GP Participant Enrolment

SECTION 1 – Principal Investigator to complete

Title of Research: eHealth tool for people with gout: a cluster randomised controlled trial

Scope of the Research and relevance to General Practice (including learning objectives)

This study is a GP Research Activity, which aims to improve the efficiency and effectiveness of management of patients with gout, who often are not adherent to their serum urate lowering therapy (ULT), and whose gout is not controlled. This cluster randomised controlled trial will evaluate the effectiveness of a mobile app, designed to assist people with gout in self-managing their gout. Specifically, the app has been developed to help individuals with gout to achieve a target serum urate of ≤ 0.36 mmol/L, and consequently control of their gout attacks and a better quality of life.

Participating GPs are requested to screen, identify and recruit at least 3 patients, who

- Have had at least two attacks of gout in the past year,
- Be receiving or eligible to receive urate-lowering therapy (ULT) to prevent attacks, and
- Have access to a smartphone or tablet device with access to the internet.

Once recruited into the study, participating patients will be provided with one of two mobile apps for one year. GPs will also be provided with information on contents of the mobile app that their patients receive. GPs will review the patients at least three times within one year after gaining consent from the patients (at the start, then again after 6 months and 12 months), and monitor their serum uric acid and creatinine levels as required.

Learning Objectives

There are five main learning objectives for participation in the activity:

1. During recruitment of patients into the study, GPs will be able to identify patients with inadequately controlled gout for potential admission to the study.
2. At the end of the study, GPs will be able to determine whether the use of an electronic self-management tool in patients with gout is effective in achieving a target serum urate level in those patients.
3. At the end of the study, GPs will be able to identify a situation in which the use of an electronic self-management tool may be beneficial for patients with gout.
4. Due to participation in the study, GPs will be able to explain why a cluster randomised controlled trial is a useful trial design in primary care and discuss best practice in recruiting patients to clinical trials.
5. After completion of eLearning session at the end of the study, GPs will be able to develop a review schedule for monitoring the effectiveness of long-term management of gout in their patients, adjust the dose of urate lowering therapy to effectively control gout, and know how to reduce the risk of adverse effects during urate-lowering therapy.

The GP's involvement will be to:

- Screen all their patients, who have presented with gout attacks in the previous year, against the eligibility criteria
- Introduce any eligible patient to the study and provide them with a participant information sheet
- If the patient is interested, gain informed consent.
- Contact the gout app research team with the patient's details.
- Review each patient at least three times within one year after gaining consent from the patient (at the start, then again after 6 months and 12 months), monitor their serum uric acid and creatinine levels as required, and provide the research team with medical information related to the patient's gout (with the patient's consent).

- Through online lectures, GPs will learn about cluster randomised controlled trials at the start of the CPD activity, and then about management of gout at completion of the trial, and answer multiple choice questions. The lectures will cover content on patient safety, including allopurinol hypersensitivity, adjusting the dose of ULT, and how to reduce the risk of adverse effects during ULT.
- At completion of the trial, GPs will be supplied with their patient's outcome data for analysis, and with the overall study results, for comparison.
- GP will be required to write a report to outline how their understanding and management of gout has been impacted by participating in the study.

Report content includes:

i. Discuss the usefulness of cluster randomised controlled trial design, and best practice in recruiting participants to clinical trials
ii. Identify and explain the similarities and differences between the findings from their own results and the overall research
iii. Outline the implications of the research findings to their general practice
iv. Explain if the GP has implemented a change in their practice to improve a systems approach to patient safety as a result of participation in the study.

SECTION 2 – GP Participant to complete

Name:	**RACGP QI&CPD number:**
Phone:	**Email:**
Address:	

How did you identify your learning need? What was your learning need?

E.g. you identified a gap in skill/knowledge due to a specific incident, identified own need in a specific area, or may be a practice based requirement.

GP signature: **Date:**