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# Telemonitoring intensive strategy in early rheumatoid arthritis

**Submission date**
02/02/2016

**Recruitment status**
No longer recruiting

**Registration date**
17/03/2016

**Overall study status**
Completed

**Last Edited**
15/11/2016

**Condition category**
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
Rheumatoid arthritis (RA) is a long-term disease causing pain, swelling (inflammation) and stiffness in the joints. It is part of a group of diseases called autoimmune diseases, where the immune system starts to attack healthy joints. In healthy people, the body produces different types of immune cells. One of these is the B-cell, which produces antibodies to fight infection. In people with RA, these do not behave properly and produce antibodies which attack a person's own body even if there is no infection. Early rheumatoid arthritis (ERA) is the name given to the first stages of the disease, when only the smaller joints, such as in the fingers and toes, are affected. By identifying and treating ERA early, it is possible to slow down the progression (worsening) of the disease. Telemonitoring is an emerging technique in which patients' conditions are monitored away from the health care provider using electronic devices, which transmit the results to the health care provider. This allows doctors to keep track of a patient's condition so that treatment can be delivered quickly and effectively. The aim of this study is to find out whether using a web-based monitoring system for patients with ERA is an effective way of controlling their condition.

Who can participate?
Adults suffering from early rheumatoid arthritis.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have five face-to-face sessions with their doctor at the start of the study and then at 3, 6, 9 and 12 months. These participants also take part in "televisits" (at 1, 2, 4, 5, 7, 8, 10 and 11 months), where they fill out a questionnaire online about any symptoms they are having, which is then sent to the doctor managing their case. This allows the case manager to monitor their condition from a distance. If any problems are flagged, then the case manager can call the participant and advice on how they might change their treatments to help lessen their symptoms and invite them to a clinic appointment if necessary. Those in the second group take part in the five face-to-face sessions with their doctor at the start of the study and then at 3, 6, 9 and 12 months only. In these sessions, their doctor is able to manage and change their treatment at their discretion. At

the start of the study and again after one year, all participants complete a number of questionnaires in order to assess how bad their symptoms are and how well they are controlling their condition.

What are the possible benefits and risks of participating?
Participants in the telemonitoring group may benefit from being able to better manage their condition, as problems can be spotted earlier because of the continuous monitoring. There are no notable risks of taking part in the study.

Where is the study run from?
Rheumatic Disease Unit, Marche Polytechnic University (Italy)

When is the study starting and how long is it expected to run for?
June 2010 to June 2015

Who is funding the study?
Marche Polytechnic University (Italy)

Who is the main contact?
Professor Fausto Salaffi

# Contact information

### Type(s)
Scientific

### Contact name
Prof Fausto Salaffi

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

N/A

# Study information

### Scientific Title
Observational study for the evaluation of safety and effectiveness of biologic drugs in patients with inflammatory rheumatic diseases based on a web platform

### Study objectives
To verify the effectiveness of a tight control strategy based on a a web platform in patients with inflammatory rheumatic diseases.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Comitato Unico Regionale – ASUR Marche, 20/04/2011

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Internet/virtual

### Study type(s)
Quality of life

### Participant information sheet
Patient information is available in Italian at www.armonitor.net/telemonitoraggio/

### Health condition(s) or problem(s) studied
Rheumatoid arthritis

### Interventions
Participants are randomly allocated to one of two groups.

Group 1: Participants have their condition monitored using the intensive telemonitoring strategy, which involves five face-to-face visits (at baseline, 3, 6, 9 and 12 months) as well as eight televisits, which involve the patient filingl out the Recent-Onset Disability Index (ROAD) form on the website (1, 2, 4, 5, 7, 8, 10 and 11 months). The results of the televisits are sent to the physician case manager, allowing them to monitor the patient's response at distance and, if necessary, directly intervene by phoning the patient. During the phone call, patients were required to modify the treatment or were encouraged to return for a follow-up visit at the clinic for any treatment modification.

Group 2: Patients are monitored using the conventional approach. This involves being assessed by a rheumatologist at baseline, 3, 6, 9 and 12 months. In this group, treatment decisions were made at any visit according to the discretion of the rheumatologist, following the standard guidelines for treating rheumatoid arthritis.

Disease activity and disease control are measured for all participants at baseline and one year.

### Intervention Type
Other

### Primary outcome measure
Disease activity, measured using the clinical disease activity index (CDAI) is measured at baseline and 1 year

### Secondary outcome measures
Comprehensive disease control (CDC), measured using the clinical disease activity index (CDAI) and the Recent-Onset Disability Index (ROAD) at baseline and 1 year

### Overall study start date
01/06/2010

### Completion date
30/06/2015

## Eligibility

### Key inclusion criteria
1. Diagnosis of rheumatoid arthritis according the 2010 ACR/EULAR criteria for RA
2. Age 18 years and over
3. Disease duration less than 1 year (the disease duration was considered from the onset of the symptoms to baseline that corresponded with the point of diagnosis and with the start of treatment)
4. Clinical Disease Activity Index (CDAI) of 22 or over

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Two cohorts of 20 and 21 patients respectively

### Key exclusion criteria

1. Visual limitations were present
2. Hard of hearing and living alone
3. Poor command of the Italian language
4. Suffering from diseases requiring hospitalization such as chronic obstructive pulmonary disease, heart disease, multiple sclerosis, extracorporeal dialysis or chronic infectious disease

### Date of first enrolment
01/01/2012

### Date of final enrolment
30/06/2014

## Locations

### Countries of recruitment
Italy

### Study participating centre
**Marche Polytechnic University**
Rheumatic Disease Unit
Via Aldo Moro, 25
Jesi (Ancona)
Italy
60035

## Sponsor information

### Organisation
Università Politecnica delle Marche

### Sponsor details
Piazza roma, 22
Ancona
Italy
60121
+39 712202324
ricerca@univpm.it

### Sponsor type
Hospital/treatment centre

### Website
www.univpm.it

### ROR

https://ror.org/00x69rs40

# Funder(s)

**Funder type**
University/education

**Funder Name**
Università Politecnica delle Marche

**Alternative Name(s)**
Polytechnic University of the Marche, UNIVPM

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
Italy

# Results and Publications

**Publication and dissemination plan**
Planned publciation in BMC Musculoskeletal Disorders.

**Intention to publish date**
30/06/2016

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Other

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 02/04/2016 | | Yes | No |