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Feasibility of a guided workbook intervention for cancer patients

Submission date 14/10/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 14/10/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 30/01/2020	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Every year, thousands of people of working age are diagnosed with cancer. After they are diagnosed or while they are receiving treatment, many people take time off from work so that they can focus of their recovery. Many cancer patients plan to return to work but have said that they would like more support with the process. WorkPlan is a workbook support package for patients who have been diagnosed with cancer and aims to help patients plan their return to work and to tackle some of the key issues that cancer patients have reported when returning to work. The aim of this study is to find out whether the WorkPlan package is an effective way of supporting cancer patients who want to return to work.

Who can participate?
Adults with cancer who were working before their diagnosis.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the WorkPlan support package. This consists of a workbook which guides participants through four weeks of structured activities aiming to help them plan their return to work and set goals to achieve this. These participants also receive monthly text messages asking whether they are currently working. Those in the second group continue to receive their usual care and are not given the workbook. Participants in this group are asked to record any support that they access and also receive monthly text messages asking whether they are currently working. These participants are given the chance to take part in the WorkPlan package at the end of the study. For participants in both groups, at the start of the study, after the four week programme and then again after 6 and 12 months, participants in both groups complete a number of questionnaires in order to assess their mood and thoughts and beliefs about working and returning to work. The time taken for each participant to return to work (if at all) from the start of the study is assessed from the monthly text messages asking if the participant has returned to work.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Queen Elizabeth Hospital and Birmingham Women's Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2015 to June 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Professor Beth Grunfeld

Contact information

Type(s)
Scientific

Contact name
Prof Beth Grunfeld

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19013

Study information

Scientific Title
A feasibility study of "WorkPlan" - a guided workbook intervention to support work-related goals among cancer survivors

Acronym

WorkPlan

Study objectives
Feasibility randomised controlled trial, with the following aims:
1. Trial data collection materials to ensure that the materials are acceptable to participants and that participants are able to provide full answers.
2. Trial the recruitment process and feasibility of recruiting participants into the study.
3. Test the acceptability among participants of the randomisation process.
4. Determine retention in control and intervention groups.
5. Conduct the ground work necessary to obtain data that will be required in the definitive trial to enable a full cost-effectiveness analysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands – Solihull (NRES) Research Ethics Committee, 12/06/2015, ref: 15/WM/0166

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
http://www.coventry.ac.uk/Global/08%20New%20Research%20Section/CTEHR/WorkPlan-Participant-Sheet.pdf

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: Bladder Cancer, Breast Cancer, Gynaecological Cancer, Renal Cancer, Prostate Cancer, Testis Cancer; Disease: Breast, Cervix, Kidney, Ovary/Fallopian tube, Prostate, Testis, Uterus/Endometrium, Vulva

Interventions
60 participants in their first four weeks of treatment for either breast, bowel, gynaecological or urological cancer who intend to return to work will attend an introductory session. During this session they participate in an interview about their work history and job role, and are provided with information about both arms of the trial and what each would involve. Participants are then be randomised at a ratio of 1:1 into either:

Control group: Participants in the control group receive usual care only for the duration of the study. They are asked to record any information or support they access during this time, and will

receive monthly texts asking about their current work status. Participants in the control group will be offered the intervention at the end of the study.

Intervention group: Participants in the intervention group are also asked to record any information and support they access during the duration of the study, and receive monthly texts asking about their current work status. They also receive the WorkPlan intervention: a 4-week guided workbook consisting of structured sections to provide guidance and support to patients. It comprises activities aimed at eliciting thoughts/beliefs, identifying targets/actions and concrete steps to achieve goals. The workbook is used during the introductory session, at home during the intervention period and as a reminder during the return to work process. Participants in the intervention group receive email support and two telephone support calls during the four week intervention period to discuss progress.

Participants in both arms of the trial are followed up for 12 months post-randomisation, at 3 time points: 4 weeks post-intervention, 6 months post-randomisation and 12 months post-randomisation. Data is collected using questionnaire packs and interviews.

Intervention Type
Other

Primary outcome measure
Time taken to return to work (number of days from the date they leave work to first period back at work).
Each month participants will receive a small number of text messages asking about their current work status (changes to their job, their job role, working hours, salary etc.) and healthcare utilisation. Any changes to working status or duties will be documented with specific reasons for non-return to work.

Secondary outcome measures
1. Anxiety is measured using the Hospital Anxiety and Depression Scale at baseline, 4 weeks, 6 and 12 months follow up
2. Depression is measured using the Hospital Anxiety and Depression Scale at baseline, 4 weeks, 6 and 12 months follow up
3. Impact of illness on work is measured using the Illness Perceptions at Work Scale at baseline, 4 weeks, 6 and 12 months follow up
4. Illness perceptions is measured using the Illness Perceptions Questionnaire Revised at baseline, 4 weeks, 6 and 12 months follow up
5. Self-reported workability is measured using the Workability Index at baseline, 4 weeks, 6 and 12 months follow up
6. Job satisfaction (if returned to work) is measured using a Brief Job Satisfaction Scaleat baseline, 4 weeks, 6 and 12 months follow up
7. Satisfaction with return to work process is measured using a single item (if returned to work)) at baseline, 4 weeks, 6 and 12 months follow up
8. Quality of life is measured using the ED-Q5 questionnaire at baseline, 4 weeks, 6 and 12 months follow up

Overall study start date
23/03/2015

Completion date
01/06/2017

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. Proficient in written and spoken English
3. Diagnosis of breast, gynaecological, urological or bowel cancer
4. Working at time of diagnosis

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
68

Key exclusion criteria
1. Returned to work at time of recruitment
2. Will not be returning to work
3. Metastatic disease or recurrence

Date of first enrolment
01/09/2015

Date of final enrolment
28/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston

Birmingham
United Kingdom
B15 2WB

Study participating centre
Birmingham Women's Hospital
Mindelsohn Way
Edgbaston
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B15 2TG

Sponsor information

Organisation
Coventry University (UK)

Sponsor details
Priory Street
Coventry
England
United Kingdom
CV1 5FB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01tgmhj36

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/05/2016		Yes	No
Results article	results	04/10/2017		Yes	No
Results article	results	21/01/2019	30/01/2020	Yes	No
HRA research summary			28/06/2023	No	No