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LivingWELL: assessing the impact of a lifestyle intervention in people attending family history clinics with an increased risk of colorectal or breast cancer.

Submission date
16/03/2015

Recruitment status
No longer recruiting

Registration date
02/04/2015

Overall study status
Completed

Last Edited
27/09/2018

Condition category
Cancer

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

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-giving-lifestyle-advice-to-people-who-have-a-family-history-of-bowel-or-breast

Contact information

Type(s)
Public

Contact name
Dr Stephen Caswell

ORCID ID
http://orcid.org/0000-0002-7153-075X

Contact details
Postdoctoral Research Assistant
University of Dundee
Division of Cancer Research
CPHNR
Mailbox 7, Level 7
Ninewells Hospital & Medical School
Dundee
United Kingdom
DD1 9SY

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LivingWELL protocol V1 04.03.15

Study information

Scientific Title
LivingWELL A feasibility study to assess the impact of a lifestyle intervention in people attending family history clinics with an increased risk of colorectal or breast cancer.

Acronym
LivingWELL

Study objectives
For people who are at greater risk of cancer due to a family history (FH) of the disease it is important to follow recommendations for cancer screening and lifestyle. NHS genetics centres in Scotland offer early detection and counselling for people with a FH of breast (BC) and colorectal (CRC) cancers but offer little guidance on lifestyle. This two arm (intervention versus usual care), two-centre, randomised study aims to assess the feasibility of delivering and evaluating a lifestyle intervention programme (LivingWELL) for patients with a FH of BC or CRC in order to inform the design of a definitive randomised control trial (RCT). The 12 week, personalised programme on physical activity, diet and weight management will be delivered by lifestyle coaches via a face to face visit, phone calls and web support. Feasibility outcomes include recruitment, programme implementation, fidelity measures, achieved measurements, retention, patient acceptability and indicative outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The East of Scotland Research Ethics Servise (EoSRES), 25/05/2015, ref: AG/15/ES/0055

Study design
Two arm two-centre randomised feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Prevention

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

Health condition(s) or problem(s) studied
Patients attending genetic screening for colorectal and/or breast cancer risk

Interventions
The LivingWELL intervention programme aims to help participants increase physical activity, modify diet, and set individual weight management goals (weight loss) in the short term towards 5% body weight loss and in the long term to foster commitment to the avoidance of weight gain. Advice will be given on -600kcal deficit dietary intake (tailored to individual preferences) and a graduated approach aimed at increasing activity to 225 to 300 minutes of moderate physical activity per week by 12 weeks for weight loss in overweight and obese adults (as recommended by SIGN25). The theoretical basis for the intervention draws on both Leventhal's Self-Regulatory Theory (which highlights the importance of the individual's beliefs regarding illness cause, identity, control/cure, timeline and consequences) and Social Cognitive Theory (SCT) which emphasises the importance of self-efficacy and the Health Action Process Approach (HAPA) which emphasises the importance of action and coping planning. Intervention participants will be scheduled for a one hour individual lifestyle coaching session in the research centre and up to 4 follow up phone consultations over a 3 month period from a lifestyle coach (LC) trained by the investigators and monitored by the trial manager and the trial working group. Participants will receive a LivingWELL intervention information pack, pedometer and a pedometer based walking programme. We will also test the feasibility of using a web-based support programme for ongoing motivational support to promote long term adherence.
The face to face session is designed to be interactive and includes:

1. A 10 minute walk and talk session during which pedometer use and walking goals will be discussed
2. Self-identification of Body Mass Index category and
3. A portion weight estimate task.

Personalised energy deficit dietary guidance (decreases in sugary drinks, fast foods, alcohol, energy dense snacks, red and processed meat and increases in fruits, vegetables and whole grains) will be discussed using the resources in the information pack and with reference to the participant's 24hour personal dietary recall collected at baseline. Intervention participants will be invited to bring a support person to the meeting. Participants will receive personalised guidance on setting personal goals and discuss how to make changes habitual by talking through their personal routines and relapse strategies for times of deviation. Motivational interviewing techniques will be used to explore self-assessed confidence to change and self-perceived benefits. Behavioural techniques, known to be effective in changing physical activity and diet, will by employed by the LCs15. These techniques focus on goal setting, action and coping plans and implementation intentions. The importance of recording and self-monitoring pedometer data, diet and drink logs and weekly body weight will be emphasised. These parameters will also form the basis for the intervention phone consultations which aim to be 15 minutes in duration and will check wellbeing, progress on implementation intentions, self-monitoring behaviours and review individual actions and coping plans. Participants will also be signposted to the study website to highlight new tips and use of personal logs. The intervention will be delivered to participants in accordance with the LivingWELL SOP: LC Intervention SOP.

Intervention Type
Behavioural

Primary outcome measure
The study will be reported in accord with CONSORT guidelines. Basic statistical analysis of indicative findings will be undertaken including descriptive statistics to enable characterisation of the cohort, chi squared tests for comparisons of proportions and paired t tests for comparisons of means. Linear regression analyses (adjusted for baseline values) will also be performed, with group allocation as a fixed effect. It is however important to note that these are indicative findings only.

Interviews with participants will be audio-recorded with participant consent, transcribed verbatim and analysed using the constant comparison methods. They will explore patient views on recruitment methods and timing, assessment procedures, programme content, interest in a 12 month intervention period, body weight goals, delivery, duration, intensity and exit strategy. In addition, participants will be asked to discuss factors influencing adherence including personal beliefs, motivation, family members, social and NHS staff support.

The following will be reported:
1. Feasibility measures: message delivery, programme implementation, fidelity to protocol, achieved measurements, recruitment, response, early retention and reported adherence.
2. Acceptability measures of recruitment, implementation and exit strategy.
3. Indicative outcomes.

Reporting on results (recruitment, retention and acceptability) will also be analysed and presented by BC and CRC risk groups.

Secondary outcome measures
N/A

Overall study start date
01/05/2015

Completion date
31/10/2016

Eligibility

Key inclusion criteria
1. Patients with a family history of colorectal or breast cancer and measured BMI>25kg/m2.
2. Age of 18 years and older

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Participants with severe cognitive impairment, or conditions where physical activity is contra-indicated
2. Unable to consent

Date of first enrolment
01/08/2015

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
NHS Tayside
Clinical Genetics
Level 6, Ninewells Hospital and Medical School
Dundee
United Kingdom
DD1 9SY

Study participating centre
NHS Grampian
Clinical Genetics Centre, Ashgrove House, Foresterhill
Aberdeen
United Kingdom
AB25 2ZA

Sponsor information

Organisation
University of Dundee

Sponsor details
Tayside Medical Science Centre
Ninewells Hospital & Medical School
Research & Development Office
Residency Block, Level 3
George Pirie Way
Dundee
Scotland
United Kingdom
DD1 9SY

Sponsor type
University/education

Website
tasc-research.org

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Chief Scientific Office (UK)

Results and Publications

Publication and dissemination plan
The clinical study report will be used for publication and presentation at scientific meetings. Trial investigators have the right to publish orally or in writing the results of the study. Summaries of results will also be made available to investigators for dissemination within their clinical areas (where appropriate and according to their discretion).

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2018		Yes	No
HRA research summary			28/06/2023	No	No