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CLASP5 (renewed online): pilot and randomised controlled trial Previous title: CLASP Renewed Online Feasibility Study

Submission date 31/07/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/08/2017	**Overall study status** Completed	
Last Edited 10/09/2025	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-an-online-programme-for-people-who-have-had-prostate-breast-or-bowel-cancer-clasp

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
34346, UKCRN 37052

Study information

Scientific Title
Cancer: Life Affirming Survivorship support in Primary care (CLASP) Programme

Acronym
CLASP

Study objectives
The aim of this study is to evaluate an online intervention offering lifestyle and wellbeing support for cancer survivors in Primary Care called Renewed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Feasibility study: North West-Greater Manchester East Research Ethics Board, 28/06/2017, ref: 17/NW/0250
CLASP5 pilot and main trial: North West-Greater Manchester East Research Ethics Board, 17/01/2018, 18/NW/0013. IRAS ref 238636

Primary study design
Interventional

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

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Malignant neoplasms of independent (primary) multiple sites

Interventions
This study consists of a website intervention. Renewed Online is a website intervention which offers lifestyle advice and wellbeing support for cancer survivors.The intervention has been developed using feedback from patients and healthcare professionals and provides modules for lifestyle (healthy eating, weight management, physical activity) and well-being (coping with emotional distress, reducing fatigue).

Participants who have completed their primary treatment for breast, prostate or colorectal cancer more than a month ago are invited to take part in the trial following a database search and mail out from their GP surgery. Each invite letter has a unique ID number. Patients are invited to log onto website, give their consent online, complete a set of screening questions and then if eligible randomized into one of 3 groups. Patients randomised into one of three groups online. Randomisation stratified by cancer type (Breast/Colon/Prostate) and quality of life (high/low EORTC score).

Group 1: Participants in this group receive the usual care with brief advice (from NHS Livewell Website).

Group 2: Participants in this group receive access to Renewed Online plus usual medical care.

Group 3: Participants in this group receive access to Renewed Online plus usual medical care along with brief human support provided by a Practice Nurse or HCA at their surgery or a central support facilitator. Supporters receive online training. Participants will have a face to face or telephone consultation with their supporter (approx. one to two weeks after logging onto the website) who will use the CARE model to support participants to use Renewed. Follow up support will offered at weeks 4 and 8 (and further sessions up to maximum of 6 if patient requests it). Support will be brief (around 10 minutes) and comprises of encouragement to use the website and patient led goals.

All participants are asked to complete online consent, screening questionnaires at baseline, six months, 12 months and a notes review at 12 months.

Intervention Type
Behavioural

Primary outcome(s)
Current outcome measures as of 08/09/2017:
Feasibility trial assessments:
1.Suitability of recruitment screening measures is assessed using Baseline Screening Measures at baseline
2. Acceptability of all trial procedures is assessed at baseline, six months and 12 months
3. Acceptability of the intervention assessed by uptake, usage and drop-out using website usage data as well as conducting qualitative interviews with participants from each cancer type to assess acceptability and feasibility of website
4. Appropriateness of human support module is measured using uptake, adherence, number of sessions completed and also by focus groups or interviews with health care workers to elicit views about the website, support arm and study
5. Suitability of outcome measures is assessed at six and 12 months
6. Providing no extensive changes are made to the intervention or trial procedures following the feasibility study the data collected will also be used as an internal pilot so taken forward for the full trial. The acceptance checklist for clinical effectiveness pilot trials (ACCEPT) will be used to assess whether pilot trial data can be taken forward to the main trial.

Provisional 'stop-go' criteria for feasibility trial:
1. To achieve a target recruitment rate of 70% measured by the number of participants who log onto the website and give consent at six months after the start of the pilot trial:
1.1. Recruitment exceeds 70% of the recruitment predicted (N>42), the main trial goes ahead with plans for increased practice recruitment
1.2. Recruitment is 50-70% of the recruitment predicted (N=30-42), then a discussion with PGfAR is instituted and assuming a plan for increasing recruitment is reasonable, the trial proceeds with monthly recruitment updates, and withdrawal of funding should recruitment not pick up
1.3. Recruitment is <50% predicted (N<30) there should be a discussion with the PGfAR Board and unless there is a credible plan to increase recruitment, progression to the main trial should be halted

Previous outcome measures:
Feasibility primary outcome measures:

1. To achieve a target recruitment rate of 70% measured by the number of participants who log onto the website and give consent at six months after the start of the pilot trial:
1.1. Recruitment exceeds 70% of the recruitment predicted (N>42), the main trial goes ahead with plans for increased practice recruitment
1.2. Recruitment is 50-70% of the recruitment predicted (N=30-42), then a discussion with PGfAR is instituted and assuming a plan for increasing recruitment is reasonable, the trial proceeds with monthly recruitment updates, and withdrawal of funding should recruitment not pick up
1.3. Recruitment is <50% predicted (N<30) there should be a discussion with the PGfAR Board and unless there is a credible plan to increase recruitment, progression to the main trial should be halted

Key secondary outcome(s)

Current outcome measures as of 08/09/2017:
Outcome measures for both feasibility and main trial
1.Primary outcome. Quality of life is measured using the EORTC Quality of Life Questionnaire-c30 as primary outcome (EORTC QLQ-c30; (Aaronson et al., 1993)), at baseline, six (the primary time point) and 12 months.
Secondary outcomes:
2. EORTC 30 subscales (particularly: Physical functioning and Emotional wellbeing)
3. Health related quality of life is measured using the EQ-5D-5L for health economics analyses (Herdman et al., 2011; Van Hout et al., 2012) at baseline, six and 12 months
4. Perceptions of human support is measured using the Treatment Appraisal Questionnaire(TAQ; (Bishop, Yardley, & Lewith, 2008) at six months.
5. Anxiety and depression is measured using the Hospital Anxiety and Depression Scale (HADS; (Zigmond & Snaith, 1983)), at baseline and 12 months
6. Fear of relapse is measured using the Fear of Relapse/Recurrence Scale (FRRS; (Greenberg et al., 1997)) modified to 3 items, at baseline and 12 months
7. Quality of life is measured using the Measure Yourself Concerns and Wellbeing questionnaire for Quality of Life (MYCAW; (Paterson, Thomas, Manasse, Cooke, & Peace, 2007) at baseline and 12 months
8. Resource use (including consultations and their reasons) and personal costs data for heath economics will be documented between baseline and 12 months
9. A modified Patient Enablement Instrument (PEI; (Howie et al., 1999; Little et al., 2008)) is measured at 12 months
Measures among those in the intervention groups:
10. Website satisfaction measure, modified for this study is measured at 12 months
11. Problematic Experiences of Therapy Scale and single item measures of self-reported adherence to website recommendations for physical activity, mental wellbeing, diet measured at 12 months (as used in POWeR trial)
12. Website usage and entries. We will analyse all website usage, which is unobtrusively automatically collected by the LifeGuide system, including time spent on each page and entries (e.g. goal setting and goal-related progress in physical activity, healthy eating, weight, and engagement with pages on fatigue and mood management).
Other measures:
13. Gender, age, marital status, years of education, ethnicity, height and weight will be documented at baseline. Cancer status and treatments prior to the trial will also be documented. Any other similar cancer support management programmes received during the trial with be documented at 12 months. Physical activity amounts is measured using a questionnaire asking about physical activity amounts, validated in a previous study (Physical Activity Checker from Diabetes Literacy trial) at baseline.

Previous outcome measures:
Feasibility secondary outcomes measures:
1.Suitability of recruitment screening measures is assessed using Baseline Screening Measures at baseline
2. Acceptability of all trial procedures is assessed at baseline, six months and 12 months
3. Acceptability of the intervention assessed by uptake, usage and drop-out using LIFEGUIDE data as well as conducting qualitative interviews with participants from each cancer type to assess acceptability and feasibility of website at 6 months
4. Appropriateness of human support module is measured using uptake, adherance, number of sessions and also by focus group participation of health care workers to elicit views about the website, support arm and study at 6 months
5. Suitability of outcome measures is assessed at six and 12 months
6. Target sample size for the trial is measured using analysis of power calculation at six moths
7. Cost is measured using a Health economist analysis using EQ-5 D-5L at baseline,6mths and 12 mths. The economic analysis of both the costs and quality of life will be mainly descriptive for the feasibility trial and will include means and standard deviations.
8. The feasibility study analysis are descriptive. However in line with the acceptance checklist for clinical effectiveness pilot trials (ACCEPT) checklist, whether pilot trial data can be taken forward to the main trial depending on trial modifications will be explored and recorded. Providing the trial goes ahead and no extensive changes are made to the intervention or trial procedures following the feasibility study the data collected will also be used as an internal pilot so taken forward for the full trial.

Completion date
31/03/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/03/2018:
1. Aged 18 years or over
2. Identifiable from GP case records
3. Have had breast, prostate or colorectal cancer.
4. Have finished primary cancer treatment (e.g. chemotherapy/radiotherapy courses) within last 10 years and primary treatment completed at least 1 month ago. This does not include active surveillance for prostate cancer patients or hormone therapy for any participants.
5. Have internet access
6. Have impaired quality of life (measured by EORTC)

Previous inclusion criteria
1. Be aged 18 yrs
2. Be identifiable from GP case records
3. Have had breast, prostate or colorectal cancer.
4. Have finished primary cancer treatment (eg chemotherapy/radiotherapy courses) within last 10 years. This does not include active surveillance for prostate cancer patients or hormone therapy for any participants.
5. Have internet access
6. Have impaired quality of life

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
2728

Key exclusion criteria
Current exclusion criteria as of 15/03/2018:
1. Currently have cancer
2. Have had more than one other type of cancer (other than breast, prostate or colon) in the last 5 year
3. Have metastatic cancer
4. Receiving any cancer treatment other than hormone therapy currently or during the last month
5. Expecting to start any cancer treatment during the study period
6. Have severe mental health problems and/or major uncontrolled depression/schizophrenia or dementia
7. Had sarcoma/lymphoma of breast
8. Another participant of the study living in the same household
9. Currently have untreated cancer unless on active surveillance for prostate cancer

Previous exclusion criteria
1. Currently have cancer
2. Have had more than one other type of cancer (other than breast, prostate or colon) in the last 5 year
3. Have metastatic cancer
4. Receiving any cancer treatment other than hormone therapy currently or during the last month
5. Expecting to start any cancer treatment during the study period
6. Have severe mental health problems and/or major uncontrolled depression/schizophrenia or dementia

Date of first enrolment
16/08/2017

Date of final enrolment
31/03/2020

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
University of Southampton
Faculty of Medicine
Primary Medical Care and Population Sciences
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Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sets generated during and/or analysed during the current study will be stored in a non-publically available repository at the University consistent with NIHR policy; the weblink will be provided in due course,the data will be anonymised, the data will become available after the final report is published and for at least 10 years, the data will be accessed by request from experienced researchers with a clear protocol for analysis to the co-PIs, who will get the agreement of the Study management committee. Where release of data is not approved we will inform PGfAR, giving the reasons, so that arbitration can be made if necessary.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/05/2025	10/09/2025	Yes	No
Protocol article	protocol	01/03/2019	30/03/2020	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No