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The digital Hope programme for people living with cancer during COVID-19

Submission date
03/11/2020

Recruitment status
No longer recruiting

Registration date
04/11/2020

Overall study status
Completed

Last Edited
08/11/2021

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
The COVID-19 pandemic has created additional challenges for people with cancer (PWC), both in terms of physical and mental health. PWC have reported concerns about the further risks to their health from COVID-19, increased anxiety relating to potential cancellation or reduction in treatments and advice from medical teams, and significant anxiety and fears of contracting COVID-19. During the UK lockdown, one in four PWC have experienced depression, anxiety and stress, and one in seven PWC experienced further decline in their physical health.

In response to the shortage of available, tailored self-management support for PWC, we co-designed a programme together with PWC, clinicians and other experts. This led to the group-based self-management programme: Help to Overcome Problems Effectively, known as the "HOPE Programme", for survivors of all types of cancer, which was originally delivered in-person. The face-to-face version of the Hope Programme has been adapted for digital delivery, and initial evaluation suggests potential effects on anxiety, depression and positive wellbeing, with positive user evaluations. A feasibility randomised controlled trial (RCT) study is the next step in the testing of this digital intervention.

The aim of this study is to test the feasibility of a digitally delivered self-management programme for PWC.

Who can participate?
Macmillan Cancer Support hold a contact list of cancer patients who had expressed interest in attending an in-person Hope programme, which has been cancelled due to COVID-19. All patients on this list were invited to take part in the study and access the digital Hope Programme self-management course. Participants must be adults over the age of 18 years, with a cancer diagnosis of any type and at any stage, be located in the UK, have access to the internet and a device that will allow them to engage with the intervention, be fluent in English to be able to engage with all the material in the intervention, and must not have been recruited by Macmillan Cancer Support via the NHS.

What does the study involve?
Participants will be asked to complete an online consent form and health and wellbeing

questionnaires including some sociodemographic questionnaires, at baseline. All study documents and questionnaires are presented online. Upon completion of consent and baseline questionnaires, participants will be randomly allocated to the intervention group (IG) or a waitlist control group (WLCG). The IG will have access to the Hope Programme starting the following week, and the WLCG will join a 6-week waiting list for the next Hope Programme. The study questionnaires will be completed at baseline, and again after 6 weeks, and then again at post-programme for the WLCG.

What are the possible benefits and risks of participating?
The digital Hope Programme has been shown to be helpful for a small group of people living with cancer in a study which did not have a control group. Participants may find the course helpful and/or may have suggestions for how it could be improved before it is put into a full scale clinical trial. Participants will be entered into a prize draw for £50 Amazon Gift vouchers for completion of all study questionnaires.
There are no direct risks of taking part in this study. Whilst we do not anticipate the questionnaires will cause any distress to participants, some of the questions will ask about their health, which may touch on topics that some participants may find sensitive. Participants are informed that they do not have to answer any questions that they are uncomfortable with. If participants do experience any distress from completing the questionnaires, they are encouraged to contact their GP, or the Samaritans.

Where is the study run from?
The study takes place completely online, and is run by Coventry University (UK).

When is the study starting and how long is it expected to run for?
March 2020 to September 2020.

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Professor Andy Turner, hsx116@coventry.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRRID: RR1-10.2196/24264

Study information

Scientific Title
The Help to Overcome Problems Effectively (HOPE) programme for people living with cancer during COVID-19: a feasibility randomised waitlist controlled trial

Acronym
HOPE

Study objectives
The aim of this study is to test the feasibility of a digitally delivered self-management programme, Help to Overcome Problems Effectively (HOPE), for people with cancer (PWC). This will inform the design of a definitive randomised controlled trial (RCT). Additionally, preliminary

assessment of the impact of the Hope programme, via secondary outcomes, will be used to assess signals of efficacy in a trial context.

The planned primary outcomes (trail feasibility objectives) of the study are to investigate:
· Recruitment rates for participation and for randomisation
· Retention and follow-up rates as the participants move through the trial
· Adherence rates to study procedures, intervention attendance, and engagement
· Sample size and effect size estimation for a definitive trial
· Progression criteria for a definitive trial

The secondary outcomes are:
· Measures of depression, anxiety, confidence to self-manage cancer (patient activation) and mental wellbeing, as indicated by scores on validated measures

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/04/2020, Coventry University Ethics Committee (Coventry University, Priory Street, Coventry, West Midlands, CV1 5FB, UK; no telephone number provided; ethics.uni@coventry.ac.uk), ref: P106024

Study design
Feasibility 1:1 randomized waitlist controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Self-management for people with cancer

Interventions
This study will employ a feasibility, randomised wait-list control group design, to explore the feasibility of a trial of the digital Hope Programme for PWC.

Randomisation is via Qualtrics survey platform, following completion of consent and baseline questionnaires.

The intervention is a six-week digital self-management programme.

Quantitative monitoring of participant progress through the online programme will be undertaken. Participants will be asked to complete standardised measures of depression, anxiety, mental wellbeing and confidence in managing their cancer.

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcome measures
1. Recruitment rates for participation and randomisation will be collected through Qualtrics. All eligible participants identified by MCS will be sent a link to the Qualtrics study survey, so we will calculate recruitment rates from those providing consent and/or completing baseline questionnaires
2. Retention and follow-up rates. Follow up will be online. Participants who become lost to follow up will be identified through Qualtrics as those not completing post programme questionnaires. It is possible that these participants may still complete some or all of the Hope programme, and so participant retention can be identified separately through engagement with the Hope platform. Participants who explicitly request to be withdrawn from the study will be categorized accordingly, but we will not contact participants to obtain reasons for not completing questionnaires.
3. Adherence rates. The Hope platform collects user engagement data such as login frequency and duration, which assists the moderators with participant engagement and experience. Participants also have the option of receiving system generated automatic nudge reminders sent to their email address. We will analyse this user engagement data to generate usage patterns and provide an overview of session attendance and participant engagement.
4. Sample size and effect size estimation. To inform sample size estimation for a future definitive trial, we will calculate the standard deviations of the continuous secondary outcomes pertaining to depression, anxiety, mental wellbeing and confidence to manage their cancer. To estimate potential effect sizes for a primary outcome in a future definitive trial, namely change in scores on key secondary outcome measures from pre- to post programme, we will calculate the difference between the mean difference pre and post programme for the intervention and control groups and divide by the pooled standard deviation at baseline

5. Progression criteria
We will collate the data from all participants in this feasibility RCT to inform progression to a definitive trial (all measured using the Hope platform):
5.1. Recruitment rate
5.2. Questionnaire completion rate
5.3. Programme completion rate

Secondary outcome measures
1. Sociodemographic and health questionnaire at baseline only, requesting the following personal information from participants: gender, age, ethnicity, marital status, highest level of education, employment and occupation, and some details about their cancer diagnosis and any other medical conditions.

Preprogramme and postprogramme (i.e. 6 weeks post-randomisation):
2. The Patient Health Questionnaire (PHQ-9) (depression)
3. The Generalized Anxiety Disorder scale (GAD7) (anxiety)

4. The Warwick Edinburgh Mental Wellbeing Scale (WEMWBS) (mental wellbeing)
5. The Patient Activation Measure (PAM®) (knowledge, skills and confidence in patients and the extent to which people feel engaged and confident in taking care of their condition)

Overall study start date
31/03/2020

Completion date
02/09/2020

Eligibility

Key inclusion criteria
1. Diagnosis of any type of cancer, at any stage
2. Adult (18 years or over)
3. Located in the United Kingdom
4. Access to the internet and a device that will allow them to engage with the intervention
5. Fluent in English to be able to engage with all the material in the intervention
6. Not recruited via the NHS

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
41

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
30/04/2020

Date of final enrolment
03/05/2020

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Coventry University
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Sponsor type
University/education

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ROR
https://ror.org/01tgmhj36

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication of feasibility RCT results in Journal of Medical Internet Research. Raw data will be available to the research team only, as per study ethical approval.

Intention to publish date
31/07/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to ethical conditions.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/11/2020	No	Yes
Protocol article	protocol	04/12/2020	12/01/2021	Yes	No
Results article		05/11/2021	08/11/2021	Yes	No