

Study protocol

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Effects and feasibility of a multi-disciplinary orientation program for newly registered cancer patients: design of a randomised controlled trial

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Abstract

Background: Diagnosis and treatment of cancer can contribute to psychological distress and anxiety amongst patients. Evidence indicates that information giving can be beneficial in reducing patient anxiety, so oncology specific information may have a major impact on this patient group. This study investigates the effects of an orientation program on levels of anxiety and self-efficacy amongst newly registered cancer patients who are about to undergo chemotherapy and/or radiation therapy in the cancer care centre of a large tertiary Australian hospital.

Methods: The concept of interventions for orienting new cancer patients needs revisiting due to the dynamic health care system. Historically, most orientation programs at this cancer centre were conducted by one nurse. A randomised controlled trial has been designed to test the effectiveness of an orientation program with bundled interventions; a face-to-face program which includes introduction to the hospital facilities, introduction to the multi-disciplinary team and an overview of treatment side effects and self care strategies. The aim is to orientate patients to the cancer centre and to meet the health care team. We hypothesize that patients who receive this orientation will experience lower levels of anxiety and distress, and a higher level of self-efficacy.

Discussion: An orientation program is a common health care service provided by cancer care centres for new cancer patients. Such programs aim to give information to patients at the beginning of their encounter at a cancer care centre. It is clear in the literature that interventions that aim to improve self-efficacy in patients may demonstrate potential improvement in health outcomes. Yet, evidence on the effects of orientation programs for cancer patients on self-efficacy remains scarce, particularly with respect to the use of multidisciplinary team members. This paper presents the design of a randomised controlled trial that will evaluate the effects and feasibility of a multidisciplinary orientation program for new cancer patients.

Trial registration: Current Controlled Trials ACTRN1260900018213

Background

There is a consensus that diagnosis and treatment of cancer contributes to psychological distress and anxiety among patients [1-3]. The literature has demonstrated that information can reduce distress by enhancing patients' sense of control. An enhanced sense of control, in turn, relieves anxiety and enhances management of illness [4]. Although the need for information exists across the continuum of cancer care [5,6] the anxiety can be particularly pronounced at the initial visit to a cancer centre [7,8]. Factors contributing to this anxiety and distress can be the lack of familiarity with the environment and with the care providers.

Researchers have investigated interventions with the aim of reducing the anxiety and distress levels among cancer patients [4,9]. One of these interventions includes orientation programs for patients who are newly registered to a cancer service. A study of 150 new cancer patients by McQuellon and research team reported that their orientation was effective in reducing anxiety, distress and depressive symptoms and enhanced knowledge and satisfaction of care [10]. In 2003, Gallant (2003) tested different methods of delivering an orientation program and found that it was more challenging to recruit patients for the face to face arms compared to the mail group [11]. The components of these orientation programs vary and generally include question and answer sessions, a clinic tour, description of procedures, provision of information. However, none of these studies have investigated the effects of orientation programs and were not conducted by a multidisciplinary team.

Self-efficacy

In the population other than cancer patients, researchers have demonstrated that self-efficacy can be enhanced through orientation and educational programs, and that higher self-efficacy is related to improved health outcomes [12-15]. Self-efficacy is a construct of Bandura's social cognitive theory [16,17], defined as a person's belief that they can perform the specific behaviours necessary to achieve their goals. A person's sense of self-efficacy should lead to attempting and persisting when encountering difficulties; their confidence in or perception of their ability to carry out tasks directly relates to their likelihood of success [18]. A variety of research on cancer patients' self-efficacy has been conducted [19-23]. Self-efficacy is a potent factor which can affect the quality of life in cancer patients. Firstly, enhanced self-efficacy directly affects quality of life positively. Secondly, it reduces perceived stress and, in turn, increases quality of life [23]. That is, cancer patients with higher self-efficacy have lower level of anxiety and distress and higher quality of life [21,23,24]. Therefore, interventions with the aim of increasing ones' self-efficacy are recommended.

Multidisciplinary team involvement

A systematic review reported that multidisciplinary care can result in positive patient outcomes [25], specifically in diagnosis and/or treatment planning [26-28], survival [29-31], patient satisfaction [26], communication and cooperation [32]. Although there is a vast body of literature supporting the positive outcomes as a result of multidisciplinary care, there is a paucity of evidence which demonstrates the importance of multidisciplinary involvement in conducting orientation programs for cancer patients. While evidence suggests that unfamiliarity with the care providers is one of the factors contributing to this anxiety and distress in this patient population [33], it is important to note that "care providers" should include every member that the patients will access care from during the continuum of cancer care. Orientation provided for cancer patients should no longer be limited to "meeting the oncologist". As the model of care has changed from a medical focus to a multidisciplinary model, health professionals conducting orientation programs should also respond to the change. However, the orientation programs documented in the literature are mainly conducted by one nurse coordinator, rather than a multidisciplinary team [10,33,34]. Therefore, research is needed to evaluate the effectiveness of an orientation program conducted by a multidisciplinary team.

Objective of the study and the current paper

The main objectives of the study are

1. To develop an orientation program conducted by a multidisciplinary team for newly registered cancer patients in terms of its impacts on the patients' self-efficacy and anxiety.
2. To test the feasibility of a randomised controlled trial of an orientation program conducted by a multidisciplinary team for all newly registered cancer patients.
3. To evaluate the effectiveness of the program on patients' self-efficacy, anxiety, stress and informational awareness.

The current paper presents the design of the randomised controlled trial that will evaluate an orientation program conducted by a multidisciplinary team for newly registered cancer patients

Methods

Method

Randomised controlled trial will be used in this study.

Ethics consideration

The study protocol has been reviewed and approved by the Royal Brisbane & Women's Hospital Health Service District Human Research Ethics Committee.

Study population

All cancer patients newly registered at a tertiary cancer care centre in Brisbane, Australia, who meet inclusion criteria will be invited to participate in the trial. Patients who consent will be randomly allocated to either the control group, who will receive normal treatment education at the start of their treatment, or the intervention group, who will receive the normal treatment education and will also attend the Orientation Program education session conducted by the multi-disciplinary team, prior to starting their treatment.

Inclusion and exclusion criteria

Patients will be eligible if they consent and are undergoing a course of radiotherapy, chemotherapy or both; have a definitive diagnosis of cancer; are over 18 years of age; are able to read and write in English and are "well" enough to complete the questionnaire. Patients will be excluded if they have had previous cancer treatments.

Randomisation and masking

Patients will be randomly allocated to either normal care (control group) with standard education provided by nurses at the first visit of treatment, or to the intervention group to participate in an extra orientation program.

Sequence generation

Blocked randomisation will be performed with a block size of four by a computer generated random number list prepared by an investigator who has no clinical involvement in the trial. Stratification by primary cancer diagnosis group will also be carried out.

Allocation concealment/implementation

After the research nurse has obtained the patient's consent, he/she will telephone a contact who is independent of the recruitment process for allocation concealment. Subsequently, baseline data will be collected. All questionnaires are self-administered by patients. Therefore, the research nurse will not have involvement in completing these questionnaires.

Blinding/masking

It is not possible to blind patients regarding the result of randomisation in this type of intervention. While it is not possible to blind the health professionals administering the orientation program, they will have no involvement in assessing and analysing the data.

Intervention

The intervention is a Multidisciplinary Orientation Program. It will be run twice weekly in the oncology outpatients department, and comprises a 5 minute 'virtual hospital tour', a talk by a registered nurse giving an overview of potential side effects of radiation therapy and

chemotherapy, and an opportunity to meet the health care team. The hospital tour highlights areas of the hospital that patients are likely to need during the course of their treatment, such as the pharmacies and the pathology department. It also will show practical areas such as the Food Court, Post Office and Automatic Teller Machines. Different parts of the Cancer Care Services building are shown - the check in desk, the different waiting areas, the day therapy unit and the radiation treatment floor. The side effects overview will include common side effects experienced by oncology patients and self care strategies. This talk was developed using the information currently given to patients in the respective treatment areas at the start of their treatment, but does not include details of specific treatment regimens.

The health care team consists of a nurse, a cancer care coordinator, a social worker, an occupational therapist, a physiotherapist, a speech pathologist and a discharge coordinator. The healthcare team each will have five minutes to give an overview of their role, how they may support the patients throughout their treatment and encounter at the cancer care centre and to give patients their contact details. The health care team each have their scripts and powerpoint slides prepared to ensure the consistency of each session. All patients attending the intervention will be given a 10-page booklet which contains the information given in the 'virtual tour' and expands on it, eg. prices for car parking, access to public transport, opening times for food outlets within the hospital, note space. It also has information about the role of each member of the health care team, telephone numbers for clinics, and tips for getting through treatment. At the end of the session there will be time for questions for both the nurse and the members of the healthcare team. Powerpoint presentation and a projector will be used to facilitate every section of the program. Scripts and notes have been designed and agreed by the health care team and will be used to ensure the consistency of each session.

Measures**Anxiety**

Anxiety will be measured using the trait anxiety version of the Spielberger's Trait Anxiety Inventory (STAI) and the Brief Profile of Mood States - Total Mood Disturbances Score (POMS-TMDS) [35-37].

The STAI was developed as a tool for investigating anxiety in normal adults, but has been used extensively for assessing anxiety in cancer patients [10,11,21,33]. The scale consists of 20 questions yielding a measure of state anxiety (S-Anxiety) which assesses how a patient feels generally. An extra 20 questions refer to trait anxiety (T-Anxiety) which refers to individual differences in "anxiety-proneness" [35]. The STAI demonstrated good psychometric

properties [35]. Reliability has been substantiated by means of test-retest correlations ($r = 0.65-0.86$) and Cronbach's alpha (median coefficient of 0.90). Scores on the scales can range from 20-80, with higher scores indicating more symptoms of anxiety [21].

The POMS-TMDS is a shorter version of the 65 item Profile of Mood States (POMS) [37]. It consists of 11 items that yield a total mood disturbance score that correlates highly ($r = 0.93$) with the longer POMS which has been utilised extensively for the cancer population [10,11,33,38]. Reliability and validity testing has been carried out successfully in patient with cancer [39]. Permission for use has been granted by the author.

Self-efficacy

The communication and attitudinal self-efficacy scale for cancer (CASE-cancer) has been selected to measure self-efficacy in the patients [19]. The CASE-cancer is a psychometrically sound tool with high internal consistency and construct validity. The scale items are performed similarly across literacy levels. It is also recommended for testing the effect of interventions to improve communication, education and involvement in cancer [19]. Permission for use has been granted by the author.

Evaluation of Oncology Clinic Questionnaire (EOCQ)

The research team has designed a tool which will specifically investigate whether patients have received particular information prior to their first treatment day (Yes/No). It has included a list of information that the research team believes to be important for patients before they commence their cancer treatment. This tool will be administered at Time 2 and Time 3.

Data collection

Participants will be asked to complete a series of questionnaires at the time of recruitment (T1), on the day of first treatment (T2), and on the seventh day of treatment (T3) which will measure patients' self-efficacy (CASE) and anxiety (STAI and POMS) at the three time points. Additionally, demographic information will be collected at T1 and the EOCQ will be collected at T2 and T3.

Sample size and power

A sample size of at least 375 in each arm of the study would be sufficient to achieve a power of 90% using 95% of confidence interval to detect a difference in the anxiety and self-efficacy scores between control group and intervention group. Assuming that approximately 25% fail to consent and a further 10% will be lost to follow-up; an additional 132 in each group will be required and the final sample will require 1,014 patients. In order to evaluate the research design and process, the current proposal is for a pilot study with 10% of the final sample (ie 102

patients, 51 in each arm). According to the statistics of RBWH Cancer Care Services, 274 new cancer outpatients receiving treatment each month. Thus, the sample size proposed is achievable over a period of 12 weeks based on our conservative estimation.

Analysis

All data will be analysed according to intention-to-treat principle. Means, standard deviations will be used to summarise overall and within subgroups defined by the range of medical, sociological, and other risk factors collected at baseline. Mean scores of POMS, STAI and CASE-cancer will be compared initially across intervention and control groups using ANOVA (repeated measures) to analyse the effect between groups over time (or Friedman test if normality is not a valid assumption). Success of randomisation will then be considered by cross-tabulating trial group with the range of factors. Any found to be in substantial imbalance will be included in multivariable linear regression models, via forced entry, to adjust the crude means and these will be reported with 95% confidence intervals. Analyses will use the SPSS (Version 16) package and a generalised linear modelling framework.

Discussion

An orientation program is a common health care service provided by cancer care centre for new cancer patients. Such programs aim to give information to patients at the beginning of their encounter at a cancer care centre. It is clear in the literature that interventions that aim to improve self-efficacy in patients may demonstrate potential health outcomes. Yet, evidence on the effects of orientation programs for cancer patients on self-efficacy remains scarce, particularly with respect to the use of multidisciplinary team members. This paper presents the design of a randomised controlled trial that will evaluate the effects and feasibility of a multidisciplinary orientation program for new cancer patients.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

RC, JW contributed to the conception and design of the study. All authors were involved in the preparation of the manuscripts. All authors read and approved the final manuscript.

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