The effectiveness of patient-tailored interdisciplinary Medical Specialist Cancer Rehabilitation compared with allied health care on quality of life in patients with complex adverse effects of cancer or the treatment.

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The research objectives of this study are divided in a primary research objective and secondary research objectives.Primary:1. To study the effectiveness on the short and long term of patient-tailored interdisciplinary MSCR compared with AHC on the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON55162

Source
ToetsingOnline

Brief title
Effcare

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer oncology

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: cancer, costeffectiveness, interdisciplinary, rehabilitation

Outcome measures

Primary outcome

Quality of life

Cancer-specific quality of life will be assessed using the EORTC QLQ-C30. The EORTC QLQ-C30 is a reliable and valid instrument that has been used in many studies evaluating clinical and psychosocial interventions in cancer patients. The 30-item EORTC QLQ-C30 incorporates a global quality of life scale and five functional scales, namely physical functioning, social functioning, role functioning, emotional functioning, and cognitive functioning; and three symptom scales, namely fatigue, pain, and nausea and vomiting. In this study, we will report the results of the global scale, the functional scales, and one symptom scale (i.e. fatigue) since these are the scales most relevant for participants who have already completed primary treatment for cancer. After applying a linear transformation procedure according to the EORTC QLQ C-30 manual, the scores of the scales range from 0 to 100. A higher score represents a higher quality of life on the global and functional scales, and a higher level of fatigue. In a previous study differences of at least ten points are

classified as a minimum clinically meaningful change.

Secondary outcome

Costs

During the study period (12 months), all participants will fill out questionnaires to assess their healthcare resource use, work status and productivity losses. Data on health care costs, patient and family costs will be collected using the Medical Consumption Questionnaire (iMCQ) on a 3-monthly basis. Health care costs include the costs of oncological care, general practice care, paramedic care, additional visits to other health care providers, prescription of medication, professional home care and hospitalization. Patient and family costs include out-of-pocket expenses such as travel expenses, over-the-counter medication, and costs for paid and unpaid help. Units resource use (GP visits, hospital days, etc.) will be multiplied by their appropriate integral cost prices. The EuroQuol-5D-5L (EQ-5D-5L) will be used to calculate quality-adjusted life years (QALYs) and consists of the EQ-5D descriptive system and the EQ VAS. The EQ-5D descriptive system comprises five health dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Each dimension comprises five levels (no problems, some problems, moderate problems, severe problems and extreme problems). The EQ VAS records the respondents* self-rated health status on a vertical graduated (0-100) visual analogue scale. An economic evaluation regarding work/work loss and health care use will be conducted as a cost-utility analysis for health-related quality of life (and changes therein) as assessed using the EQ-5D. Indirect non-medical cost data related to production losses through work

loss days and work cutback days will be sampled with the Productivity Costs Questionnaire (iPCQ) for the measurement (and valuation) of productivity costs. It has been tested in several Dutch samples of patients and workers. The modular questionnaire covers all relevant aspects of the relationship between health and productivity, including absence from work, compensation mechanisms that may reduce productivity loss, reduced productivity at work (efficiency losses) and productivity costs at the level of organizations. Indicators of return to work (RTW) are time to partial and to full RTW, meaning the number of calendar days between end of treatment and first day at work, and time to full RTW corrected for partial RTW.

Fatigue

For the assessment of fatigue, we will use the Dutch version of the MFI Multidimensional Fatigue Index (MFI). It contains 20 questions on the following domains: general fatigue, physical fatigue, mental fatigue, loss of motivation and reduced activities. The psychometric properties of the MFI have been tested in cancer patients undergoing chemotherapy and radiotherapy. Internal consistency of the separate scales was good in a Dutch samples with Cronbach's alpha coefficients ranging from 0.79 to 0.93. Construct validity was assessed by correlating the MFI-20 to activities of daily living, anxiety and depression. Significant relations were assumed. Convergent validity was investigated by correlating the MFI scales with a visual analogue scale measuring fatigue and with a fatigue-scale derived from the Rotterdam Symptom

Checklist. Results support the validity of the MFI-20.

Physical fitness

Cardiorespiratory fitness will be measured using a cardiopulmonary exercise test on a bicycle ergometer with expiratory gas analysis. Cardiorespiratory fitness is expressed as maximum oxygen uptake per minute in milliliters per kilogram body weight (ml/min/kg) and the maximum workload (W). During the test, participants are asked to cycle constantly at 60-65 rounds per minute (rpm). Gas exchange is measured using a breath-by-breath gas analysis system. At the start of the test expiratory gas analysis is performed in participants at rest for three minutes. Subsequently, participants start cycling with a workload of 20 watts. The workload increases stepwise every minute by 10, 15, 20 or 25 watts, depending on the participant*s fitness, whereby the test should last between 10 and 15 minutes. During the test, the participant is encouraged to keep going by the physician. The test is completed when the participant no longer able to maintain the prescribed rate of 60-65 rpm due to exhaustion. For safety, blood pressure, heart rate and heart rhythm are monitored. The test is discontinued in the event of clinical symptoms or intervention by the physician (e.g. in case of ECG abnormalities, severe dyspnea, excessive increase in blood pressure).

Aerobic capacity and endurance will be assessed using the six-minute walk test (6MWT). The test has been used in a variety of chronic disease in adult and pediatric populations as well as in healthy adults. Muscle strength will be determined by means of the 1-RM test of the quadriceps and biceps muscles using

a handheld dynamometer and leg press (Micro Force Evaluating & Testing, Hoggan Health Industries Inc., USA). All measurements will be performed at least three times. The peak forces will be recorded and the mean values analyzed.

Psychological distress

Two questionnaires will be used to assess psychological distress. First, participants will fill out the Center for Epidemiologic Studies Depression Scale (CES-D), which is a brief self-report questionnaire that measures depressive symptoms in the general population. The CES-D consists of 20 questions about various symptoms of depression as experienced in the past week. It consists of four subclasses: depressive affect, somatic symptoms, positive affect, and interpersonal relations. The CES-D has excellent psychometric properties and is sensitive to changes over time in cancer patients. Second, to assess symptoms of fear in participants, we will use the State Trail Anxiety Inventory (STAI). This questionnaire contains 20 items divided over two subscales and can measure anxiety at both poles of the normal affect curve (state vs. trait).The STAI can be administered across a range of socio-economic status levels and requires a reading age no higher than 12 years. The Dutch version has been validated and has good psychometric properties.

Physical activity levels

Physical activity will be measured by accelerometer and a questionnaire. An accelerometer is a small lightweight physical activity monitor (Actigraph GT9X

Link). Participants will be instructed to wear the accelerometer for seven consecutive days following their baseline and follow-up measurements. Accelerometry has been shown to be a reasonably valid method for objectively assessing physical activity in adults.(38) Raw accelerometer data are converted into counts, which are subsequently used to quantify time spent in sedentary behavior, light-, moderate- and vigorous-intensive physical activity. The SQUASH (Short Questionnaire to Assess Health-Enhancing Physical Activity) is a commonly used instrument in the Netherlands to assess physical activity. It was developed by the Dutch National Institute of Public Health and the Environment (RIVM) to measure physical activity with respect to occupation, leisure time, household, transportation means and other daily activities. The SQUASH was designed to give an indication of the habitual activity level and was structured in such a way that it would be possible to assess compliance to physical activity guidelines. It has been shown to be valid in measuring physical activity among the Dutch population.

Societal and work participation

Participants will fill out the Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P). This questionnaire is about daily life and consists of four parts: time spent on working, studying and attending to household duties; performance of certain activities; experiencing restrictions in daily life; and satisfaction with daily life. The USER-P appears to be a valid measure to rate objective and subjective participation in persons with physical disabilities. The following items will also be registered to determine

work reintegration:

- employment prior to diagnosis

- duration of absence from work (paid or unpaid)

- adjustment of working hours after treatment

- reintegration to similar or different work

Adherence to the program

Participants in both groups will be asked to fill out a rehabilitation log. The time to fill out this log will be less than one minute, only on therapy days. From the registration systems of the AHC professionals and the rehabilitation center the actual attendance rate of the participant can be scored. Adherence to the MSCR program will additionally be assessed by contacting the specialists in Rehabilitation Medicine of the patients. Adherence to AHC will be done by contacting the AHC professionals and the specialized oncological nurse of the included patients. Health care uptake is also included in the IMCQ questionnaires.

Study description

Background summary

Improvements in the screening, early detection, and effective treatment of cancer has led to a rapid increase in the numbers of cancer survivors (1). Cancer survivors suffer from a range of adverse effects that may include fatigue, pain, reduced physical fitness, anxiety and depression * all of which impair quality of life, reduce function in activities of daily living, and hinder work participation. Given the current and expected numbers of cancer survivors, this poses a serious public health problem. For example, in 2005, 22,000 persons in the Netherlands were considered unfit for work due to a

current or past diagnosis of cancer.

In the Netherlands, patients with cancer have several options for rehabilitation. One of these options is to receive therapy from allied health care(AHC) professionals. Often advised by oncological nurses, or general practitioners or self-referral, patients visit individual physiotherapists, psychologists, dieticians or other AHC professionals. A second option is to rehabilitate at an interdisciplinary medical specialist rehabilitation facility where patients receive patient-tailored interdisciplinary rehabilitation. The goal of both interventions is to support patients in overcoming the adverse effects of cancer and its treatment, and to improve their health-related quality of life. Previous studies in patients with cancer have shown that physical exercise is effective in alleviating fatigue, reducing depression and improving physical fitness, muscle strength and health-related quality of life Other studies have shown that psycho-education and cognitive behavioural therapy (CBT) can be effective in reducing fatigue, depression and anxiety. Combined interventions * usually a combination of exercise and psycho-education or CBT * have also been shown to improve quality of life and physical fitness and to reduce fatigue. A combination of interventions, tailored to the patient*s individual needs, may optimize the quality of life of cancer patients. To improve the quality of cancer rehabilitation in the Netherlands, the clinical practice guideline *Cancer Rehabilitation* was first developed in 2011 and adopted by the Netherlands Society of Rehabilitation Medicine. In subsequent years, the guideline was revised and given the title *Medical Specialist Rehabilitation in Oncology*. It is a product of the Netherlands Comprehensive Cancer Organization and published on the Oncoline website. The goal of this guideline is to ensure that every patient experiencing physical and psychosocial problems due to the cancer and cancer treatment receives timely referral for adequate rehabilitation care. For patients with complex and coherent multiple problems, referral to a specialist in rehabilitation medicine is indicated so that they can participate in an interdisciplinary MSCR program. For patients after completing the curative treatment limited evidence-based recommendations are included in the guideline. The guideline recommends that an MSCR program is patient-tailored and that it includes an aerobic and progressive resistance training program of at least moderate intensity. It also recommends CBT for survivors who are still fatigued one year after finishing curative treatment.

Since the numbers of cancer survivors are increasing, and cancer care needs to be kept affordable, economic evaluations of effective interventions are of importance to guide decision-making. Studies that have addressed the cost-effectiveness of cancer rehabilitation are limited in number and have several drawbacks: they are heterogeneous in design, are not representative of the MSCR program as described in the Dutch guideline, were performed mainly in other countries, and have had contradicting results. In parallel, societal costs can be reduced by providing patients with suitable rehabilitation to alleviate the adverse effects of cancer. However, health budgets are under

pressure, and for wide acceptance of rehabilitation and after care programs for cancer patients in society, it is important to know whether or not such programs are cost-effective. In the Netherlands, the MSCR program has been reimbursed by basic health care insurance since 2011. Other types of care that patients may be referred to in AHC, such as physiotherapy or psychotherapy, are not always covered by basic health care insurance, and patients often have to finance this care themselves.

Despite the fact that multidisciplinary rehabilitation programs are increasingly being recommended in (inter)national guidelines, evidence for the effectiveness of such programs is scarce. Until now it is not known whether an MSCR program that follows the Dutch guideline has a positive effect on the health, quality of life, activities in daily life and societal and work participation of cancer survivors and if the MSCR program is more effective than AHC. The federation of rehabilitation (VRA) acknowledged this as a major knowledge gap and research priority. It is also unknown what the costs of MSCR are relative to AHC. In addition, no evidence exists on the long-term differences in outcomes of both interventions.

Study objective

The research objectives of this study are divided in a primary research objective and secondary research objectives.
Primary:
1. To study the effectiveness on the short and long term of patient-tailored interdisciplinary MSCR compared with AHC on the quality of life in patients with complex adverse effects due to cancer.
Secondary:
2 To study the cost-effectiveness of patient-tailored interdisciplinary MSCR when compared with AHC.
3 To study the effect of patient-tailored interdisciplinary MSCR in terms of fatigue, physical fitness, psychological distress, activity level, return to work and societal participation when compared with AHC.
4. To study the adherence to both the MSCR and AHC group.

Study design

We will perform a multicentre prospective randomized controlled trial with two arms: one arm will receive MSCR, while the other arm will receive AHC.

Intervention

MSCR group
Participants will follow a MSCR program according to the guideline. In this guideline, it is recommended that a patient-tailored treatment program is determined for each patient, taking into account the characteristics of the

disease and the preferences and personal goals of the patient. The rehabilitation program can consist of the following interventions: physical exercise training, coaching in energy distribution, psychosocial intervention, dietary advice, and advice on work reintegration. In the guideline no advice is given on the durationof the rehabilitation program. Generally, in a period of 12 weeks the individual goals of MSCR are reached. For each intervention a more extensive description, including goals, in- and exclusion criteria, is available.

AHC group
Patients in the AHC group will receive patient-tailored care by AHC professionals who are experienced and preferably certified for treating cancer patients. The AHC that will be given is a combination of therapies consisting of physiotherapy, psychology and/or dietetics. The patient will be contacted by the oncological nurse for further coordination. The oncological nurse will also monitor the progress of the patients during the program. Health care that is not covered under health insurance (physiotherapy) will be reimbursed. Health care uptake will be closely monitored by the researcher, by contacting the health care professionals and monitoring the IMCQ questionnaires.

Study burden and risks

All participants will fill out 8 questionnaires and will visit the study centers for assessment of 3 performance tests. The questionnaires can be filled out in 45 minutes, online or in the rehabilitation institution. In total the questionnaires are filled out four times, except for the cost questionnaires (EuroQol-5D-5L, IMCQ, IPCQ) that are filled out five times. The total time needed to complete the performance tests is one hour at baseline and at 12 weeks. At 6 and 12 months the performance tests can be done in 15 minutes, since a maximum exercise test is only performed at baseline and at 12 weeks. In case of abnormalities on the maximum exercise test participants are referred to a cardiologist. Risk that a SAE will occur is not higher than in care as usual. Participants in both groups can benefit from participating in the study when the program results in better physical fitness, more emotional balance, less fatigue or other benefits. In addition, the rehabilitation program can support the participants in maintaining a healthy and physically active life style. Participants in the AHC group are excluded from a MSCR program for a time period of 6 months. After this period, participants will be allowed to participate in a rehabilitation program if the participant still meets all the inclusion criteria of MSCR..

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- adults older than 18 years
- primary treatment with curative intent was finished less than 12 months ago (adjuvant hormonal or is allowed)
- types of cancer: breast, prostate, lymphoma, gynecological, colorectal
- complex adverse effects of cancer or cancer treatment as determined using the Lastmeter

Exclusion criteria

- serious diseases that might hamper a patient*s capacity to carry out intensive exercise (e.g. severe heart failure: New York Heart Assaciation (NYHA) criteria class 3 & 4 and COPD Gold 3 & 4)
- severe psychopathology
- patients who are undergoing primary or palliative cancer treatment
- inability to understand the Dutch language

- patients who finished their cancer treatment more than 12 months ago

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-05-2022
Enrollment:	176
Type:	Actual

Ethics review

Approved WMO Date:	31-05-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-12-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL71960.042.20
Other	NL7888