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Motivational nursing intervention on treatment adherence in heart failure patients

Submission date	Recruitment status	[_] Prospectively registered
16/12/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/12/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/03/2012	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effectiveness of a motivational nursing intervention based on the stages of change on treatment adherence in heart failure patients [Évaluation de leffet dune intervention infirmière Motivationnelle Selon les Stades de Changement (MSSC) sur des comportements dauto-soins chez des patients atteints dinsuffisance cardiaque]

Acronym
PROJET MSSC

Study objectives
We hypothesise that, compared to the control group, patients in the intervention group will have better self-care behaviour and management, as well as higher levels of confidence and conviction to change their self-care behaviour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institut de Cardiologie de Montréal Ethics Committee gave approval on the 14th November 2008 (ref: 08-1074)

Study design
Randomised controlled trial, single centre

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Treatment adherence/self-care behaviour in heart failure patients

Interventions
The nurse from the heart failure clinic will refer eligible patients to the research nurse. After giving their informed consent, the patients will fill out the baseline questionnaire and will be randomly assigned to either the intervention or control group.

Intervention group:
The research nurse will meet with patients to evaluate the self-care behaviour that will be targeted by the intervention. The nurse will then start the first intervention by evaluating the patients "stage of change", as well as their confidence and conviction to change. Following this assessment, the nurse will propose stage-specific interventions to help the patient. Those interventions were developed previously in a study on smoking cessation, and have been adapted to our heart failure population. The research nurse will undertake this assessment-intervention process three times:
1. In person prior to the patient's discharge from the heart failure clinic
2. By telephone 4 ± 2 days following discharge, and
3. By telephone 10 ± 2 days following discharge

Control group:
There will be no specific intervention by the research nurse. The patients will return home and continue with standard-follow up from the heart failure clinic.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Self-care frequency and self-care management will be measured at baseline and one month following randomisation using the following measures:
1. The Self-Care of Heart Failure Index (SCHFI) Sections A and B. Section A is an 11-item questionnaire which measures the frequency of self-care behaviours including exercise, low-salt diet, fluid restriction, daily weight or medication using a 4-point Likert scale. A higher score indicates an optimal frequency of self-care behaviours. Section B, a 6-item questionnaire, is divided in three subsections. Section 1 contains one item using a 4-point Likert scale, section 2 contains three items using a 4-point Likert scale and section 3 contains two items using a 5-point Likert scale. Summing these answers provides a total score; higher scores indicate optimal management of self-care.
2. The Therapeutic Self-Care Tool (TSCT) measures the patients' ability to initiate and perform activities aimed at maintaining health, managing health problems, and restoring functioning, using a 12-item questionnaire and a 5-point Likert scale. A higher score indicates better self-care capacities.

Secondary outcome measures
The following variables will be measured at baseline and one month following randomisation:
1. The frequency of specific heart failure self-care behaviours will be measured in the treatment group only, using the Self-Care of Heart Failure Index. To assess this variable, we will use only the item(s) referring to the behaviour on which the intervention is focused. For example, if a patient is focusing on a low salt diet, only the item assessing this self-care behaviour will be retained.
2. Confidence to change will be measured using the Questionnaire of Health Belief. The first subscale, an 8-item questionnaire, uses a 5-point Likert scale to measure the perception of barriers to change. A higher score indicates a higher level of confidence, or fewer barriers.
3. Confidence specific to heart failure patients will be measured using the Self-Care of Heart Failure Index Section C. This is a 6-item questionnaire which uses a 4-point Likert scale to measure confidence in respecting self-care. A higher score indicates a higher level of confidence.

4. Conviction to change will be measured using the Questionnaire of Health Belief second subscale. This is a 4-item questionnaire which uses a 5-point Likert scale to measure the perception of benefits to change. A higher score indicates fewer benefits.
5. Acceptability of the intervention will be measured using the Treatment Acceptability and Preference Questionnaire. This is a 4-item questionnaire which uses a 5-point Likert scale to measure the patients' opinion of the acceptability of a treatment. A higher score indicates greater acceptability of the treatment. An overall satisfaction question is also asked.
6. Feasibility of the intervention will be assessed by documenting the number of patients who:
6.1 Are eligible
6.2. Agree to participate in the study
6.3. Remain in the study one month after randomisation
7. Progression through the stages of change will be assessed using the evaluation made by the research nurse following each contact. At the beginning of each contact, the nurse will use an algorithm to determine the patient's stage of change. We will give a score of 1 to patients who progress to a higher stage over the course of the three contacts, and a score of 0 to patients who did not progress.

Overall study start date
24/11/2008

Completion date
01/04/2009

Eligibility

Key inclusion criteria
1. Aged 18 years or more, either sex
2. Diagnosis of heart failure
3. French language
4. Physical and cognitive ability to answer a written questionnaire and to communicate by telephone
5. Physical and cognitive ability to read and sign a consent form
6. Problems with at least one self-care behaviour for HF patients (exercise, low-salt diet, fluid restriction, daily weight or medication) as evaluated by a clinic nurse

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Hospitalised at the time of enrolment
2. Final discharge from the heart failure clinic (i.e. no more follow-up)

Date of first enrolment
24/11/2008

Date of final enrolment
01/04/2009

Locations

Countries of recruitment
Canada

Study participating centre
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Sponsor information

Organisation
Montreal Heart Institute (Institut de cardiologie de Montréal) (Canada)

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Sponsor type
Research organisation

Website
http://www.icm-mhi.org/en/index.html

ROR
https://ror.org/03vs03g62

Funder(s)

Funder type
Research organisation

Funder Name
Groupe de recherche interuniversitaire en interventions en sciences infirmières du Québec (GRIISIQ) (Canada)

Funder Name
Ministry of Education, Leisure and Sport (Ministère de léducation, loisirs et sport [MELS]) (Canada)

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?
Results article	results	01/03/2010		Yes	No