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A pilot trial to investigate the impact of a personalised self-management lifestyle programme using mobile technology on the health and wellbeing of cancer survivors

Submission date
14/03/2018

Recruitment status
No longer recruiting

Registration date
02/05/2018

Overall study status
Completed

Last Edited
05/10/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
In Ireland an average of 37,000 new cases of cancer are diagnosed each year and it is predicted that Ireland will see a doubling in the incidence of cancer by 2040. However, the good news is that more people are living longer after cancer and even being cured in more than half of all cases. Cancer treatment is difficult and can affect how someone is able to get back to work, care for their loved ones or just be involved in life again. Often there are hospital appointments (called 'follow-up') but these rarely help people get their general health back on track. The researchers want to see if they can improve how people feel both physically and psychologically after they have had cancer. This involves approaching people who have had cancer and are overweight and asking them to take part in this study. Being overweight has been shown to make people feel less well overall and has been shown to affect cure rates following cancer. The aim of this study is to find out whether personalised mHealth (mobile technology) lifestyle self-management improves the outcomes of cancer survivors with BMI over 25.

Who can participate?
Adults who have completed cancer treatment and have a BMI over 25

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. The intervention group are given support and advice to improve their diet and to improve how active they are by providing them with a programme that suits their needs. They are compared with the control group who receive usual care. Mobile phone technology is used to help those who are trying to change their diet and exercise patterns. All participants are followed up 6 months after they start the programme to see how their weight, fitness and wellbeing have improved.

What are the possible benefits and risks of participating?
It is expected that this programme will increase the quality of life and health of participants. The risk to safety of engaging in physical exercise is expected to be minimal compared with the risks

associated with day to day life. The intervention involves advice given by health professionals on diet and physical activity and will be appropriate for the participants' ability and integrated into their current lifestyle.

Where is the study run from?
1. Letterkenny University Hospital (Ireland)
2. National University of Ireland, Galway (Ireland)

When is the study starting and how long is it expected to run for?
August 2017 to September 2018

Who is funding the study?
Irish Cancer Society (Ireland)

Who is the main contact?
Dr Jenny Groarke

Contact information

Type(s)
Public

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LET17RIC

Study information

Scientific Title

A pilot trial evaluating an intervention using Behaviour Change Techniques (information, goal-setting, graded tasks, self-monitoring, review and feedback) and mobile technology versus standard care to increase physical activity, reduce BMI, and improve the health and wellbeing of overweight/obese cancer survivors

Study objectives
Does a personalised mHealth (mobile technology) lifestyle self-management improve physical and psychological outcomes of a subgroup of cancer survivors with increased health risks related to lifestyle behaviours?

The focus of the present study will be to collect high quality data (both quantitative and qualitative) on the impact of providing patients with personalised goals and feedback as well as the feasibility of using mHealth technologies as an adjunct to standard medical practice to improve health outcomes in an 'at risk' population. This study will do so by providing patients with a Fitbit device which enables self-monitoring as well as generate detailed data and feedback on health outcomes compared with standard medical care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National University of Ireland, Galway Research Ethics Committee, 12/09/2017, ref: 17-May-20

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Overweight/obese cancer survivors

Interventions
The study is employing a 2 groups (experimental and control) x 3 time-points (baseline, 3 months, 6 months) mixed Analysis of Variance design to investigate the impact of a personalised solution versus standard care on primary and secondary health outcomes. Participants are randomly allocated to control or intervention group.

Participants in the intervention condition will wear a Fitbit activity monitor for the duration of the 6-month study. Summary data will be visible on the tracker's display and additional physical activity (step count) and sleep data will be available on the Fitbit application for the study condition. The FitBit device allows for an assessment of the behaviour change strategies of self-monitoring, combined with other self-regulatory skills (e.g., goal setting, frequent behavioural feedback) (Cadmus-Bertram, et al., 2015). The experimental group will received a personalised dietary and physical activity intervention which will employ an educational component along with a shared decision-making and a goal-setting model. The self management programme is interdisciplinary in nature and will be delivered by a host of healthcare professionals (Nurses, Physiotherapists, Dieticians, and Psychologists). Participants will attend group educational sessions (n=15 approx per group). In these sessions, lifestyle education and advice will be given with an opportunity for individualised advice/support. This self-management programme will provide the structure for interventions to include imparting knowledge, empowering an individual to make lifestyle change, motivating behavioural change and sustaining such positive lifestyle choices going forward.

Weekly goals and overall targets for physical activity will be agreed and established for each subject (increase daily step count by 10% each week). Participants in the intervention group will receive an SMS on week 2, 3, 6, 8 and 12 providing review and feedback on physical activity goals.

Participants in the control group will also be provided with a FitBit device to track health outcomes but the display panel on the device will not present summary data for participants in the control group and they will not have access to the application. The control group will not undergo a personalised intervention but rather be only be given standardised lifestyle advice as they attend the Oncology service and will have no other additional intervention beyond this.

Intervention Type
Behavioural

Primary outcome measure
1. Average daily step count, measured via Fitbit device continuously for 6 months
2. BMI and weight, recorded at baseline, three month follow-up (Time 1), and six month follow-up (Time 2)

Secondary outcome measures
1. Sleep quality, measured via Fitbit device continuously for 6 months
The following measures are recorded at baseline, three month follow-up (Time 1), and six month follow-up (Time 2):
2. Physical fitness, measured using 6-minute walk test - resting HR, BP, Sp02, recovery HR, BP, Sp02
3. Dietary behaviour, measured using Food Frequency Questionnaire (Mulligan, Luben, Bhaniani et al., 2014)
4. General health status (MOS SF-36; Ware et al, 2000), fatigue (Mendoza, Wang, Cleeland, et al., 1999), self-efficacy (Schwarzer & Jerusalem, 2010), exercise self-efficacy (Bandura, 2006), exercise-related social support (Sallis et al., 1987)

Overall study start date
31/08/2017

Completion date

13/09/2018

Eligibility

Key inclusion criteria
Adults with a solid cancer diagnosis with a calculated BMI > 25 post completion of acute cancer treatment who attend Oncology in Letterkenny University Hospital during the recruitment phase

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

Total final enrolment
123

Key exclusion criteria
1. <18 years old or >70 years old
2. Performance status of 2 or more (ECOG scale)
3. Terminally unwell
4. Those who do not wish to use mobile technology
5. Those whose English is not of sufficient standard to provide informed consent or receive education

Date of first enrolment
01/12/2017

Date of final enrolment
10/01/2018

Locations

Countries of recruitment
Ireland

Study participating centre
Letterkenny University Hospital
Ireland
F92 AE81

Study participating centre
National University of Ireland, Galway
Ireland
091

Sponsor information

Organisation
National University of Ireland, Galway

Sponsor details
School of Psychology
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Sponsor type
University/education

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Charity

Funder Name
Irish Cancer Society

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

Results and Publications

Publication and dissemination plan

The following publications are planned:
1. Protocol for a pilot RCT of a personalised self-management lifestyle programme using mobile technology on the health and wellbeing of cancer survivors. [Protocol paper]. Anticipated date of submission: May 2018
2. The impact of a personalised self-management lifestyle programme using mobile technology on the health and wellbeing of cancer survivors: An RCT. [Original Article]. Anticipated date of submission: December 2018
3. A feasibility study of the acceptability of and engagement with an mHealth intervention aiming to improve lifestyle self-management in cancer survivors: A qualitative analysis. [Original article]. Anticipated date of submission: March 2019

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as the research team at present do not have the mechanism to fully and confidently deidentify the large amount of data gathered by the Fitbit (e.g., metadata including GPS location). The data collected by Fitbit will be held on a secure virtual server at NUIG, and questionnaire data collected at baseline, three month follow-up and six month follow-up will be stored in a secure locker in Letterkenny University Hospital for 5 years in accordance with the data protection act.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/08/2019	05/10/2022	Yes	No
Results article	Acceptability	16/02/2021	05/10/2022	Yes	No
Results article	Effectiveness	05/07/2021	05/10/2022	Yes	No