A guided workbook intervention (WorkPlan) to support work-related goals among cancer survivors: Protocol of a feasibility randomised controlled trial [ISRCTN56342476]

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Abstract

Background: Returning to, and staying in, work following illness is associated with better physical and psychological functioning. Not working has been shown to be associated with reduced self-esteem, lowered self-efficacy and decreased belief in one's ability to return to the workplace. Although there is a growing body of research looking at what predicts return to work following cancer treatment, there are fewer studies examining interventions targeting return to work.

Objective: The primary objective is to assess the feasibility and acceptability of a theoretically-led workbook intervention designed to support cancer patients in returning to work, to inform a fully-powered randomised controlled trial.

Methods: This is a multi-centre feasibility randomised controlled trial, where the main analysis utilises a qualitative approach. Sixty participants (aged 18-65 years) who have received a diagnosis of cancer and who intend to return to work will be randomised into either the WorkPlan intervention group or a usual care group (ratio 1:1). Participants in the intervention group will receive a guided workbook (which contains activities aimed at eliciting thoughts and beliefs, identifying targets and actions and concrete steps to achieve goals) and will receive telephone support over a four week period. The primary outcome measure is time taken to return to work (in days), and secondary outcome measures include mood, quality of life, illness perceptions and job satisfaction. Data will be collected through postal questionnaires administered immediately post-intervention and at 6 and 12 month follow-ups. In addition, interviews will be undertaken immediately post-intervention (to explore acceptability of the intervention and materials) and at 12 month follow-up (to explore perceptions of participation in the trial and experiences of returning to work).

Discussion: Currently no standardised return to work intervention based on targeting cancer patients' beliefs is in existence. If shown to be feasible and acceptable the results will inform a future full randomised controlled trial and has the potential to provide a valuable and cost-efficient tool in supporting cancer survivors in the return to work process.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): ISRCTN56342476

Keywords

Oncology; Cancer; Return to work; Intervention; Protocol; RCT

Introduction

Returning to, and staying in, work following illness is associated with better physical and psychological functioning. Not working has been shown to be associated with reduced self-esteem, lowered self-efficacy and decreased belief in one's ability to return to the workplace [1]. Employment is important not only for individual and societal economic reasons [2] but because being out of work is thought to cause, contribute to and aggravate adverse health outcomes [3,4]. Furthermore, work is an important component of quality of life [5]. The observed relationship between unemployment and negative health outcomes is thought to be mediated by factors such as socioeconomic status, financial anxiety and a stress pathway involving physical changes including hypertension and lowered immunity [6,7]. Although there is a growing body of research looking at what predicts return to work (most commonly defined as returning to work quicker and improved self-reported ability to undertake one's role, termed workability) following cancer treatment, there are fewer studies examining interventions targeting return to work.

Over 100,000 people of working-age receive a diagnosis of cancer each year in the United Kingdom (UK) [8]. Earlier diagnosis and improvements in treatment survival rates have led to an increase in the number of cancer survivors. UK policy reviews have highlighted a need for more research into the challenges of living with cancer [9,10]. For many cancer survivors returning to work is a realistic outcome. Many patients do well following treatment, however, some experience ongoing negative outcomes from the disease or treatment (including pain, fatigue and low mood), which may impact on everyday functioning, including work [11]. Over a quarter of cancer survivors report high symptom burden one year post-diagnosis, even after treatment termination [12]. In addition, many cancer survivors still undergo some form of treatment/monitoring for substantial periods of time following termination of active treatment. Return to work rates of between 23% and 75% have been reported [13] and cancer patients are 1.4 times more likely to be unemployed than healthy individuals [4]. Furthermore, return to work rates have been shown to vary across cancer types [14] and longer return to work times have been reported among patients undergoing certain treatments (surgery/chemotherapy) [15], experiencing fatigue [16] or reporting a non-supportive work environment [17]. Although some cancer types have a high return to work rate we know that across cancer types we see a significant proportion of patients return to work too early or in an

inappropriate manner, which results in them taking additional sick leave or leaving the workplace [16]. In addition, a large proportion of cancer patients report modifications in working hours, wages and work patterns as well as reporting perceived reductions in workability [13]. Cancer survivors have been shown to have similar work-disability levels to those reported in other chronic conditions (i.e. stroke, diabetes, heart disease, arthritis) but significantly higher work-disability levels when compared with age-matched adults with no reported chronic condition [18]. This supports the finding that cancer survivors often report difficulties in achieving productivity levels similar to healthy counterparts [19].

Predictors of longer time to return to work include a range of disease and treatment, work-related and psychological factors [20]. The relative role of each of these factors is difficult to determine, primarily because few studies directly compare these factors or studies focus on either a single cancer type or a mixed-cancer sample. However, a recent study [14] examined these factors across four distinct cancer types and identified that, in addition to optimal symptom management and appropriate workplace adaptations, specific cancer (e.g. holding negative beliefs about the consequences of cancer) and treatment-related perceptions (beliefs about controlling the effects of cancer at work) predicted return to work.

Cancer patients have reported apprehensions about returning to work, related to concerns about ongoing treatments and concerns about their level of physical fitness [21]. Depressive symptoms are also associated with reduced return to work rates and both partial and full resumption of work may help alleviate depressive symptoms by challenging dysfunctional beliefs [22]. Research from non-cancer disease groups also supports the importance of psychological factors in the return to work process. Among patients diagnosed with coronary heart disease, depression has been shown to impact on functional recovery and to predict failure or delay in returning to work [23,24]. Other psychological factors such as illness perceptions are also predictive of reemployment and occupational functioning [25,26,27] as are perceptions of work-related disability (independent of physician report of disability) [28].

Specifically, in the field of cancer a number of intervention and trial protocols have been published. Such interventions include a 12 week occupational physician led intervention focused on increasing physical activity in cancer survivors to support return to work [29]; a

case management approach focusing on signposting/referring patients to services (e.g. physiotherapy, occupational or psychological therapy) that may support return to work [30]; and a tool that cancer survivors use to guide discussions about working [31]. Although this tool was initially well received it focused on guiding questions during interactions with employers/healthcare professionals and not on beliefs and barriers that impact on workability and work behaviour. In addition, a recent Cochrane systematic review identified the need for more high-quality randomised controlled trials (RCT's) to enhance return to work among cancer patients [32]. Moreover, a recent a meta-synthesis of qualitative research studies highlighted the need for vocational interventions with cancer patients to be person-centred and for such interventions to acknowledge the role of social, clinical and work-related factors [33].

Current study

Feasibility studies are conducted before a main study and are used to estimate key parameters to support the design a full RCT [34]. This feasibility randomised controlled study will trial and evaluate the WorkPlan guided workbook intervention, which is a theoretically-led intervention aimed at targeting known psychological factors to improve work-related outcomes among cancer survivors. The primary objective of the study is to trial the workbook intervention and data collection materials, to ensure that the materials are acceptable to participants and that participants are able to provide full answers. This objective will be met through five aims.

Aim 1: Trial data collection materials to ensure that the materials are acceptable to participants. We will identify whether the materials are acceptable to participants and that participants understand and are able to complete the required tasks.

Aim 2: Trial the recruitment process and feasibility of recruiting participants into the study. We will observe whether we are able to meet the required monthly recruitment targets, identify which methods of recruitment are most successful in attracting participants into the study and determine if changes could be made to future studies to improve recruitment.

Aim 3: Test the acceptability among participants of the randomisation process. As part of the final interview process we will discuss the randomisation process with participants to determine the level of understanding regarding this process and satisfaction with the information provided about the randomisation process.

Aim 4: Determine retention in control and intervention groups. We will observe the retention rates in the control and intervention groups to the 12-month follow-up. Where possible we will aim to determine reasons for attrition in both arms.
Aim 5: Conduct the ground work necessary to obtain data that will be required in the definitive trial to enable a full cost-effectiveness analysis. Measures to be used in a full trial will be administered for acceptability.

The study is funded by the National Institute for Health Research (NIHR), and registered with the UK Clinical Research Network (UKCRN ID: 19013). Ethical approval for this study has been obtained from West Midlands – Solihull (NRES) Research Ethics Committee (Reference: 15/WM/0166), and the study is registered with the International Standard Randomized Controlled Trial Number (ISRCTN) registry [ISRCTN56342476]. The Protocol Version is v4.1 date 11.11.2015. The recruitment status is open (participants are currently being recruited and enrolled into the study).

Method

Eligibility Criteria

Inclusion criteria: Patients who have received a diagnosis of breast, gynaecological, urological or bowel cancer (which has not been classified as metastatic disease or recurrence); are at least two weeks post treatment initiation; are aged between 18 and 65 years; were working at the time of diagnosis and who are not currently working but intend to return to work.

Participants will be recruited to the study from multiple UK hospital sites. We aim to recruit 60 participants to the whole study, who will be randomised into either the intervention or the usual care group. There are currently no clear guidelines for estimating an appropriate sample size for feasibility studies. This is not a hypothesis testing study and therefore the sample size is based on pragmatic assumptions around feasible recruitment figures and the number of participants required to estimate the key parameters around the feasibility of a full RCT.

WorkPlan Intervention

The WorkPlan package is theoretically led and based around the Self-Regulation Model [35] and Goal Setting Theory [36], which have been applied previously in return to work

interventions. The intervention was developed using an intervention mapping methodology. This methodology is used for designing and implementing complex interventions or programs (interventions that comprise a number of separate elements that are essential to the functioning of the intervention as a whole). The WorkPlan intervention is delivered as a 4-week guided workbook intervention, consisting of structured sections and activities to provide guidance and support to patients. These structured sessions are broken down into 4 chapters which participants are encouraged to work through during each week of the intervention period. The workbook comprises activities aimed at eliciting thoughts/beliefs, identifying targets/actions and concrete steps to achieve goals, and leads to participants creating a "return to work plan" in the fourth and final week, incorporating all elements from the workbook into a personal return to work plan. A resources section is also included to signpost participants towards relevant avenues of further support. Multiple copies of the plan page will be available to encourage changes to be made when necessary, and these plans can be used as a tool when meeting with employers to aid discussion around returning to work. An intervention manual has also been developed in tandem with the workbook, to be used by the researchers alongside the delivery of the intervention.

Intervention group

Patients in the intervention group will be guided through the initial exercises and given a detailed overview of the workbook. They will be encouraged to discuss the workbook with their partner, family or friends. Two and four weeks later telephone support discussions will be made by the researchers to discuss progress. The workbook is used during the introductory session, at home during the intervention period and as a reminder during the return to work process.

Usual care group

Participants will receive usual care which focuses on clinical care and optimal symptom management, and will be offered the workbook at the end of the study. In order to prevent participants from undertaking activities within the workbook the following precautions have been included in the design: (1) the information sheets and the pre-randomisation discussion do not include the content or the focus of the intervention and (2) the workbook will not be

available to view and will only be provided following the 12 month follow-up time-point for that patient.

Participants in either group may access other information and support relating to work post-treatment, but will be asked to record any resources or information they receive or access during the trial.

Procedure

Potential participants will be recruited when they are at least two weeks post treatment initiation (Figure 1). Patients will be identified through breast cancer, gynaecological cancer, colorectal cancer or urological cancer clinics, through multidisciplinary team meetings and by placing posters in clinics, chemotherapy suites and computerised tomography (CT) scan waiting areas. Clinicians will have leaflets and information packs (outlining the study and providing contact details) available for patients. Study materials have been translated into the five most commonly used languages among people of working age in Birmingham, according to the 2011 Census (Bengali, Chinese (standard), Polish, Punjabi and Urdu). Interpreters will be provided if required.

Through all routes potential participants will be provided with contact details for the researchers and asked to contact one of the researchers by telephone or email. Details for the project website will also be displayed on the leaflets and posters, where potential participants can access further information about the study. Participants who express interest in the study will be provided with an information sheet and eligibility screening questionnaire. Eligible patients will be sent an invitation to attend an assessment interview at the hospital or over the telephone, where a researcher will outline the study and randomisation process, explain the patient information sheet and obtain written consent (if explained via telephone, researchers will obtain verbal consent after explaining the study and will ask participants to return a written consent form via post). If participants provide additional consent, the researchers will inform their general practitioner (GP) about their participation in the study. Participants will receive £20 when they complete the assessment interview, to cover their time and any travel expenses.

Allocation and Stratification.

The researchers will randomise participants into one of the two arms using a central online and text system, Sealed Envelope [37], at a ratio of 1:1 between the intervention group and usual care group. During the randomisation process participants will be stratified by age (18-50 or 51-65) and cancer type (breast, bowel, gynaecological or urological). Patients with different cancer diagnoses may have specific impairments or side effects due to the location of the cancer or the treatments received. Hence, stratifying for cancer type balances out any effects that might be due to this variable. Treatments undertaken during the follow-up period will be monitored in both arms of the trial. Participants are informed about their group allocation (guided intervention or usual care), and participants allocated to the usual care group will be informed that they will be offered the workbook after the 12 month follow-up.

Blinding

The researchers will be aware of group allocation at randomisation and during follow-up, in order to provide telephone support to participants in the intervention group. However, the Principal Investigator will be blind to participant group allocation to reduce bias when analysing data.

Data Collection Methods

Study Outcomes

The main outcome measures of a full RCT will be used (e.g. time to return to work). At each time-point participants will be asked to recall the date of return to work (paid or unpaid employment, whether a different job, reduced hours/salary, full-time or part-time). Any changes in working status/duties will be documented as will specific reasons for non-return to work (e.g. unavailability of job, ongoing medical concerns) to determine whether to incorporate these into a full trial. Secondary outcome measures include mood, satisfaction with return to work and satisfaction with the return to work process. Although not appropriate for a feasibility trial we would aim to undertake sub-group analysis of the primary outcome measure by cancer type/site in a future definitive RCT.

Data will be collected at four time points during the study: at baseline and four-week (post-intervention), six-month and 12-month follow-ups. At each time-point participants will

complete questionnaires comprising (1) Illness Perceptions Questionnaire – Revised [38], (2) Brief Illness Perception at Work Scale [39], (3) Hospital Anxiety and Depression Scale [40], (4) Work Ability Index [41], (5) Single item of satisfaction with return to work (if returned to work), (6) Satisfaction with Work Scale [42] (if returned to work), (7) EQ-5D-5L (Quality of Life) [43] and (8) Visual Analogue Scale measure of Quality of Life (single item) [44]. Questionnaire packs will be posted to participants with a pre-paid self-addressed envelope. In addition, participants will be asked to provide details of their use of services and information utilised through a text-based service, which participants will be able to respond to via text message. A maximum of four text messages will be sent to each participant at the end of each month for the duration of the study, to gather information on their current work status and healthcare utilisation. Monthly questions were chosen as research shows that memory for GP appointments is around four weeks, and therefore we could not rely on accurate recall if healthcare utilisation was only recorded at six-monthly follow-ups [45,46]. The text-based service can also be used for reminders to participants to complete and return questionnaire packs if there is missing data.

Interviews

Twenty participants in the intervention group will be asked to undergo a post-intervention (intervention group) and 12-month post randomisation interview (intervention and usual care groups). Participants will be asked to participate sequentially until the recruitment target is reached. Interviews will be conducted over the telephone or face to face, depending on the participant's preference. The post-intervention interview schedule will focus on gaining perceptions of (1) how the intervention was delivered, (2) aspects of the intervention which individuals found useful and (3) compliance with the intervention, how aspects of the intervention were utilised and recommendations for change. The 12 month interview schedule will include twenty participants from both the intervention and usual care groups. These interviews will explore (1) experiences of the randomisation process, (2) general perceptions of the trial, and (3) the personal return to work process of each individual. Both groups will be asked about their experience of being part of either the intervention or usual care group and how this may have impacted on their return to work as well as any additional support received regarding return to work.

Data Management

To maintain confidentiality all participants will be given a unique identifier which will be used on all hard copy and database records. Patient names will not be used. Clinical and research government guidelines will be followed for safe and confidential storage of participant personal data (such as password protected data files), which only the research team directly involved in the study will have access to. If a participant chooses to withdraw from the study, identifiable data which has already been collected with consent would be retained and used in the study, but no further data would be collected from the participant.

Analysis plan

Qualitative analysis

Although this is a mixed methods study the main focus of the analysis of the study will be qualitative. Interviews will be recorded, transcribed verbatim and analysed using Framework analysis [47] to identify emergent themes.

Quantitative analysis

The purpose of this feasibility study is not hypothesis testing. Furthermore, it is anticipated that the sample size will be underpowered to undertake the full analysis that would be utilised in a full trial (Analysis of Covariance (ANCOVA) adjusting for baseline values). Baseline characteristics will be reported as mean and standard deviations or medians and interquartile ranges for continuous data and as n (%) for categorical data. Differences between the intervention and control groups for the primary outcome measure will be examined. Secondary outcome measures will be assessed using independent samples t-tests (significance level set at 0.05).

Economic analysis

Although an economic evaluation is not suitable in the context of a feasibility trial we will undertake a descriptive economic analysis focusing on the resource usage of the intervention (intervention materials, time, follow-ups/support), self-reported indirect costs including days of sickness payments/unemployment benefit and healthcare utilisation. The EQ-5D-5L will be used to inform the changes in quality of life over time, and these can ultimately contribute to the calculation of quality-adjusted life years (QALYs) in a full economic evaluation.

Data Monitoring

This is a feasibility, rather than a full trial and so a data monitoring committee will not be convened. However, the project steering committee will review safety and efficacy data throughout the trial. Personal data will be accessed by the research team only, and will be stored or accessed for between 6 and 12 months after the study has ended.

Ethics

Ethical approval for this study has been obtained from West Midlands – Solihull (NRES) Research Ethics Committee (Reference: 15/WM/0166). Although we do not envisage the need for protocol modifications, any amendments to the protocol will be communicated to the research team by the Principal Investigator and if relevant to the trial participants, the researchers will inform them via post.

Harms

As the trial focuses on a workbook based intervention aimed at promoting return to work, we do not envisage any adverse events or a need to stop the trial prematurely. It is unlikely that the intervention would cause distress, although participants may experience distress while discussing their work in the context of having experienced cancer. However, procedures will be in place for participants to access other psychological support services if required.

Dissemination Policy

Results from the study will be reported and disseminated through publication in peer-reviewed scientific journals and presentations at relevant conferences. Participants will be asked to indicate if they would like a lay summary of the findings of the study, which will then be posted or emailed to them.

Discussion

There is currently no available standardised return to work intervention focused on targeting cancer patients' beliefs. Previous research [48,49] has demonstrated that both cancer patients and organisations report that such an intervention would be invaluable to facilitating return to work and ensuring work retention. Undertaking a feasibility study is critical to inform the

planning of a larger, fully-powered randomised controlled trial to improve work-related outcomes among cancer survivors. The results of the study will be used to modify the trial materials and methodology (if required) and to determine likely recruitment and retention rates for a larger trial. Furthermore, if appropriate, the results of the feasibility study will be used to inform a sample size calculation for a future (appropriately powered) randomised controlled trial of the intervention with a longer follow-up period. If a future fully powered RCT were to demonstrate that the WorkPlan intervention is more effective in supporting return to work than usual care then this will allow us to implement an effective and deliverable intervention, providing a valuable, yet cost-efficient tool in supporting people who have received a diagnosis of cancer in planning and achieving supported return to work, and greater satisfaction with work and the return to work process.

Methodological considerations

One strength of this study is that it utilises a theoretically based intervention. The study follows the best practice guidelines set out by the Medical Research Council (MRC) in the development and evaluation of complex interventions [50] and published recommendations for pilot studies [51-54]. The intervention package was developed in several stages. A review of the literature identified that few studies focusing on return to work had targeted participants' beliefs and yet the role of beliefs in the performance of numerous behaviours, including return to work, has previously been documented [55,56]. Following on from this a prospective questionnaire study was developed and administered to identify which clinical, work-related and psychological variables influence the return to work process among cancer patients. As part of this study qualitative interviews were also undertaken to gain further information about the patients' vocational aspirations, perceptions of the process of returning to work and beliefs regarding their ability to return to work. The study demonstrated the role played by illness perceptions and beliefs about the impact of illness on return to work, as well as differences in predictive factors across cancer types [14,57,58]. The results of this research were used to map the intervention components through an intervention mapping methodology. This methodology is used for designing and implementing complex interventions or programs (interventions that comprise a number of separate elements that are essential to the functioning of the intervention as a whole). It has been used for over 20 years for systematically designing multifaceted programs involving numerous interventions directed at various individuals and

environments [59]. This methodology is suited to the development of a return to work programme as this is a complex intervention, requiring a tailored and multifaceted approach. Further strengths of the study include that the chosen self-reported outcome measures relate directly to the components addressed through the intervention, that resources are available to support a diverse sample within the study and that a qualitative analysis approach will be utilised. Qualitative methods are increasingly applied in the developmental stages of randomised controlled trials of complex interventions [59]. Qualitative methods are often used to help understand participants' understanding and experience of an intervention. Individual in-depth interviews allow exploration of why some participants may respond more positively to the intervention and what modifications to the intervention may be required to suit different groups of participants (for example there may be differences between cancer types and occupation types, as well as specific gender based needs).

Conclusion

The study may be the first step in the development of several long-term benefits and may have some immediate benefits for the sample who participate in this feasibility study. The intervention will provide cancer survivors with the skills and confidence to manage their return to work. The intervention may improve long-term job retention among cancer survivors with the potential also to be adapted for other conditions. Furthermore, the intervention may have long-term implications for improving psychological outcomes among cancer survivors through improvements in well-being, mood and physical functioning, all of which could impact on the utilisation of National Health (NHS) services.

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Conflicts of Interest

None declared.

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Figure 1: Study flowchart showing allocation to groups