the overall trial end date.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V1.2	13/03/2018	02/10/2018	No	No
Protocol file	version V2	18/12/2018	26/04/2019	No	No
Results article		14/10/2022	01/11/2022	Yes	No
HRA research summary			28/06/2023	No	No