

Motivational nursing intervention on treatment adherence in heart failure patients

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| Submission date 16/12/2008 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 23/12/2008 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 21/03/2012 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

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

R-1520

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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>

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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 l'éducation, 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 |