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Phone call follow-up after RheumAtologIcal rehabilitation Stays: Evaluation of effects

Submission date
31/05/2011

Recruitment status
No longer recruiting

Registration date
21/06/2011

Overall study status
Completed

Last Edited
15/07/2019

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Inflammatory rheumatic diseases represent a major burden to the individual patient and to the society. Rheumatic diseases are characterized by inflammatory processes that may lead to joint damage and various degrees of disability. Current treatment focuses on early diagnosis and early use of medication that improves the disease. However, a major proportion of patients has remaining disability and does still need rehabilitation. Several studies have shown that patients with rheumatic diseases benefit from rehabilitation, but the effect seems to fade over time, and most patients are back to their initial health status six to twelve months after discharge from rehabilitation. A major challenge is therefore to help patients maintain self-management strategies introduced in the rehabilitation period, and thereby enhance a longer lasting effect of rehabilitation.

Goal planning or goal setting is considered an important part of rehabilitation practice. Several studies show that goal planning can influence patients' adherence to treatment regimes and improve immediate patient performance, but evidence regarding how it may improve results after rehabilitation programmes is inconsistent. Rehabilitation goals often address life style changes which involve a process over some time before settled as a new habit. This process involves both mental and behavioural elements, and may by the end of a rehabilitation stay still be unclear and fragile.

Telephone follow-up to support individualized goals and action plans has been reported to increase the effect of a rehabilitation program compared to control groups receiving more general health screening topics or no telephone calls at all. A tailored patient follow-up program as an extension to the rehabilitation stay may therefore prevent fading of the achieved results.

The objective of goal setting involves a change in patient behaviour. Theories of behaviour and behaviour change may therefore guide goal setting interventions. Motivational interviewing is a strategy based on cognitive behavioural theory, and is designed to motivate and prepare people for behaviour change. Several studies conclude that the use of cognitive behavioural approaches in exercise programs and other self-management interventions increase their effectiveness in patients with rheumatic diseases, and a recent review concluded that common features of effective self-management programs where that they included explicit use of cognitive

behavioural therapy, individualized weekly action plans with progress review, that they had written records of agreements made between patients and health worker (protocols) with participant hand-books, and that they were lead by the same trained leaders.

Based on previous described research and professional agreement between health workers at different rheumatology departments in the South-East of Norway, a new and potentially more effective rehabilitation program has been developed.

The main aim of this study is to measure and decide the usefulness of this new rehabilitation program (the PRAISE-program) compared to the current traditional rehabilitation programmes. The expected usefulness of the new program will be expressed in terms of goal attainment and health benefits for participating patients, and with regard to if it saves money compared to the costs involved.

Who can participate?
Patients who are admitted to the participating rehabilitation units with one of the following inflammatory rheumatic diagnoses: Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, systemic lupus erythematosus and juvenile idiopathic arthritis. In addition patients with generalized arthritis with affection of either hip or knee can take part in the study.

To take part you need to be:
1. Aged 18 years or older
2. Have a good understanding of Norwegian language

Patients with mental dysfunction or severe psychiatric disorder, and patients with rheumatic diseases undergoing rehabilitation after orthopedic surgery can not participate in the study.

Patients will be recruited through information from health professionals at the participating centers at admission to the rehabilitation stay and those who are interested will receive written information about the study. To enrol, participants will have to give their informed consent.

What does the study involve?
The new program (PRAISE-program) is based on existing rehabilitation programs delivered at different rheumatology departments and rehabilitation centres in the South-East of Norway, but the following four elements have been added:
1. A structured goal-setting and evaluation process during the rehabilitation stay, including deciding of goals to proceed with in the patient's home-setting after discharge
2. A self-help booklet for use under and after the rehabilitation stay
3. A follow-up program consisting of four phone-calls from a health care provider at the hospital, directed at goal attainment and motivation for continued effort
4. Organized and thorough use of motivational interviewing in the goal setting and evaluation process, as well as in the follow-up phone calls. Motivational interviewing is a form of conversation aimed at preparing people for change

While one group will receive the PRAISE program, the other group will receive traditional rehabilitation with no other support after discharge than what is usually provided (treatment as usual). Both groups will receive medical treatment as usual.

What are the possible benefits and risks of participating?
There are no known risks to participants.

All participants, including controls, will receive rehabilitation which may improve their health and physical function.

Participants randomized to the intervention group will additionally receive a structured, individualized goal setting program, a self.help-booklet and a follow-up program consisting of four phone calls from health care providers located at the different hospitals and rehabilitation centres. The phone call follow-up will be directed at pursuing individual goal attainment and enhance motivation for continued effort. All these elements are expected to increase the health benefits of their rehabilitation stay.

Where is the study run from?
The study takes place at various rheumatological rehabilitation departments at hospitals and a rehabilitation center in the South-East of Norway, with a total of six departments/centres participating in the enrolment.

When is the study starting and how long is it expected to run for?
Patients will be enrolled in the study between August 2011 and June 2012. Follow-up examinations will continue towards July 2013.

Who is funding the study?
Health Region South-East of Norway

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of structured goal planning and tailored follow-up in rehabilitation for patients with inflammatory rheumatic diseases: a stepped wedge cluster randomised trial

Acronym
PRAISE

Study objectives
The main objective of this trial is to evaluate goal attainment, health effects and cost effectiveness of the new rehabilitation program (PRAISE) compared to the current traditional rehabilitation programs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Norwegian Regional Committee for Medical Research Ethics Health Region South-East approved on 19/05/2011, ref: 2011/909
2. The Privacy Protection representative at Oslo University Hospital approved on 31/03/2011, ref: 2011/6602

Study design
Interventional multicentre stepped wedge cluster randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Inflammatory rheumatic diseases / rehabilitation

Interventions
The new program (PRAISE) is based on existing rehabilitation programs delivered at rheumatology departments and rehabilitation centres in Health Region Sout-East Norway, but the following four elements have been added:
1. A structured goal-setting and evaluation process during the rehabilitation stay, including deciding of goals to proceed with in their home-setting after discharge
2. A self-help booklet for use under and after the rehabilitation stay
3. A follow-up program consisting of four phone-calls from health care provider at the hospital directed at goal attainment and motivation for continued effort
4. Systematic use of motivational interviewing in the goal setting and evaluation process, as well as in the follow-up phone calls

The control group will receive traditional rehabilitation with no other support after discharge than what is usually provided (treatment as usual).

Both groups will receive medical treatment as usual.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Goal attainment and health related quality of life measured by the Patient Generated Index (PGI).

PGI is an individualised instrument which is completed in three stages:
1.1. In stage one the respondent is asked to identify up to five important areas of their life that are affected by their rheumatic disease.
1.2. In stage two the respondents is asked to rate these areas on a numeric rating scale from 0 - 6 where 0 = as bad as could possibly be, and 6 = as good as could possibly be.
1.3. In stage three, respondents are asked to distribute ten points to indicate the relative importance of each of the areas described in stage one, with most points allocated to the most important areas.

The PGI may thereafter serve as a basis for developing individual rahabilitation goals, and the scores and re-scorings to evaluate attainment of these goals.

Secondary outcome measures
1. The Arthritis Self-Efficacy Scales (ASES) for pain and symptoms
2. Pain and fatigue measured on Numeric Rating Scales (NRS)
3. Other aspects of health related quality of life measured by the SF-36 domains Bodily Pain (BP), Role Physical (RP), Mental Health (MH), Vitality (VT), General Health (GH), Role Emotional (RE) and Social Functioning (SF).
4. In addition data on health care resource allocation and costs will be collected
The data will be collected at baseline, discharge and follow-up at 26 weeks and 52 weeks after discharge.

Overall study start date
23/08/2011

Completion date
30/06/2013

Eligibility

Key inclusion criteria
1. Patients admitted to the participating rehabilitation centres with one of the following inflammatory rheumatic diagnoses: rheumatoid arthritis, psoriatric arthritis, ankylosing spondylitis, systemic lupus erythematosus, juvenile idiopathic arthritis or generalised osteoarthritis effecting either the hip or knee
2. Aged 18 years or older
3. A good understanding of Norwegian language
4. Able and willing to sign the informed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A total of 312 patients will be recruited into the study

Total final enrolment
389

Key exclusion criteria
1. Cognitive impairment
2. Severe psychiatric disorder
3. Patients with rheumatic disease undergoing rehabilitation after elective orthopaedic surgery

Date of first enrolment
23/08/2011

Date of final enrolment
30/06/2013

Locations

Countries of recruitment

Norway

Study participating centre
The National Resource Center for Rehabilitation in Rheumatology (NRRK)
Oslo
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Sponsor information

Organisation
Diakonhjemmet Hospital (Norway)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02jvh3a15

Funder(s)

Funder type
Government

Funder Name
Health Region South/East (Norway)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/05/2014		Yes	No
Results article	results	01/11/2018	06/02/2019	Yes	No
Results article	results	10/11/2017	06/02/2019	Yes	No
Results article	results	01/04/2018	06/02/2019	Yes	No
Results article	results	01/11/2018	15/07/2019	Yes	No