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Development of a complex intervention for the treatment of gout in primary care

Submission date	Recruitment status	[ ] Prospectively registered
23/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/07/2013	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7525

Study information

Scientific Title
Development of a complex intervention for the treatment of gout in primary care: a non-randomised observational treatment and qualitative study

Acronym
DCI-Gout

Study objectives
Phase 1 contains the development and feasibility work that is required prior to the community based RCT:
1. To develop a practical and acceptable nurse-led complex intervention for gout
2. To explore the potential barriers to such an intervention and adapt the intervention for optimial effectiveness
3. Address the following question: given optimal circumstances (i.e., a dedicated expert gout clinic), can application of the key component of the current management guidelines achieve the therapeutic target (serum uric acid [SUA] less than 360 umol/L)?

To identify possible barriers to the delivery of, and adherence to the intervention, indepth interviews will be arranged with 12 participants with gout, GPs and practices nurses. In addition, 6 GPs and 6 practice nurses will also be invited to participate in a focus group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee 2 approved on the 12th October 2009 (ref: 09/H0408 /94)

Study design
Non-randomised observational treatment and qualitative study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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: Primary Care Research Network for England, Musculoskeletal; Subtopic: Not Assigned, Musculoskeletal (all Subtopics); Disease: Musculoskeletal, All Diseases

Interventions
Interventions will be based on the key elements of high quality gout management included in the EULAR and BSR guidelines. Following clinical assessment, study participants will be advised with respect to lifestyle modifications and, if relevant, will be prescribed licensed serum uric acid lowering medication (e.g., Allopurinol). The medication, dose and frequency will be dependent up on individual requirements. The number of attendances will also be based on the individual's clinical requirements.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Serum uric acid reduced to below 360 umol/L at 12 months

Secondary outcome measures
Clinical outcomes such as frequency of acute attacks and number and size of tophi will be recorded

Overall study start date
01/02/2010

Completion date
31/05/2010

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of gout
2. SUA greater than 360 umol
3. Male and female, lower age limit of 30 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Key exclusion criteria
Gout cases with a SUA less than 360 umol/L (GPs asked not to contact patients with terminal illness or severe mental illness and those unable to give informed consent)

Date of first enrolment
01/02/2010

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham City Hospital
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
University Park
Nottingham
England
United Kingdom
NG7 2RD

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type

Charity

Funder Name
Arthritis Research Campaign (ARC) (UK) (ref: 18827)

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	01/06/2013		Yes	No