Evidence-based practice of cancer-related fatigue management

| Submission date | Recruitment status | Prospectively registered |
|-------------------|----------------------|-----------------------------|
| 11/11/2016 | No longer recruiting | ☐ Protocol |
| Registration date | Overall study status | Statistical analysis plan |
| 23/11/2016 | Completed | Results |
| Last Edited | Condition category | Individual participant data |
| 22/11/2016 | Signs and Symptoms | Record updated in last year |

Plain English summary of protocol

Background and study aims

Fatigue (extreme tiredness) is one of the most common side effects in cancer patients. Not only does the disease itself cause symptoms of fatigue, but the aggressive treatments such as chemotherapy and radiotherapy can make them particularly wsevere. Cancer-related fatigue (CRF) is extremely common but not routinely screened for, assessed, or treated during the symptom management of cancer patients. Currently, a growing and persuasive body of evidence on CRF is accumulating. This study is about how to integrate the evidence into the CRF routine care and eventually improve the CRF nursing quality. The aim of this study is to investigate the effectiveness of an evidence-based nursing practice model of cancer-related fatigue (CRF) management in hospitalized adult patients, using the Promoting Action on Research Implementation in Health Services (PARIHS) framework.

Who can participate?

Nurses working in cancer units of the university-affiliated adult hospital in Suzhou between May to September 2015 and patients admitted to those units who have cancer related fatigue.

What does the study involve?

Nurses undergo training in the cancer-related fatigue (CRF) management programme as part of standard practice. This involves learning how to implement the strategy with patients. At the start of the study and then after the programme has been implemented, nurses complete a range of questionnaires designed to measure their knowledge, attitudes and behaviors regarding CRF. In additions, patients being treated on the wards also complete a number of questionnaires designed to measure their CRF self-management ability.

What are the possible benefits and risks of participating? There are no direct benefits or risks involved with participating in this study.

Where is the study run from? First Affiliated Hospital of Soochow University (China)

When is the study starting and how long is it expected to run for? February 2014 to September 2015

Who is funding the study?
Suzhou Science and Technology Development Project (China)

Who is the main contact? Dr Li Tian

Contact information

Type(s)

Scientific

Contact name

Dr Li Tian

Contact details

Nursing school Soochow University No. 1 Shizi Street Suzhou China 215006

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Implementation of evidence into practice for cancer-related fatigue management of hospitalized adult patients using the PARIHS framework

Study objectives

The aim of this study is to explore an evidence-based nursing practice model of cancer-related fatigue (CRF) management in hospitalized adult patients, using the Promoting Action on Research Implementation in Health Services (PARIHS) evidence-implementation framework as the theoretical structure, to provide guidance for similar nursing practices.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical ethics committee, First Affiliated Hospital of Soochow University, 25/03/2014, ref: 2014-147

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Cancer-related fatigue (CRF)

Interventions

Nurses undergo training on the evidence and procedure to be implemented as part of standard practice. This involves concept of evidence-based nursing; the necessity for CRF EBN practice implementation; the content, source, quality, and strength of the evidence recommendations; the related practice procedures to be implemented; the assessment tools to be used; and the quality review standards of CRF nursing practice.

At baseline and after the implementation at the admission of the next treatment cycle that following the implementation, patients complete a number of questionnaires designed to measure their CRF self-management ability and the changes in CRF scaling. In addition, nurses also complete questionnaires designed to measure their knowledge, attitudes and behaviors regarding CRF.

Intervention Type

Primary outcome measure

- 1. Nurses' experiences and insights are collected using the in-depth individual face-to-face semistructured interviews at the end of the implementation in September 2015
- 2. Nurses' knowledge, attitudes and behaviors regarding CRF (NKAB-F) are measured using a survey designed for the purpose of this study at baseline and at the end of the end of the implementation
- 3. Patients' CRF self-management ability is measured using the CRF self-management scale and self-efficacy questionnaire for CRF management (SQFM) at baseline and at the admission of the next treatment cycle that following the implementation

4. Patients' CRF scores are evaluated daily by the nurses during their hospitalization using 0-10 scale. After the discharge, patients assess the CRF scores themselves daily and are required to record it in their CRF diaries

Secondary outcome measures

Research setting's nursing standards, regulations and procedures are collected using interviews at baseline and at the end of the implementation.

Overall study start date

08/02/2014

Completion date

30/09/2015

Eligibility

Key inclusion criteria

Nurses:

- 1. Working in the departments of medical oncology and radiotherapy of a university-affiliated adult hospital in Suzhou between May to September 2015
- 2. Willing to participate

Patients:

- 1. Admitted to the departments of medical oncology and radiotherapy of a university-affiliated adult hospital in Suzhou from May to September 2015
- 2. Diagnosed as having cancer related fatigue
- 3. Willing to participate

Participant type(s)

Mixed

Age group

Adult

Sex

Both

Target number of participants

at least 30 participants

Key exclusion criteria

Refusal to participate.

Date of first enrolment

10/07/2015

Date of final enrolment

10/08/2015

Locations

Countries of recruitment

China

Study participating centre First Affiliated Hospital of Soochow University

No.188 Shizi Street Suzhou China 215006

Sponsor information

Organisation

Nursing School, Fudan University

Sponsor details

No. 305 Fenglin Road Shanghai China 200032

Sponsor type

University/education

ROR

https://ror.org/013q1eq08

Funder(s)

Funder type

Other

Funder Name

Suzhou Science and Technology Development Project

Results and Publications

Publication and dissemination plan

Planned publication in a peer reviewed journal.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from sdfyytl@163.com

IPD sharing plan summary

Available on request