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The AGIR program A self-management program for patients with arthrosis including educational workshops for primary care health professionals

Submission date
05/03/2012

Recruitment status
No longer recruiting

Registration date
25/07/2012

Overall study status
Completed

Last Edited
16/06/2014

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Osteoarthritis is the most common form of long-term pain and it affects around 10% of the world's population. This has serious impact on the health of the patients and healthcare costs. According to current research, the actual treatment appears to be insufficient. Ideally, these patients should be supported by multidisciplinary teams. Therefore, we are carrying out the AGIR program (Un programme dAutoGestion pour les patients arthrosiques et de formation pour les cliniciens de la première ligne supporté par une équipe Interdisciplinaire Régionale). The aim of this program is to improve quality of life for patients, including self-management for osteoarthritis patients and educational workshops for primary care health professionals supported by an interdisciplinary team. We would also like to assess the feasibility of implementing the AGIR program in family medicine groups (FMGs) and to assess its efficiency before proceeding with a major study.

Who can participate?
The study aims to recruit 6 FMGs, including about 180 patients, 30 physicians, 12 nurses, 50 pharmacists and 12 physiotherapists. Patients suffering from osteoarthritis for at least six months can take part.

What does the study involve?
First, we will recruit doctors and nurses from six FMGs . The doctors will refer 30 eligible patients to the research team. Then we will recruit the patients. If they accept, we will ask their pharmacists to participate in the study. In the meantime, some physiotherapists near the FMG will be invited to join. All patients should complete a telephone interview and a questionnaire at the beginning of the study and after the eight month follow-up. The doctors will also have to fill in a questionnaire at start of the study and after the eight-month follow-up. When all clusters will be formed, FMGs will randomly be allocated to the AGIR group or usual care group. Patients and healthcare professionals from AGIR group will receive the educational program and will be followed-up for eight months. After the follow up, the program will be offer to usual care group.

What are the possible benefits and risks of participating?
The participation in this study could help the osteoarthritis patients to improve the management of their disease and the communication with their care providers. The doctors will learn about osteoarthritis and long-term pain and to share this knowledge with all other health care professionals. In addition, the participation to AGIR will contribute to the advancement of knowledge. If this program is beneficial, it could be extended to larger population. There will be no risk to participating in this study; the only inconvenience is the time that participants will have to spend to respond to the questionnaire at the start and at the end of the study.

Where is the study run from?
This Study has been set up by the Canadian Institutes of Health Research (CIHR) in partnership with AstraZeneca, and part of the study is also funded by Pfizer Canada Inc.

When is study starting and how long is it expected to run for?
The recruitment is begun January 2012. The study ended in April 2013.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Programme AGIR - A self-management program for osteoarthritis patients and training for frontline clinicians supported by an Interdisciplinary Team Regional (Un Programme d AutoGestion pour les patients arthrosiques et de formation pour les cliniciens de la première ligne supporté par une équipe Interdisciplinaire Régionale)

Acronym
AGIR

Study objectives
The objectives of this study are to assess the feasibility of implementing the AGIR program in family medicine groups (FMGs) and to assess its potential efficacy in a pilot clinical trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Center for Health and Social Services Laval (Research Ethics Committee of the Centre de santé et de services sociaux de Laval) (Quebec, Canada) approved in December 2011

Study design
Multicentre cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Arthrosis

Interventions
Four FMGs will be assigned to the AGIR program and two FMGs will be assigned to usual care.

The AGIR program includes specific educational workshops for community pharmacists and for healthcare professionals (primary care physicians, nurses, pharmacists and physiotherapists). The pharmacists workshop will last around two hours and will be offered by a community pharmacist with an expertise in chronic pain. For healthcare professionals, two three-hour workshops will be offered in participating FMGs. These workshops will be offered by a team including an arthrosis specialist, a family physician, a nurse, a pharmacist and a physiotherapist. Primary care physicians assigned to the AGIR program will also have access to a telephone service allowing them to contact an arthrosis specialist in order to discuss the follow-up of study patients.

For patients assigned to the AGIR program, two workshops will be offered. The first workshop will include oral presentations and exercises, and will be offered by a nurse, a pharmacist and a physiotherapist. The second workshop will consist of group sessions, and will be specific to the patients types of arthrosis-related pain. Patients and healthcare professionals assigned to usual care will not have access to the AGIR program but will have the opportunity to receive the AGIR workshops at the end of the study.

Participants of both study groups will be followed-up for eight months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Quantitative measurements:
1. Socio-demographic characteristics of patients, measured using a telephone questionnaire performed at study entry (T0)
2. Characteristics of arthrosis-related pain, measured using a telephone questionnaire performed at study entry (T0) and at the end of the follow-up (T8)
3. Patients psychosocial functioning, measured using a self-administered questionnaire and a telephone questionnaire at T0 and T8
4. Patients arthrosis-related knowledge and self-management, measured using a self-administered questionnaire and a telephone questionnaire at T0 and T8
5. Patients physical activity, measured using a self-administered questionnaire at T0 and T8
6. Patients use of healthcare services covered by the Régie de lassurance maladie du Québec (RAMQ, Quebecs general insurance program for medical and pharmaceutical services) six months preceding study entry and at T8, measured using the RAMQ administrative databases
7. Patients use of healthcare services not covered by the RAMQ six months preceding study entry and at T8, measured using a telephone questionnaire at T0 and T8
8. Patients pharmacotherapy six months preceding study entry and at T8, measured using the RAMQ administrative databases for patients covered by the RAMQ and using the reMed database for patients with private insurance plans
9. Patients use of over-the-counter medications and natural products, measured using a telephone questionnaire at T0 and T8
10. Patients satisfaction and expectations regarding their treatment, measured using a self-administered questionnaire at T0 and T8
11. Patients risk of opioid addiction, measured using the self-administered questionnaire Opioid Risk Tool (ORT) at T0
12. Healthcare professionals socio-demographic characteristics and actual practice, measured using self-administered questionnaire performed at T0 and T8
13. Healthcare professionals pain-related knowledge, attitudes and beliefs, measured using the self-administered questionnaire KnowPain-50 (KP-50) at T0 and T8

Key secondary outcome(s))
Qualitative measurements:
1. Perceptions of patients and healthcare professionals regarding the AGIR educational workshops and clinical tools, measured using qualitative interviews at the end of the follow-up (T8)
2. Perceptions of healthcare professionals regarding the medical services provided to patients following the AGIR educational workshops and the utility of the telephone service, measured using qualitative interviews at T8
3. Perceptions of patients regarding the medical services received following the AGIR educational workshops, measured using qualitative interviews at T8

Completion date
30/04/2013

Eligibility

Key inclusion criteria
Family medicine groups (FMGs)
1. Be located in Monteregie (Quebec, Canada)
2. Be located in a minimal distance of 25 km of another participating FMG

3. Refer 30 eligible patients of which at least 20 accept to participate in the study; and
4. Have at least two physicians, one nurse, two pharmacists and two physiotherapists who accept to participate in the study

Patients:
1. Be 18 years or older
2. Have an arthrosis diagnosis since at least six months as confirmed by the primary care physician
3. Arthrosis is the main cause of pain
4. Feel arthrosis-associated pain at least two times per week
5. Describe the arthrosis-associated pain as at least 4 out of 10 on a scale where 0 represents no pain and 10 represents the worst possible pain"
6. Have an usual community pharmacy located 10 km or less from the FMG
7. Speak and read French
8. Accept to participate in two educational workshops if the FMG is allocated to the AGIR program
9. Accept to participate in the study and sign the informed consent form

Community pharmacies:
1. Be located less than 10 km from a participating FMG
2. Have at least one patient participating in the study
3. One pharmacist from this pharmacy accepts to represent the pharmacy by assisting to the AGIR workshop for healthcare professionals; and
4. Sign the informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patients:
1. Report cancer-related chronic pain; and
2. Have dementia, an important psychiatric disorder or another medical condition preventing informed
consent and/or the conduct of a telephone interview in the opinion of the physician or the nurse

Date of first enrolment
15/01/2012

Date of final enrolment

30/04/2013

Locations

Countries of recruitment
Canada

Study participating centre
Équipe de recherche en soins de première ligne
Laval
Canada
H7M 3L9

Sponsor information

Organisation
Canadian Institutes of Health Research (CIHR) (Canada)

ROR
https://ror.org/01gavpb45

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
AstraZeneca (Canada)

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics, AZ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Pfizer Canada Inc. (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary