

Home based Education and Learning Program for Gout (HelpGout)

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I would once again like to thank the committee for awarding us this grant of to enable us to undertake this work.

OBJECTIVES

To undertake a study of a home-based, individualised, structured educational intervention in a sample of gout patients (n=50) to determine;

- Feasibility
- Acceptability to patients
- Impact on serum urate
- Impact of self reported flares of gout and gout activity
- Impact on health literacy

RESEARCH PLAN

We aimed to work with the HELP-AF team to develop educational content for people with gout, with the aim of testing the feasibility of delivering this education in this study.

Study Design: 16 week randomized, controlled, intervention study with 2 arms: home-based, individualised, structured educational intervention or usual care.

Arms: Participants will be randomly allocated to one of the 2 arms using a random number generator, stratified by site.

1) Structured educational intervention: Two home visits (at weeks 2 and 6) will be undertaken to deliver structured education focused around key messages Patients received a booklet as an ongoing reminder of the three messages. The booklet will also outline a flare plan for patients to follow during an acute attack of gout to avoid going to hospital. This will include developing an emergency management plan with their doctor and a dedicated telephone service for advice from a rheumatologist.

A point of care serum urate will be measured during the home visit, and urate lowering therapy escalated according to a predefined dose escalation regimen.

Proposed Key Messages:
Importance of background urate lowering therapy
Management of acute gout flares
Role of lifestyle modification. Messages will be personalised to target areas where behaviour change is needed.

2)Usual Care: Participants receive usual care.

Primary Outcome measures:

Feasibility: Feasibility will be assessed through compliance, acceptability and adverse events.

Compliance will be measured through serum urate testing at week 16. Acceptability will be measured through number of withdrawals and a participant survey administered at week 16 to determine acceptability of interventions to participants. Adverse events will be collected throughout the study.

Secondary Outcome measures:

Effectiveness: Effectiveness will be assessed through change in serum urate between week 0 and week 16, the number of self reported gout flares between week 0 and week 16 and the change in Gout Activity Score between week 0 and 16. Impact on health literacy as assessed by the Gout Knowledge Questionnaire.

Sample Size: convenience sample of n = 50. As this is a feasibility study, power analysis was not performed

RESULTS:

We have worked with the Help AF team to develop educational content for people with gout. We have created a personalised action plan, a nurse manual and a detailing guide. These are attached as additional documents.

We obtained ethics approval, but then faced delays in obtaining governance due to the COVID 19 pandemic and associated severe staff shortages in Western Australia. We then faced issues with the opening of the boarder, and Western Australian wave of the pandemic. The staff shortages, together with the need to socially isolate meant the investigators felt it best to alter the protocol to allow telehealth visits.

The altered protocol has bene approved, but remains in the governance face, as once again, staff shortages and furloughing pushes out approval times.

We expect approval to be granted by XXX, and we aim to start the study early in the second half of 2022, to be completed early 2023