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A study evaluating the effect of Educational Needs Assessment Tool (ENAT) focused patient education on health outcomes in patients with rheumatoid arthritis

Submission date
21/01/2011

Recruitment status
No longer recruiting

Registration date
21/01/2011

Overall study status
Completed

Last Edited
22/10/2015

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
A research review about outcomes for patients with rheumatoid arthritis has questioned patient education and its effects, claiming that any benefits patients gain are small and short lived. This begs the question 'is time spent by health professionals giving patient education good value?' It has been suggested that one reason the research review found little evidence to support patient education is that patients and health professionals have different views about the kind of education that should be given and the best time to give/receive it. Another reason suggested for the lack of good outcomes is that the measurements used to test research outcomes have not been the best ones or the most appropriate to use. The ENAT questionnaire was developed for this reason. Our research looked at whether the patients who have education based on the ENAT patient-completed questionnaire received more suitable education by the Clinical Nurse Specialist, show better health outcomes, and have more long-term health benefits than those who did not use the ENAT.

Who can participate?
Patients aged 18 years or over diagnosed with rheumatoid arthritis.

What does the study involve?
Patients were randomly allocated into two groups. One group received and completed the ENAT and this was used as a guide by the Rheumatology Nurse to provide patient education in addition to the patients' usual care. The second group received usual care from the same nurse. Both groups completed three other validated and reliable health assessment questionnaires which were used to assess their outcomes. Sixteen patients from two hospitals and four nurses from three hospitals were invited to be interviewed to find out their view on using the ENAT.

What are the possible benefits and risks of participating?
We cannot promise that the study will benefit you. Future patients may benefit from the knowledge gained in this study. The use of an easily completed and quick to use questionnaire

would benefit patients and practitioners. It would enable pracititioners to provide patients with the information that they need to self care effectively at the time they need it in a speedy and structured format.There are no identifiable risks or disadvantages in taking part in this study. The only minor burden may be for those participants who are chosen for the interviews will have to attend an extra hospital visit.

Where is the study run from?
Barnsley Hospital (UK).

When is the study starting and how long is it expected to run for?
June 2010 to March 2012.

Who is funding the study?
National Institute of Health Research (NIHR) (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9230

Study information

Scientific Title

A multicentre randomised controlled interventional process of care study evaluating the effect of Educational Needs Assessment Tool (ENAT) focused patient education on health outcomes in patients with rheumatoid arthritis

Acronym
ENAT

Study objectives
The study hypothesis is that 'the use of the Educational Needs Assessment Tool (ENAT) to determine the educational needs of rheumatoid arthritis (RA) patients will lead to improved outcomes, and demonstrate long term benefits'. The study will look at whether the patients who are given education based on a patient-completed questionnaire called the ENAT, get more relevant education, show better health outcomes and have more long-term health benefits than those who do not use the ENAT. 130 RA patients will be randomised into an Experimental Group (EG) or Control Group (CG). The EG will complete the ENAT prior to seeing a Clinical Nurse Specialist (CNS) at weeks 0, 16 and 32. For the EG, the CNS will use the ENAT as a template to meet the patients perceived educational needs in addition to usual care. The CG will receive their usual care from the CNS without the aid of the ENAT.

The primary patient outcome will be change in self efficacy. Secondary measures comprise physical function, psychological status, pain, social interaction and knowledge of disease. To determine the ENAT's usability within the practice setting, semi-structured qualitative interviews will take place with the practitioners and a purposive sample of patients. They will be selected to represent a range of age, gender, disease activity, disease duration and level of general education. Randomisation will be completed by a Research Associate who will have the randomisation codes. The Project Coordinator will be blinded as to who receives the ENAT. Randomisation to take place in the Rheumatology Outpatients Departments at two sites: Barnsley Hospital NHS Foundation Trust and Rotherham Hospital NHS Foundation Trust.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Yorkshire REC, 03/03/2010, ref: 10/H1310/8

Study design
Multicentre randomised controlled interventional process of care trial

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
Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions
130 RA patients will be randomised into an Experimental Group (EG) or Control Group (CG).

The EG will complete the ENAT priot to seeing a Clinical Nurse Specialist (CNS) at weeks 0, 16 and 32. For the EG, the CNS will use the ENAT as a template to meet the patients perceived educational needs in addition to usual care. The CG will receive their usual care from the CNS without the aid of the ENAT.

Study entry: single randomisation only.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To evaluate the effectiveness of ENAT-focused patient education on the health outcomes of RA patients, measured at baseline, 16 weeks and 32 weeks.

Secondary outcome measures
1. To establish whether the patients perceive they are getting an equally good or inadequate education
2. To evaluate the usability of the ENAT in a clinical setting

Measured at baseline, 16 weeks and 32 weeks.

Overall study start date
01/06/2010

Completion date
01/03/2012

Eligibility

Key inclusion criteria
1. Positive diagnosis of rheumatoid arthritis defined by the American Rheumatism Association (ARA) criteria
2. Aged 18 years or above, either sex
3. Ability to complete questionnaires unaided

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 130; UK sample size: 130

Key exclusion criteria
Patients with a history of severe mental health problems which would impair their ability to provide informed consent should be excluded

Date of first enrolment
01/06/2010

Date of final enrolment
01/03/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barnsley Hospital NHS Foundation Trust
Barnsley
United Kingdom
S75 2EP

Sponsor information

Organisation
Barnsley Hospital NHS Foundation Trust (UK)

Sponsor details
Research & Development Department
Pogmoor Road
Barnsley
England

United Kingdom
S75 2EP

Sponsor type
Hospital/treatment centre

Website
http://www.barnsleyhospital.nhs.uk/

ROR
https://ror.org/00yx91b22

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

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	01/04/2015		Yes	No
Results article	results	01/06/2016		Yes	No